Work Package 4 – Sustainability and Cooperation across Europe

Sustainability plan, policies and scenarios for long-term sustainability
WP4 D4.2

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In collaboration with the WP4 partners and WP1, WP2, WP3, WP5, WP6, WP7, WP8, WP9 leaders
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JATC2 JOINT ACTION ON TOBACCO CONTROL

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1. Introduction

This Deliverable **D4.2** describes how the JATC2 project's results can be sustainable and possibly continued after the end of the JATC2 project, and it is complementary to the other WP4 Deliverables, all available on the JATC2 website (https://jaotc.eu/useful-material-jatc-2/):

D4.1 *Policy dialogues on sustainability of JATC 2 actions and possible contributions to Europe's Beating Cancer Plan*

D4.3 *Establish the framework for a cooperation with the European Commission on the JATC2 deliverables contribution to Europe's Beating Cancer Plan*

The content of this Deliverable is divided into three parts:

1. **Roadmap** consisting of the onepagers describing main activities, sustainability, barriers and lessons learned for each WP.

2. **Sustainability plan** of JATC2 activities (Annex 1) and Post-JATC2 recommendations completed by the Work Package leaders (WP2, WP3, WP5, WP6, WP7, WP8, WP9).

3. Four **Guidance documents** (Annex 2), prepared to guide some the activities of JATC2 on best practices and for supporting sustainability of tobacco control:

- √ **Guidance on how to identify best practices on tobacco control in Europe,** which reports and describes international and European resources for best practices in tobacco control, with a guidance of assessment criteria for evaluating potential best practices.
- √ **Guidance on Core module questionnaire,** led by THL, used by WP8 and WP9 for their own questionnaires to identify potential best practices in smoke and aerosol-free environments and tobacco endgame strategies respectively.
- √ **Guidance for the treatment of nicotine dependence,** a joint document by WP4 and WP9, which recommends 5 Good Practice Statements mainly based on the well-known effectiveness of smoking cessation therapies.
- √ **Guidance on how to counteract the Tobacco Industry Interference,** containing templates of the Declaration of Interest and of a Code of Conduct to be personalized by Member States.

2. Roadmap: WPs onepagers

The following Onepagers present a concise overview of each work packages activities, providing a roadmap of their key elements, including sustainability, barriers and key-lessons learned. The Onepagers are a synthesis of the full sustainability plan questionnaires/tables compiled by the WP leaders and that are included in the Annex 1.

The objective of the Roadmap is to facilitate mutual learning and experience exchange on tobacco control actions among EU countries, describing proposals and recommendations to ensure sustainability of JATC2 results and possible further developments to make long-term impact in tobacco control.

WP2

WP2 aims to maximise the impact of the project by supporting the consultation with stakeholders and the dissemination of the project's results to the target audiences.

JATC2 results play an important role in defining the material and the ways of communication in the field of tobacco control in Europe, by bringing a harmonised approach to sharing the solutions to common problems.

The deliverables produced in WP2 are developed for the JATC-2 target audiences, including EU

Member States regulators and national policymakers, research institutes and researchers, non-governmental organisations, general public under FCTC article 5.3 conditions. These interested stakeholders should consider JATC-2 recommendations when updating existing policies, formulating new ones, initiating research, communicating tobacco-control information and educating the public on tobacco-related health effects.

Visual Identity (D2.1) and **Dissemination Plan** (D2.3) can continue to act as a source of JATC2-related information for all target audiences. Deliverables include the website (https://jaotc.eu/), social media accounts (Twitter:https://twitter.com/jatc2_, Instagram: https://www.instagram.com/jatc2_, Facebook: https://www.facebook.com/jatobaccocontrol2), leaflets, newsletters, press releases, and other dissemination and communication activities such as the JATC2 final conference. A press-release is planned to be produced after the final conference to inform all relevant stakeholders.

The Stakeholder analysis (D2.2) has created a network of interested stakeholders to ensure that the project findings reach the relevant end-users.

The deliverables are public and they as well as their constituents, such as leaflets, newsletters, press releases will be available through the website (https://jaotc.eu/useful-material-jatc-2) and in the CIRCABC internal platform (https://circabc.europa.eu/ui/group/0fa614cf-8769-4f8d-b81e-e5cd7c837185) which can be accessed by the JATC2 network.

The **Layman version of the final report** (D2.6) will be targeted to a non-specialist audience and it will serve to inform decision makers and non-technical parties of the Joint Action objectives and results.

In order to ensure the **sustainability** of the JATC-2 WP2 activities, the leader, National Public Health Organisation of Greece (NPHO), has ensured that the JATC-2 website as the main communication tool, will remain available for an additional **13 months** after the end of the project.

In addition, the broad outreach of the European Network for Smoking and Tobacco Prevention (ENSP), a JATC2 stakeholder and collaborator, through its active and verified list of almost 3.000 researchers, advocates and policymakers in the European Region, can be used to promote and disseminate JATC2 activities to stakeholders.

There is limited funding to tobacco control stakeholders in Europe. WP2 proposes funding to be ensured by the European Commission in order to continue running the website. Funding for tobacco control activities, including educational and communication activities, should be ensured by the governments and the related authorities for at least three years. Wider collaboration with the European Network for Smoking and Tobacco Prevention and scientific organizations such as the European Respiratory Society or the European Cancer Leagues, could also be a way to circumvent the obstacle of the tobacco industry lobbying efforts in the field of public communication.

Continuation of JATC2 by a JATC3, or similar project, oriented towards a tobacco-free Europe, is strongly recommended as the best way of establishing a coordinated, sustainable tobacco control action at the European level.

Key lessons learned have been the importance of disseminating the tobacco control recommendations of an international collaboration, such as JATC-2, to the relevant stakeholders, including EU Member States regulators and national policymakers, researchers, non-governmental organizations, and the public. These recommendations can be considered when updating existing policies, formulating new ones, initiating research, communicating tobacco control information and educating the public on tobacco and nicotine-related health effects. The existence, maintenance and continuous update of a tobacco control stakeholder network can facilitate information exchange and communication of important advances in tobacco and nicotine products' control activities. A dedicated website, social media campaigns, newsletters, leaflets, and press releases to inform all relevant stakeholders are effective ways of communicating both at the EC and Member States' level. Wider collaboration of the EC and the Member States with non-profit and scientific organizations such as ENSP and ERS is valuable in the efforts of combating tobacco industry in the field of public communication.

WP3

WP3 aims to evaluate the outputs and outcomes of the JATC2 and to support the optimization of the internal processes necessary for their achievement.

WP3 is a supporting work package. It gives recommendations on the implementation of further joint actions.

The utility and usability of some main outputs of the JATC2 will be determined by interviews with the intended addressees. The aim is to provide feedback to improve future outputs in line with the Europe's Beating Cancer plan.

The main documents produced by WP3 are:

The Evaluation Plan D3.1 (D3.1-Evaluation-Plan.pdf (jaotc.eu)

The interim evaluation report (D3.2) is available at https://jaotc.eu/wp-content/uploads/2023/10/D3.2-Interim-Evaluation-Report.pdf

The final evaluation report (D3.3) will be available on the JATC2 website section of WP3 "Outcome and useful material" at https://jaotc.eu/useful-material-jatc-2/. That includes an outcome evaluation with a focus on the utility and usability of some main outputs of the JATC2. It also provides a series of recommendations for future projects to aid the project implementation. The recommendations will also be available on the JATC2 website section of WP3 "Outcome and useful material" once the report has been submitted and approved.

The evaluation reports are aimed to inform several other Joint Actions. They give insight into challenges and lessons learnt within the JATC2, and provide information and recommendations for the implementation of future joint actions.

The evaluation reports contribute to the **sustainability of the JATC2** as they aid future projects in creating their own evaluation plans and practices, allowing future projects to adapt specific tools to their individual needs.

The **sustainability** focus of WP3 is on its use for planning future projects. WP3 provides a series of recommendations for future projects to aid the project implementation, included in the Final Evaluation Report (D3.3). The recommendations that will be provided at the end of Joint Action will include recommendations on steps to be taken for the planning phase, the beginning and during the course of the project.

WP3 does not produce any results or recommendations that can be used on a national policy level. Implementation in national policies after the end of JATC2 depends on the approach of each country whether the focus of implementation is on proposals submitted by the Commission or whether individual reports of the JATC2 are also allowed to feed into a country's direct policy once they are finalized.

WP3 does not anticipate any barriers for implementation of the recommendations.

Dissemination/communication plan includes

- publication of materials in the publication database of the Austrian Agency for Health and Food Safety (AGES) Research Portal: https://www.ages.at/en/research/research-portal
- presentations at relevant training events.

The **key lessons learned** from the JATC2 evaluation highlight the importance of early and clear project planning, including well-defined tasks and realistic proposals, coupled with close cooperation and, whenever possible, physical meetings to enhance teamwork and motivation. Emphasizing sustainability is crucial for the long-term success and impact of future projects. Effective communication tools, consistent staff members, and thorough documentation are critical

for maintaining coordination and knowledge retention throughout the project's duration.

Additionally, knowledge-sharing efforts, such as the JATC2 website, knowledge hub meetings and webinars, and other platforms like the 'Knowledge Sharing Archive', the 'Smoke and Aerosol Free Best Practices' website, and the 'Tobacco Endgame Toolkit', are greatly appreciated and should continue beyond the joint action to maximize ongoing collaboration and learning.

WP5

WP5 aims to analyse EU-CEG data and enhanced laboratory capacity for regulatory purposes.

The overall objective of the WP5 is to strengthen and support the EU member state national competent authorities capacities to use EU-CEG data and to enforce the applicable standards, doing so through the efficient utilisation of scarce expertise and technical resources at the EU level and by avoiding duplication. WP5 works for wide implementation of best practices, including utilising independent laboratories for tobacco analyses.

In terms of the tobacco control laboratories network, WP5 advises to take the example of the EU reference laboratories settled under the EU Food Law. Certain labs could be "reference laboratory" for a specific analysis under the supervision of Joint Research Centre - European Commission. There would be specific EU budget to run such mandates and organize collaborations abroad (with WHO TobLabNet among other things).

The main documents produced by WP5 are:

EU-CEG data integration from MS-Rep to local databases at national scale (D5.2)

Dashboard and how-to guide to analyse EUCEG data at national scale (D5.4)

Centralizing the EU-CEG database in a EU agency might be a good option to gain efficiency in the future for handling EU-CEG data in a harmonized manner. National experts would still have access to their data and could participate in assessment panels under the remit of the EU agency. Thus, providing legal EU frameworks with specific budgets could be a good solution to make the **activities sustainable in the future**. The national activities could also receive a complementary funding based on what is done now in the different EU MS.

The question of fees collection from the industry should be considered both for EU-CEG declarations and product testing: having a EU centralized fees collection could ensure more stability in the funding and avoid discrepancies between EU member States.

Provided it is hosted by European Commission institutions, the **activities will be sustainable** like other existing legal-based frameworks (Food Law, REACH & CLP regulations).

Key lessons learned: it is necessary to design an internal organisation which ensure independency between the staff in charge of interactions with manufacturers (EU-CEG support helpdesk, product analyses, fee collections, administrative communication) and the staff in charge of assessment (example of Novel Food approval system with DG SANTE for interactions with manufacturers and EFSA for assessment).

The **dissemination** will continue through EC organised meetings on tobacco control.

WP6

WP6 aims to facilitate research, regulation and enforcement related knowledge sharing between EU member states in order to strengthen the EU Member States in the enforcement of tobacco product regulation.

That is a vital part of achieving the goals in Europe's Beating Cancer Plan and prevention of tobacco related cancer cases.

The activities and outcomes of WP6 are continuously disseminated through hosting of knowledge hub meetings, through the archive for knowledge sharing in CIRCABC and by sending out information about the network using the contact list that was created by WP6.

WP6 has created a roadmap which contains a clear guideline on how the knowledge hub meetings are to be planned and hosted in order to make sure, that the meetings will be able to continue as smoothly and with as much coherence as possible in the future. The main principles are:

- knowledge hub meetings hosted biannually,
- knowledge sharing archive maintained on CIRCABC as a platform,
- online forums maintained for dialogue within the knowledge sharing archive.

It is challenging to see the relevance of implementation of the deliverables in national policies after the end of JATC-2. However, it is the view of WP6, that **the knowledge sharing network (KSN)** could optimally continue as a permanent EU network after the project is finalised. One proposal for achieving this would be to let the responsibility of planning the knowledge hub meetings and maintaining the remaining elements of the knowledge sharing network such as the archive, the online dialogue forums, contact lists, etc., to be distributed by letting the participants take turns in chairmanship of the KSN.

Certain tasks have been identified to ensure the sustainability of the activities linked to the archive for knowledge sharing, including ensuring access, sharing information on how to set notifications, managing folders and performing minor administrative tasks (creating and monitoring a shared inbox for communication, for instance). The estimated time allowance to complete these tasks are one-two hours monthly. The activity can be sustainable as long as relevant organisations in the EU member states find it valuable to participate in the knowledge sharing network.

For **sustainability** purposes WP6 also proposes creation of a tobacco enforcement network - an **Administrative Cooperation Group (AdCo).** This can serve as a prerequisite for establishment of fixed networks with relevant tobacco control authorities. In order to establish mandatory participation in the AdCo groups, it is recommended to include the initiation of a tobacco enforcement network in the revision of the TPD. WP6 recommends DG SANTE to initiate an AdCo group through the Commission under article 32 of the Market Surveillance Regulation (MSR). Thus, to ensure that the knowledge generated and shared within the network is archived and accessible, it is recommended to use an **archive** facility already existing within the EU platform CIRCABC. The archive has been created as an interest group in accordance with objective 6.3 and it is designed for relevant authorities to join the network. The archive will be able to continue autonomously from JATC-2 after the project is finalised.

The **main barrier** for the continuation of the activities in WP6 is the potential lack of interest and engagement from relevant authorities and organisations within the EU member states to allocate the necessary resources to actively engage and participate in the knowledge sharing network. This risk could possibly be circumvented by following the above suggestion of continuing the network as an AdCo-group and subsequently make participation mandatory. **Key lessons learned** have been the implementation of more effective activities following the conclusion of JATC-2, WP6 recognised that introducing the archive and newsletters earlier would have been beneficial. Initiating knowledge sharing among EU member states sooner could foster stronger engagement and more efficient dissemination of vital information.

WP7

WP7 is aimed at gathering and gaining knowledge about the health effects and regulatory implications of e-cigarettes and novel tobacco products.

WP7 has prepared six reports, five information sheets for policy makers and two scientific publications that will be disseminated on the JATC2 website and to the stakeholders in relevant networks. To ensure that the results and recommendations are known to EU-regulators and can be implemented in policies, one task has been dedicated to dissemination activities.

A webinar was organized in May 2024, where findings were shared and feedback from relevant stakeholders (EU regulators and NGOs) is collected in order to optimise suitability of information sheets. That will increase the chances of implementation of WP7 recommendations.

Common approach document for evaluation of health impact and abuse liability is available on JATC2 website (M.7.5-Common-approach-for-evaluation-of-health-impact-and-abuse-liablity.pdf (jaotc.eu)

Also recommendations have been formulated and addressed to EU-policy makers about regulation of e-cigs and novel products in order to protect EU citizens' health.

WP7 recommends:

- To facilitate data sharing by use of data sharing agreements as well as developing easy to use software tools that facilitate merging and comparing datasets. This recommendation is closely related to the work conducted in WP5.
- To establish a network of enforcement agencies that can develop a harmonized approach. This recommendation is closely related to the work conducted in WP6 and it is expected that they will have more specific recommendations on this topic.
- To collect data on adverse incidents after e-cigarette or NTP use in a more structural, harmonized way. Suitable approaches can range from having a central team collecting data from hospitals to providing users the possibility to enter data on a website. Some amount of funding is needed to facilitate this type of work. NGO's may be interested to contribute to launching a website or campaign, but for a structural EU-wide data collection at least a strong EU-wide network is required and therefore involvement of governments is vital.
- To revise TPD in order to establish comprehensive regulation which includes all of these products and potential future developments.
- To consider platforms such as CIRCABC or Knowledge Archive to share knowledge and keep each other informed of latest developments in terms of products and regulation, however it is important to keep the platform active and ensure that people will actually use/ keep using it.
- To share information in deliverables D7.1 and D7.2 which are published on the JATC website. The results from task 7.2 provide insight into factors contributing to health risks of e-cigarettes and novel tobacco products, harmful substances in their ingredients and emissions and perceptions and use patterns. Based on these outcomes recommendations have been formulated for stricter regulation and enforcement of mentioned products. The milestones and deliverables related to this work are/will be published on the JATC2 website. The outcomes will be disseminated to the scientific community in one or two open access publications.
- To make sure all WP leaders constructively contribute to sustainability related activities. To make sure sustainability is strongly embedded in the project, WP leaders should have a small amount of person months in the sustainability WP and should be encouraged (during the project preparation phase) to incorporate sustainability related activities in their proposal.

Sustainability can be ensured by disseminating the WP7 findings and conclusions to those who can use them for further research and regulation.

Key lessons learned have been that the actual implementation of policy recommendations, which

were disseminated through a webinar, depends on many factors out of control such as finances and political will. Whether WP7 was actually successful in creating impact in terms of sustainable implementation of the recommendation, can only be measured at a later stage, not within JATC2.

WP8

WP8 aims to outline and disseminate best practices in order to address the upcoming challenges for smoke-free environments in Europe (FCTC Art 8) and to assess tobacco advertisement, promotion and sponsorship implementation and impact in Europe (FCTC Art 13).

The expansion of smoke-free environments is a crucial element within the Tobacco Endgame Strategy that is contemplated in the Europe's Beating Cancer Plan.

SYMPOSIUM **on Smoke and Aerosol Free Environments: "Learning from Practices to Improve Smoke- and Aerosol-Free Environments (SAFE) in Europe" (Milestone 8.4).**

The objective of the symposium was to identify learning key aspects of practices on Smoke and Aerosol Free Environments.

The outputs obtained from the Symposium such as the Symposium report and the dissemination video (https://www.youtube.com/watch?v=fav2NekuNuA) will be available for consultation by EU Member States through a variety of dissemination strategies: CIRCABC, JATC2-website, JATC2-social media platforms, scientific papers and the digital platforms from the Catalan Institute of Oncology (ICO) such as YouTube, Twitter and ICO Website https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-SymposiumReport_JATC2_WP8_PDF.pdf.

The main barriers against the expansion of SAFE practices and enforcement of SAFE practices were identified, such as industry lobby, lack of comprehensive legislation, lack of human and financial capacity, reluctance of governments, lack of training for authorities and/or public sector etc.

In regards to funding to ensure sustainability – the practices that have funding in the framework of a public policy are positive in terms of sustainability. It is also important to consider elements such as: a team for design, implementation and evaluation; partnerships; resources for training; dissemination on rewards and benefits; institutional support and legislation. It is crucial to have the outcomes of the activity available on platforms that ensure sustainability.

Products from WP8 will be published in a scientific journal with open access. The products highlight not only the importance of SAFE which is very much related to Europe's Beating Cancer plan, but it also focuses on how to make SAFE practices sustainable.

The Tobacco Control Unit of ICO (coordinator of WP8) is actively involved in different projects and activities related to tobacco control. There is availability to continue to disseminate and use the findings and work done within WP8-JATC2.

CONSULTATION

The consultation on SAFE has identified necessary practices to guarantee sustainability.

- A team to sustain an effort, an administration, NGO or another body in charge of the whole process - institutional anchoring.
- Evaluation - demonstrate that it is working or you lose interest from stakeholders.
- Partnership - partnership are important for trust and shared ability.
- Training and resources available to help achieve and maintain a smoke-free environment.
- Focus and disseminate potential rewards and benefits of implementing the practice to motivate support for the implementation.

- Human resources.
- Institutional support.
- Legislation.

The outputs obtained from the consultation have been compiled in a web-based repository. This web-based searchable repository contains information on 43 SAFE practices gathered in a consultation to 110 experts of Joint Action on Tobacco Control 2 (JATC2). The repository is accessible at www.smokefreebestpractices.eu.

The repository is connected to an ICO server that has high probability to be sustainable. An idea of giving the possibility to experts to upload new and/or other practices not yet contemplated in the repository is being considered.

The main domain was bought for a 5 year period starting in 2023.

The Weight of Evidence paper (Deliverable 8.1) for supporting the expansion of smoke and aerosol free environments and the Position Paper (Deliverable 8.2) on best practices on second hand smoke and aerosol protection and evidence supporting the expansion of smoke and aerosol free environments (SAFE) are expected to be used by Member States to design their national policies on SAFE.

The Position Paper on SAFE is available on CIRCABC, JATC2 website and the ICO website: https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/JATC2-WP8_Deliverable 8.2_PositionPaper-2.pdf

Also available at the ICO website:

The **Protocol for the consultation on SAFE best practices and barriers and opportunities**):

https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/20221130_JATC2_WP8_protocolSAFE_-PDF-1.pdf

The **Report on SAFE best practices:**

https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-consultation-report-Annex-1_JATC2_WP8.pdf

https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-consultation-report_Annex-2_JATC2_WP8.pdf

The **Report on barriers and opportunities for SAFE:**

https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE_barriersandopportunities_JATC2layout-2.pdf

Webinar on SAFE was conducted in November 2022, along with WP4-JATC2. The recording and presentations of this webinar are available on the JATC2 website: https://jaotc.eu/secondhand-smoke-and-aerosols-exposure-in-europe/

Key lessons learned have been: 1- the variety of strategies of smoke and aerosol free environments implementation declared by informants, that apply to different settings and policies adopted by Member States. These strategies can be studied by policy makers for cross-country knowledge sharing that improves their application and sustainability. Also, highlighted the need of harmonisation of smoke free laws (across and within countries). 2- the evidence of the need to overcome the tobacco advertisement, promotion and sponsorship loopholes and to tackle the harmfulness, spread and misleading advertising of emerging products, by identifying innovative strategies addressing social media, strengthening monitoring and making tobacco and nicotine products less attractive. This evidence ultimately highlights the need for a new TAD.

WP9

WP9 aims to provide tools to put forward actions in line with the Europe's Beating Cancer Plan, to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040.

The deliverables produced in WP9, including reports, scientific articles, webinars and an online toolkit, are developed for policy-makers, regulators, civil society and researchers in the field of tobacco control in the region. The materials and events will be promoted in relevant channels and to relevant stakeholders in collaboration with WP2 and WP6. Publication channels include scientific journal articles, JATC2 website (publications, webinar recording) and D9.3 online toolkit, available at https://jaotc.eu/useful-material-jatc-2/. The online toolkit, also available directly from www.tobaccoendgametoolkit.eu, provides policy options and materials to assess the feasibility of different options in different tobacco control contexts. The toolkit can be utilized by different stakeholders to understand the concept and learn from experiences from other countries. Publications and the online toolkit also provide information of the challenges and ways to protect the policy development from industry influence, and support for addressing common myths related to tobacco endgame.

A general recommendation to all countries is to strengthen the implementation of the WHO FCTC, integrated also in the Sustainable Development Goals as target 3.a. As shown in the first WP9 scientific article and D9.1 report, the low implementation of the WHO FCTC is an issue in Europe when considering the feasibility of tobacco endgame goals and measures. ('Tobacco endgame in the WHO European Region: Feasibility in light of current tobacco control status.' https://doi.org/10.18332/tid/174360). The WHO FCTC encourages its Parties to adopt and implement forward-looking measures that go beyond the requirements and recommendations of the treaty (Article 2.1). The deliverables and publications from WP9 also raise awareness of this. A policy brief 'Forward-looking tobacco control measures and tobacco endgame'compiles basic information and key considerations and is also available translated into few national languages among partner countries.

WP9 provides a synthesis of the existing scientific evidence on tobacco endgame measures and recommendations for research in D9.2 Recommendations for research on forward-looking tobacco control policies and tobacco endgame strategies, built on an article 'Tobacco endgame measures and their adaptation in selected European countries: A narrative review synthesis' (doi: 10.18332/tpc/186402). An overview of tobacco endgame in Europe is provided in the article 'Tobacco endgame goals and measures in Europe: current status and future directions' (Tobacco Control Published Online First: 17 June 2024. doi: 10.1136/tc-2024-058606). The methods and the tobacco endgame framework used in WP9 have been compiled into **an indicator compendium (M9.1)**.

Some of the activities initiated in the JATC2 can be partially continued through the new JA PreventNCD- project, where WP9 lead THL participates to three work packages (WP5, WP9, WP10). Those include tasks which address the effective implementation of tobacco policies, good practices in monitoring Article 5.3 of the WHO FCTC, and provision of brief advice in tobacco and nicotine cessation. Other upcoming JAs should also be utilized to build **sustainability**.

Key lessons learned have been the importance of information exchange and international collaborations such as JATC-2, which provide the platform to examine the enablers and challenges in tobacco endgame in different tobacco control contexts, and facilitate awareness raising and dissemination of measures that are likely to have a substantial impact to advance the EU Tobacco-Free Generation -goal.

Annex 1: Sustainability plan of the JATC2 Work Packages activities

The following tables were sent to WP leaders to gain insight into how they plan or expect their WP activities to be implemented and continued after the end of the JATC2 project, and particularly the expected duration, funding and human resources.

The draft table was initially prepared by ISS and then completed in collaboration with HSE and other JATC2 partners during a breakout session in Madrid, led by ISS, within the JATC2 Consortium meeting in April 2022.

The participants and WP4 partners in the session were:

Renata Solimini (Italian National Institute of Health, Italy, WP4),

Benoit Labarbe (ANSES, France, WP5),

Cristina Gomez (Ministry of Health, Spain, collaborating partner),

Frances O'Donovan (Ministry of Interior and Health, Denmark, WP1),

Maurice Mulcahy and Margaret Ruddy (Health Service Executive, Ireland, WP4),

Angeliki Lamprou (National Public Health Organization, Greece, WP2),

Anna Mar López Luque (Institut Català d'Oncologia, Spain, WP8).

The questionnaire was then sent out to all the WP leaders, who filled in all the relevant information related to sustainability and the proposals and recommendations for the continuation of the WP activities after the end of the JATC2.

Sustainability of the activities of WP2

Type of activity	WP2 – Dissemination
Main aims and objectives	WP2 aims to maximise the impact of the project by supporting the consultation with stakeholders and the dissemination of the project's results to the target audiences. Specifically, WP2 has the following objectives: - To develop the plan and tools to disseminate, as widely as possible, the process, updates, and recommendations of JATC2 by producing manuscripts, policy reports, conference abstracts and digital leaflets/documentation and by organizing a final project conference to conclude the project's activities. - To set up a network of interested stakeholders involved in tobacco control in all Member States, including existing networks and EU-funded or international projects, policymakers, professionals, other stakeholders, and a wider audience at the EU level, in order to disseminate the outputs of the Joint action through multiple avenues of communication.
Results and Implementation	By establishing an efficient tobacco-control communication mechanism between EU MS and through the dissemination channels, the results of JATC2 will potentially become cornerstones of the National Plans for Tobacco Control in EU MS. The deliverables produced in WP2, including the network of interested stakeholders, the website, leaflets, newsletters, press releases and other dissemination and communication activities, are developed for the JATC2 target audiences, including EU Member States regulators and national policymakers, research institutes and researchers, NGOs, general public under FCTC article 5.3 conditions. These interested stakeholders at the national (and European level) should take action in considering JATC2 recommendations when updating existing policies, formulating new ones, initiating research, communicating tobacco-control information and educating the public on tobacco-related health effects.

Europe's Beating Cancer plan	Dissemination of JATC2 outputs, results, and recommendations through WP2 activities, including the creation of interested stakeholders' network, is expected to contribute to further reduction of smoking prevalence and further cancer prevention in the EU by - activating the scientific research, education and communication for tobacco control – one of the leading causes of cancer in Europe. - assisting the harmonisation of legislative and administrative measures to be taken for tobacco control in the national level.
Funding to ensure sustainability What are your proposals for the necessary funding to ensure the results and policy recommendations of JATC2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	The dissemination and communication activities of WP2 are developed for the JATC-2 target audiences, including EU Member States regulators and national policymakers, research institutes and researchers, NGOs, general public under FCTC Article 5.3 conditions. These interested stakeholders at the national (and European level) should take action in considering JATC2 recommendations when updating existing policies, formulating new ones, initiating research, communicating tobacco-control information and educating the public on tobacco-related health effects. For the time being, there is limited funding to tobacco control stakeholders in Europe, except for the European Network for Smoking and Tobacco Prevention (ENSP). At the national level tobacco control communication activities vary by country and may be characterised by autonomous and non-coordinated actions of different duration. JATC2 results can play an important role in defining the material and the ways of communication in the field of tobacco control in Europe, by bringing a harmonised approach to sharing the solutions to common problems. Regarding funding to ensure the sustainability of the JATC2 WP2 activities, the leader (NPHO) has ensured that the JATC2 website as the main JATC2 communication tool, will be available for an additional **13 months** after the end of the project. Following this period, we propose funding to be ensured by the EC, so the website remains on. Since funding is directly related to the national health or public health plans' priorities, a further decline in smoking prevalence among the population should be included in the priorities. Thus, funding for tobacco control activities, including educational and communication activities, should be ensured by the government and the related authorities for at least three years. Collaboration with ENSP could also be beneficial.
Timeframe estimated	The WP2 leader (NPHO) has ensured that the JATC-2 website as the main JATC2 communication tool, will be available for an additional **13 months** after the end of the project.
How-to-guide/guidance documents/Roadmaps	- JATC2 material (logos, leaflets, newsletters, press releases) – attached and provided via ECAS and CIRCABC - Website, social media accounts (i.e., Twitter, Facebook, Instagram, etc.) - Stakeholders analysis (policy makers and regulators, tobacco inspectors, European Parliament Members, experts, researchers) - Participation in conferences and preparation of manuscript submissions in peer reviewed publications. All the above have been prepared and/or maintained/supported within the activities of WP2 and they can be utilized by all WPs partners. The final JATC2 meeting is under preparation. The leaflets, newsletters, press releases and the website (provided funding of its maintenance after the end of the project is ensured) (D2.1 and D2.3) can continue to act as a source of JATC2-related information for all target audiences. The Stakeholder analysis (D2.2) has created a network of interested stakeholders, including existing networks, to ensure that the project findings reach the relevant end users. The Layman version of the final report (D2.6) will be targeted to a non-specialist audience and it will serve to inform decision makers and non-technical parties of the JA objectives and results.

Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	It is difficult to compete with TI in the field of public communication, due to lobbying efforts by the TI and the funding available to the TI vs. the JATC2. Wider collaboration with ENSP (a stakeholder that we -JATC2 have already established collaboration with) and the scientific organisations such as the European Respiratory Society or the European Cancer Leagues, could be a way to circumvent this obstacle.
Stakeholders	The broad outreach of the European Network for Smoking and Tobacco Prevention, through its members and listserv can be used to enhance dissemination to stakeholders. ENSP maintains an active and verified list of almost 3.000 researchers, advocates and policymakers in the European Region who can promote and disseminate JATC2 activities.
Dissemination/ communication plan	The deliverables produced in WP2, including the network of interested stakeholders, the website, social media accounts, leaflets, newsletters, press releases, and other dissemination and communication activities such as the JATC2 final conference, are developed for the JATC2 target audiences, including EU Member States regulators and national policymakers, research institutes and researchers, NGOs. The JATC2 website will remain available under NPHO funding for an additional 13 months after the end of the project and it will act as a source of JATC2 information for all target audiences. The deliverables that are public as well as other JATC2-related material, such as leaflets, newsletters will also be available through the website and CIRCABC. Six newsletters are planned, of which two have already been released. A press release was issued for the 2023 WNTD, and an additional press release is foreseen to be produced after the final conference and inform all relevant stakeholders.
Recommendations	Continuation of JATC2 by a JATC3 is strongly recommended as the best way of establishing a coordinated, sustainable tobacco control action at the European level. The aim of JATC3 is proposed not to be focused on tobacco products regulation but to be mostly oriented towards a tobacco-free Europe. Coordinated scientific research, education and communication is recommended as the main axis of our next step in tobacco control in Europe.

Sustainability of the activities of WP3

Type of activity	**Evaluation of the JATC2** **Actions undertaken to support project partners and to determine if JATC2 is being implemented as planned and reaches the objectives**
Main aims and objectives	General objective To evaluate the outputs and outcomes of the JATC2 and to support the optimization of the internal processes necessary for their achievement. Specific objectives Objective 3.1: To develop an evaluation plan in line with international evaluation standards that will outline the features of the evaluation with regard to objectives, purpose, scope and methodological approach and include a data collection plan, data collection tools as well as a work plan and the description of the planned workflow. Objective 3.2: To implement the evaluation plan throughout the duration of the project. Objective 3.3: *To assess the outcomes of JATC2 with a focus on the utility of its outputs for European Tobacco Control activities.*

Results and Implementation	How do you expect to ensure that your results and policy recommendations from a) your WP WP3 is a supporting work package. Its aim is to support the project partners and to determine if the JATC2 reaches its objectives. WP3 does not produce any results or recommendations that can be used on a national policy level. It gives recommendations on the implementation of further joint actions. b) the JATC2 overall The technical WPs deal with current issues, which is very welcomed. Especially the knowledge hub meetings (WP6) provide great insight into relevant topics and how to deal with them. Can be implemented in national policies after the end of JATC2? *It depends on the approach of each country whether the focus of implementation is on proposals submitted by the Commission or whether individual reports of the JATC2 are also allowed to feed into a country's direct policy once they are finalized.*
Europe's Beating Cancer plan	Identify how your WP and JATC2 may contribute to the Europe's Beating Cancer Plan in the best possible way (related to WP activities): The evaluation reports give insight into challenges and lessons learned within the JATC2. Therefore, it provides information and recommendations for the implementation of future joint actions. Furthermore, the utility and usability of some main outputs of the JATC2 will be determined by interviews with the intended adressees. The aim is to provide feedback to improve future outputs in line with the Europe's Beating Cancer plan.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the the results and policy recommendations of JATC2 can be sustained /progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/ policies)	How do you fund it? Does it come from the Department of health or similar organizations or institutions? Is it part of some repayment scheme from the industry or not? In general, the non-smoker protection measures, and their publication are granted from public funds of the Ministry of Health directly to grant applicants after application and/or are financed from funds of the federal states according to local requirements. For the control of tobacco and related products, the collection of a cost-covering annual fee by the polluters (manufacturers, importers, distributors) is provided by law. The sustainability focus of WP3 is on its use for planning future projects.
Timeframe estimated	For how long this activity can be sustainable? The evaluation reports should be used to inform several other Joint Actions.
How-to-guide/guidance documents/Roadmaps	Specify which guidance/how-to-guide/roadmaps have been prepared within the activities of the WP, which can be considered "best" practice to support continuation and sustainability of the activities (you can also provide it as attachment to this questionnaire): *The main documents produced by WP3 are the interim evaluation report (D3.2) available at:* https://jaotc.eu/wp-content/uploads/2023/10/D3.2-Interim-Evaluation-Report.pdf *and the final evaluation report (D3.3), that will be available on the JATC2 website section of WP3 "Outcome and useful material" (*https://jaotc.eu/useful-material-jatc-2/*). Both have a focus on the internal evaluation (what works well and what does not work well within the JATC2, as well as challenges and lessons learned). D3.3, the final evaluation report, will additionally include an outcome evaluation with a focues on the utility and usability of some main outputs of the JATC2.* *These reports as well as the Evaluation Plan D3.1 (*D3.1-Evaluation-Plan.pdf (jaotc.eu)*) contribute to the sustainability of the JATC2 as they aid future projects in creating their own evaluation plans and practices and allows them to adapt specific tools to their individual needs.*

Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	Among the barriers specify possible industry interference to the mentioned activities and how would you circumvent or counteract them: None
Stakeholders	Identify stakeholders, MS leader or associations, NGOs, to be involved in these activities and that can contribute effectively in the sustainability of these activities: Any individual or group involved in or planning research projects.
Dissemination/ communication plan	What practical steps do you intend to take to communicate and disseminate the outputs of JATC2 e.g. what stakeholders will you share information with, will you hold a briefing session/webinar for the Department of Health official, will you hold workshops to progress any items - The transfer to the relevant department of the Ministry of Health. - Forwarding to the Scientific Advisory Board of the Ministry of Health. - Forwarding to The Austrian National Public Health Institute (Gesundheit Österreich GmbH, GÖG) -> www.goeg.at/English which advises the Ministry of Health on strategic health issues. - The publication in the publication database of the Agency for Health and Food Safety - Research Portal: https://www.ages.at/en/research/research-portal - Communication to the stakeholders of the individual federal states via the responsible contact point in the Ministry of Health. - The presentation at relevant training events.

Recommendations (for the sustainability of WP activities and Europe's beating cancer plan)	The sustainability focus of WP3 is on its use for planning future projects. *WP3 provides a series of recommendations for future projects to aid the project implementation. The recommendations can be found in the Final Evaluation Report (D3.3.) and will be available on the JATC2 website section of WP3 "Outcome and useful material" once it has been submitted and approved (https://jaotc.eu/useful-material-jatc-2/).* The recommendations that will be provided at the end of the project may include, but are not limited to the following: Planning phase of the project: • Close cooperation in the drafting process of the project, if possible, also in combination with a physical meeting. • Project and task description should be as clearly defined as possible but should allow for changes in case of a shift in information needs, practicability, etc. • Realistic proposals. o Project proposals often exhibit high levels of ambition, and deviations from the anticipated outcomes can lead to feelings of frustration, which in turn may result in a loss of motivation. • More funding for physical meetings, and organisation of a physical kick off meeting. o The all-digital nature of the project in the first 14 months created some issues in the JATC2, especially regarding the involvement of some partners and overall teamwork and networking. Some partners even described the first consortium meeting as a turning point in the JATC2. Copenhagen was the first chance for project partners to really get to know each other and to network. Commitment and investment in the project have improved in many WPs after this meeting. • Bureaucratic issues within the organisations should be solved before the start of the project or at least in the very beginning (e.g. hiring of staff, hiring of subcontractors, etc.). • Cooperation with other WPs should be included in the WP description and synergies between WP should be clearly defined and communicated. o I might be helpful if every WP leader has at least a very small amount of PM in the supporting WPs (Coordination, Dissemination, Evaluation, Sustainability). • Every WP should include at least one (sub-)task regarding sustainability. o A heightened emphasis on sustainability could potentially yield overall benefits for forthcoming projects. In the beginning of the project • Emphasising the need for cooperation and teamwork before the beginning of the project and especially at the beginning. o Securing responses to requests can prove challenging, particularly when they pertain to organizational and bureaucratic matters. Despite the potential for organizational requests to not always be accorded top priority, their fulfillment remains essential for ensuring the effective management of the project. • A "project-dictionary" might be helpful. o It should include explanations for important terms (e.g. PMs), description of the project and its main tasks and aims, timelines, links to important websites and tools, key staff member and their contact info, etc. It needs to be updated during the course of the project. • Task allocation need to be clear and according to expertise. o It may be more advantageous to allocate fewer individuals to larger tasks, each contributing more person-months, rather than distributing many individuals across smaller tasks with fewer person-month commitments. • Encouragement of the use of provided platforms (e.g. Circa BC, Knowledge Sharing Platform, Knowledge hub meetings,..). o Information may get lost in emails, and knowledge can be stored and be accessible to a wider audience. • Internal WP communication: finding tools that everybody WANTS TO and CAN use for information exchange. (Microsoft teams, CIRCABC,..). During the course of the project • Consistent staff members, especially in key functions o maybe even some full-time staff members? • Clear and consistent coordination, to offer guidance for all project partners. • Good and consistent internal dissemination of information (e.g. newsletters, updates). • Good documentation of (thought-)processes in decision making and of general information, to avoid knowledge loss in case of staff turnover. • Regular monitoring of resources and PMs.

Sustainability of the activities of WP5

Type of activity	EU-CEG data and enhanced laboratory capacity for regulatory purposes
Main aims and objectives	The overall objective of this WP is to strengthen and support the EU MS national competent authorities (NCAs) capacities to use EU-CEG data and enforce the applicable standards through the efficient utilisation of scarce expertise and technical resources at the EU level by avoiding duplication and wide implementation of best practices (including independent laboratories for tobacco analyses).
Results and Implementation	After the end of JATC2, EC/DG SANTE (with EC/JRC) will remain a focal point for EU-CEG data and tobacco control laboratories related matters. End-users from national competent authorities and laboratories targeted through JATC2-WP5 are part of the different committees and meetings organised by EC. Use of CircaBC extranets to share documents and information, update of diffusion contact lists, frequent meetings and designation of a person/ organisation responsible for maintaining the networks are the key points for making the activities sustainable in the future.
Europe's Beating Cancer plan	The main contribution of JATC2-WP5 to Europe's Beating Cancer is to improve the assessment of ingredients and their health risks through different sources: better handling of EU-CEG declarations, better knowledge of the products through laboratory analyses.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the the results and policy recommendations of JATC2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	Centralizing the EU-CEG database in a EU agency might be a good option to gain efficiency in the future for handling EU-CEG data in a harmonized manner. National experts would still have access to their data and could participate to assessment panels under the remit of the EU agency. Regarding the tobacco control laboratories network, one could take the example of the EU reference laboratories settled under the EU Food Law. Under the supervision of EC/JRC, some labs could be "reference laboratory" for a specific analysis. There would be specific EU budget to run such mandates and organize collaborations abroad (with WHO TobLabNet inter alia). Thus, providing legal EU frameworks with specific budgets could be a good solution to make the activities sustainable in the future. The national activities could also receive a complementary funding based on what is done now in the different EU MS. The question of fees collection from the industry should be considered both for EU-CEG declarations and product testing: having a EU centralized fees collection could ensure more stability in the funding and avoid discrepancies between EU member States.
Timeframe estimated	Provided it is hosted by EC institutions, the activities will be sustainable like other existing legal-based frameworks (Food Law, REACH & CLP regulations).
How-to-guide/guidance documents/ Roadmaps	**D5.4 Dashboard and how-to guide to analyse EU CEG data at national scale**: https://jaotc.eu/wp-content/uploads/2024/07/D.5.4.-Dashboard-and-how-to-guide-to-analyse-EU-CEG-data-at-national-scale.pdf
Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	It is needed to design an internal organisation which ensure an independency between the staff in charge of interactions with manufacturers (EU-CEG support helpdesk, product analyses, fee collections, administrative communication) and the staff in charge of assessment (example of Novel Food approval system with EC/DG SANTE for interactions with manufacturers and EFSA for assessment).
Stakeholders	EC/DG SANTE, EC/JRC, WHO TobLabNet, possibly other EU agencies, EU MS competent authorities and laboratories. (Since the information managed is sensitive for policy-making and enforcement, it is difficult to work with other stakeholders like NGOs).
Dissemination/communication plan	The dissemination will continue through EC organised meetings regarding tobacco control.

Sustainability of the activities of WP6

Type of activity	WP6 – Enforcement of tobacco product regulation
Main aims and objectives	The main aim of WP6 is to facilitate knowledge sharing on tobacco enforcement. In order to obtain this, WP6s three objectives are: - To identify and map all EU authorities within the field of tobacco regulation. - To establish a network of tobacco regulation authorities with the purpose of enhancing knowledge sharing between enforcement authorities across the EU. - To ensure that relevant information about enforcement of tobacco regulation is archived and accessible to all relevant EU authorities.
Results and Implementation	Since the objective of WP6 is to facilitate knowledge sharing between the different EU member states, it is challenging to see the relevance of implementation in national policies after the end of JATC-2. However, it is the view of WP6, that **the knowledge sharing network (KSN)** could optimally continue after the project is finalised by being established as a permanent EU network. One proposal for achieving this would be to let the responsibility of planning the knowledge hub meetings and maintaining the remaining elements of the knowledge sharing network such as the archive, the online dialogue forums, contact lists, etc., be distributed by letting the participants take turns having the chairmanship of the KSN. Another proposal for achieving the sustainability of the knowledge sharing network would be to include the creation of a tobacco enforcement network in the revision of the TPD, as an Administrative Cooperation Group (AdCo) which would ensure, that participation in the network would become mandatory.
Europe's Beating Cancer plan	The overall objective of Europe's Beating Cancer Plan (EBCP) is to improve the prevention, detection, treatment and management of cancer in the EU while reducing health inequalities between and within member states. In order to prevent future cancer cases by addressing key risk factors, such as smoking, the EBCP sets out to achieve a 'Tobacco-Free Europe' and a 'Tobacco-Free Generation', where less than 5% of the population uses tobacco by 2040. Therefore, WP6 urge that knowledge sharing between EU member states regarding research, regulation and enforcement of nicotine and tobacco products is a vital part of achieving the goals in Europe's Beating Cancer Plan. WP6 knowledge hub meetings, establishing an archive in CIRCABC, and fostering knowledge sharing between EU authorities all contribute to Europe's Beating Cancer Plan.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the results and policy recommendations of JATC-2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	Not able to answer at this point as it depends on the final decision on how to continue the activities of WP6 after JATC-2 is finalised. However, assuming the necessary funding to continue the activities of WP6 has been finalised, certain tasks have been identified to ensure the sustainability of the activities: maintaining the archive including allowing access, share information on how to set notifications, managing folders and minor administrative tasks – creating and supervising a shared inbox for communication. The estimated hours to complete these tasks are one-two hours monthly.
Timeframe estimated	The activity can be sustainable as long as relevant organisations in the EU member states find it valuable to participate in the knowledge sharing network. Therefore, indefinitely.

How-to-guide/guidance documents/ Roadmaps	**WP6 has created a roadmap which describes how the knowledge sharing network is to be created and maintained around:** **1) knowledge hub meetings hosted biannually,** **2) a knowledge sharing archive created using CIRCABC as a platform, 3) online forums for dialogue within the knowledge sharing archive.** The roadmap also contains a clear guideline on how the knowledge hub meetings are to be planned and hosted in order to make sure, that the knowledge hub meetings will be able to continue as smoothly and with as much coherence as possible in the future.
Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	The main barrier for the continuation of the activities in WP6, is the potential lack of interest and engagement from relevant authorities and organisations within the EU member states to allocate the necessary resources to actively engage and participate in the knowledge sharing network. This risk could possibly be circumvented by following the above suggestion of continuing the network as an AdCo-group and subsequently make participation more mandatory.
Stakeholders	Inspectors and regulators.
Dissemination/communication plan	The activities and results of WP6 are continuously disseminated through the hosting of knowledge hub meetings, the archive for knowledge sharing and by sending out information about the network using the contact list that was created by WP6 at the beginning of JATC-2, where relevant EU authorities within the field of tobacco regulation were initially mapped.
Recommendations (for the sustainability of WP activities and Europe's beating cancer plan)	In order to secure a sustainable flow of knowledge sharing (after the conclusion of JATC-2), it is strongly recommended to facilitate **Administrative Cooperation Groups (AdCo)**, where the chairmanship is alternate between the countries in the network. This prerequisite the establishment of fixed networks with relevant tobacco control authorities. In order to establish mandatory participation in the AdCo groups, it is recommended to include the initiation of a tobacco enforcement network, in the revision of the TPD. Therefore, we recommend DG SANTE initiate an AdCo group through the Commission under the Market Surveillance Regulation (MSR) under article 32. Thus, to ensure the knowledge generated and shared within the network is archived and accessible, it is recommended to use an archive mechanism existing within the EU platform. An archive has already been created as an interest group in CIRCABC in accordance with objective 6.3, to allow for external relevant authorities to join the network as well as making sure that the archive will be able to continue autonomously from JATC-2 after the project is finalised.

Sustainability of the activities of WP7

Type of activity	Health impact and regulatory implications of e-cigarettes and novel tobacco products
Main aims and objectives	1. To gain insight into the variation of novel tobacco and e-cigarette products in/between countries. 2. To evaluate the use, abuse potential and health risks of novel tobacco products and e-cigarettes. 3. To harmonise collection of e-cigarette (and novel tobacco products) associated adverse incidents across the EU. 4. To support EU MS training, capacity building and information sharing on novel tobacco products and e-cigarettes.
Results and Implementation	WP7 is mostly aimed at gathering and gaining knowledge, about the health effects of e-cigarettes and novel tobacco products. Sustainability in this respect would relate to making sure that our findings and conclusions are disseminated to those who can use them for further research and regulation. Results from task 7.1 will be used to create awareness about the range of e-cigarette and novel (tobacco) products in the EU markets, and country efforts of regulating them. This information is shared in deliverables D7.1 and D7.2 which are (/will be) published on the JATC website. Moreover, the results from task 7.2 provide insights into factors contributing to health risks of these products (M7.5), harmful substances in their ingredients and emissions (M7.6 + D7.3), and perceptions and use patterns (D7.4). Based on these outcomes we formulated recommendations for stricter regulation and enforcement of these products, in order to protect the health of EU citizens. The milestones and deliverables related to this work are (or will be) published on the JATC2 website. The outcomes will be disseminated to the scientific population in one or two open access publications. Further, in task 7.3 we identified current approaches for collecting data on adverse health incidents after e-cigarette or NTP use in order to formulate recommendations for a more harmonized approach. A webinar workshop was organized in October 2023 to discuss good and best practices in collecting data on adverse incidents with WP7 partners and relevant stakeholders, such as EU regulators. Recommendations will be formulated in our deliverable D7.6 that is to be published on the JATC website. To ensure that our results and recommendations are known to EU-regulators and can be implemented in policies, we dedicated one task in our WP to dissemination activities; In task 7.4 information sheets for regulators are prepared to share the findings and regulatory implications of WP 7. Moreover, a webinar will be organized in May 2024, where we will share our findings and welcome feedback from relevant stakeholders (EU regulators and NGOs) in order to optimise suitability of our information sheets and increase the chances of implementation of our recommendations.
Europe's Beating Cancer plan	We add to the knowledge about health risks of using e-cigarettes and novel tobacco products and (potentially) harmful and carcinogenic substances in their contents and emissions. We also make recommendations to EU-policy makers about regulation of e-cigs and novel products in order to protect EU citizens' health.

Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the the results and policy recommendations of JATC2 can be sustained /progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/ policies)	RIVMs work in the JATC is partially funded by the Dutch Ministry of Health. We are not aware of any possibilities for obtaining extra funding. However, WP7 partners are prepared to collaborate in writing a potential grant proposal to obtain external funding.
Timeframe estimated	There are currently no funds available to extent activities beyond the JATC deadline. However, the activities can be continued within a new *Joint Action JA-07 Health promotion and disease prevention including smoke- and aerosol- free environments*
How-to-guide/guidance documents/Roadmaps	M7.5 outlines a common approach for evaluation of health impact and abuse liability (M.7.5-Common-approach-for-evaluation-of-health-impact-and-abuse-liablity.pdf (jaotc.eu) We are developing 5 information sheets to inform regulators about health risks and regulatory implications of novel tobacco products and e-cigarettes.
Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	Tobacco /e-cigarette industry is generally not in favour of stricter regulation of their products and may try to assert their influence on policy makers (lobby) to delay or prevent implementation of our policy recommendations. Moreover, policy makers weigh different interests and therefore there is a chance that recommendations have no follow-up.
Stakeholders	Tobacco-regulators of all EU MS and other participating countries, as well as relevant NGO's that are able to resonate our outcomes and recommendations to policy makers.
Dissemination/ communication plan	WP7 is preparing six report deliverables, five information sheets for policy makers and two scientific publications that will be disseminated on the JATC2 website and to the stakeholders in our networks. We are also hosting a webinar which is open to EU regulators and NGO's.

Recommendations	It is unfortunate that funding for JATC only includes the duration of the project, this hampers the creation and implementation of sustainable actions. It would be useful to include efforts to find further funding options/resources/grants as a task in the sustainability WP (in future JATCs). Moreover, to make sure sustainability is strongly embedded in the project, WP leaders should have a small amount of person months in the sustainability WP and should be encouraged (during the project preparation phase) to incorporate sustainability related activities in their proposal. The network resulting from participating in JATC and JATC is extremely useful and this important to maintain. For example, countries should be facilitated to keep informing each other of developments in their markets and regulatory approaches. E-mail updates are useful as they are usually seen by their addressees and thus also have an alerting function. To avoid overflowing inboxes the use of a platform such as circa-bc or knowledge archive may be considered, however it is important to keep the platform active and ensure that people will actually use/ keep using it. Manufacturers data submitted to the EU-CEG is a valuable source of information, to inform regulators of market developments and evaluate effects of changes in regulation. However it is complicated to work with and share between partners. We recommend facilitate data sharing by use of data sharing agreements as well as developing easy to use software tools that facilitate merging and comparing datasets. This recommendation is closely related to the work conducted in WP5 and we expect that they will have more specific recommendations on this topic. Several new nicotine products (tobacco surrogates, such as nicotine pouches and inhalers, and nicotine containing heated products based on tea) are currently not regulated on an EU level. To ensure harmonized action, TPD revisions should establish comprehensive regulation that includes all of these products and potential future developments. Further, enforcement of ingredient regulation is complicated, for example due to unspecific definitions in the TPD ('ingredients that facilitate inhalation') but also due to differences in approaches and resources between countries. It is recommended to establish a network of enforcement agencies that can develop a harmonized approach. This recommendation is closely related to the work conducted in WP6, and we expect that they will have more specific recommendations on this topic. Finally, we will make recommendations for more structural, harmonized collection of data on adverse incidents after e-cigarette or NTP use. Suitable approaches can range from having a central team collecting data from hospitals to providing users the possibility to enter data on a website. But in any case, some amount of funding is needed to facilitate this type of work. NGO's may be interested to contribute to launching a website or campaign, but for a structural EU-wide data collection at least a strong EU-wide network is required and therefore involvement of governments is preferred.

Sustainability of the activities of WP8 (Symposium)

Type of activity	Systematic consultation to experts and Member States representatives on existing best practices, barriers and opportunities to protect the EU population from SHS exposure (Milestone 8.1)
Main aims and objectives	To **assess barriers and opportunities** to protect population from exposure to second-hand tobacco smoke and from exposure to aerosols produced by electronic cigarettes, heated tobacco products and other novel tobacco products. To **identify best practices** to protect the population from exposure to second-hand tobacco smoke and from exposure to aerosols produced by electronic cigarettes, heated tobacco products and other novel tobacco products.
Results and Implementation	The **Weight of Evidence paper (Deliverable 8.1) for supporting the expansion of smoke and aerosol free environments,** is a document resulting from the consultation to experts (Milestone 8.1), the literature review on SAFE conducted within WP8, the information from the EU report on SAFE and TAPS legislation, the information from Tobacco Control Scale and the specific report on barriers and opportunities for SAFE expansion and compliance. Available at CIRCABC, JATC2 website and ICO website: https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/JATC2_WP8_Deliverable8.1_-WeightofEvidence.pdf The **Position Paper (Deliverable 8.2) on best practices on second hand smoke and aerosol protection and evidence supporting the expansion of smoke and aerosol free environments (SAFE)**, is a document resulting from different activities conducted in WP8 (Consultation, Symposium, Literature review and Weight of evidence paper). Available at CIRCABC, JATC2 website and ICO website: https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/JATC2-WP8_Deliverable8.2_PositionPaper-2.pdf These D8.1 and D8.2 are expected to be used by Member States to design their national policies on SAFE.
Europe's Beating Cancer plan	The **expansion of Smoke free environments is a crucial element within the Tobacco Endgame Strategy** that is contemplated in the Europe's Beating Cancer Plan.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the the results and policy recommendations of JATC2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	From the consultation on SAFE to experts conducted within WP8, there are **20 practices with institutional and human resources support, along with six with training of staff as an important issue to guarantee sustainability**.
Timeframe estimated	The outputs obtained from the Consultation have been compiled in a web-based repository: www.smokefreebestpractices.eu This repository is connected to an ICO server that has **high probability to be sustainable.** The main domain was bought for a 5 year period starting in 2023. The estimated timeframe of these elements **will depend on the sustainable strategies of JATC2-WP2.**

<table>
<tr><td>How-to-guide/guidance documents/ Roadmaps</td><td>Available at the ICO website:
The Protocol for the consultation on SAFE best practices and barriers and opportunities):
https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/20221130_JATC2_WP8_protocolSAFE_-PDF-1.pdf
The Report on SAFE best practices:
https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-consultation-report-Annex-1_JATC2_WP8.pdf
https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-consultation-report_Annex-2_JATC2_WP8.pdf
The Report on barriers and opportunities for SAFE:
https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE_barriersandopportunities_JATC2layout-2.pdf</td></tr>
<tr><td>Barriers for the continuation of the activity including Article 5.3 (and possible solutions)</td><td>Results from the consultation to experts on Smoke and Aerosol Free Environments (SAFE)
Table 1. Barriers for the expansion of SAFE policies, n=63
<table>
<tr><th>Response categories</th><th>N=63</th><th>%</th></tr>
<tr><td>Tobacco industry lobby and funding activities</td><td>15</td><td>23.8</td></tr>
<tr><td>Reluctance and low commitment of government and competent authorities for the expansion</td><td>13</td><td>20.6</td></tr>
<tr><td>Claims of specific settings against the expansion</td><td>13</td><td>20.6</td></tr>
<tr><td>Misinformation about current nicotine and tobacco products</td><td>7</td><td>11.1</td></tr>
<tr><td>Lack of capacity and public or professional support for enforcing</td><td>6</td><td>9.5</td></tr>
<tr><td>Other</td><td>4</td><td>6.3</td></tr>
<tr><td>No barrier</td><td>5</td><td>8.1</td></tr>
</table></td></tr>
<tr><td>Stakeholders</td><td>There is a list of contacts relevant to SAFE policies in EU to be crosschecked whether can be made public.
The list of national stakeholders is available from WP6.</td></tr>
<tr><td>Dissemination/communication plan</td><td>A webinar on SAFE was conducted in November 2022, along with WP4-JATC2. The recording and presentations are available at:
https://jaotc.eu/secondhand-smoke-and-aerosols-exposure-in-europe/

An additional webinar on SAFE was conducted in November 2023, (Milestone 8.5) with the objective to disseminate thoroughly the WoE on SAFE results. The recording and presentations are available at:
https://jaotc.eu/jatc2-wp8-webinar-on-safe-webinar-on-the-evidence-for-supporting-the-expansion-of-smoke-and-aerosol-free-environments-safe-to-other-indoor-and-outdoor-areas/

Also, within the working plan of WP8 there is a Systematic Literature review on SAFE that will be conveniently published and disseminated.

In parallel, ICO is promoting and supporting along with several stakeholders a Spanish campaign in line with “Smoke Free Generation” and “Endgame Strategy”.

Implementation research is conducted through a recently launched project on “Smoke Free Homes”.</td></tr>
</table>

Recommendations	It is crucial to have the **outcomes of the activity** available on platforms that ensure sustainability. The relevant materials related to the Symposium activity such as the symposium report and the dissemination video of the event are available on the official JATC2 website but also on the digital platforms from the Catalan Institute of Oncology (ICO) such as YouTube, Twitter and ICO Website are connected to an ICO server, **therefore sustainability is expected**. **In regards to SAFE, the following recommendations were mentioned by experts of the consultation**: ongoing or recently started national 'smoke-free' or 'smoke-free generation' strategies as well as local campaigns and education for the general population to understand SAFE policies. Transparency of industrial financial operations, funding for smoking cessation services or for enforcing SAFE policies, and imposing a significant fine to deter.

Sustainability of the activities of WP8 (Consultation)

Type of activity	**Symposium on Smoke and Aerosol Free Environments: "Learning from Practices to Improve Smoke- and Aerosol-Free Environments (SAFE) in Europe" (Milestone 8.4).**
Main aims and objectives	The objective of the symposium was **to identify learning key aspects of practices on Smoke and Aerosol Free Environments** that were informed by experts on a consultation conducted within the framework of JATC-2 in 2022.
Results and Implementation	The **Position Paper (Deliverable 8.2) on best practices on second hand smoke and aerosol protection and evidence supporting the expansion of smoke and aerosol free environments (SAFE)**, is a document resulting from different activities conducted in WP8 (Consultation, Symposium, Literature review and Weight of evidence paper). This D8.2 is expected to be used by Member States to design their national policies on SAFE. It is available on CIRCABC, JATC2 website and the ICO website: https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/JATC2-WP8_Deliverable8.2_PositionPaper-2.pdf
Europe's Beating Cancer plan	The **expansion of Smoke free environments is a crucial element within the Tobacco Endgame Strategy** that is contemplated in the Europe's Beating Cancer Plan.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the results and policy recommendations of JATC2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	From the Symposium working groups we identified that, in regards to **funding to ensure sustainability**, it's important to consider that, practices that have funding in the framework of a public policy are positive in terms of sustainability because it means they can be available for a long time. Further funding is available within the new *Joint Action JA-07 Health promotion and disease prevention including smoke- and aerosol- free environments* that will start in 2025. It is also important to consider elements such as: a team for design, implementation and evaluation; partnerships; resources for training; dissemination on rewards and benefits; institutional support and legislation. Further details on these elements can be found in the section "Recommendations" below.
Timeframe estimated	The outcomes of the activity will be available on public websites that are connected to an ICO server and therefore, timeframe is not an issue moving forward. The estimated timeframe of the outputs obtained from the Symposium **will depend on the sustainable strategies of JATC2-WP2**.

How-to-guide/guidance documents/ Roadmaps	The **Symposium Report**, available in CIRCA-BC and the ICO website: https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/SAFE-SymposiumReport_JATC2_WP8_PDF.pdf
Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	The following points were discussed in the Symposium as follows: 1) The main barriers against the expansion of SAFE practices are: the industry lobby, the reluctance of governments, the lack of monitoring and sales regulation, and claims of specific settings (hospitality sector) against the expansion. 2) The main barriers against the enforcement of SAFE practices are: the lack of comprehensive legislation (partial bans do not work), the lack of human and financial capacity, reluctance of governments, lack of training for authorities and/or public sector, as well as the lack of dedicated funding for tobacco control research and interventions.
Stakeholders	There is a list of contacts relevant to SAFE policies in EU to be crosschecked whether can be made public. The list of national stakeholders is available from WP6.
Dissemination/communication plan	The **outputs obtained** from the Symposium such as the **Symposium report** and the **dissemination video** (https://www.youtube.com/watch?v=fav2NekuNuA) will be available for consultation by EU Member States through a variety of dissemination strategies: CIRCABC, JATC2-website, JATC2-social media platforms, scientific papers and the digital platforms from the Catalan Institute of Oncology (ICO) such as YouTube, Twitter and ICO Website. A **webinar on SAFE** was conducted in November 2022, along with WP4-JATC2. The recording and presentations of this webinar are available on the JATC2 website: https://jaotc.eu/secondhand-smoke-and-aerosols-exposure-in-europe/ MoH Spain is involved in WP8 and other WPs. They attended the Symposium. In parallel, ICO is promoting and supporting a Spanish campaign in line with “Smoke Free Generation” and “Endgame Strategy” along with several national stakeholders. Implementation research is conducted through a recently launched project on “Smoke Free Homes”.

Recommendations	It is crucial to have the **outcomes of the activity** available on **platforms that ensure sustainability**. The relevant materials related to the Symposium activity such as the symposium report and the dissemination video of the event are available on the official JATC2 website but also on the digital platforms from the Catalan Institute of Oncology (ICO) such as YouTube, Twitter and ICO Website are connected to an ICO server, **therefore sustainability is expected**. From the consultation on SAFE to experts on tobacco control conducted within WP8, there are 20 practices where institutional and human resources support, along with six where training of staff were identified as an important issue to guarantee sustainability. From the Symposium working groups we identified the following recommendations **for a practice to be sustainable**: • **Team:** you need a team in order to sustain an effort. You need to have an administration and NGO or another body in charge of the whole process: you need institutional anchoring. It need for memory, for purpose, for resources, etc. • **Evaluation:** you can only sustain something that you can demonstrate that it is working or you lose interest from stakeholders. • **Partnership:** you need to relay on partners to make the practice sustainable for the pressure to maintain it. Partnership are important for trust and shared ability. • **Training and resources** available to help achieve and maintain a smoke-free environment: for the public (for example workers) but also for the people in charge of compliance (managers). Also helps for implementation and transferability. • **Focus and disseminate potential rewards and benefits** of implementing the practice to motivate support for the implementation. • **Human resources**. • **Institutional support**. • **Legislation**. • It's important to ensure the continuation of the practice on the **long term** with: o Regular assessment and monitoring. o Regular information campaigns specific to the practices. • **Coalition between civil society and local authorities** to guarantee that the processes will be followed even if the political change. • **Funding by public resources**: practices that have funding in the framework of a public policy are positive in terms of sustainability because it means they can be available for a long time. **Step by step strategy** that it is clearly described.

In Summary – Sustainability for JATC2 WP8

- Products from WP8 will be published in a **scientific journal** with open access.
- Products (published and not published) will be available on different **websites**.
  - o Most importantly, on the Tobacco Control Unit Website, connected to an **ICO server**. Therefore, sustainability is not expected to be an issue, short, mid or long-term.
  - o The products include reports, papers, videos, webinar recordings, etc. **Good variety.**
  - o The products highlight not only the importance of SAFE which is very much related to **Europe's**

Beating Cancer plan, but it also focuses on how to make **SAFE practices sustainable**.

- The **web-based repository** will also be available and connected to an **ICO server**.
  - o An idea of giving the possibility to experts to upload new and/or other practices not yet contemplated in the repository is being considered.
- The Tobacco Control Unit of ICO (coordinator of WP8) is actively involved in different projects and activities related to tobacco control. There is availability to continue to disseminate and use the findings and work done within WP8-JATC2.

Sustainability of the activities of WP9

Type of activity	WP9 – Best practices to develop an effective and comprehensive tobacco endgame strategy
Main aims and objectives	The WP9 aims to provide tools to put forward actions in line with the Europe's Beating Cancer Plan, to help create a 'Tobacco-Free Generation' where less than 5% of the population uses tobacco by 2040. Additionally, WP9 supports the implementation of the "Global Strategy to Accelerate Tobacco Control: Advancing Sustainable Development through the Implementation of the WHO FCTC 2019–2025" and "Making tobacco a thing of the past: Roadmap of actions to strengthen implementation of the WHO Framework Convention on Tobacco Control in the European Region 2015–2025." Specifically, the WP9 has the following objectives: - To identify and assess tobacco endgame strategies and forward-looking tobacco control policies for the European region. - To explore best practices in the development, implementation and evaluation of tobacco endgame strategies and forward-looking tobacco control policies. - To promote best practices and facilitate the development of national tobacco endgame strategies in Europe, in synergy with WP4 and other WPs.

Results and Implementation	The deliverables produced in WP9, including reports, scientific articles, webinars and an online toolkit, are developed for policy-makers, regulators, civil society and researchers in the field of tobacco control in the region. The deliverables provide background and definitions for tobacco endgame, case studies on different approaches to it in the region, potential best practices in developing, implementing and evaluating tobacco endgame or innovative measures, and templates that can be utilized to systematically assess feasible policy options in the local tobacco control context. Critical aspect in ensuring that these also reach the target audience and can benefit national policy development is the dissemination and continued knowledge sharing, for which good collaboration with WP2, WP4 and WP6 is essential. This may be supported also by the Decision FCTC/COP10(12) Forward-looking tobacco control measures (in relation to Article 2.1 of the WHO FCTC) adopted by the COP10 in February 2024. The COP decided to establish an expert group to to identify and describe forward-looking tobacco control measures and measures, to consider, in conducting its research and elaborating its findings, Party experience and published literature, and prepare a report of its findings to COP11. Besides the deliverables **D9.1 Report of tobacco endgame strategies for the European region** and **D9.2 Recommendations for research on forward-looking tobacco control policies and tobacco endgame strategies**, the WP9 has produced the following scientific articles: • González-Marrón A, Koprivnikar H, Tisza J, Cselkó Z, Lambrou A, Peruga A et al. Tobacco endgame in the WHO European Region: Feasibility in light of current tobacco control status. Tobacco Induced Diseases. 2023;21(November):151. https://doi.org/10.18332/tid/174360 • Ruokolainen O, Ollila H, Laatikainen T, et al. Tobacco endgame measures and their adaptation in selected European countries: A narrative review synthesis. Tobacco Prevention & Cessation. 2024;10(April):18. doi:10.18332/tpc/186402. • Ollila H, Ruokolainen O, Laatikainen T, Koprivnikar H et al. Tobacco endgame goals and measures in Europe: current status and future directions. (submitted) • SoliminiR, Ruokolainen O, Cselko Z, Koprivnikar H, Spizzichino L, Papachristou S et al. Good Practice Statements for the treatment of nicotine dependence. Tobacco Prevention & Cessation. 2023;9(July):24. https://doi.org/10.18332/tpc/167964 (in collaboration with WP4) One additional manuscript based on the interviews conducted among partner countries is under preparation. Further, WP9 has produced a policy brief **'Forward-looking tobacco control measures and tobacco endgame'** available at https://jaotc.eu/useful-material-jatc-2/, integrated later also in the **D9.3 EU Tobacco endgame toolkit** upon its launch in June/July 2024. The milestone **M9.1 WP9 Indicator compendium** compiles the working methods as well as summary of the external workshop **M9.2 Workshop for key policy makers, regulators and researchers to discuss traditional and forward-looking approaches** and internal partner workshop to discuss and develop the tobacco endgame framework to guide the work in the WP9.

Europe's Beating Cancer plan	WP9 is at the very core of JATC2 in raising awareness of the Tobacco-Free Generation goal of the EU Cancer Plan, and providing different tools that can facilitate the development of national tobacco endgame strategies and policies, hence support countries taking the necessary steps towards meeting the regional goal. The regional goal cannot be reached without more countries stepping up their tobacco control efforts. WP9 facilitates knowledge-sharing and peer-learning through presenting case studies and addressing challenges and opportunities in different tobacco control contexts, and organizing events and participating to external events where JATC2 and WP9 objectives can be promoted. WP9 provides a review of the relevant scientific evidence, as well as of the status of the WHO FCTC implementation to help countries identify where more work and focus in needed in their national context.
Funding to ensure sustainability. What are your proposals for the necessary funding to ensure the the results and policy recommendations of JATC2 can be sustained / progressed at national level (the aim is to create a stable budget on tobacco control in terms of: human resources, budget/type of funding to ensure the continuation of the intervention or activity, possibility to use resources already in place for other purposes/policies)	In WP9, as part of the feasibility assessment, a template will be developed and disseminated in the online toolkit (D9.3) and in a guidance document in collaboration with WP4 to help countries systematically assess the needed funding, and potential costs and savings, related to different policy options (including do nothing or continue with current implementation of the WHO FCTC). The measures needed to achieve the level of tobacco use set in the Tobacco-Free Generation goal (<5% by 2040) are very different depending on country context, so the needed funding and suitable funding sources are also dependent on the local context. Some of the activities initiated in the JATC2 can also be partially continued through the new JA PreventNCD-project, where WP9 lead THL participates to three work packages (WP5, WP9, WP10) that include tasks which address the effective implementation of tobacco policies, good practices in monitoring Article 5.3 of the WHO FCTC, and provision of brief advice in tobacco and nicotine cessation. Moreover, a new Joint Action **JA-07 Health promotion and disease prevention including smoke- and aerosol- free environments** will start in 2025 and it is a chance to continue the WP9 activities. For JATC2 partners, it is essential to follow and participate, when possible, to upcoming Joint Actions addressing topics that are relevant for strengthening tobacco control and dissemination of forward-looking measures in the EU.
Timeframe estimated	To achieve the Tobacco-Free Generation goal by 2040, countries need to develop activities and adopt regulatory measures within this time-frame.
How-to-guide/guidance documents/ Roadmaps	Especially D9.3, the online tobacco endgame toolkit, will host potential best practices, case studies and template(s) that can be utilized by different stakeholders to identify and assess feasibility of different policy options to advance or take steps towards tobacco endgame strategies or measures in different tobacco control contexts. In November 2021, WP9 organized an external workshop to present case studies from WP9 partner countries and to discuss the concept and gather insights on challenges and enablers in this field. In 2023, WP9 and WP4 jointly organized a webinar to raise awareness and disseminate information of case studies from WP9 partners as well as internationally recognized initiatives and of industry tactics against tobacco endgame. In 2024, a policy brief was published to introduce the concept and provide general guidance. The methods and the tobacco endgame framework used in WP9 have been compiled into an indicator compendium, available on the JATC2 website.

Barriers for the continuation of the activity including Article 5.3 (and possible solutions)	The WP9 gathers information of challenges and barriers in different ways: as part of current status assessment utilizing the WHO FCTC implementation data, with a separate WP9 questionnaire on tobacco endgame, and through interviews of relevant stakeholders in several partner countries with differing tobacco control contexts. Challenges that have already been identified include different difficulties in implementing the requirements and recommendations of the WHO FCTC, insufficient capacity for tobacco control, less developed support for tobacco cessation, and tobacco industry interference. One clear solution for several countries is to improve the implementation of the Article 5.3 in order to protect the policy development from industry influence, and to enable the often small human resources to focus on implementation of effective measures – instead of being distracted by industry initiatives aiming to delay policy-making and maximize profits instead of protection of health. Publications and D9.3 online toolkit also provide information of the challenges and ways to overcome these.
Stakeholders	Stakeholders are dependent on the country context. WP9 encourages collaboration and contribution from different stakeholders through active knowledge sharing between WP partners, and with external audience through the organized events and by presenting different approaches as case studies in the online toolkit and in other dissemination events. In general, key stakeholders include experts working with tobacco control regulations or enforcement, policy-makers, researchers, IGOs and NGOs.
Dissemination/communication plan	WP9 has already organized an external virtual workshop on tobacco endgame in the beginning of the project and organized another webinar in collaboration with WP4 in 2023 to disseminate WP9 findings and share relevant other initiatives. The webinar recording from the joint webinar with WP4 '**Making the tobacco endgame a reality**' is available on the JATC2 website https://jaotc.eu/wp4-wp9-making-the-tobacco-endgame-a-reality/. WP9 lead has also participated to different external conferences/webinars to present WP9 objectives, activities and observations. The audience in both organized and external events consists mostly of regulators, civil society and researchers. Relevant other stakeholders have also been invited to present their recent work in the WP9 regular meetings to raise awareness and discuss potential synergies. The materials and events will be promoted in relevant channels and to relevant stakeholders in collaboration with WP2 and WP6. Publication channels include scientific journal articles, JATC2 website (publications, webinar recording), and D9.3 online toolkit.
Recommendations	WP9 provides **recommendations for research in D9.2 report (scientific article)**. For the development, implementation and evaluation of tobacco endgame strategies and measures, the D9.3 online toolkit will provide policy options and materials to assess the feasibility of different options in different tobacco control contexts. A general recommendation to all countries is to strengthen the implementation of the WHO FCTC, integrated also to the Sustainable Development Goals as target 3.a.

1 Vital Strategies. Sustainable Funding Mechanisms for Population-Level Tobacco Control Communication Programs. Position Paper. 2017. Available from: https://www.vitalstrategies.org/wp-content/uploads/2017/02/VS_Sustainpaper_Final_light.pdf

WP4 Survey: Sustainability of tobacco control policies and activities

This **Survey** was presented during the online WP6 Knowledge hub meeting, 27 February 2024.

Authors: Renata Solimini (ISS, Italy), Frances O'Donovan (MoH, Denmark)

Reviewers: Hanna Ollila (THL, Finland), Maurice Mulcahy (HSE, Ireland)

Introduction

Tobacco control is a sustainable policy at macro-level because tobacco use comes with very large social costs[1]:

- Tobacco-attributable diseases account for a substantial proportion of health-care costs from preventable cancers, lung diseases and heart conditions, which are borne by the state in many countries.
- Tobacco use causes losses in productivity due to smokers missing work more frequently because of illness and dying prematurely.
- Second-hand smoke causes disease among non-smokers. The children of smokers also miss more school due to second-hand smoke triggering asthma and other lung health concerns.
- Smoking causes many fires (discarded cigarettes).

Governments' commitment is required to take action to adopt and ensure sustainable policies and to examine all options for multi-year funding commitment, long-term plan for tobacco control and appropriate annual budget stable for a longer period.

Policies aiming at saving economic and social costs due to tobacco/nicotine-related dependence, reducing mortality and morbidity of the countries, should be effective ad cost-efficient.

Currently, there is lack of finance for tobacco, or this finance is not stable over time. Moreover, a barrier is the tobacco industry interference in the policies and activities of EU MS.

At micro level, sustainability includes specific actions and procedures aiming at reducing costs of tobacco control activities. One of these actions is the use of resources already in place: it is important the collaboration between countries in sharing lessons learned and adapting creative materials from other countries and organizations (best practices). A best practice of a country may be transferred to other countries with limited costs.

Another way to save costs is the preparation/dissemination of guidance documents indicating a specific procedure or homogeneous actions to support EU MS in tobacco control, and of evidence-based clinical practice guidelines.

Financial resources for tobacco control are affordable when obtained from tobacco/nicotine products taxes or EU-CEG fees paid by the Industry. Another source can be fines or damages payable by the tobacco industry for violations of tobacco control legislation.

In some countries, governments require broadcasters to air tobacco public health messages free of charge. Antismoking advertisements, disclaimers about the harms of tobacco must be shown ahead of any media content promoting tobacco use, such as in cinemas ahead of films depicting tobacco use or in television program. In the United States, fears about such anti-tobacco counter-

2 International Union Against Tuberculosis and Lung Disease (The Union). Index of Tobacco Control Sustainability (ITCS) – a tool to assess and guide national tobacco control programmes to become sustainable. 3rd edition. Paris: the Union Department of Tobacco Control; 2021. Available from: https://theunion.org/sites/default/files/2021-12/Index%20of%20Tobacco%20Control%20Sustainability%202021%20FINAL%203.pdf

3 International Union Against Tuberculosis and Lung Disease (The Union). Index of Tobacco Control Sustainability (ITCS) – a tool to measure the sustainability of national tobacco control programmes.Edinburgh: the Union Department of Tobacco Control; October 2016. Available from: https://theunion.org/sites/default/files/2020-11/The%20Union%20Index_of_Tobacco_Control_Sustainability__24_Country_Assessments_2016.pdf

advertising encouraged the tobacco industry to discontinue airing ads on television.

Sustainability indicators at country level

Sustainability is dependent upon the following subjects[2]:

Financial resources (e.g. national budget allocated specifically for tobacco control)

Policies (e.g. national law, tobacco taxation, law against tobacco industry corporate social responsibility, Article 5.3 in ministry of health policy and across all ministries)

Structures (e.g. national strategy, national tobacco control unit and focal point, civil society network, tobacco-related mortality and morbidity data system, and tobacco control data and economic and social costs, human resources for implementation).

A set of 31 indicators that are critical or important factors for a sustainable national tobacco control programme.

Indicators grouped by subject[3]:

POLICY

National Policy against Tobacco Industry Corporate social responsibility

Tobacco taxation >75% of retail sales price

>4 MPOWER policies in place

Tobacco taxation increases faster than inflation plus GDP growth

Code of Conduct for government officials and staff

Ministry of health Article 5.3 policy

Article 5.3 policy across all ministries

CAPACITY-BUILDING

Capacity-building plan for Tobacco Control personnel

Capacity-building plan for non-Tobacco Control specific personnel

Capacity-building plans on research and evaluation

EVIDENCE

Tobacco Control-related mortality and morbidity data recording system

Global Tobacco Surveillance System (GTSS) surveys

Economic and social costs data

STRUCTURE

National Tobacco Control law

Civil society Tobacco Control network

Civil society representation in national Tobacco Control advisory committees

National Tobacco Control Unit

National Tobacco Control strategy

Evaluation built into all major policy implementation plans

National evaluation framework in place

Human resources for implementation

Tobacco Control and non-communicable diseases form part of national health policy

National focal point post

Intergovernmental co-ordination mechanism

National advisory committee

Tobacco control forms part of national development plan

FINANCE

National Tobacco Control budget (annual)

Health Promotion fund for or including Tobacco Control

National budget allocation for Tobacco Control capacity-building

Mass media campaigns funded

Development assistance funding includes Tobacco Control

Sustainability of tobacco control in Europe: indications from the WP4-WP9 Webinar Making the tobacco endgame a reality

This is the 3rd webinar in the JATC2 Work Package 4 series. The webinar is hosted by Health Services Executive (HSE), Environmental Health Services, Ireland in collaboration with Finnish Institute for Health and Welfare (THL) and partners of the JATC2 Work Package 9.

Webinar objectives:

- To showcase tobacco endgame approaches in Europe and internationally
- To discuss potential enablers and barriers
- To develop collaborations and networks

The video and the presentations are available from: https://jaotc.eu/wp4-wp9-making-the-tobacco-endgame-a-reality/

In the end of the webinar several measures were proposed for sustainability in tobacco control in EU Member States.

Measures for sustainability in tobacco control in Europe:

- Common strong EU policy on tobacco control
- European policy and Code of Conduct (FCTC Art.5.3) against tobacco industry interference and CSR
- Stable budget and human resources on tobacco control
- Institutional support, collaboration and dissemination of tobacco control activities
- Leveraging public support and civil society action
- Focus on structural changes, measurable goals, and effective measures building on the WHO

FCTC (the harm reduction arguments used by TI and the difficulties in regulating new products are causing distraction among policy-makers. The purpose of this is to move the focus away from known effective measures in the WHO FCTC, which would just need to be implemented better, and also going further with innovative measures)

- Data and surveillance of economic and social costs, tobacco-related mortality and morbidity
- Support for tobacco cessation

SURVEY

BACKGROUND OF RESPONDENT

Total respondents: 26

		Answers	Ratio
Regulator		5	19.23 %
Enforcement		12	46.15 %
Researcher		9	34.62 %
Policy maker		5	19.23 %
Other		3	11.54 %
No Answer		0	0 %

Some of them responded to have more than one background:

Regulator; Researcher; Policy maker

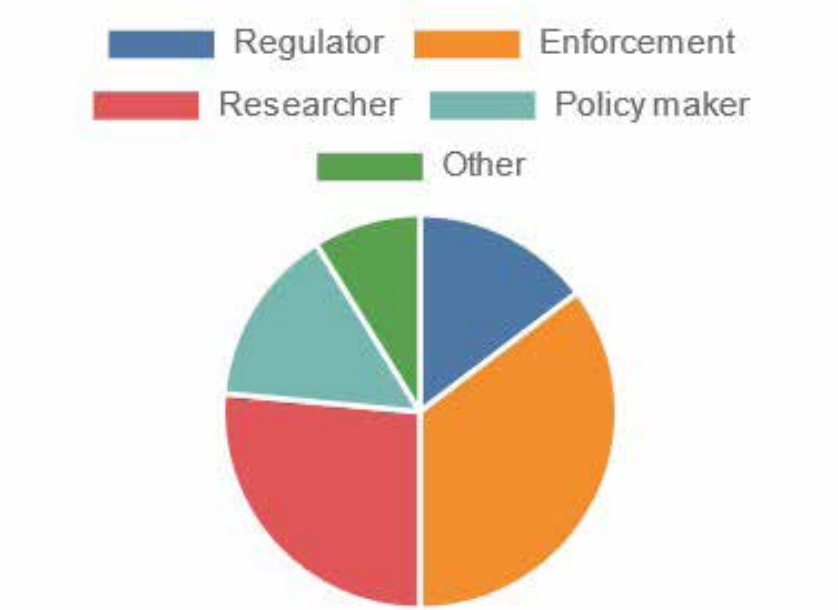
Enforcement; Researcher; Policy maker

Regulator; Enforcement; Policy maker

Regulator; Researcher

Researcher; Other: Country Team Member of JATC2

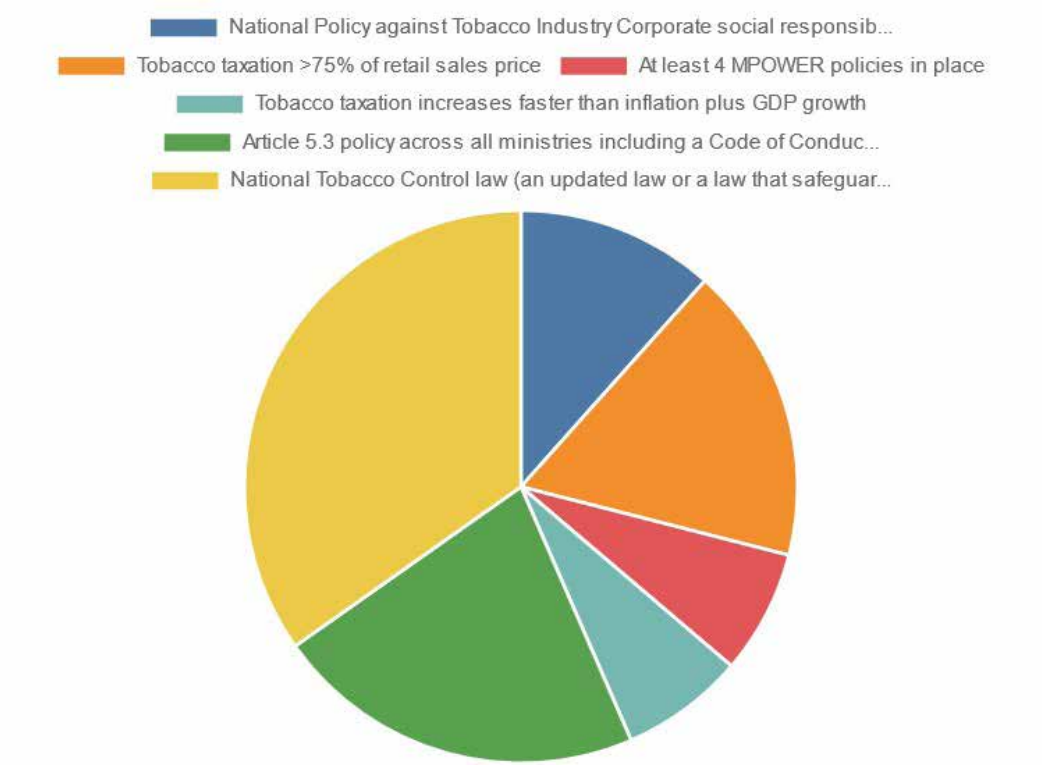
Other: Inspector



Which of the following indicators do you consider to be most important for the sustainability of your national tobacco control measures? Please select at least 1 per topic:

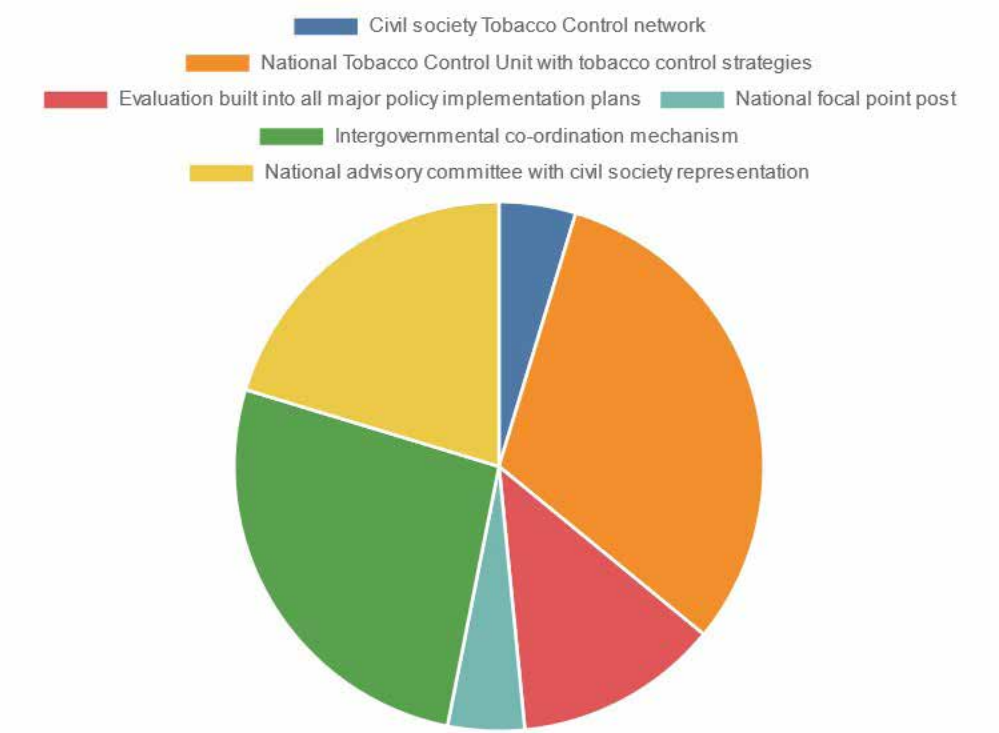
POLICY

		Answers	Ratio
National Policy against Tobacco Industry Corporate Social Responsibility		8	30.77 %
Tobacco taxation >75% of retail sales price		12	46.15 %
At least 4 MPOWER policies in place		5	19.23 %
Tobacco taxation increases faster than inflation plus GDP growth		5	19.23 %
Article 5.3 policy across all ministries including a Code of Conduct for government officials and staff		15	57.69 %
National Tobacco Control law (an updated law or a law that safeguards against new emerging products) and Tobacco control as a part of national development plan		24	92.31 %
No Answer		0	0 %



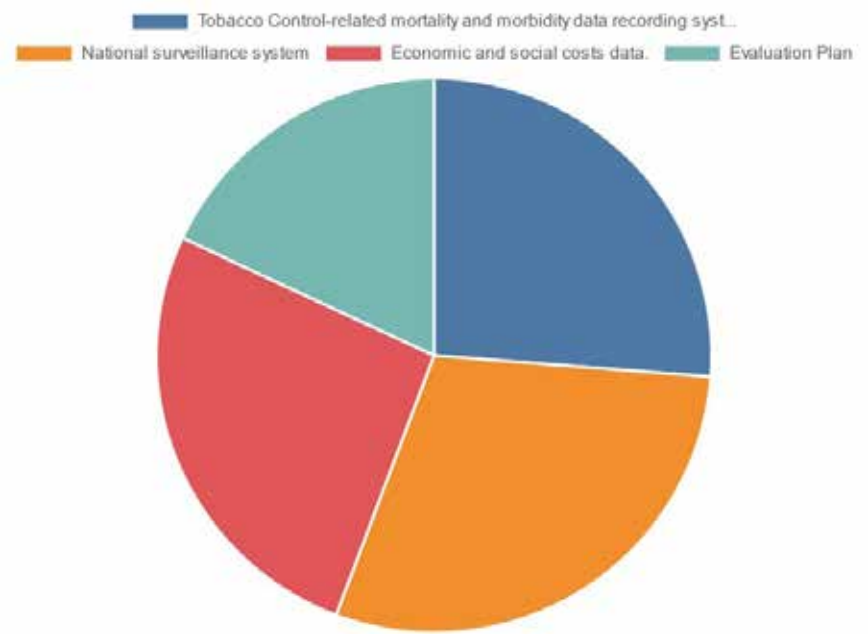
STRUCTURE

		Answers	Ratio
Civil society Tobacco Control network		3	11.54 %
National Tobacco Control Unit with tobacco control strategies		20	76.92 %
Evaluation built into all major policy implementation plans		8	30.77 %
National focal point post		3	11.54 %
Intergovernmental co-ordination mechanism		17	65.38 %
National advisory committee with civil society representation		13	50 %
No Answer		0	0 %



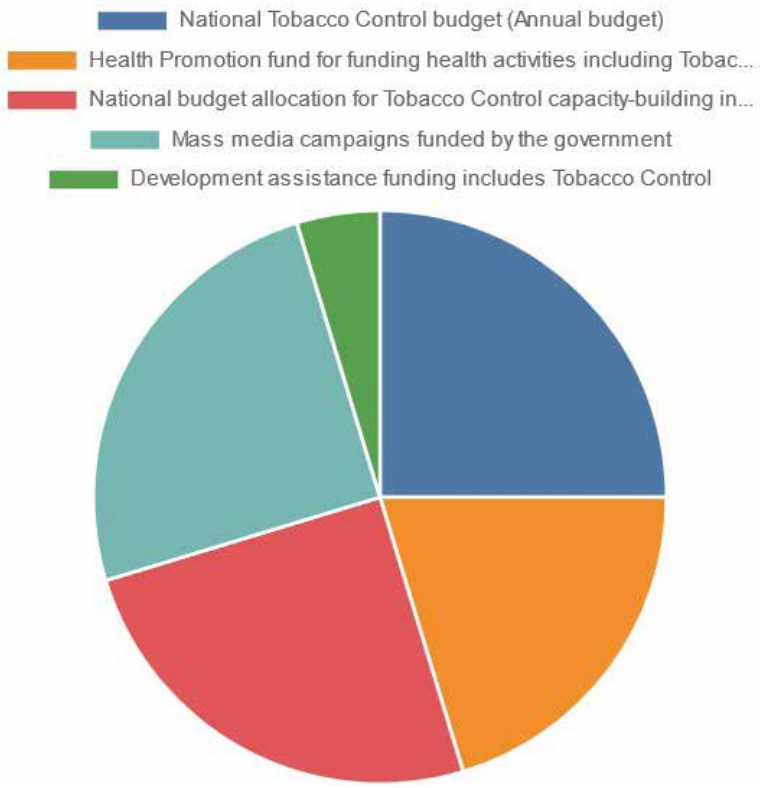
EVIDENCE

		Answers	Ratio
Tobacco Control-related mortality and morbidity data recording system.		16	61.54 %
National surveillance system		18	69.23 %
Economic and social costs data.		16	61.54 %
Evaluation Plan		11	42.31 %
No Answer		0	0 %



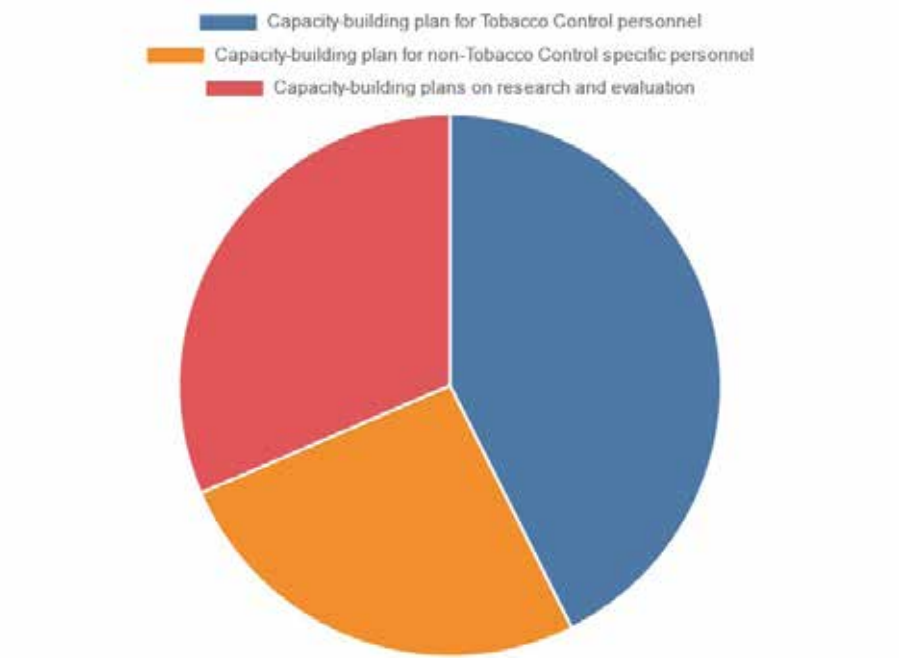
FINANCE

		Answers	Ratio
National Tobacco Control budget (Annual budget)		16	61.54 %
Health Promotion fund for funding health activities including Tobacco Control activities		13	50 %
National budget allocation for Tobacco Control capacity-building including human resources for implementation		16	61.54 %
Mass media campaigns funded by the government		16	61.54 %
Development assistance funding includes Tobacco Control		3	11.54 %
No Answer		0	0 %



CAPACITY-BUILDING

		Answers	Ratio
Capacity-building plan for Tobacco Control personnel		23	88.46 %
Capacity-building plan for non-Tobacco Control specific personnel		14	53.85 %
Capacity-building plans on research and evaluation		17	65.38 %
No Answer		0	0 %



Question with free text answers

What other areas, if any, do you feel are critical to tobacco control sustainability at your country level?

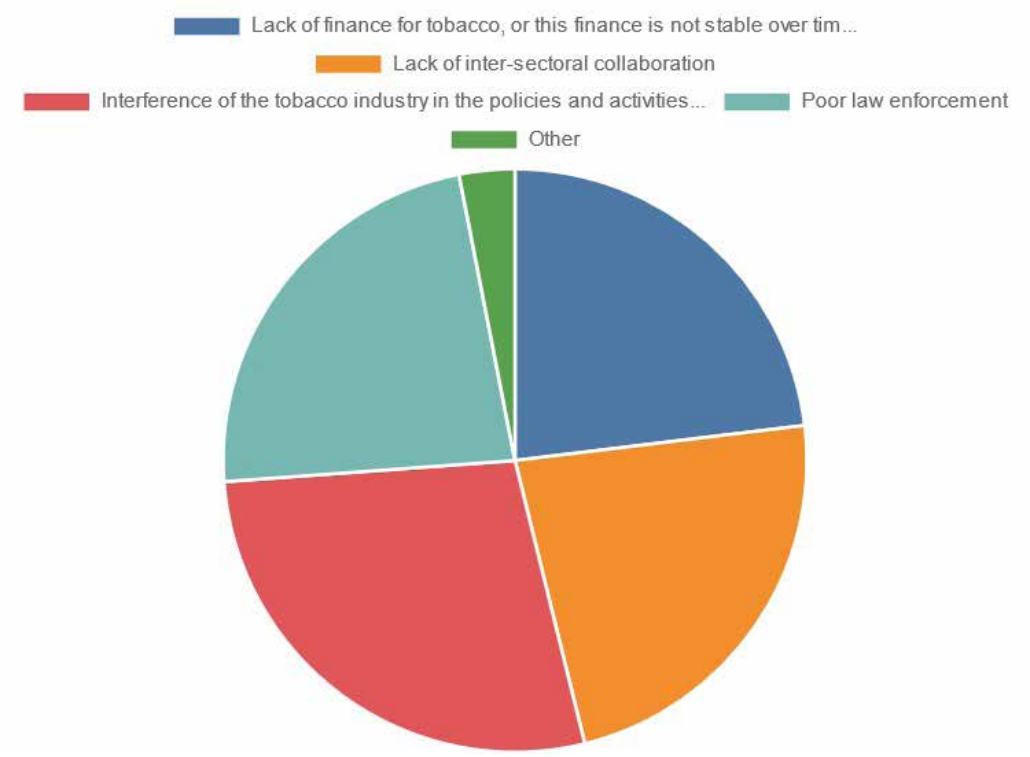
- Measures concerning online retail and cross-border retail
- Capacity building for political decision makers, parlamentarians etc, as the industry has vast access to them by lobbying, experts have less direct access

What do you think are the barriers to Sustainability in tobacco control?

		Answers	Ratio
Lack of finance for tobacco, or this finance is not stable over time		15	57.69 %
Lack of inter-sectoral collaboration		15	57.69 %
Interference of the tobacco industry in the policies and activities of EU MS		18	69.23 %
Poor law enforcement		15	57.69 %
Other		2	7.69 %
No Answer		0	0 %

Other:

- tobacco industry producing new products that are not covered by the law - they are very creative
- lack of political will
- Poor priority in comparison to other fields of policy
- Lack of resources and political will to pursue ambitious tobacco and nicotine control



Questions with free text answers

How important is sustainability of JATC-2?

Extremely important as it will greatly facilitate and ensure the coordination between the participating MS on tobacco control.
Essential
It's the basis of this action
High, because of the exchange of knowledge and best practice and moreover of informal networking
Very important
Very important because of the great amount of work already done that needs to be followed up and needs to produce some benefits.... All the knowledge generated by JATC2 should be considered and implemented recommendations raising from all WPs
The knowledge-sharing is very important as we can learn a lot more from the MS represented in the JATC2.
Highly important
Very important.
Very important since it gives the opportunity to deal with the new emerging tobacco and nicotine products and contribute to a new TPD and TAD
very important
Very important to continue exploitation of the results and collaboration between MS, for achieveing reduction of smoking and use of emerging tobacco/nicotine products.
High, because more healthy adults - which includes less smokers - can contribute to slow down the shortage of skilled workers in western democratic societies.

Which indicators are more important than others for JATC-2's sustainability?

Structure - A tobacco control network with partners of JATC2 being members Capacity Building - Capacity building plan based on JATC2 outputs within each participating MS Policy - Code of Conduct
Policies and regulations. In our country's experience, always we have implemented a comprehensive law against tobacco, we have observed a decrease in consumption (in National surveys)
people
Passing on information and experience
monitoring and evaluation of tobacco control activities ; strengthen MPOWER; civil society motivation and intersectoral collaboration
All are equally important but to answer the question POLICY and FINANCE are more important than others.
Capacity building for those working in tobacco control, also on research and evaluation Article 5.3 policies at EU level
Finance and policy commitment
policy and evidence
Funding, article 5.3 policy and adopt a code of conduct, intersectoral collaboration

Name the top 3 most important indicators for JATC-2 in your country

Policy: Article 5.3 policy across all ministries including a Code of Conduct for government officials and staff Capacity Building based JATC-2 outputs
Policy (Laws) Structure (a good network joining regulators, doctors, researchers and civil society) Evidence (Surveys and other measurement tools)
control on the field very strong legislation people who are working of these 2 topics
sustainability, policy making, monitoring and evaluation
Tobacco taxation increases faster than inflation plus GDP growth Article 5.3. policy across all ministries Finance indicators - stable and appropriate financing and human resources
Finance, Policy, Evidence
policy, structure and capacity building
article 5.3 and adopting Code of conduct across all ministries stable funding National Tobacco Control law safeguards also against new emerging products

What do you propose is the best course of action, if a new JATC-3 is not funded, how can tobacco control activities continue at European level?

The funding of a new Joint Action on Tobacco Control would help and sustain the ongoing partnership for better health using a cost effective model, with networks, outreach and cutting edge solution and policy based research. At present a new joint action is not planned and we therefore need to think of other ways of sustaining European collaboration on tobacco control

EC to maintain the network and establish an efficient tobacco-control communication mechanism between EU MS
Extensive use of common information tools such as CIRCABC. This provides us real info in real time about what are doing other countries in similar circumstances.
1. traceability of tobacco products 2. novel tobacco products and related products such as pouches, herbal sticks 3. synthetic nicotine (impact on health and addiction, laboratory methods, tax policy) 4. successful tobacco campaigns especially for targeted groups children, young adults
The European network should continue. It should be coordinated by the Commission
Knowledge hubs are a good option but insufficient.... There should be a Commission to follow up progress of tobacco control at EU level. The follow up should not only include tobacco but NICOTINE
Creating a Think-Tank to stay in touch/exchange/communication having at least annual meetings, where future forms and participation as well as funding can be discussed and agreed upon.
Capacity building and best practices, research sharing, showing tobacco industry practices etc. on webinars, such as the one today Cautioning the European Commission that the goal for 2040 will not be achieved if directives are delayed in revising Some part could be done under the new JA Prevent NCD
Use of a joint platform in order to exchange knowledge and built collaboration activities between Member-States
More active use of CIRCABC as a common knowledge sharing hub.
Through FCTC articles implementation and evaluation at a national level followed by mandatory country reports at COP
collaboration can continue, also through the knowledge hub, but without an official project funded could be more difficult

Annex 2: Guidance documents

The four guidance documents produced by WP4 in collaboration with other WPs and JATC2 partners are as follows:

1. How to identify best practices on tobacco control in Europe (lead ISS) [Milestone 4.3] on page 60.

2. Questionnaire to identify relevant policies and best practices in relation to tobacco endgame strategies, smoke-free environments, TPD and TAD in MS (lead THL) [Milestone 4.4] on page 98.

3. Good Practice Statements for the treatment of nicotine dependence (lead ISS) on page 108.

4. How to counteract the interference of tobacco industry (lead ISS) on page 128.

The following articles, taken from two guidance documents: Good Practice Statements for the treatment of nicotine dependence and How to counteract the interference of tobacco industry, were published in the *Tobacco Prevention & Cessation* journal:

Solimini R, Ollila H, Gallus S, Havermans A, Talhout R, Kilibarda B et al. **Preventing and countering the interference of tobacco industry: Recommendations from the Joint Action on Tobacco Control 2.** Tobacco Prevention & Cessation. 2024;10(May):21. doi: https://doi.org/10.18332/tpc/188094

Solimini R, Ruokolainen O, Cselko Z, Koprivnikar H, Spizzichino L, Papachristou S, González-Marrón A, Nunes E, Carnicer-Pont D, Fernandez E, López AM, Demosthenous E, Kilibarda B, Gallus S, Gómez-Chacón C, Keć I, Valentic M, Ollila H. **Good Practice Statements for the treatment of nicotine dependence**. Tob Prev Cessat. 2023 Jul 12;9:24. doi: 10.18332/tpc/167964. https://www.tobaccopreventioncessation.com/Good-Practice-Statements-for-the-treatment-of-nicotine-dependence,167964,0,2.html

1. How to identify best practices in tobacco control in Europe

Guidance prepared by ISS (lead beneficiary), M4.3, in collaboration with WP4 partners.

Version	Date	Author	Reviewers/co-authors and date
First draft	2 February 2022	ISS - Renata Solimini in collaboration with CARM, FFIS	ICO – Dolores Carnicer Pont, Olena Tigova, Esteve Fernandez THL – Hanna Ollila 3 February 2022
Second draft	17 February 2022	ISS - Renata Solimini	THL - Hanna Ollila ICO - Dolores Carnicer Pont, Olena Tigova, Esteve Fernandez MS – Cristina Gómez-Chacón CIPH - Dijana Mayer 21 February 2022
Third draft	4 March 2022	ISS - Renata Solimini	MS – Cristina Gómez-Chacón, Javier Japanero 31 March 2022
Fourth draft	6 May 2022	ISS - Renata Solimini	NPHO - Stathis Papachristou THL - Hanna Ollila 17 May 2022
Fifth draft	17 June 2022	ISS – Renata Solimini	ICO – Dolores Carnicer Pont, 27 June 2022
Sixth draft	1 July 2022	ISS - Renata Solimini	MS – Cristina Gómez-Chacón 5 Juy 2022

Seventh draft	11 July 2022	ISS - Renata Solimini	ICO - Dolores Carnicer Pont, Anna Mar Lopez, Esteve Fernandez 13 July 2022
Eight draft	14 July 2022	ISS - Renata Solimini	

Table of Contents

Introduction

Within the European project *Joint Action on strengthening cooperation between interested Member States and the Commission in the area of Tobacco Control (JATC 2)*, the horizontal Work Package 4 *Sustainability and cooperation across Europe*, has the general objective to ensure sustainability and uptake of the JATC 2 actions both during and after the implementation of the actions across EU MS, through strengthening of the cooperation of the competent authorities for a harmonised application and enforcement of the TPD and TAD in an effort to promote EU public health.

The present Report describes the documentation and the tools related to Tasks 4.2a and 4.2b of **Objective 4.2** to facilitate the exchange of knowledge and best practices on the application and effective enforcement of the TPD and TAD.

Specifically, part of the activities of the **Task 4.2.a** are as follows:

"To identify and disseminate best practices on the application and enforcement of the TPD, TAD and smoke-free environments, and development of guidance documents [M4.3], how-to-guides and other documentation or manuals for tasks aiming at harmonisation of technical approaches or representing best practices in tobacco regulatory science in collaboration with WP5, WP8, WP9 and other WPs. This task will be developed through three actions. First, the "Guidance document on how to identify best practices in tobacco control" will be prepared. Best Practices is a horizontal element in JATC 2, with specific activities to be developed in WP4 (TPD and TAD), WP8 (smoke- free environments) and WP9 (end-of-game strategies). Therefore, it is important to have a guide at the beginning of JATC 2 that establishes a common procedure during JATC 2 and useful in the future for its correct implementation. It is a methodological document that makes it possible to identify actual best practices (evaluated and recognized by official bodies) and potential best practices (not yet evaluated and recognized by official bodies). Besides it will also have a quick tool to evaluate these possible best practices as actual best practices".

The synthesis of the best practices identified as such, in collaboration with WP8 and WP9, will be published in the Sustainability Report [D4.2] which will be accessed through the JATC 2 website.

In this regard, a **Guidance on how to identify best practices in Tobacco control in Europe (Milestone 4.3)** is included in this Report, as well as the **Guidance of the Questionnaire Core Module to identify relevant policies and best practices in relation to tobacco endgame strategies, smoke-free environments, TPD and TAD in MS (Milestone 4.4)**, developed in **Task 4.2b**, is presented in the **Annex 1** of this document**.**

Activities of **Task 4.2b** are as follows: "*To identify forward-looking tobacco control policies beyond TPD and TAD and best practices in the development, implementation and evaluation of these policies in collaboration with WP9.*

To design and administer a questionnaire to collect information from the MS competent authorities and other relevant stakeholders (M4.4), in order to produce an overview of the state of readiness, and support needed, of the countries in the European region, to move forward in the development of national tobacco endgame strategies in line with the Tobacco-Free Generation goal of Europe's Beating Cancer Plan.

This questionnaire is one of the elements defined in the "Guidance document on how to identify best practices in tobacco control" and the results will be analysed jointly with those responsible for the corresponding WP. The information arising from this task can contribute to all deliverables of WP4, in addition to contributing to the tasks and deliverables in WP9".

The *Core module for a Questionnaire to identify relevant policies and best practices in relation to tobacco endgame strategies, smoke-free environments, TPD and TAD in MS*, will be supplemented with other modules focused on the specific objectives of the vertical work packages WP8 (smoke-free environments) and WP9 (tobacco endgame strategies).

Objective

To provide a guidance of assessment criteria for evaluating potential best practices in TPD, TAD and smoke-free environments, as well as to identify potential best practices through a Core module questionnaire properly designed.

To search and select additional resources of relevant documentation (grey literature and scientific literature) on best practices either at European or International level.

Methods

- Search for documentation of agencies and international organizations reporting resources of best practices on tobacco control in terms of International and European grey literature.
- Search for scientific literature on best practices on tobacco control through international databases such as PubMed, Cochrane Library, Health Research Premium Collection, British Nursing database, BMJ Best Practice (this also for grey literature) or search engines such as Science Direct and Google Scholar.
- Selection of relevant documentation retrieved for the preparation of a set of criteria to evaluate potential best practices, with scoring, and for the finalization of a Core module for a Questionnaire on potential best practices (M4.4) to be administered to competent authorities of Member States and stakeholders. This Core module (see Appendix 1) is composed of some core questions that can be a guidance for the questionnaires to be developed by the other vertical Work packages (such as WP8 and WP9), which might add other questions focused on their own specific objectives.

Results

European best practices in tobacco control (i.e fulfilling the assessment criteria to identify best practices reported by the European Commission) were identified (n=11), through the access to the European Best Practices Portal, at the date of June 15, 2022.

Additional resources related to International and European grey literature and scientific literature related to best practices in tobacco control are also reported for consultation.

Moreover, results of the questionnaires for the identification of potential best practices by WP8 and WP9 will be analysed and a number of European potential best practices will be assessed as effective best practices (this number will be available after all consultations, by the end of JATC 2).

1. Definitions of WHO Best Buys, Good Practices and Best Practices

Best practices are a valuable source of practice-based evidence on effective public health interventions implemented in real-life settings [1].

The World Health Organization (WHO) considers policies proven to be effective as “Best Buys”.

The European Commission Best Practice Portal considers three types of actions: awards, good practices and best practices.

Good practices concept usually is used to refer to well established interventions in health, already proven to be effective and recommended, and are included in a Guide to be implemented and followed regularly by professionals.

Best practices are referred to interventions that have shown evidence of effectiveness in a particular setting, have been evaluated under certain criteria and that are likely replicable/transferable to other

countries, situations or sectors.

Therefore, it appears that both terms can be used indistinctly.

Indeed, some European countries has developed their own portals on Good/Best practices including well-defined criteria to evaluate them, similar to the European Portal of Best Practices (**Table 1**).

In the next paragraphs the four categories of practices are defined and described, with all the relevant references related to websites, scientific and grey literature.

Table 1. Examples of the national best practice portals in EU countries

Portal's name	Website of the best/good/promising practice portal	Country
The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) best practice portal	http://www.emcdda.europa.eu/best-practice_en	European
The European Agency for Safety and Health at Work (EU-OSHA) Healthy Workplaces Good Practice Awards	https://osha.europa.eu/en/publications/good-practice-awards-flyer/view	European
Praxisdatenbank Gesundheitliche Chancengleichheit (database of health promotion projects)	https://www.gesundheitliche-chancengleichheit.de/praxisdatenbank/	Germany
Leefstijlinterventies (Lifestyle interventions)	https://www.loketgezondleven.nl/leefstijlinterventies	The Netherlands
PRO.SA Banca dati di progetti e interventi di prevenzione e promozione della Salute (Database of projects and interventions in health promotion and disease prevention)	https://www.retepromozionesalute.it/	Italy
Portal for the exchange of examples of good practice in the field of public health	https://www.nijz.si/publikacije/merila-za-vrednotenje-intervencij-na-podrocju-javnega-zdravja	Slovenia
Profibaza (Database of health interventions)	https://profibaza.pzh.gov.pl/	Poland
Répertoire des interventions efficaces ou prometteuses en prévention et promotion de la santé (Directory of effective or promising interventions in prevention and health promotion)	https://www.santepubliquefrance.fr/a-propos/services/interventions-probantes-ou-prometteuses-en-prevention-et-promotion-de-la-sante/repertoire-des-interventions-efficaces-ou-prometteuses-en-prevention-et-promotion-de-la-sante	France
Buenas Prácticas (BBPP) en el Sistema Nacional de Salud (Collection of good practices in the National Health System in Spain)	https://www.mscbs.gob.es/organizacion/sns/planCalidadSNS/BBPP.htm	Spain

(modified from: Stepien M, Keller I, Takki M, Caldeira S. European public health best practice portal - process and criteria for best practice assessment. Arch Public Health. 2022 May 6;80(1):131. doi: 10.1186/s13690-022-00892-5).

1.1 WHO best buys

The WHO Best Buys are policies that have proven to be effective or promising high-impact in a specific area (*Smoking*) of Noncommunicable Diseases (NCDs) and which may be prioritised by EU countries' authorities may include:

- Measures to increase price, increase the use of warnings and labels, and reduce advertisement, sponsorship and promotion of tobacco products;
- Measures to control the availability and density of tobacco retailers [2];
- Promotion of health literacy and awareness raising tailored to the needs of disadvantaged individuals and communities;

- Promotion of work-based support programmes to quit smoking, complemented by primary health care programs that may reach also unemployed persons [3];
- Promotion of programmes to quit smoking using eHealth technology [4];
- Adjust legislation to cover new tobacco-related products to avoid legislative gaps in face of new forms of consumption.

1.1.1 Examples of WHO Best Buys Interventions

Best buys with cost effectiveness analysis (CEA)

1. Increase excise taxes and prices on tobacco products

2. Implement plain/standardized packaging and/or large graphic health warnings on all tobacco packages

3. Enact and enforce comprehensive bans on tobacco advertising, promotion, and sponsorship

4. Eliminate exposure to second-hand tobacco smoke in all indoor workplaces, public places and public transport

5. Implement effective mass-media campaigns that educate the public about the harms of smoking/ tobacco use and second-hand smoke [5, 6].

Effective interventions with CEA

1. Provide cost-covered, effective and population-wide support (including brief advice, national toll -free quit line services) for tobacco cessation to all those who want to quit.

Other recommended interventions from WHO guidance (CEA not available)

1. Implement measures to minimize illicit trade in tobacco products

2. Ban cross-border advertising, including using modern means of communication

3. Provide mobile phone based tobacco cessation services for all those who want to quit.

1.2 Good Practices

The JA-CHRODIS[4] defines **'good practice'** in accordance with the definition by the Food and Agricultural Organization of the United Nations:

"A good practice is not only a practice that is good, but a practice that has been proven to work well and produce good results, and is therefore recommended as a model. It is a successful experience, which has been tested and validated, in the broad sense, which has been repeated and deserves to be shared so that a greater number of people can adopt it."[5]

In general, good practices are right actions, proven to be effective and successful, based on the best available scientific knowledge, may be transferable and represent an innovative element for the health system, and are included in a Guide to be implemented and followed regularly by professionals (e.g. legislative changes to behavioural interventions targeting specific population or patient groups) [7, 8].

4 Joint Action CHRODIS Work Package 5. Good practices in the field of health promotion and chronic disease prevention across the life cycle - Outcomes at a glance. https://publichealth.ie/sites/default/files/CHRODIS%20WP5%20at%20a%20glance_web.pdf

5 http://www.fao.org/docrep/017/ap784e/ap784e.pdf

The good practice guide provides the basis for good professional practice in public health. It applies to all members of the core public health workforce, including public health practitioners and specialists and those training to become practitioners and specialists.

Good Public Health Practices are designed to:

- Assist the public, public health professionals, colleagues and employers to better understand what good practice in public health should look like
- Guide public health professionals when planning their Continuing Professional Development (CPD)
- Act as a source document for public health professionals in preparing for appraisals and revalidation
- Inform the framework within which public health professionals will be appraised and recommended for revalidation
- Be a reference source whenever a person's registration or professional practice is called into question.

1.2.1 Examples of Good Practices

- WHO. Compendium of good practices in the health sector response to viral hepatitis in the WHO European Region. WHO 2020.[6]

In line with implementation of the Action Plan for the Health Sector Response to Viral Hepatitis in the WHO European Region, the WHO Regional Office for Europe launched an official call for good practices on viral hepatitis in May 2019. National health authorities, intraregional programmes, national technical focal points and programmes, civil society organizations (CSOs) and nongovernmental organizations (NGOs) responding to viral hepatitis were invited to submit exemplary practices. The narratives were collected over six months from May to November 2019, compiled and evaluated against pre-defined criteria, and technically reviewed by WHO experts in the Regional Office. This compendium includes 34 practice examples from 18 Member States in the WHO European Region authored by various actors in the collective response to viral hepatitis, including government and national viral hepatitis programmes, academia, public health/research institutes and NGOs and CSOs.

- Organisation for Economic Cooperation and Development (OECD) Good Practices

The OECD iLibrary[7] website is available to search for 'good practices' (string search (Title, Authors or ISSN/ISBN/DOI contains 'good practices') AND from (IGO collection contains '"igo/oecd"'). Among the results (n=103) are documents such as OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring (n=17), OECD Digital Economy Papers (n=3), OECD Regulatory Policy Working Papers (n=3), ecc.

- The Good Public Health Practices (GPHP)[8,9]

The Faculty of Public Health in London (UK) produced a document providing the basis for good professional practice in public health. It applies to all members of the core public health workforce, including public health practitioners and specialists and those training to become practitioners and specialists.

6 https://apps.who.int/iris/bitstream/handle/10665/333494/9789289055161-eng.pdf?sequence=1&isAllowed=y

7 https://www.oecd-ilibrary.org/search?value1=good+practices&option1=quicksearch&facetOptions=51&facetNames=pub_igold_facet&operator51=AND&option51=pub_igold_facet&value51=%27igo%2Foecd%27&publisherId=%2Fcontent%2Figo%2Foecd&searchType=quick

8 Faculty of Public Health of London. Good Public Health Practice. https://www.fph.org.uk/professional-development/good-public-health-practice/

9 Faculty of Public Health of London. Good Public Health Practice framework. 2016. https://www.fph.org.uk/media/1304/good-public-health-practice-framework_-2016_final.pdf

- Good Practices in Workplace Health Intervention

Models of Good practice from companies of different sectors and size. More than 250 case studies have received the European Network for Workplace Health Promotion (ENWHP) recognition as models of good practice for their work beyond the norms of occupational health and safety[10].

- Healthier together EU Non-communicable Diseases Initiative

Non-communicable diseases (NCDs) represent 80% of the disease burden in the Member States. Complementing the Europe's Beating Cancer Plan, the European Commission is addressing the main NCDs: the *Healthier together' – EU Non-Communicable Diseases (NCDs) initiative to support EU countries in identifying and implementing effective policies and actions to reduce the burden of major non-communicable diseases and improve citizens' health* on December 15, 2021 was launched [9]. The *Healthier Together - EU NCD Initiative* is a toolkit to help EU countries reduce the burden of NCDs and improve the citizens' health by supporting action of the Member States and stakeholders. It identifies effective policies and best/promising practices selected by Member States and stakeholders, essential for providing helpful guidance and **identify good practices** for other countries to consider and benefit from. It also maps the legal and financial tools that can be used to implement those actions.

The *EU NCD Initiative* is also innovative as a process: the document is being co-created with the Member States with input from stakeholders, and ample consultation of Commission services, the WHO, the OECD and the European Investment Bank.

1.3 European Best Practices in tobacco control Best Practices

- Definition of Best Practice

The European Commission 3rd Health Programme states that, in order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles, good practices should be identified and disseminated, and their uptake promoted, addressing in particular the key lifestyle related risk factors with a focus on the EU added value [10].

Based on the review of the Guide for documenting and sharing "Best Practices" in Health Programmes (WHO – Regional Office for Africa) [11], documents and manuals concerning good practices compilation procedures available at the EC Health and Food Safety Best Practice Portal [12] and at the Spanish Ministry of Health [13], the term "best practice" has been defined as follows:

"A **BEST PRACTICE** is a relevant policy or intervention implemented in a real life setting and which has been favourable assessed in terms of adequacy (ethics and evidence) and equity as well as effectiveness and efficiency related to process and outcomes. Other criteria are important for a successful transferability of the practice such as a clear definition of the context, sustainability, intersectorality and participation of stakeholders".

Documenting and sharing "Best Practices" affords one the opportunity to acquire knowledge about lessons learned and to continue learning about how to improve and adapt strategies and activities through feedback, reflection and analysis in order to implement larger-scale, sustained, and more effective interventions [11].

- Definition of Potential Best Practice

A **POTENTIAL BEST PRACTICE** within the JATC2 project is an intervention, policy, practice or initiative in Tobacco control implemented at national, regional or local level and not recognized as

10 European Network for Workplace Health Promotion portal of good practices. https://www.enwhp.org/?i=portal.en.good-practices

best practice by an official European body, but which would be susceptible to being if it fulfilled the criteria of a European Best Practice.

- Difference between European best practices and potential best practices

Best practices are those that were evaluated and recognized by European official bodies (such as the European Commission); while potential best practices are those that have not yet been evaluated and recognized by European official bodies.

A potential best practice requires an evaluation to become a best practice. Therefore, this guidance will have a chapter with instructions to do a best practice evaluation.

From the **portal on best practices of the European Commission** [12], a number of best practices on tobacco control (n= 11) were retrieved, by searching using the following keywords: Health promotion, Specific non-communicable disease or group of diseases, Promotion and Prevention.

The portal of the European Commission reports that "*The Best Practice Portal is designed to help to find reliable and practical information on implemented practices recognized as the best in the area of health promotion, disease prevention, and the management of non-communicable diseases. It also provides an overview of practices collected and transmitted in actions co-funded under the Health Programmes. Practices can be submitted for assessment through this portal. Every practice, as long as evaluated as "best" against the criteria adopted by the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (Steering Group), will be published in the portal and might be brought to the attention of Member State representatives for further transfer and broader implementation*".

The two countries **Bulgaria and Ireland produced best practices**, as reported in the classification below.

The **Bulgaria**'s best practice in health promotion field, reports that it was formally evaluated and that "*The evaluation of the Total Ban on Smoking includes compliance with the ban; population's opinion on the total ban, reduction of people who smoke; Second Hand Smoke; reduction in the number of tobacco-induced diseases and all negative health consequences associated with tobacco use. The evaluation results achieved the objective and further monitoring established slow positive changes in population's behavior related to tobacco smoking (about 2% reduction)*".

The other from **Ireland** reports that "*There is not yet a formal review or evaluation report on the Tobacco Free Ireland policy and its allied programme as the term of the policy is still ongoing. The policy was published in 2013 and will conclude in 2025, at which stage the success of the policy in meeting its aim of a smoking prevalence of less than 5% can be assessed. In the interim, the Irish government continues to produce annual reports of progress on smoking reduction...It is therefore not possible to provide a clear answer of yes/no to the question - did the practice succeed regarding the main aim and objectives outlined earlier. There was no other option available*".

BULGARIA, 2017. Total Ban on Smoking in Indoor and Some Outdoor Public Places[11]

Classification	Best practice
Type of practice	Policy
Health area/topic	Health promotion

The National Assembly in Bulgaria passed amendments to the Law of Health, which introduced a total ban on smoking in indoor and some outdoor public places from 1 June 2012. The ban of smoking includes: adjacent terrain and sidewalks of nurseries, kindergartens, schools, student

11 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=56

dormitories and places where social services are provided for children, playgrounds, open public spaces, which organize activities for children and students, sports and cultural venues, summer cinemas and theatres.

IRELAND, 2017. Tobacco Free Ireland - Ireland's tobacco control policy and programme operating under the Healthy Ireland Framework for Health and Wellbeing 2013-2025[12]

Classification	Best practice
Type of practice	Policy
Health area/topic	Health promotion

The Tobacco Free Ireland policy and allied tobacco control programme aims to create an Ireland that is tobacco-free by 2025. This would mean that less than 5% of the Irish population would smoke by 2025. Ireland was the first country in Europe to propose a target of less than 10% for smoking prevalence.

The Irish government intends to achieve this goal through the implementation of an evidence-based, comprehensive, ambitious and integrated set of measures which will ultimately reduce the number of people starting to smoke and increase the numbers of people successfully quitting smoking. National policy level initiatives are being implemented in the area of regulation, legislation and monitoring. Regional and local level initiatives are being implemented in the areas of enforcement and delivery of smoking cessation support and support for development of smoke-free spaces.

EU Health Awards for NGOs

In 2018, the European Commission rewarded outstanding initiatives by Non-Governmental Organizations (NGOs) on the prevention of tobacco use that have contributed to a higher level of public health in the EU (2018 EU Health Award for NGOs) [14].

A number of policies that have proven to be effective or promising in this area, including approaches that particularly target girls or boys, are:

- School based programmes for preventing smoking, which also involve parents and carers, and take social influence and social competence into consideration;
- Practices on influencing the environment, for instance in sport canteens.

The following best practices were prize winners in the field of health promotion and prevention and of Information/awareness raising campaign in tobacco smoking [15].

GREECE, 2018. SmokeFreeGreece[13]

Classification	Runner-up in DG SANTE NGO award 2018
Type of practice	Information/Awareness Raising Campaign Intervention Training
Health area/topic	Promotion and Prevention

The main objective of the SmokeFreeGreece initiative is to enhance the awareness of Greek youth on tobacco addiction through educational interventions within the context of the school community with the aim to reduce tobacco prevalence and initiation among youth in Greece.

12 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=50

13 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=368

GERMANY, 2018. Education against Tobacco[14]

Classification	Second Prize in DG SANTE NGO Health Award 2018
Type of practice	Information/Awareness Raising Campaign mHealth
Health area/topic	Promotion and Prevention

On the school level, the Education Against Tobacco programme addresses 10-15 years old adolescents by using a multimodal approach which takes advantage of the students smartphones by implementing self-developed apps (i.e. the face morphing app "Smokerface").

GERMANY, 2018. Unfair tobacco[15]

Classification	runner-up in DG SANTE NGO award 2018
Type of practice	Information/Awareness Raising Campaign
Health area/topic	Promotion and Prevention

The main objective of this project is to promote policy change towards a holistic approach to tobacco control by raising awareness on the negative impact of tobacco on sustainable development and the tobacco industry's strategies of political interference and aggressive marketing to youth. The specific objective is *Promote health, prevent diseases and foster supportive environments for healthy lifestyles* as referred to in the EU Third Health Program 2014-2020. In particular, the initiative addresses thematic priorities such as *Risk factors such as use of tobacco and passive smoking* and *Tobacco legislation.*

IRELAND, 2018. Irish Cancer Society X-HALE Youth Smoking Prevention Programme[16]

Classification	First Prize in DG SANTE NGO Health Award 2018
Type of practice	Information/Awareness Raising Campaign Intervention Training
Health area/topic	Promotion and Prevention

Since 2011, the Irish Cancer Society has worked in partnership with over 270 youth groups from across Ireland to drive the movement towards a tobacco free generation. Using a training the trainers approach, the X-HALE programme equips youth organisations with the skills and framework to address tobacco in their communities. In youth friendly sessions organised by the youth organisations, young people are encouraged to explore the impact of tobacco and the factors that influence their decision to start smoking. Young people that participate in these sessions are empowered to become tobacco free advocates. In 2015, the X-HALE programme was further extended to include training delivery and resource provisions to school teachers.

14 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=362

15 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=361

16 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=364

SLOVENIA, 2018. Reducing the Consumption of Tobacco, Related Products and Alcohol among the Inhabitants of the Republic of Slovenia[17]

Classification	runner-up in DG SANTE NGO award 2018
Type of practice	Information/Awareness Raising Campaign Intervention Training
Health area/topic	Promotion and Prevention

One of the outcomes of this initiative is that all layers of population are informed about the dangers of smoking and about the smoking cessation instruments – what they are and where can be accessed. While managing educational workshops in schools some students thank for the Slovenian Coalition for Public Health, Environment and Tobacco Control (SCTC) work, ask for materials to take home as an aid to help their parents stop smoking.

Many pupils and students are resolved to never start smoking and are shocked to hear how many pregnant women smoke and how this affects their unborn children.

SLOVENIA, 2018. Youth Network No Excuse Slovenia[18]

Classification	Third Prize in DG SANTE NGO Health Award 2018
Target group	policy makers school pupils tobacco sellers
Type of practice	Information/Awareness Raising Campaign Intervention Training
Health area/topic	Promotion and Prevention

The No Excuse Slovenia programme focuses on training young people as activists in the fight against tobacco. Through a training for activists targeting 14 to 15 years old and a subsequent school-based training targeting 7th grade primary students and 1st grade secondary students, the programme focuses on the following (a) development of social skills; (b) the development of drug prevention skills (c) the development of decision-making skills and (d) the correction of wrong normative assumptions among young people. Since its onset, 613 young people have completed the 1000 hour training programme for activists and another 135 000 participants have been reached through the school-based programme.

Moreover, a **selection of Good practices** is reported below.

The first document is from Italy and it is related to health promotion in Workplace, the following other two are on Specific non-communicable disease or group of diseases prevention.

ITALY, 2017. Workplace Health Promotion - Lombardy WHP Network[19]

Classification	Good practice
Type of practice	Workplace intervention
Health area/topic	Health promotion

17 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=365

18 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=367

19 http://www.chrodis.eu/wp-content/uploads/2017/03/the-lombardy-workplace-health-promotion-network.pdf

The Lombardy Workplace Health Promotion Network is made up of companies which recognize the value of corporate social responsibility and undertake health actions (evidence-based) of different nature: informational (smoking cessation, healthy eating, etc.), organizational (canteens, snack vending machines, agreements with gyms, stairs health programmes, walking / biking from home to work, smoke-free environment, baby pit-stop, etc.) and collaboration with others in the local community.

BELGIUM, SPAIN, FRANCE, ITALY, ROMANIA, SLOVENIA, GREECE, ALBANIA, ARMENIA, GEORGIA, KOSOVO, NORTH MACEDONIA, RUSSIA, SERBIA, UKRAINE, 2021. ENSP actions to support WHO FCTC Article 14 implementation in Europe[20]

Health area/topic	Specific non-communicable disease or group of diseases

The implementation of the European Network for Smoking and Tobacco Prevention actions to support WHO FCTC Article 14 implementation in Europe.

ENSP initiative on Smoking Cessation (EPACTT and EPACTT PLUS projects) aimed to develop and expand an accredited curriculum for tobacco cessation in 16 European countries and in English and enhanced the formulation of a network of healthcare professionals that will be dedicated to advancing evidence-based tobacco dependence treatment. The objectives concerning the eLearning curriculum in particular, were to increase healthcare professionals' knowledge, and to change attitudes, self-efficacy (perceived behavioural control) and intentions in delivering tobacco treatment interventions in their daily clinical life.

DENMARK, 2021. End-gaming tobacco with Personalized and Integrated Care (EPIC).[21]

Health area/topic	Specific non-communicable disease or group of diseases

EPIC is an evidence-based practice and one of the two actions in the Central Denmark Region's and the 19 municipalities' Tobacco End-game Strategy 2030. Overall objectives include: reducing smoke related health problems; reducing illness and death caused by smoking; reducing inequality in health specific objectives; strengthening integrated smoke intervention; establishing electronic referral system between relevant actors; implementing personalized smoking cessation services; increase use of the municipalities smoking cessation services; 65% of citizens enrolled in a smoking cessation offer complete the program; 45% of citizens are non-smokers when the smoking cessation program is completed; 30% of citizens are non-smokers 6 months after completing the smoking cessation program.

2. How to evaluate potential best practices

The criteria herein described are proposed for the interested researchers and experts who might consider to evaluate a potential best practice [16, 17].

As previously mentioned at the beginning of Chapter 1, "good ", "best" or even "promising" practice are all synonymous terms and indicate a public health measure that produces desirable outcomes in improving health in real-life settings and which can be adopted elsewhere [1,18].

Nonetheless, following the European assessment criteria, a best practice should show evidence of effectiveness and efficiency, possible replicability in another setting (transferability), sustainability,

20 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=379

21 https://webgate.ec.europa.eu/dyna/bp-portal/practice.cfm?id=378

ethical soundness, relevance, and community and stakeholder participation [1, 16-18].

The assessment of a potential best practice should include Exclusion, Core and Qualifier criteria and their own sub-criteria, described hereinafter.

The Exclusion criteria will assess adequacy and completeness of the information provided, and specifically the following aspects (sub-criteria):

- **Relevance**: The description of the practice should include information whether it is a priority public health area, a strategy or a response to an identified problem at Local/Regional level, National level or European level, and/or put in place to support the implementation of legislation.

- **Intervention characteristics**: The choice of the target population is clearly described (scope, inclusion and exclusion group, underlying risk factors, etc.). A detailed description of the methodology used is provided. SMART (Specific, Measurable, Assignable, Realistic, Time-related) objectives are defined and actions to take to reach them are clearly specified and easily measurable. The indicators to measure the planned objectives are clearly described (process, output and outcome/ impact indicators). The contribution of the target population, carers, health professionals and/or other stakeholders as applicable was appropriately planned, supported and resourced. The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks. Information on the optimization of resources for achieving the objectives. An evaluation process was designed and developed including elements of effectiveness and/or efficiency and/or equity including information affecting the different stakeholders involved. The documentation (guidelines, protocols, etc.) supporting the practice is presented properly, referenced throughout the text and easily available for relevant stakeholders (e.g. health professionals) and the target population.

- **Evidence and theory based:** Scientific excellence or other evidence (e.g. grey literature) was used and analysed in a conscious, explicit and thoughtful manner. The intervention is built on well-founded theory/principles and is evidence based. The relevant concepts are stated and explained.

- **Ethical aspects**: The practice guarantees ethical values. The practice must be respectful of the basic bioethical principles of Autonomy, Non-maleficence, Beneficence and Justice. The practice includes measures aimed at protecting the rights of individuals, according to national and European legislation. Conflicts of interest (including potential ones) are clearly stated, including measures taken. Relevant information is adequately presented to patients/persons, ensuring conscious and informed decision making.

The Core criteria will assess the effectiveness and efficiency of the practice as well as the equity (sub-criteria) as follows:

- **Effectiveness and Efficiency of the intervention**: The practice must work and achieve results that are measurable. The practice has been evaluated from an economic point of view. The practice includes an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks.

- **Equity**: As the reduction of inequities is a major issue in Europe, a practice that includes elements that promote equity, should be ranked higher (for example, if considering a gender perspective).

The Qualifier criteria will assess transferability of the practice to other settings/contexts, its sustainability, ability to foster collaboration among different sectors and the inclusion of stakeholders (sub-criteria), as follows:

- **Transferability**: This criterion refers to the practice capacity to being transferred to other settings or scaled up to a broader target population/geographic context. The practice uses instruments that allow for replication (e.g. a manual with a detailed activity description). The description of the practice includes all organizational elements, identifies the limits and the necessary actions that were taken

to overcome legal, managerial, financial or skill-related barriers. A communication strategy and a plan to disseminate the results has been developed and implemented. The practice has already been successfully transferred. The practice shows adaptability to difficulties encountered during its implementation.

- **Sustainability**: The practice can be implemented over a long period of time with no (or minor) additional resources, adapting to social, economic and environmental context. The practice has institutional/financial support, an organizational and technological structure and stable human resources. The practice presents a financial report. The practice provides training of staff in terms of knowledge, techniques and approaches in order to sustain it. A sustainability strategy has been developed taking into account a range of contextual factors (e.g. health and social policies, innovation, cultural trends and general economy, epidemiological trends). A contingency plan has been drawn up.

- **Participation**: The structure, organization and content (also evaluation outcomes and monitoring) of the practice was defined and established together with one or more of the following: the target population and families or caregivers and more relevant stakeholders and civil society; Mechanisms facilitating participation of several agents involved in different stages of the intervention as well as their specific role, have been established and well described; Elements are included to promote empowerment of the target population (e.g. strengthen their health literacy, ensuring the right skills, knowledge and behaviour).

- **Intersectoral collaboration**: Ability of the practice to foster collaboration among the different sectors involved. The practice has been jointly implemented by several sectors. A multidisciplinary approach is supported by the agents involved. A continuum-of-care approach is encouraged through collaboration between social, health and/or other services. The practice sets up coordination arrangements involving all different stakeholders (e.g. professional associations, public institutions, educational establishment, employers).

Assessment steps and final rating of a potential best practice

To assess a potential best practice, the evaluation is sequential, starting with the Exclusion Criteria. The threshold score for each exclusion aspect/item/sub-criterion, is n. 3 "**Good. The proposal addresses the criterion well, but a number of shortcomings are present**"; being the grouping score threshold for these criteria, equivalent to 13 out 20 points (68%). If these Exclusion Criteria are passed, then you can proceed with the Core criteria and the Qualifier criteria assessment.

In the final rating, only practices summing up 34 to 50 points (i.e. 68%) as a minimum total score are labelled as "best".

For the details on the scoring, see next chapter 2.1 "Criterion assessment: scoring for sub-criterion and final assessment".

2.1 Criterion assessment: scoring for sub-criterion and final assessment

This scoring has already been previously proposed in the assessment guidelines of the iPAAC joint action [17].

Each sub-criterion will be assessed on a scale from 0 to 5**.**

Justification on the score awarded may be described briefly in the corresponding section.

Proposals achieving an overall score of 34 out 50 points (68%) or more will be considered "best practice"**.**

Please complete the following summary evaluation chart:

2.1.1 The points, rating and the description of the scoring for each sub-criterion

0 – Proposal fails to address the criterion or cannot be assessed due to missing or incomplete information.	○
1 – Poor. The criterion is inadequately addressed or there are serious inherent weaknesses.	○
2 – Fair. The proposal broadly addresses the criterion, but there are significant weaknesses.	○
3 – Good. The proposal addresses the criterion well, but a number of shortcomings are present.	○
4 – Very good. The proposal addresses the criterion very well, but a small number of shortcomings are present.	○
5 – Excellent. The proposal successfully addresses all relevant aspects of the criterion. Any shortcomings are minor.	○

Justification/argument (max 750 characters)

2.2 Example of content of a best practice document

This content description is taken from a best practice implemented in Ireland (*Tobacco Free Ireland - Ireland's tobacco control policy and programme operating under the Healthy Ireland Framework for Health and Wellbeing 2013-2025*, year 2017[22]), and fulfilling the assessment criteria above reported.

In general, important items to be present in a best practice document should be:

- Description of the overall aims of promising practice/policy;

- Information on whether the intervention has been piloted and/or evaluated;

- Information on whether the intervention is cost-effective and sustainable.

See the table below for the characteristics in the best practice document as well as the next paragraph regarding the Assessment Criteria as are reported in the document from Ireland.

Summary/Abstract including: Introduction and European context Policy intervention Policy implementation Main areas of action
Keywords
Country or Countries
Level of complexity
Implementers (authors)
Main aims and objectives of the practice
Target population
Coverage of the interventions
What core activities have been implemented? What are the main results obtained from the development of the practice? Did the practice succeed regarding the main aim and objectives outlined earlier? Has the practice been formally evaluated?
Main lessons to be learned
Barriers to knowledge transfer
Type and sources of funding

22 http://platform.chrodis.eu/clearinghouse?id=2601

2.2.1 Content to consider for each sub-criterion of the assessment criteria

DESCRIPTION OF THE PRACTICE	Was the design of the intervention appropriate and built upon relevant data, theory, context, evidence, previous practices (including pilot studies)?	Did the design thoroughly describe the practice in terms of purpose, SMART objectives, methods (i.e. recruitment, location of intervention, concrete activities, and timeframe (sequence, frequency, and duration)?	Did the design thoroughly describe the practice in terms of purpose, SMART objectives, methods (i.e. recruitment, location of intervention, concrete activities, and timeframe (sequence, frequency, and duration)?
ETHICAL CONSIDERATIONS	Was the intervention implemented equitably (proportional to needs)?	Were potential burdens (including harm) of the intervention addressed for the target population? YES (harm just for smokers that have no possibility to smoke everywhere	Were the intervention's objectives and strategy transparent to the target population and stakeholders involved?
TARGET POPULATION	Was the target population/s defined on the basis of needs assessment including strengths and other characteristics?	Was the engagement of intermediaries/multipliers used to promote the meaningful participation of the target population?	
EQUITY	In design, were relevant dimensions of equity adequately taken into consideration and targeted (i.e. gender, socioeconomic status, ethnicity, rural-urban area, vulnerable groups)?	During implementation, were specific actions taken to address the equity dimensions?	
EVALUATION	Did the evaluation results achieve the stated goals and objectives? Did the intervention use a defined and appropriate evaluation framework for assessing structure, processes and outcomes? (i.e. validated tools, evidences of the results of the evaluation linked to actions to reshape the implementation accordingly, efficiency assessment of the intervention (after implementation) (e.g. cost versus outcome)	Did the intervention have any information/monitoring system in place to regularly deliver data aligned with evaluation and reporting needs?	Specifically, what has been measured? Process (respondents, method, and participants' satisfaction); effects (impact/outcomes); others.
GOVERNANCE AND PROJECT MANAGEMENT	Did the intervention include an adequate estimation of the human resources, material and budget requirements in clear relation with committed tasks?	Were sources of funding specified in regards to stability and commitment?	Were organisational structures clearly defined and described (i.e. responsibility assignments, flows of communication and work and accountabilities)?
EMPOWERMENT AND PARTICIPATION	Was the intervention designed and implemented in consultation with the target population?	Did the intervention achieve meaningful participation among the intended target population?	Did the intervention develop strengths, resources and autonomy in the target population? (I.e. assets-based, salutogenic approach)

COMPREHEN-SIVENESS OF THE INTERVENTION	Did the intervention have a comprehensive approach to health promotion addressing all relevant determinants (i.e. including social determinants) and using different strategies (i.e. setting approach)?	Was an effective partnership in place during the implementation of the practice (i.e. multidisciplinary, intersector, multi-sector, and alliances with main stakeholders)?	Was the intervention aligned with a policy plan at the local, national, institutional or at international level?
SUSTAINABILITY	Is the continuation of the intervention ensured through institutional ownership that guarantees funding and human resources, and/or mainstreamed?	Is there a broad support for the intervention amongst those who implement it?	Is there a broad support for the intervention amongst the intended target population?
POTENTIAL OF SCALABILITY AND TRANSFERABIL-ITY	Is the potential impact on the population targeted assessed (if the intervention is scaled up)?	Are there specific knowledge transfer strategies in place (evidence to practice)?	Is there an analysis of requirements for eventual scaling up such as foreseen barriers and facilitators, available? (i.e. resources, organisational commitment, ...)

3. Additional resources of European and International best practices

Health Promotion and Disease Prevention Knowledge Gateway (a reference point for public health policy makers with reliable, independent and up-to date information on topics related to promotion of health and well-being) of the European Commission Best Practice Portal, was retrieved the following page: **Tobacco and Smoking**[23], that includes National and international policy recommendations and implemented policies aiming to decrease tobacco use or exposure to tobacco smoke.[24]

3.1 Best practices from WHO Regional Office for Europe and/or reported by EU MS

World Health Organization, Regional Office for Europe. **Factsheets on WHO FCTC implementation through MPOWER in the WHO European Region (2020).** Available from: https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/factsheets-on-who-fctc-implementation-through-mpower-in-the-who-european-region-2020

The WHO Framework Convention on Tobacco Control (WHO FCTC) provides the legal foundation for countries to implement and manage tobacco control. In 2008, the WHO introduced a package of six evidence-based measures under the acronym of MPOWER, which support scale-up of provisions of the WHO FCTC at country level. These measures include: Monitoring tobacco use and prevention policies; Protecting people from tobacco smoke; Offering help to quit tobacco use; Warning about the dangers of tobacco; Enforcing bans on tobacco advertising, promotion and sponsorship; and Raising taxes on tobacco. The implementation of these measures have proven to reduce tobacco consumption. The WHO has published five reports (in 2011, 2013, 2015, 2017, and 2019) on the activities of all countries in relation to these six measures as well as a factsheet on the implementation of the MPOWER measures specifically in the WHO European Region in 2019.

This factsheet describes that in 2019 most countries of the European Region appear to be performing well in monitoring tobacco use and prevention policies (74% of the countries offer this measure at the recommended implementation level compared to 38% globally) and in warning about the dangers of tobacco (72% versus 47% globally). The factsheet also describes that the European

23 https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/tobacco-smoking_en

24 https://knowledge4policy.ec.europa.eu/health-promotion-knowledge-gateway/tobacco-smoking-policies-6_en

Region is performing better than globally on raising taxes on tobacco (47% versus 20%). The fact that more than half of European Region countries levy taxes below best-practice level, seems a missed opportunity to raise funds for tobacco control and the health sector broadly.

Offering support to quit tobacco use is at the recommended implementation level in 15% of the European Region countries, compared to 12% globally. In particular this measure should therefore be addressed in future policy actions. The percentage of countries with comprehensive smoke-free laws is lower in the European Region than at global level (26% and 32% respectively). With 21 countries having partial laws in 2019, more needs to be done to introduce comprehensive smoke-free laws to protect people from the harms of second-hand smoke. Furthermore, almost twice as many countries at global level ban all forms of advertising, promotion and sponsorship of tobacco products than in the WHO European Region (25% versus 13%).

World Health Organization, Regional Office for Europe. **Tobacco Control Playbook (2019)**. WHO, 2019. https://www.euro.who.int/__data/assets/pdf_file/0011/395687/Tobacco-Control-Playbook-final.pdf

World Health Organization, Regional Office for Europe. **Tobacco-free generations - Protecting children from tobacco in the WHO European Region (2017)**. WHO, 2017. https://www.euro.who.int/__data/assets/pdf_file/0008/343376/20170428_WHO-TobaccoFreeGeneration-DRAFT09.pdf

HUNGARY. World Health Organization, Regional Office for Europe. **Tobacco control in practice**. **Article 8: Protection from exposure to tobacco smoke - the story of Hungary**. WHO 2014. https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2012/tobacco-control-in-practice/article-8-protection-from-exposure-to-tobacco-smoke-the-story-of-hungary

World Health Organization, Regional Office for Europe. Loring B. **Tobacco and inequities. Guidance for addressing inequities in tobacco-related harm**. WHO, 2014. https://www.euro.who.int/__data/assets/pdf_file/0005/247640/tobacco-090514.pdf

World Health Organization, Regional Office for Europe. **Bibione. Breathe by the sea. The story of a smoke-free beach in Italy (2014)**. WHO, 2014.https://www.euro.who.int/__data/assets/pdf_file/0019/249013/Bibione-Breath-by-the-Sea-updated-version.pdf

World Health Organization, Regional Office for Europe. **Empower women – Combating tobacco industry marketing in the WHO European Region**. WHO, 2010. https://www.euro.who.int/en/publications/abstracts/empower-women-combating-tobacco-industry-marketing-in-the-who-european-region

Other practices suggested by MS participants in the Joint Action on Tobacco Control 2, not evaluated yet

CROATIA. **Excises on tobacco products - effective instrument for reducing prevalence of smoking.** https://tobacconomics.org/files/research/478/Policy-Brief-Croatia.pdf

This policy related to Croatia has been suggested by the Croatian Institute of Public Health (CIPH).

3.2 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

From the best practice portal of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) [19] were reported several practices on tobacco control. They are all based on systematic reviews of the literature (mostly Cochrane, but also non-Cochrane) assessed for the significant effect on the desired outcome (reduction of the substance use).

List of Evidence Summaries				
Title	**Area**	**Substance**	**Target group(s) or setting(s)**	**Evidence rating**
School-based multiple risk behaviour interventions to prevent tobacco use	Prevention	tobacco	young people	Beneficial
Multi-substance interventions addressing tobacco and/or cannabis to reduce use	Treatment	cannabis, tobacco		Likely to be beneficial
Anti-tobacco multi-component community interventions	Prevention	tobacco	communities	Likely to be beneficial
Standalone mass-media campaign for tobacco consumption	Prevention	tobacco		Evidence of ineffectiveness
Anti-tobacco mass-media campaigns in combination with school programmes	Prevention	tobacco	school, young people	Unknown effectiveness
Standalone anti-alcohol/tobacco peer programmes	Prevention	alcohol, tobacco	school	Unknown effectiveness
Family- or individual-level multiple risk behaviour interventions to prevent tobacco use	Prevention	tobacco	young people	Unknown effectiveness

Evidence ratings[25]

The available information on the effects of specific interventions are examined and then ranked them as described below.

Beneficial: **Interventions for which precise measures of the effects in favour of the intervention were found** in the systematic reviews of randomised controlled trials (RCTs), and that were recommended in guidelines with reliable methods for assessing evidence (such as GRADE*). An intervention ranked as 'beneficial' is suitable for most contexts.

Likely to be beneficial: Interventions that were shown to have limited measures of effect, that are likely to be effective but for which evidence is limited, and/or those that are recommended with some caution in guidelines with reliable methods for assessing evidence (such as GRADE). An intervention ranked as 'likely to be beneficial' is suitable for most contexts, with some discretion.

Trade-off between benefits and harms: Interventions that obtained measures of effects in favour of harm reduction and/or are recommended in guidelines with reliable methods for assessing evidence (such as GRADE), but that showed some limitations or unintended effects that need to be assessed before providing them.

Unknown effectiveness: Interventions for which there are not enough studies or where available studies are of low quality (with few patients or with uncertain methodological rigour), making it difficult to assess if they are effective or not. Interventions for which more research should be undertaken are also grouped in this category.

Evidence of ineffectiveness: Interventions that gave negative results if compared with a standard intervention, for example.

* GRADE is an approach to grading the quality of evidence and strength of recommendations.

3.3 Publications office of the European Union

A research for best practices in the field of tobacco has been conducted on the European Union Publications Office website[26]. Results are the followings:

25 see https://www.emcdda.europa.eu/best-practice-portal-%E2%80%93-about-evidence-database_en

26 https://op.europa.eu/en/search-results?p_p_id=eu_europa_publications_portlet_search_executor_SearchExecutorPortlet_INSTANCE_q8EzsBteHybf&p_p_lifecycle=1&p_p_state=normal&queryText=Best+practices+tobacco&facet.studies=&facet.

- European Commission, Directorate-General for Health and Consumers, **Identifying best practices in actions on tobacco smoking to reduce health inequalities: final report**, European Commission, 2015, https://data.europa.eu/doi/10.2772/20144
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3.4 Resources on International best practices

A documentation search for grey literature, particularly reports by public health organizations was conducted with the keywords: best practice and tobacco control.

WHO

In 2008, the WHO introduced the **MPOWER** package, **comprised of best-practice cost-effective interventions outlined in the WHO Framework Convention on Tobacco Control (WHO FCTC)**, to assist in the country-level implementation of effective practices to reduce the demand for tobacco.

The MPOWER package consists of six intervention categories: **M: monitor tobacco use**; **P: protect people from tobacco smoke**; **O: offer help to quit tobacco use**; **W: warn about the dangers of tobacco**; **E: enforce bans on tobacco advertising and promotion**; **R: raise taxes on tobacco products**.

WHO has systematically tracked and reported the extent of country-level implementation of the six MPOWER categories in the WHO Reports on the Global Tobacco Epidemic.

- WHO Global health Observatory. **Tobacco Control**. https://www.who.int/data/gho/data/themes/theme-details/GHO/tobacco-control
- **WHO report on the global tobacco epidemic 2021: addressing new and emerging products**. Geneva: World Health Organization; 2021. https://apps.who.int/iris/rest/bitstreams/1359088/retrieve

WHO FCTC

- **2021 Global Progress Report on Implementation of the WHO Framework Convention on Tobacco Control.** Geneva: World Health Organization; 2021. https://untobaccocontrol.org/downloads/fctc/who-fctc-gpr/WHO-FCTC-Global-Progress--Report.pdf
- WHO FCTC. **Country examples, case studies and good practices**. https://fctc.who.int/publications/country-examples-case-studies-and-good-practices
- WHO FCTC. **Best practices on implementation of the tobacco advertising and display ban at point of sale (Article 13 of the WHO FCTC) a four-country study: Ireland, Norway, Finland and the United Kingdom**. 2021. https://www.who.int/fctc/publications/best_practices_art13_whofctc.pdf
- WHO FCTC. **Best practices in implementation of the Convention in countries**. https://www.who.int/fctc/implementation/bestpract/en/
- WHO FCTC. **Best practices in implementation of Article 9 of the WHO FCTC Case study: Brazil and Canada**. 2015. https://www.who.int/fctc/publications/Best_practices_in_implementation_of_Article_9.pdf
- WHO FCTC. **Advanced country practices in the implementation of WHO FCTC Article 13 and its guidelines Combatting cross-border advertising and depiction of tobacco in entertainment**

media. 2018. https://www.who.int/fctc/publications/WHO-FCTC-Article-13_best_practices.pdf

- WHO FCTC. **Best practices in the implementation of WHO FCTC Article 10 (Regulation of tobacco product disclosures)**. 2015. https://www.who.int/fctc/implementation/publication/Best-practices-in-implementation-article-10.pdf
- Global experiences with tobacco taxation and tax administration have been used by WHO to develop a set of 'best practices' for maximising the effectiveness of tobacco taxation: World Health Organization. **WHO Technical Manual on Tobacco Tax Administration**. Geneva: World Health Organization, 2010. http://www.who.int/tobacco/publications/tax_administration/en/index.html
- WHO Framework Convention on Tobacco Control & World Health Organization. **WHO Framework Convention on Tobacco Control: guidelines for implementation Article 5.3; Article 8; Articles 9 and 10; Article 11; Article 12; Article 13; Article 14**. 2013 edition. https://apps.who.int/iris/bitstream/handle/10665/80510/9789241505185_eng.pdf?sequence=1
- The Canadian tobacco regulatory regime, identified as one of the best by WHO and the WHO Study Group on Tobacco Product Regulation (TobReg), incorporates mandatory periodic emissions testing, emissions disclosure based on all characteristics of the tobacco product, and labelling requirements which mandate large, clear health warnings and informational messages:

- **Best practices in tobacco control: regulation of tobacco products**: Canada report / WHO Study Group on Tobacco Product Regulation. WHO, 2005. https://www.who.int/publications/i/item/best-practices-in-tobacco-control-regulation-of-tobacco-products-canada-report-who-study-group-on-tobacco-product-regulation

US CDC

According to US CDC, Best practices are a coherent set of actions that have increased performance in a given context and are expected to yield similar results in similar contexts. They are evaluated as "best" against the criteria adopted and recognized by a Committee.

- An evidence-based guide to help states plan and establish comprehensive tobacco control programs:

Centers for Disease Control and Prevention. **Best Practices for Comprehensive Tobacco Control Programs** — 2014. Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. https://www.cdc.gov/tobacco/stateandcommunity/guides/pdfs/2014/comprehensive.pdf

- **Smoking Cessation: A Report of the Surgeon General.**

https://www.cdc.gov/tobacco/data_statistics/sgr/2020-smoking-cessation/index.html#full-report

TOBACCO-FREE KIDS

- Campaign for tobacco-free kids, Johns Hopkins Bloomberg School of Public Health, International Union against tuberculosis and lung disease. **Assessing Compliance with Smoke-Free Laws. A "How-to" Guide for Conducting Compliance Studies.** 2014. https://www.tobaccofreekids.org/assets/global/pdfs/en/SF_compliance_guide_en.pdf
- Campaign for tobacco-free kids. **Smoke-free environments: smoke-free laws benefit the economy**. 2019. https://www.tobaccofreekids.org/assets/global/pdfs/en/SF_help_economy_en.pdf

EVIDENCE-BASED RESOURCE GUIDE SERIES of SAMHSA

Substance Abuse and Mental Health Services Administration (SAMHSA): **Reducing Vaping Among**

Youth and Young Adults. SAMHSA Publication No. PEP20-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory, Substance Abuse and Mental Health Services Administration, 2020. https://store.samhsa.gov/product/Reducing-Vaping-Among-Youth-and-Young-Adults/PEP20-06-01-003?referer=from_search_result

CANADA

- Registered Nurses' Association of Ontario. **Evidence Booster: Best Practice Guideline Implementation to Reduce Smoking.** 2017. https://rnao.ca/sites/rnao-ca/files/Evidence_Booster-Autumn_2017_smoking_FINAL_0.pdf
- Registered Nurses' Association of Ontario. (2017). **Integrating Tobacco Interventions into Daily Practice** (3rd ed.) Toronto, ON: Registered Nurses' Association of Ontario. https://rnao.ca/sites/rnao-ca/files/bpg/FINAL_TOBACCO_INTERVENTION_WEB.pdf
- Canadian Task Force on Preventive Health Care. **Recommendations on behavioural interventions for the prevention and treatment of cigarette smoking among school-aged children and youth**. CMAJ February 27, 2017 189 (8) E310-E316; DOI: https://doi.org/10.1503/cmaj.161242. https://www.cmaj.ca/content/cmaj/189/8/E310.full.pdf

University of Waterloo

- **Tobacco Labelling Resource Centre** https://tobaccolabels.ca/

Tobacco Labelling & Packaging Toolkit https://tobaccolabels.ca/toolkit/

This website was developed to help promote effective, evidence-based labelling policies, with the support of the Framework Convention Alliance and the International Union Against Tuberculosis and Lung Disease.

OCEANIA

Australia and New Zealand are considered by WHO best practices countries in tobacco control. Here below documentation and reports:

- The Royal Australian College of General Practitioners. **Supporting smoking cessation: A guide for health professionals**. 2021. https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation
- **Tobacco control**. https://www.health.gov.au/health-topics/smoking-and-tobacco/tobacco-control
- Ministry of Health. **The New Zealand Guidelines for Helping People to Stop Smoking Update**. 2021. https://www.health.govt.nz/publication/new-zealand-guidelines-helping-people-stop-smoking-update
- **Tobacco control in New Zealand**. https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/tobacco-control-new-zealand

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

OECD. **Guidebook on best practices in public Health.** OECD 2022. https://oe.cd/best-practices

The guidebook helps countries prevent and manage non-communicable diseases (NCDs) by encouraging the dissemination of proven best practice interventions.

- Select interventions according to five best practice criteria and assess their transferability potential to a new region;

- Implement best practice interventions into a new region using a general framework for defining implementation in terms of "who does what, when, and how":
- Evaluate implemented best practice interventions by laying out the steps involved in developing and executing an evaluation study.

OECD. **Applying Evaluation Criteria Thoughtfully**. OECD Publishing, Paris, 2021. https://www.oecd-ilibrary.org/docserver/543e84ed-en.pdf?expires=1648462620&id=id&accname=guest&checksum=B265C1BE081A9875007BDC00DDD0F194

The Organisation for Economic Co-operation and Development (OECD) has established common definitions for six evaluation criteria – relevance, coherence, effectiveness, efficiency, impact and sustainability – to support consistent, high-quality evaluation. These criteria provide a normative framework used to determine the merit or worth of an intervention (policy, strategy, programme, project or activity). They serve as the basis upon which evaluative judgements are made.

OECD/DAC Network on Development Evaluation. **Better Criteria for Better Evaluation. Revised Evaluation Criteria Definitions and Principles for Use**. OECD 2019. https://www.oecd.org/dac/evaluation/revised-evaluation-criteria-dec-2019.pdf

This document describes how the OECD DAC Network on Development Evaluation (EvalNet) revisited the definitions and use of the OECD DAC evaluation criteria in 2018-2019. The document lays out adapted definitions for relevance, effectiveness, efficiency, impact and sustainability, and for one new criterion, coherence. The document describes how the criteria should be used thoughtfully, and adjusted to the context of the intervention and the intended users' needs.

3.5 Scientific literature on international best practices in tobacco control

A literature search was performed through the following criteria and databases:

Timeframe: 2012-2022. Keywords: best practice; tobacco control; smoking. Limited to: Full text articles.

Search Databases: PubMed, Web of Science, Cochrane Library, Health Research Premium Collection, British Nursing database, BMJ Best Practice (this also for grey literature).

Search engines: Science Direct, Google Scholar.

- Scollo M, Branston JR. **Where to next for countries with high tobacco taxes? The potential for greater control of tobacco pricing through licensing regulation**. Tobacco Control 2022;31:235-240. https://tobaccocontrol-bmj-com.iss.idm.oclc.org/content/31/2/235
- Peck K, Rodericks R, Irvin L, et al. **Identifying best practices in adoption, implementation and enforcement of flavoured tobacco product restrictions and bans: lessons from experts**. Tobacco Control 2022;31:32-39. https://tobaccocontrol.bmj.com/content/31/1/32.abstract
- Huang V, Head A, Hyseni L, O'Flaherty M, Buchan I, Capewell S, Kypridemos C. **Identifying best modelling practices for tobacco control policy simulations: a systematic review and a novel quality assessment framework**. Tob Control. 2022 Jan 11:tobaccocontrol-2021-056825. https://tobaccocontrol.bmj.com/content/early/2022/01/10/tobaccocontrol-2021-056825.long
- Matulewicz RS, Bjurlin MA, Carvalho FL, Mossanen M, El-Shahawy O. **Best practices for assessing and reporting tobacco use in urology oncology practice and research.** Urol Oncol. 2021 Aug;39(8):446-451.https://www.sciencedirect.com/science/article/pii/S1078143921001897

- Giannopoulos E, Papadakos J, Cameron E, Brual J, Truscott R, Evans WK, Giuliani ME. **Identifying Best Implementation Practices for Smoking Cessation in Complex Cancer Settings**. Current Oncology. 2021; 28(1):471-484. https://doi.org/10.3390/curroncol28010049
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- Weiss Y, Bristow B, Karol DL, Fitch M, McAndrew A, Gibson L, Court A, Curle E, Di Prospero L. **Exploring Tobacco Use and Smoking Cessation Best Practices From the Perspectives of Individuals With Lung Cancer and Health Care Professionals**. J Med Imaging Radiat Sci. 2020 Mar;51(1):62-67. https://www.sciencedirect.com/science/article/pii/S1939865419306903
- M Seitz C, Lawless J, Cahill S, O' Brien A, Coady C, Regan C. **The Adoption, Implementation, and Impact of Smoke-Free Policies among Gaelic Athletic Association Clubs in Ireland: A Qualitative Study**. Int J Environ Res Public Health. 2020 Mar 10;17(5):1785. doi: 10.3390/ijerph17051785. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7084469/
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2. Questionnaire to identify relevant policies and best practices in relation to tobacco endgame strategies, smoke-free environments, TPD and TAD in MS

Core module questionnaire – Prepared by THL (Lead beneficiary), M4.4., in collaboration with WP4 partners.

This core module has been used by WP8 and WP9 for the preparation of questionnaires to identify best practices on smoke free environments (WP8) and best practices

Version	Date	Author	Reviewers/co-authors and date
First draft	30 May 2021	CARM-FFIS	THL – Hanna Ollila ICO - Dolores Carnicer Pont, Olena Tigova, Esteve Fernandez ISS – Renata Solimini 3 February 2022
Second draft	8 February 2022	THL – Hanna Ollila	ISS – Renata Solimini 8 February 2022; ICO - Dolores Carnicer Pont, Olena Tigova, Esteve Fernandez 15-16 February 2022.
Third draft	17 February 2022	THL – Hanna Ollila	MS - Cristina Gómez-Chacón 21 February 2022
Fourth draft	24 February 2022	THL – Hanna Ollila	MS - Cristina Gómez-Chacón 28 February 2022
Fifth draft	2 March 2022	THL – Hanna Ollila	ICO - Dolores Carnicer Pont, Olena Tigova, Esteve Fernandez 9 March 2022 IPHS – Biljana Kilibarda 10 March 2022
Sixth draft	30 March 2022	THL – Hanna Ollila	NPHO - Stathis Papachristou 15 May 2022 WP8 piloting feedback 14 June 2022
Seventh draft	5 July 2022	THL – Hanna Ollila	

Best practices in tobacco control

Introduction

This questionnaire collects information of potential best practices in tobacco control *in the EU Member States, and in other countries in the WHO European Region, as part of the Work Package 4 "Sustainability and Cooperation across Europe" of the EU Joint Action on Tobacco Control 2 (JATC2).*

Potential best practice *is an intervention, policy, practice or initiative in tobacco control implemented at national, regional or local level, which has not yet been evaluated and recognized as best practice by an official European body (such as the European Commission), but which would be susceptible to being if it fulfilled the criteria of a European Best Practice (*https://webgate.ec.europa.eu/dyna/bp-portal/*).*

In the JATC2, the potential best practices collected through this questionnaire will be analysed and shared in the deliverables of the project, to facilitate information exchange and best practice dissemination in the region. We will keep you informed about how the information you provided has been used in the JATC2. Also, ask your permission to include your name in the list of key informants consulted in our deliverables.

This questionnaire may ask for some details that you do not have at hand at the moment, and filling in the information can take some time. We appreciate that you provide as much information as possible. During the completion of the questionnaire, you may therefore save your draft and continue

later. After completion, you may print/save a pdf of your responses. If you identify multiple different potential best practices in your country, please submit the form separately for each. The criteria and sub-criteria that are utilized to assess potential best practices are explained in detail online https://ec.europa.eu/health/sites/default/files/major_chronic_diseases/docs/sgpp_bestpracticescriteria_en.pdf.

Please submit the questionnaire no later than XX 2022.

By accepting the following statement, you give your consent to the processing of your personal data:

I consent to the processing (collection and further processing) of my personal data for research purposes of the Joint Action on Tobacco Control 2. Submission of the data is made on a voluntary basis and consent can be withdrawn at any time, without any consequences. Data are collected according to the Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000.

- I confirm that the provided information is correct and may be used for the purposes indicated.
- I understand and agree that my name and institution can be listed in the JATC2 website and reports.

CONTACT INFORMATION OF THE PERSON WHO IS COMPLETING THE QUESTIONNAIRE:

First name:

Last name:

Position:

Institution:

Country: [Drop-down list of WHO Euro countries]

Email:

Website and other (optional) contact details:

In your country, are there any national best practice portals that collect best practices in the prevention of tobacco use, tobacco use cessation, or tobacco control in general?

- No
- Yes

If you responded Yes, please provide a link to the portal website:

In your country, can you identify a potential best practice in tobacco control related to the following themes?

Please select all themes that apply to the practice.

- Yes, related to the Tobacco Products Directive (TPD) - 2014/40/EU
- Yes, related to the Tobacco Advertising Directive (TAD) - 2003/33/EC
- Yes, related to the WHO Framework Convention on Tobacco Control (WHO FCTC)
- Yes, related to the Europe's Beating Cancer Plan
- Yes, related to tobacco endgame goals and strategies
- Yes, related to tobacco use cessation

- No, we do not have any potential best practice under these themes [if selected and submitted, survey ends]

GENERAL INFORMATION OF THE PRACTICE

Title/Name of the practice

Please indicate the title of the practice (in original language and English translation, if the original language is not English). Please do not use acronyms.

Type of practice

Please select all that apply for this practice.

- Information/Awareness raising campaign
- National health promotion programme
- Policy/Action plan/Action programme/Strategy
- Regulation/Ban
- Monitoring/Surveillance/Evaluation/Research
- Enforcement/Implementation
- Health care service delivery
- Intervention
- Tool/Instrument/Guideline
- Screening
- Training
- E-health, mHealth
- Health in All Policies
- Other, please specify

Specification of other:

Please summarize the best practice:

1000 character(s) maximum

Please briefly describe the kind of potential best practice and its main characteristics. For example, was it an intervention on general population or a specific population group? Or was it a policy or about a novel change on organisational/managerial models?

Website with more information of the practice

Please also provide a website for more information of the practice, if available.

If the best practice is described in a publication which is not available on public domain, you can upload the publication file(s) here.

Which is the current phase of the best practice?

- The practice is at the first stage of implementation but not yet totally developed

- The practice has been developed/adopted but not yet enforced
- The practice has been implemented (enforced/promoted) but not yet evaluated
- The practice has been evaluated
- The practice has been evaluated and registered in a best practice portal [if selected and submitted, the survey ends]
- Don't know

What is the justification *(need or problem)* **and context** (existing evidence and theory) **for developing** this practice?

500 character(s) maximum

What are the OVERALL GOAL and the SPECIFIC OBJECTIVES of the practice?

500 character(s) maximum

The overall goal is the general indication of the practice's contribution to society in terms of its longer-term benefits. The specific objectives are concrete statements describing what the practice is trying to achieve in order to reach the overall goal.

What methods are/were used in the practice?

500 character(s) maximum

Methods should be explicitly linked to the objectives. They should describe how the (specific) objectives were reached, what were the essential tasks performed, e.g. intervention protocol, survey methods, panel of experts, training development, etc.

Who has the responsibility to coordinate and/or implement the practice?

Other organizations or entities here can be for example municipalities, regions, public agencies, universities, NGOs, or private institutions.

- My organization
- My organization, together with other organizations or entities (please name the others in the text box)
- Other organizations or entities (please name the others in the text box and confirm you have their consent to share the practice)

Please describe the roles of different organizations or entities in the coordination and/or implementation or the practice.

Duration of the practice

- The practice is ongoing (please provide start date)
- The practice has ended (please provide start and end date)

Start date [calendar selection]

End date [calendar selection]

What is the geographical scope of the practice?

- International (specify the names of the participating countries in the text box)
- National
- Regional (specify the regions in the text box)
- Local (specify the cities/municipalities or other local units in the text box)

Specification of the geographical scope:

If any, which is the specific target population?

The target population are persons or entities who are expected to be/were positively affected by the action.

Please mark all that apply. If there is no specific target population, select "general population".

- General population
- Gender specific groups
- Age specific groups
- Socioeconomic position (including educational level)
- Certain levels in education system
- Cultural/ethnic background
- Vulnerable groups (Disability)
- Vulnerable groups (Diseases)
- Vulnerable groups (Prisoners)
- Vulnerable groups (Sexual diversity, e.g., LGBTQ)
- Vulnerable groups (Pregnant women)
- Vulnerable groups (Immigrants/Refugees)
- Urban setting
- Rural settings
- Don't know
- Other (specify)**Please describe the specific target groups or settings:**

500 character(s) maximum

A proper target group specification provides a clear definition including information about the demographic characteristics, the needs and social norms with regard to the health problem(s) of interest, the size (i.e., the numbers that will be reached by the action), and the method to reach these people.

Have the target population and other stakeholders been involved in the adoption/development, implementation or evaluation of the practice?

Please, specify in which phase (development, implementation or evaluation) they have been involved in.

[MATRIX QUESTION LIKE IN THE WP8 MODULE – ALL ROWS HAVE RESPONSE OPTIONS DEVELOPMENT/IMPLEMENTATION/EVALUATION]

- Representatives of the target population(s)
- International/European public health authorities
- National public health authorities
- Regional public health authorities
- Local public health authorities

- Health care professionals
- Stakeholders from other than the health sector
- Researchers/academics
- Schools
- Private companies
- Civil society organisations
- Other

Description of how the target group(s) and stakeholders have been involved:

500 character(s) maximum

Enforcement of the practice

500 character(s) maximum

If relevant for the practice, please provide information on how the enforcement of the practice was set and who/which entity was in charge of the supervision and controlling of its compliance.

OUTCOMES, EVALUATION, TRANSFERABILITY AND SUSTAINABILITY

What are the main outcomes of the practice?

500 character(s) maximum

Please describe the most important quantitative and/or qualitative *obtained results and main lessons learned.*

Please clearly and precisely summarize the main outcomes regarding achieved improvements, impact and/or eventual negative effects, and whether or not the desired outputs and outcomes of the practice changed during the implementation of the practice. The outcomes are the changes that have occurred because of the practice i.e. when the specific objectives/overall goal are reached.

What indicators are used in the monitoring of the process and outcome of the practice?

500 character(s) maximum

Indicators are variables measuring the performance of an action and the level to which the set objectives are reached. Process, output and outcome/impact should be reported.

How is the practice evaluated?

- By an external partner
- Internally
- Evaluation is not yet conducted, but it is agreed and foreseen
- No evaluation is agreed
- Don't know

Evaluation methods [shown only if evaluation conducted or foreseen]

500 character(s) maximum

Please specify the organizations that conducted the evaluation.Please explain how the evaluation was carried out (both process and outcome). Please also describe the planned evaluation methods if the evaluation is agreed and foreseen. Please also describe if any economic evaluation took/will take place.

Link to a website that provides more information of the evaluation process and results: [shown only if evaluation conducted or foreseen]

If the evaluation is described in a publication that is not available in the public domain, you may upload the

publication file(s) here: [shown only if evaluation conducted or foreseen]

Level of transferability and/or scalability

Please select the most suitable option from the following.

- Transferability has not been considered. The practice has been implemented on local/regional/national level and transferability has not been considered in a systematic way.
- Ready for transfer, but the practice has not been transferred yet. The practice has been developed on local/regional/national level and transferability has been considered and structural, political and systematic recommendations have been presented. However, the practice has not been transferred yet.
- The practice has been transferred (i.e. scaled-up) within the same country/region. The practice has been scaled-up to other locations or regions or at national scale in the same country.

Have any barriers or challenges been identified in the transfer or scaling up?

500 character(s) maximum

Sustainability

Please select all that apply.

- The practice has institutional support and stable human and material resources
- The practice provides training of staff in order to sustain it
- A sustainability strategy has been developed
- None of the above options

Please describe how sustainability was achieved in economic terms, in capacity building and leadership:

500 character(s) maximum

How is the practice funded?

Please select all that apply.

- Own resources
- External resources - public (specify in the text box)
- External resources - private, excluding tobacco industry (specify in the text box)
- External resources - private, including tobacco industry (specify in the text box)
- No funding required
- Don't know
- Other (specify in the text box)

Specification of the funding:

What are the equity and ethical principles underpinning the practice?

500 character(s) maximum

Please provide information about e.g. ethical review and oversight, ethical training for staff and stakeholders and of the strategy for managing adverse events. When individual data is collected, please also indicate if individual's rights have been protected (according to national and European legislation). Please describe how absence of conflicts of interest is taken into account regarding the activities.

3. Good Practice Statements for the treatment of nicotine dependence

A joint guidance prepared by ISS (lead beneficiary) and WP4 partners in collaboration with WP9 partners, within the following tasks:

Work Package 4 - Sustainability and Cooperation across Europe (Objective 4.2, Task 4.2a)

Work Package 9 - Best practices to develop an effective and comprehensive tobacco endgame strategy (Objective 9.1, Task 9.1b)

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The full text is available at this link: http://www.tobaccopreventioncessation.com/pdf-167964-92242?filename=Good%20Practice%20Statements.pdf

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Introduction

Smoking is one of the main preventable cause of illness and early death worldwide [1, 2]. A recent systematic review provided comprehensive and up-to-date estimates of the evidence on the health effects of smoking [3]. Smoking cessation is therefore one of the most important actions to take for improving health status and enhance quality of life [4-6].

The effects of smoking cessation appear more rapidly. As the studies of Doll and Peto confirmed, persons who began smoking in early adulthood but stopped before 40 years of age avoided more than 90% of the excess risk during their next few decades of life, as compared with those who continued to smoke. Smokers who stopped at 50 years of age also benefited from smoking cessation as they avoided more than half the excess risk, although substantial hazards persisted. Those who have smoked cigarettes since early adulthood but stop at 30, 40, or 50 years of age gain about 10, 9, and 6 years of life expectancy, respectively, as compared with those who continue smoking [7, 8].

The fourth Conference of the Parties (COP4) to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC) [9] in 2010 adopted guidelines for the implementation of Article 14 of the Convention [10]. According to Article 14 Parties should develop national guidelines and effective measures to encourage and assist tobacco cessation and treatment [11].

Accordingly, clinical guidelines for the treatment of tobacco dependence have been developed over the years by many countries worldwide [12-17], including the Tobacco Dependence Treatment Guidelines by the European Network for Smoking and Tobacco Prevention (ENSP), which have been translated into many languages [18].

In the last decade new products have emerged on the market, often promoted by industry as less harmful alternatives to tobacco smoking, but in fact attracting new consumers and making them addicted to nicotine: Electronic Nicotine Delivery Systems (ENDS, i.e. electronic cigarettes), Heated Tobacco Products (HTPs, i.e. tobacco heated without reaching ignition) and Oral Nicotine Products (ONPs, i.e. nicotine pouches) [19]. ONPs are a new category of tobacco product, growing in popularity. They are similar to snus but they do not contain leaf tobacco. The products are still derived from tobacco and contain nicotine, which is harmful to young people in any form. Some types of ONPs are using synthetic nicotine that isn't derived from tobacco leaf, raising additional concerns about misleading consumers who may assume that nicotine that doesn't come from tobacco is somehow safer than tobacco-derived nicotine. The use of flavouring in tobacco products has been proven to appeal to youth, and additives may increase both product attractiveness and nicotine addictiveness [19, 20-22]. Another category of emerging products which may contain nicotine or tobacco are the novel herbal products. These products are raising concern in some European Countries including Hungary.

The first European Join Action on Tobacco Control highlighted the importance of including HTPs and ENDS users in the same approach (5As) and treatments (combination of counselling and pharmaceutical treatment) considered for smoking cessation [23].

It is also important to point out that the assessment of nicotine dependence due to tobacco smoking in medical practice does not usually consider ENDS, HTP, ONP or any other new and emerging nicotine product dependence. Recent studies tackled this challenge using different scales or tests, such as the PATH dependence scale (a 16-item scale assessing tobacco dependence, on a 1–5 scale) [24], the Fagerström Test for Nicotine Dependence (FTND), the Nicotine Dependence Syndrome Scale, the Cigarette Dependence Scale and versions of these scales adapted for ENDS and nicotine gums [25]. One study measured nicotine dependence levels with FTND and the findings suggest that ENDS may have a higher addictive potential than conventional cigarettes among young adults [26].

Moreover, young ENDS users described unique and increased symptoms of vaping dependence requiring more refined measures and indicators [27, 28]; hence it is important to separately assess dependence from conventional cigarettes and ENDS in dual users [29].

At present, there is no evidence of the effectiveness of treatments for nicotine dependence caused by the use of new tobacco and nicotine products. The studies including people using these products are very few and therefore the GRADE methodology [30] is currently possible only for studies covering tobacco smoking cessation treatments, since they are including large sample sizes.

Nonetheless, we can still include consumers of new and emerging tobacco and nicotine products in some of the effective treatments for smoking cessation, considering the existing literature reporting indirect or low quality evidence (mainly due to the poor sample size).

This is possible for several reasons:

a) The rationale is that the substance capable of inducing dependence in consumers of conventional tobacco products (such as cigarettes), of novel tobacco products (such as HTPs) and nicotine products (e.g. ONPs or ENDS), is nicotine [31]. The cessation of the use of the new products that contain this active ingredient must therefore refer to drugs capable of acting on nicotinic receptors, as already happens for conventional cigarettes.

b) Pharmaceutical treatments like Nicotine Replacement Therapy (NRT) and Varenicline, given the specific action on nicotinic receptors in general and on α4β2 receptors, are adequate drug treatments for withdrawal symptoms presenting upon quitting new tobacco and nicotine products. Bupropion, a nicotinic antagonist, may also be suggested. Cytisine is not a first-line medication but is a promising cessation treatment, which is cost-effective [32] and can be alternatively proposed because it is a natural compound known to have partial agonist activity at the α4β2 nicotinic receptor [33-36].

c) Several international organizations or institutions such as WHO, Australian Department of Health, Scientific Committee on Health Environmental and Emerging Risks (SCHEER) of the European Commission, European Respiratory Society, Karolinska Institutet in Sweden, the US National Academies of Sciences, Engineering, and Medicine and the US Substance Abuse and Mental Health Services Administration, have reported potential adverse effects on health of ENDS and/or HTPs [37-47]. In fact, there are concerns that while they may expose users to lower levels of some toxicants than conventional cigarettes, they may also expose users to higher levels of other toxicants. It is not clear how this toxicological profile translates into short- and long-term health effects. Recently, the German Federal Institute for Risk Assessment analysed the content of nicotine in ONPs and some of them were found to have nicotine contents approaching 50 mg per pouch, as well as tobacco-specific nitrosamines (TSNAs), posing a high health risk for consumers [48].

d) Treatment of nicotine dependence, whether it is caused by vaping, smoking, or due to nicotine being absorbed through any other new tobacco or nicotine products, is increasingly included in programs for cessation (such as the programs of the American Lung Association) [49].

e) Nicotine dependence is a concerning issue. All new and emerging tobacco and nicotine products pose the risk of nicotine dependence, and in certain cases may make users increasingly addicted to nicotine, considering also that many users become dual users or polyusers (consume more than one tobacco or nicotine product), or consume products that contain additives and high contents of nicotine salts, which are likely to increase their addictiveness [50-52]. Moreover, those who try to quit conventional cigarettes using

ENDS or any other tobacco product, are less likely to stay away from cigarettes and have risk of relapsing to smoking, at least according to recent studies conducted in US and Italy [53-55]. In case smokers successfully quit using ENDS, it is observed that most of them (80%) keep using ENDS after one year [56], hence the final goal should be the complete cessation of any kind of addictive nicotine product.

Scope

This guidance provides Good Practice Statements (GPS) for the treatment of nicotine dependence in the

users of new and emerging tobacco or nicotine products. Some of the treatments (pharmacotherapy and counselling) already effective for smoking cessation can be valid and adaptable to the purpose. Vulnerable groups (e.g. children, youth, pregnant women) might be cautiously included on a case-by-case basis. This guidance is not related to harm reduction in terms of complete (if not only partial) switching from conventional cigarettes to any other new and emerging tobacco or nicotine product.

Good Practice Statements

Considering the concerning actual and potential future scenario of consumers use of new and emerging tobacco and nicotine products sustaining nicotine addiction worldwide, and following the GRADE working group guidances on Good Practice Statements (GPS) [57 – 59], it is important to include new tobacco and nicotine products users in some of the treatments already available for smoking cessation.

GPS are important actionable statements about interventions that would do substantially more good than harm or vice versa, but which cannot be subject to a formal assessment of the quality of the evidence as expected by the GRADE method for formulating recommendations. GRADE proposed the following five criteria to assess the appropriateness of issuing a GPS [59] and differentiate them from GRADE recommendations:

(1) statement is clear and actionable;
(2) message is necessary regarding healthcare practice;
(3) implementation of the statement is likely to result in large net positive consequences;
(4) summarisation of evidence would be a poor use of guideline panel's time;
(5) the rationale connecting the indirect evidence used to support the statement is clear and explicit.

GPS to tackle nicotine dependence may be formulated in the (frequent) case that other types of tobacco and nicotine products users are not included in the studies' population. The interventions proposed in the GPS are already interventions that are evidence-based for smoking cessation, but that can be adapted and valid to treat dependence from other new and emerging tobacco, nicotine or related products. Some literature should exist to support the formulation of a GPS (e.g. reports of international organizations or agencies, reviews, case reports, clinical trials).

For consumers of heated tobacco products, smokeless tobacco and nicotine-containing products (e.g. ENDS, nicotine pouches or any other new and emerging nicotine product with an addictive potential), the proposed GPS are the followings:

GPS 1. It is reasonable to give brief cessation advice. Brief cessation advice should consist of asking about the details of product use (type(s) of product(s), frequency of use, nicotine content, and duration of use), advising to quit, and assessing readiness to quit. [Good Practice Statement].

For consumers motivated to quit:

GPS 2. It is reasonable to offer pharmacotherapy to treat nicotine withdrawal symptoms. Pharmacotherapy include the use of nicotine replacement therapy (NRT) in its different formulations and/or combinations (slow release and rapid release), as well as varenicline. It is also possible to use bupropion, or alternatively cytisine, according to clinical considerations and patient choice. [Good Practice Statement].

GPS 3. It is reasonable to offer individual or group counselling combined with pharmacotherapy. The choice of pharmacotherapy depends on clinical considerations and patient preferences [Good Practice Statement].

GPS 4. It is reasonable to consider nicotine replacement therapy (NRT) with counselling in youth or pregnant women unable to quit with counselling alone. [Good Practice Statement].

GPS 5. It is reasonable to use a digital intervention1. [Good Practice Statement].

[1] Digital intervention means a software-based intervention made accessible via computer, tablet, mobile phone, video and social network through:

- Applications on mobile phones or text messages (SMS) and other modes of communication via wireless and mobile phones.

- Online and computer-based programs.

- Other platforms: social media (Facebook, Twitter, Instagram) and "Chat rooms".

Interactive web-based behavior change programs have been found to be more effective. Counselling is advised as an addition to interventions based on text messaging, mobile apps, and web-based interventions.

The rationale of the above GPS is based on the following literature:

a) A report from the Canadian Agency for Drugs and Technologies in Health (CADTH), suggesting that is "reasonable to manage vaping cessation in a way similar to smoking cessation" [60];
b) WHO indications on how to quit e-cigarettes by using existing tools such as toll-free quit lines, text message programmes and specialized tobacco dependence treatments to quit [61];
c) A summary of the literature on management and treatment for vaping cessation in adolescents, suggesting NRT for adolescents who want to quit vaping and have symptoms suggestive of nicotine dependence. "This practice is supported by the strong indirect evidence of efficacy for other forms of nicotine addiction, although the efficacy of NRT for vaping cessation has not been directly demonstrated" [62];
d) A clinical case report on the successful treatment of an e-cigarette user with NRT [63];
e) A systematic review on smokeless tobacco cessation suggesting that varenicline, nicotine lozenges and behavioural interventions may help smokeless tobacco users to quit [64];
f) A monograph about counselling for vaping cessation in adults and adolescents [65];
g) A synthesis of the literature to inform vaping cessation interventions for young adults indicating promising technology-based interventions (e. g. text messaging, apps) and individualized

intervention (e.g. one-on-one counselling) [66];

h) A review commentary providing preliminary clinical guidance on how to deal with vaping among young people with a specific focus on screening and evaluation, counselling and pharmacotherapy. Youth who experience nicotine cravings and withdrawal, should be offered pharmacotherapy such as NRT. With respect to bupropion and varenicline data of effectiveness on vaping cessation are presently unknown, but they might be considered in combination with behavioral interventions as part of a comprehensive vaping cessation plan [67];
i) A clinical perspective suggesting that an intuitive approach to treating adolescent vaping would be to apply interventions developed for tobacco cessation (pharmacological interventions such as NRT, bupropion, and varenicline), cognitive-behavioral therapy and digital interventions [68].
j) A Randomized Controlled Trial which enrolled 2588 young e-cig consumers, assigning a group to a "This is Quitting (TIQ)" program based on personalized, interactive text messages, compared to a control group. The study reports that e-cig abstinence, assessed at 7 months, was greater among participants assigned to the TIQ program than in the control group [69];
k) A retrospective study on the usefulness of the smartphone app-based smoking cessation program for conventional cigarettes, heated tobacco products, and dual use [70];
l) Recommendations from Cancer Council Victoria on cessation interventions for e-cigarette users [71];
m) An online program of the American Lung Association for young people to stop using any tobacco or nicotine product [72].
n) A guide of the Substance Abuse and Mental Health Services Administration, including online programs and text messages for the prevention of vaping among youth and young adults and reducing e-cigarette use and vaping [47].

It has to be noted that the GPS n. 2 and 3 suggest pharmacological interventions including NRT, varenicline, bupropion and cytisine.

However, while for NRT and Varenicline there are some studies, including a systematic review for the treatment of smokeless tobacco dependence [64], and a case report of a successful treatment of ENDS dependence with NRT [63], which explicitly reported their effectiveness; for bupropion the suggestion of use is based on an intuitive approach, indicating that treatments effective for smoking cessation, could be applied also to vaping cessation [60, 67, 68]. For cytisine, no studies mentioning it, but the assumption is that it is α4β2 receptor partial agonist, similarly to varenicline.

This clarification is needed in order to suggest the use of these two medical treatments on a case-by-case basis, according to patient clinical features.

With respect to adolescents and youth they are included in some of the programs above mentioned as well as in some reviews and studies [47, 62, 65-69, 72]. Moreover, the Centers for Disease Control and Prevention provide exhaustive information on ENDS use and related risks for kids, teens, and young adults, including resources and programs for vaping prevention and quitting [73].

As regards to pregnant women the American College of Obstetricians and Gynecologists recommended that healthcare and obstetric care professionals should inquire about all types of tobacco or nicotine use and that clinicians should individualize care by offering psychosocial, behavioral, and pharmacotherapy interventions.Available cessation-aid services and resources, including digital resources, should be discussed and documented regularly at prenatal and postpartum follow-up visits [74].

Conclusion and Sustainability

GPS for the treatment of nicotine dependence in consumers of new and emerging tobacco and

nicotine products other than conventional tobacco cigarettes, with a clear and explicit rationale connecting the supporting indirect evidence, are particularly needed in the healthcare practice. Moreover, it is necessary to conduct studies on large samples of users of these products to get clear evidence on the proper treatment.

Currently, it is important to provide indications as GPS to treat all people addicted to new and emerging tobacco or nicotine products, and motivated to quit. These GPS are also sustainable, the treatments are already effective for smoking cessation and the consequences are likely beneficial for public health.

Definitions of the products considered in the GPS

Smokeless tobacco

Smokeless tobacco product means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use.[1]

- Chewing tobacco means a smokeless tobacco product exclusively intended for the purpose of chewing;
- Nasal tobacco means a smokeless tobacco product that can be consumed via the nose;
- Tobacco for oral use means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets.

Nicotine pouches

Tobacco-free nicotine pouches. These products are sold as pre-portioned pouches, but instead of containing tobacco leaf, are filled with white nicotine-containing powder or salts. The pouches are placed between the lip and gum, and require no spitting or refrigeration.[2]

Electronic cigarettes (or ENDS – Electronic Nicotine Delivery Systems)

Electronic cigarette means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges.[3]

Heated tobacco products

A novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by user(s).[4]

1 DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, Art. 2 (5-8). https://eur- lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=EN

2 Robichaud MO, Seidenberg AB, Byron MJ. Tobacco companies introduce 'tobacco-free' nicotine pouches. Tob Control. 2020;29(e1):e145-e146. doi: 10.1136/tobaccocontrol-2019-055321. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7239723/

3 DIRECTIVE 2014/40/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC, Art. 2 (16). https://eur- lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0040&from=EN

4 COMMISSION DELEGATED DIRECTIVE (EU) .../...of 29.6.2022, amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products. https://health.ec.europa.eu/system/files/2022-06/c_2022_4367_1_act_en.pdf

Novel herbal products

Novel herbal products for smoking, vaping or heating (which requires a separate device) contain a mixture of different herbs, plants, fruits or blends which may or may not contain nicotine and/or tobacco.

Note: other new and emerging nicotine or related products which have addictive potential could appear on the market in the near future, but for which no definition currently exists.

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4. Guidance on how to counteract the interference of tobacco industry

A Guidance prepared by ISS (lead beneficiary), in collaboration with WP4 partners and other partners of the JATC 2.

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Table of Contents

Abstract

This guidance focuses on the recommendations for counterig Tobacco Industry interference in tobacco control activities and policies of the European MS, to further progress the implementation of Article 5.3 and its guidelines unanimously adopted by the Conference of the Parties of the WHO FCTC in 2008.

Among the main recommendations are the filling out of a Declaration of Interests (DoI) and the adoption of a specific Code of Conduct (CoC) in in tobacco-related activities for public officials, government staff, researchers. For this purpose the guidance provide templates of the DoI to be signed and the CoC to be personalized by the MS and made publicly available on the agencies and ministries websites.

Some examples of the main Tobacco Industry tactics for interfeering policies and research on tobacco and nicotine products is also reported to further raise awarness on this issue.

1. Introduction

This Guidance document is produced under the Joint Action on Tobacco Control 2 project (JATC-2). The JATC-2 is a European Union (EU) funded project that brings together 21 Member States in a consorted effort to promote public health through the exchange of good practices between Member States in order to improve implementation of the Tobacco Products Directive (TPD). JATC-2 brings together experts and unique national perspectives with the aim of developing comprehensive research on tobacco control policy measures and making that research available to Member States at all levels of government.

Work Package 4 (WP4) of JATC-2, with 10 partners (9 countries) focuses on activities that ensure sustainability and uptake of the JATC-2 actions both during and after the implementation of the JATC-2 objectives across EU member states (MS). This Guidance document is a product of WP4's Objective 4.2, prepared in collaboration with partners from other WPs. The aim of this objective is to promote best practices among the EU MS on the application and effective enforcement of the TPD and Tobacco Advertising Directive (TAD), and supporting sustainability of the tobacco control activities and cooperation among EU MS

Tobacco consumption is the single largest avoidable health risk, and responsible for nearly 700.000 premature deaths every year in the EU. Despite the progress made in recent years, the number of smokers in the EU is still high: 26% of the adult population and 29% of young Europeans aged 15-24 years smoke (European Commission, 2022). The international community is concerned about the devastating worldwide health, social, economic and environmental consequences of tobacco consumption and exposure to tobacco smoke. The TI continues to fight proven policies and programs that reduce tobacco smoking and to undermine tobacco control measures, influencing scientific research, politics, law, education and the media (Gannon, 2022).

The monitoring and control of use of conventional tobacco and emerging tobacco and nicotine products (e.g. electronic cigarettes, heated tobacco products, nicotine pouches, novel herbal products with tobacco and/or nicotine) in Europe will contribute to the reduction of demand for these products. In the EU, this can be achieved in synergy with an implementation of current relevant EU directives (i.e., TPD and TAD) and their comprehensive and successful update, as well as with an effective silencing of the TI interference, coherent with article 5.3 of the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC) (WHO FCTC, 2013; Straarup et al., 2022).

The WHO FCTC requires Parties to adopt a comprehensive range of measures designed to reduce the impacts of tobacco on population health and economy. WHO FCTC recognizes that TI interference poses the greatest threat to tobacco control. It has been documented that the TI has used strategies to subvert, hinder and prevent tobacco control efforts (WHO, 2019). The guidelines

for implementation of Article 5.3 of the WHO FCTC on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the TI, unanimously adopted by the Conference of the Parties (COP) of the WHO FCTC in 2008 (decision FCTC/COP3(7)), is one of the most important cross-cutting provisions of the Convention providing implementation guidelines. It requires Parties to protect their tobacco control and public health policies from commercial and other vested interests of the TI (WHO FCTC, 2013; GGTC, 2022; WHO FCTC, 2021).

Article 5.3 requires parties to be transparent and accountable when dealing with the TI. The main actions to be undertaken are: rejecting partnerships, de-normalizing so-called Corporate Social Responsibility (CSR) activities, raising awareness on TI tactics, signing a Declaration of Interests (DoI), formulating, adopting and implementing a Code of Conduct (CoC) for public officials prescribing the standards with which they should comply in their dealings with the TI, and refusing any preferential treatment for the TI (GGTC, 2021a; SEATCA, 2015).

Referring to the efforts of the ministries of health or the national tobacco control councils/agencies (GGTC, 2021a), the **least reported actions recommended within Article 5.3 implementation in the Countries worldwide** are:

- Require information from TI to be transparent and accountable;

- *Do not give preferential treatment to the TI.*

In contrast, the **most frequently reported areas of Article 5.3 implementation** are:

- Efforts to limit interactions with the TI;

- *Avoid conflicts of interests.*

With respect to TI interference, the Global Center for Good Governance in Tobacco Control (GGTC) in 2021 published a global survey "The Global Tobacco Industry Interference Index", on how governments are responding to TI interference and protecting their public health policies from commercial and vested interests as required under the WHO FCTC (GGTC, 2021b). This Survey has been updated and published in November 2023 (Assunta, 2023).

A similar survey "The European Tobacco Industry Interference Index" based on the data of the GGTC and focusing on the European context, has been published by the Smoke Free Partnership (SFP, 2021).

The survey analyzed how 16 countries in the WHO European Region, and the institutions of the European Union, are affected by TI interference, and how far they have progressed in the implementation of Article 5.3 and its Guidelines.

The following six indicators related to TI influence have been included:

1. **Participation in policy development**;

2. **Corporate Social Responsibility**;

3. **Benefits to the TI**;

4. **Unnecessary interaction with TI**;

5. **Transparency**;

6. **Conflict of interest**.

Overall, throughout the European region, TI has attempted to influence policy development with a varying degree of success. No country covered by this survey has fully implemented Article 5.3 of the WHO FCTC. No country in the region is immune from TI interference: preventive measures and transparency are lacking, although there is room for improvement (SFP, 2021).

The **2023 European Index** released on November 14, 2023**, involved 20 countries o**f the WHO European Region (four more than the previous 2021 Index) and **one more indicator** wad added to the six already mentioned above: **7. Preventive measures** (i.e. the recommended measures to prevent TI interfering, including the disclosure of records of interactions between government officials and representatives of TI, and to prohibit TI contributions to public institutions). The 2023 Index confirmed the heterogeneity observed in terms of transparency regarding interactions with TI, success of the TI attempts to influence policy-making decisions, and opposing tobacco control measures among the EU countries, with some best practice examples from the Netherlands, France and UK (Olefir et al., 2023).

It Is fundamental for the JATC2 to provide recommendations and tools to support EU countries in countering TI interference.

In terms of policy development in particular, the provision and implementation of comprehensive and effective legislation/regulation is fundamental to effective tobacco control. Several countries now apply a Regulatory Impact Analysis (RIA) approach in their decision making /law making processes in relation to tobacco control. Protecting such RIA processes and lawmaking from TI interference is therefore also critical and fundamental.

The more countries are informed about the TI tactics to influence policies, the better chance they have to effectively prevent them, and therefore achieve a smooth implementation of tobacco control measures, reducing tobacco consumption and preventing tobacco-related illness and death (Gannon, 2022).

Another important point to consider, highlighted by US Action on Smoking and Health (ASH USA), is the nexus between tobacco control and human rights (ASH USA, 2023a). The TI's cigarette production and marketing directly conflicts with human rights objectives: "All people have a fundamental right to breathe clean air and governments are obliged to protect everyone's health as a fundamental human right" (WHO, 2023). A human rights approach requires governments to protect their citizens by implementing tobacco control laws and strategies to end the tobacco epidemic (ASH USA, 2023b).

1.1 Human rights approach to ending tobacco use

To raise awareness and address the human rights issue, during the *17*th *World Conference on Tobacco or Health, Cape Town, South Africa*, on 9 March 2018, participants agreed to 27 general principles relating to human rights and tobacco control (Cape Town Declaration, 2018).

This is the summary of the general principles of the Cape Town Declaration (the text is as reported in the *Cape Town Declaration on Human Rights and a Tobacco-free World © Cape Town Declaration summary by ASH / Unfairtobacco*):

- The production, marketing and sale of tobacco is incompatible with the human right to health and other rights;
- Governments have obligation to address the human rights implications of tobacco production, marketing, sale and consumption;
- The WHO FCTC is grounded in fundamental human rights and freedoms;
- The tobacco industry and industry-funded groups can never be a partner in tobacco policy;
- The tobacco industry should not benefit from trade and investment agreements.

The Declaration calls for:

- Governments to include tobacco policy in human rights reporting;
- Civil society to provide information on tobacco policy to human rights bodies;
- Individuals and organizations to bring legal cases to support efforts to limit production, advertising, and marketing of tobacco products as violations of the human right to health;

- The Special rapporteur on the right of everyone to the highest attainable standard of physical and mental health to include the right to a tobacco-free world as a component of the human right to health in his thematic and country reports;
- The Human Rights Council to affirm the right to a tobacco-free world;
- The exclusion of the tobacco industry from any benefits of trade and investment agreements;
- Scientists, research entities, foundations, and civil society organizations to reject or cease collaboration with the Philip Morris International-funded Foundation for a Smoke-Free World and similar public relations initiatives of the tobacco industry.

Previously, in September 2016, the Danish Institute for Human Rights (DIHR) began working to carry out a human rights assessment in the tobacco company Philip Morris International (PMI) (Danish Institute for Human Rights, 2017).

The work was completed and they decided to end their engagement with PMI.

In May 2017 DIHR reported that:

"*There can be no doubt that the production and marketing of tobacco is irreconcilable with human right to health*";

"*For the tobacco industry, the UN Guiding Principles on Business and Human Rights therefore require the cessation of the production and marketing of tobacco*";

"*We hope our input will enable PMI to better understand how the corporate responsibility to respect human rights applies to their business and take the necessary action*".

Most recently, in February 2024, the tenth session of the Conference of the Parties of the WHO FCTC adopted a Panama declaration (FCTC/COP10(11)) urging Parties to consider including WHO FCTC implementation efforts when engaging with United Nations human rights mechanisms and bodies. Further, this was reiterated in the decision FCTC/COP10(20), which additionally requested the Convention Secretariat to foster coordination and collaboration with entities in the United Nations system pursuing human rights mandates in order to raise awareness of the importance of the WHO FCTC implementation in the fulfilment of human rights. All the decisions are listed and publicly available on this page: https://storage.googleapis.com/who-fctc-cop10/Decisions/index.html.

1.2 Sustainability

The WP4 objective 4.2 is to facilitate the exchange of knowledge and best practices on the application and effective enforcement of the TPD and TAD. Part of this objective is the task 4.2a, which includes the preparation and development of guidance documents, how-to-guides and other documentation that may support EU MS in the implementation and the continuation of JATC-2 actions after the end of the project.

This guidance aims at supporting EU MS in the actions to counteract TI interference in tobacco control policies and activities. Recommendations, templates of the Declaration of Interest (DoI) and Code of Conduct (CoC), and examples about TI tactics are herein provided in order to support countries in the fight against TI interference and for a stronger implementation of the Article 5.3 of the WHO FCTC in the EU.

Indeed, to ensure sustainability of the tobacco control activities and policies, it is important to counteract the TI interference as outlined in Article 5.3 of the FCTC and to ban TI's Corporate Social Responsibility (CSR) initiatives.

If all the EU countries implemented the recommendations of this Guidance, signed a DoI, and adopted the CoC, we could avoid waste of financial and human resources to fight against TI aggressive

interference at many levels; we could envisage a tobacco and related products-free society with high economic saves, a better optimization of the available resources and improved health conditions of the populations. This would build capacity and facilitate national actions to progress towards the Tobacco-Free Generation goal of the EU Cancer Plan. Further, by following the recommendations related to maximizing transparency related to participating to the Conference of the Parties of the WHO FCTC, the decisions guiding the implementation of the treaty on global and regional levels would be better protected from industry interference.

2. Scope of this guidance

This guidance document outlines the main recommendations and actions that European MS (public officials, researchers/scientists, stakeholders, government employees) should follow and undertake, in order to prevent TI's interference and promoting accountability and transparency.

The first part of the document is related to recommendations and actions to follow, for all those involved in tobacco control activities and committed to counteract and avoid TI interference.

The second part of this document provides templates of the **DoI** and of the **CoC** that should be used to support implementation of recommendations.

The DoI template is mostly taken from the one available on the WHO website (WHO, 2014), with some modifications, also incorporating a part from the DoI included in the Toolkit *Preventing Tobacco Industry Interference: A Toolkit for Advocates and Policymakers, Based on the Guidelines for the Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control* of the Southeast Asia Tobacco Control Alliance (SEATCA), Health Justice (SEATCA, 2015). This toolkit is an important resource that should be read in conjunction with this guidance.

The template of the CoC was kindly provided by Mary Assunta (Head of Global Research and Advocacy at Global Center for Good Governance in Tobacco Control), who participated in the 1st WP4 webinar organized by Health Service Executive (HSE), Ireland, with a presentation about *Addressing Tobacco Industry Interference – A Global Index on Article 5.3* and *learnings from Regional tobacco in SEAR (South-East Asia Region)*.

Another important document to be read in conjunction with this guide, is the *Guidance for Public Officials on Interacting with the Tobacco Industry* by the Australian Government, Department of Health. This document contains the legal framework placed on public agencies and officials under Article 5.3 of the WHO FCTC, as a part of a comprehensive strategy of tobacco control (Australian Government, 2019).

Currently, regulatory tobacco control landscape include emerging tobacco and nicotine products, such as electronic cigarettes, heated tobacco products, nicotine pouches, novel herbal products with tobacco and/or nicotine, due to the increasing integration between their manufacturers and the TI (Australian Government, 2019). Therefore, it is highly recommended that the MS include new and emerging tobacco and nicotine products in the implementation of Article 5.3 (WHO, 2023).

Lastly, this guidance reminds of the existing recommendations to maximize transparency in connection with the Conference of the Parties of the WHO FCTC by summarizing the key decisions and guide for participants.

3. Recommendations

In the global tobacco treaty, WHO FCTC, includes a process designed to protect public health policies from the interests of the TI, requiring that **all public or semi-public institutions "**should interact with the tobacco industry only when and to the extent strictly necessary to enable them to effectively regulate the tobacco industry and tobacco products**"** (WHO FCTC, 2013).

As a project committed to strengthening tobacco control, it is of utmost importance that JATC-2 activities and more in general tobacco control policies of the countries, are protected from commercial and other interests of the TI, by involving agencies, public health institutions and ministries (e.g. Ministries of Health, Ministries of Economy and Finance, Ministries of Agriculture) in implementing the recommendations proposed in this guidance.

Participants in JATC-2 as well as in other tobacco control projects either at international or national level, should be committed to sign the DoI and update it regularly (for example, it is mandatory to report any new interests have arisen in the meantime). Moreover, it is important that each EU MS adopt a CoC, personalize it and publishes it on governmental website and on the websites of key regulatory authorities and public health institutions.

The following recommendations are a synthesis of the more detailed ones reported in *Toolkit for Advocates and Policymakers, Based on the Guidelines for the Implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control* (SEATCA, 2015) and in the *Guidance for Public Officials on Interacting with the Tobacco Industry* by the Australian Government (Australian Government, 2019), with the exception of the number 12, which is originally created by the authors of this guidance.

It is strongly recommended that the governments adopt the following measures:

1. Raise public awareness about tobacco control, TI interference and tactics and their negative implication to public health.

2. Adopt a CoC based on Article 5.3 FCTC to set common standards for EU officials and public officials/government employees, researchers/scientists of EU countries.

3. With respect to the public officials/government and agencies employees, all interactions with the TI, including front groups that are funded by tobacco and related industries, must be prohibited unless strictly necessary for regulatory purposes (e.g. the development of law or policy that directly regulates the TI and tobacco products). Meeting must be only with stakeholders registered in the EU Transparency Register.

4. Public Agencies and officials must also ensure that staff members are aware of Article 5.3 and monitor any interactions with TI that are out of the ordinary. Transparency of all meetings and interactions with the TI requires that:

- Detailed information (e.g. the date of the meeting, the organizations represented and a broad description of the issue discussed, related records, minutes, telephone notes and mails, all the communications from tobacco producers and related organizations) must be disclosed on the relevant agency website. For instance, the Danish Health Agency to ensure transparency in the Danish Health Authority's interaction with the TI, publishes on their website all the communications, inquiries and minutes from tobacco producers and their interest organizations (Danish Health Authority, 2023).
- A minimum of two officials must be present at all times in any meeting or interaction.
- For email interactions, at least one other official to all communications must be in copy.
- All meetings or interactions must be recorded and the information about the meeting should include:

  - the date, location, nature and method of the interaction or contact;

- the names of the parties and individuals involved;
- the matters discussed or considered and any decisions taken;
- any follow up activity planned or anticipate;
- detailed minutes of the meeting.

5. Not allowing any official or employee of government or of any semi/quasi-governmental body to accept payments, gifts, or services, monetary or in kind, from the TI.

6. Not allowing such official to accept TI contributions on behalf of government or private entities, and not endorsing, supporting, forming partnerships with, or participating in activities of the TI including activities described as 'socially responsible'.

7. Not allowing TI to work with governments (e.g. to address the illicit trade in tobacco or supporting environmental projects); to promote products purportedly claiming to be less harmful than conventional tobacco products; to provide scholarships or organize or endorse youth or public education initiatives.

8. Preferential tax exemptions, grant incentives, privileges or benefits must not be provided to TI.

9. Activities described as "socially responsible" by the TI, including financial contributions to non-government organizations, must be denormalized and prohibited.

10. Declaring any conflict of interest with respect of tobacco/nicotine industry before starting a tobacco control relevant project/program or work on tobacco control (see the Paragraph 4.1 related to the DoI for further specifics), and regularly update it in case new interests or changes raise up. No organization or individual with a commercial or vested interest in the TI should be involved in developing or implementing public health and related policies/programs on tobacco control. Any current, previous or proposed connection, involvement or relationship with the TI should be disclosed.

11. Information that is offered by the TI outside of disclosures required by law, should be treated with caution and carefully scrutinized to minimize opportunities for the TI to manipulate information, cause confusion among the public and government, and undermine public health policies in relation to tobacco control. Creating the perception of cooperation between government and the TI can bolster the TI's reputation and generate public acceptance for tobacco companies.

12. Requiring transparency of information from TI and related organizations (such as the Foundation for Smoke Free World - FSFW, see chapter 5), and particularly: to provide their annual budget, and to require various organizations receiving money from the FSFW to provide their budget.

The above recommendations are in line with those of the SFP report on the 2021 and 2023 European TI interference index (SFP, 2021; Olefir et al., 2023), which recommend that, at European level, Institutions and agencies should adopt a uniform, mandatory set of specific rules regarding interactions with the TI, in line with Article 5.3 and its Guidelines and with the Ombudsman's Decisions* (SFP, 2016).

Ombudsman's decision has found that "by refusing to implement proactive disclosure of meetings with TI help by officials in all Commission departments in line with the practice in place at DG SANTE, the European Commission is guilty of maladministration". To the date of the report on interference index (November 2021), no such proactive transparency policy specifically regarding meetings with the TI has been implemented at the Commission, nor at the other EU Institutions (SFP, 2021).

The WHO recommends an effective counteracting TI interference by a "whole-of-government approach which ensures all sectors, including, for example, ministries of trade or commerce, are engaged in the enforcement of tobacco control policies and upholding Article 5.3".

The following ten government actions are reported by WHO for preventing political lobbying and interference of TI (WHO, 2023):

1. Requiring disclosure of, and clearly communicating, funding sources for research institutions, academics, and scientific studies to prevent unseen biases in science on which policy may

be based, as well as to clarify the motivations of nongovernmental organizations, business and trade associations, consumer groups, think tanks, professional associations and others seeking involvement or input in tobacco control policies.

2. Rejecting partnerships and non-binding or non-enforceable agreements with the tobacco industry and those working in its interests, including financial support, incentives and endorsement of tobacco industry activities related to tobacco control.
3. Raising awareness about the known addictive and harmful properties of tobacco and nicotine-containing products, and about tobacco industry interference with tobacco control policies.
4. Denormalizing and, to the extent possible, regulating and banning publicity around activities described as "socially responsible" by the tobacco industry.
5. Prohibiting the dissemination of misleading information relevant to tobacco control policies.
6. Requiring that information from the tobacco industry on marketing, lobbying and philanthropic activities is disclosed and that the information provided by them be transparent and accurate, with regular, truthful, complete and precise information on tobacco industry activities. All government interactions with the industry should be recorded and made available to the public.
7. Putting in place and enforcing effective conflict of interest policies for policy-makers and officials engaged in developing, implementing and enforcing tobacco control policies.
8. No government privileges or influence should be afforded to any tobacco and nicotine companies and state-owned tobacco enterprises should be treated the same as other tobacco companies.
   * The Ombudsman investigates different types of poor administration, for example: unfair conduct, discrimination, abuse of power, lack of information or refusal to provide it, unnecessary delays, incorrect procedures by EU institutions, bodies, offices & agencies.
9. Ensuring that health and non-health agencies take consistent action, adhering to Article 5.3 and applying the Guidelines for implementation.
10. Blocking interaction between government and front groups that are funded by tobacco and related industries "purporting to work for a smoke-free world" (speech by Dr Tedros Ghebreyesus).

In every two years, the governing body of the WHO FCTC – the Conference of the Parties (COP) – gathers to make decisions that guide the implementation of the treaty for the coming years. In the eight session of the COP, the Parties made an important decision FCTC/COP8(12) on maximizing transparency of delegations and observers, which:

- Emphasized the need to be alert to interference by the tobacco industry in tobacco control efforts of the Parties and the need to be informed of activities of the tobacco industry that interfere with the implementation of the WHO FCTC;
- Recognized the importance of protecting sessions of the COP and its subsidiary bodies while also upholding the WHO Accountability Framework to "make available reliable and timely information about existing conditions, decisions and actions relating to its activities, in an accessible, visible and understandable fashion, unless the information is deemed confidential";
- Recalled recommendation 4.9 of the Guidelines for the implementation of Article 5.3 of the WHO FCTC (the Guidelines), which states that Parties should not nominate any person employed by the tobacco industry or any entity working to further its interests to serve on delegations to meetings of the COP, its subsidiary bodies or any other bodies established pursuant to decisions of the COP;
- Recalled also recommendation 8.3 of the Guidelines, which states that Parties should ensure that representatives of a State-owned tobacco industry do not form part of delegations to any meetings of the COP, its subsidiary bodies or any other bodies established pursuant to decisions of the COP; and
- Urged Parties to
  a. accelerate and strengthen implementation of Article 5.3 of the WHO FCTC and of the Guidelines;

b. to remain vigilant towards tobacco industry strategies and tactics to interfere in the setting and implementation of their public health policies with respect to tobacco control;
c. to consider recommendations 4.9 and 8.3 of the Guidelines when designating members of their delegations to meetings of the COP, its subsidiary bodies or any other bodies established pursuant to decisions of the COP;

Following this, the guidance for participants of COP (FCTC/COP/10/DIV/2/Rev.1) and MOP (FCTC/MOP/3/DIV/2/Rev.1) **in relation to the Protocol to eliminate illicit trade in tobacco products nowadays provide clear instructions for the accreditation process for their representatives, which should be followed**:

"In accordance with decisions FCTC/COP8(12) and FCTC/MOP1(15), the Convention Secretariat respectfully reminds Parties to observe Article 5.3 of the WHO FCTC and to be mindful of the recommendations 4.9 and 8.3 of the Guidelines for the implementation of Article 5.3 of the WHO FCTC when designating their representatives to the meetings of the COP and MOP. Further, the COP and MOP require Parties, when designating their representatives to the meetings of the COP and MOP, to indicate, by any means or format of their preference (for example, in the accreditation document or in a separate letter), that they have observed Article 5.3 of the WHO FCTC and have been mindful of the recommendations 4.9 and 8.3 of the Guidelines. In this regard, in accordance with the above-referenced decision, the Parties shall indicate the following:

"When designating its representatives to the Tenth session of the Conference of the Parties/Third session of the Meeting of the Parties, [name of the Party] has observed Article 5.3 of the WHO FCTC and has been mindful of the recommendations 4.9 and 8.3 of the Guidelines for implementation of Article 5.3 of the WHO FCTC."

The procedures set forth as per decisions FCTC/COP8(12) and FCTC/MOP1(15) apply to the designation of delegations from States non-Parties."

The annexes of the decision FCTC/COP8(12) also contain templates for the declaration of interest.

4. Templates

In this section two Templates are proposed: The Declaration of Interest (DoI) (section 4.1) and the Code of Conduct (CoC) (section 4.2). Both of these templates represent two complementary actions in order to counteract TI interference.

With respect to the DoI, one of the ways to jumpstart monitoring TI interference is to have a policy that mandates Agencies to require a DoI to be filled out as a standard operating procedure in all meetings, events, before starting a project on tobacco control (e.g. by coordinators or leading investigators as well as by all project participants), or as a requirement for all employees in Governments and Ministries.

The following template of DoI is the one proposed by WHO, giving several examples, so that people will consider all the relevant aspects. Moreover, the DoI should be regularly updated (e. g. every six months) in case new interests or changes arise.

4.1 Declaration of Interest

The template of DoI herein provided is adapted and modified from the WHO DoI (WHO, 2014) and from the DoI included in the Toolkit of the Southeast Asia Tobacco Control Alliance (SEATCA), Health Justice (SEATCA, 2015).

To ensure the highest integrity and public confidence in its activities, any expert, scientist, public

official or government employee, is required since the beginning of their working activity to disclose any circumstances that could give rise to a potential conflict of interest related to tobacco and/or nicotine products. This disclosure should be updated every 6 months or even less, in case they will start a new activity or project related to tobacco and/or nicotine products.

A **potential conflict of interest (CoI)** is any interest that may affect, or may reasonably be perceived to affect, the experts, scientists, public or government officials objectivity and independence.

On this DoI form any expert, scientist, public or government officials should disclose financial, professional or other interest relevant to the subject of the work or meeting in which they have been asked to participate in or contribute towards, and any interest that could be affected by the outcome of the meeting or work. They should also declare relevant interests of their immediate family members (i.e. spouse or partner with whom they have a similar close personal relationship, and their children) and, if they are aware of it, relevant interests of other parties with whom they have substantial common interests and which may be perceived as unduly influencing their judgement (e.g. employer, close professional associates, administrative unit or department).

Answering "Yes" to a question on this form does not automatically disqualify the person or limit his/her participation in a specific activity. The answers will be reviewed by an independent scientific or technical committee/supervisory authority to determine whether you have a CoI relevant to the subject at hand. One of the outcomes listed in the next paragraph can occur depending on the circumstances (e.g., nature and magnitude of the interest, timeframe and duration of the interest).

The committee/supervisory authority may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If, however, a declared interest is determined to be potentially or clearly significant, one or more of the following three measures for managing the CoI may be applied. The committee/supervisory authority allows full participation, with public disclosure of the interest; (ii) mandates partial exclusion (i.e., the person will be excluded from that portion of the meeting or work related to the declared interest and from the corresponding decision making process); or (iii) mandates total exclusion (i.e., the person will not be able to participate in any part of the meeting or work).

All potentially significant interests will be disclosed to the other participants at the start of the activity, and at least every six months participants will be asked if there have been any changes. As regards to scientists or researchers, public or government officials they must communicate if any changes in the interests have been occurred, during their regular working activity.

A summary of all declarations and actions taken to manage any declared interests will be published in resulting reports and work products. Completing this DoI form means that the person agrees to these conditions.

If the person is unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, he/she must disclose that a conflict of interest may exist and the Committee/Supervisory authority may decide that he/she be totally excluded from the meeting or work concerned, after consulting with the person.

Declaration of Interest

Name:	
Institution:	
Email:	

Date and title of meeting or work, including description of subject matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below

First, you need to answer to a general question, then you can respond to all the subsequent questions that are more specific and give the possibility to better specify the eventual connection with tobacco and/or nicotine industry.

If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse or partner with whom you have a similar close personal relationship, and your children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

TOBACCO AND NICOTINE PRODUCTS (answer without regard to relevance to the subject of the meeting or work)

Consistent with the principle that there is an irreconcilable conflict of interest between the tobacco industry and its representatives on the one hand, and public health on the other hand, within the past 4 years, have you had employment or received research support or other funding, contribution or compensation, directly or indirectly, financial or otherwise, from any tobacco and/or nicotine products manufacturer, wholesale distributor, importer of tobacco or nicotine products, tobacco/ nicotine products retailers, or any parent, affiliate, branch, or subsidiary of a tobacco and/or nicotine product manufacturer, wholesale distributor, importer or retailer, front group, or any other individual or organization, such as an interest group, advocacy organization, lawyer, law firm, scientist, lobbyist, advertising agency, business, or foundation, that represents or that works to further the interests of the tobacco and nicotine industry or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco or nicotine products or representing the interests of any such entity?

Yes ☐ No ☐

Please specify your type of direct or indirect connection with tobacco or nicotine industry sector, responding to the following questions, where appropriate.

1. EMPLOYMENT AND CONSULTING

Within the past 4 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work?

1a Employment Yes ☐ No ☐

1b Consulting, including service as a technical or other advisor Yes ☐ No ☐

2. RESEARCH SUPPORT

Within the past 4 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

2a Research support, including grants, collaborations, sponsorships, and other funding Yes ☐ No ☐

2b Non-monetary support (include equipment, facilities, research assistants, paid travel to meetings,

etc.), Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work? Yes ☐ No ☐

3. INVESTMENT INTERESTS

Do you have current investments in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes ☐ No ☐

3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company) Yes ☐ No ☐

4. INTELLECTUAL PROPERTY

Do you have any intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

4a Patents, trademarks, or copyrights (including pending applications) Yes ☐ No ☐

4b Proprietary know-how in a substance, technology or process Yes ☐ No ☐

5. PUBLIC STATEMENTS AND POSITIONS (*during the past 3 years*)

5a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes ☐ No ☐

5b Have you held an office or other position, paid or unpaid, where you represented interests or defended a position related to the subject of the meeting or work? Yes ☐ No ☐

6. ADDITIONAL INFORMATION

6a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage? Yes ☐ No ☐

6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes ☐ No ☐

6c Has any person or entity paid or contributed towards your travel costs in connection with this meeting or work? Yes ☐ No ☐

6d Have you received any payments (other than for travel costs) or honoraria for speaking publicly on the subject of this meeting or work? Yes ☐ No ☐

6e Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes ☐ No ☐

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not describe the nature of an interest or if you do not provide the amount or value involved where relevant, the conflict will be assumed to be significant.

Nos. 1 - 4: Type of interest (e.g., identity of tobacco-related commercial entity, nature of interest/s or relationship, etc.), question number and category (e.g., Intellectual Property 4a Copyrights) and basic descriptive details	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)
Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details				
In case of any past interests related to the tobacco industry, please list the details of such interests (name of tobacco company or of person or entity representing the tobacco industry, date of involvement, details of involvement)				

CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product.

DECLARATION. **I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.**

Should there be any change to the above information, I will promptly notify the responsible staff of the committee/agency supervisory authority and complete a new declaration of interests form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the final results or completion of the activity concerned.

Date:

Signature

4.2 Code of Conduct

The following template, containing all the steps for an adequate application of CoC, has been provided to WP4 by the Global Center for Good Governance in Tobacco Control (GGTC)[1]. All MS committed to counteract the TI's interference, can adopt it and personalize it.

Each country should consider a government body/agency in charge of the implementation of the CoC and should make their CoC public on their Websites, in order to promote transparency.

At international level, Australia adopted a CoC for public officials (Australian Government, 2019).

Most EU MS do not have a CoC in tobacco control. Nonetheless, as a best practice example, a few EU MS have adopted some preventive measure to avoid TI interference in tobacco control (Olefir et al., 2023):

- The Netherlands has a protocol of conduct for officials in engaging with the TI, a code of integrity that directly references Article 5.3, and a complete disclosure of meetings between officials and the TI. Besides having an official guidebook on Art.5.3 compliance, official communications in the Netherlands regularly reference Art. 5.3;

- In France TI has to register its lobbying activities in a special registry that is publicly accessible;

- In the United Kingdom and Denmark, there are some policies but they are followed only by the health department.

Most of the CoC provisions provided by Guidelines implementing Article 5.3,[2] such as receipt of gifts and public disclosure, are already covered by existing laws and rules. However, these proposed rules specifically mentioned the TI. The definition of the TI also is very broadly worded to comply with the Guidelines implementing Article 5.3. It aims to include individuals, organizations or entities working to promote the interest of the TI.

This template of CoC also has provisions on Divestment and Whistleblower Protection.

The challenge is to have in place programs to monitor and report the government employees/officials dealings and relationships with the tobacco industry. These programs will help us determine how well we are complying with Article 5.3.

Adherence to the CoC might be indicative of how comprehensive the need is to intervene with an effective, proportionate, dissuasive administrative fine or other corrective measure from the supervisory authority.

I. Rationale

Tobacco is the single most preventable cause of death in the world today. The spread of the tobacco epidemic is a global problem with serious consequences for public health and calls for the widest possible international cooperation and participation of all countries in an effective, appropriate and comprehensive international response.

The WHO FCTC, the world's first global public health treaty requires the State Parties to adopt a comprehensive range of measures designed to reduce the devastating health and economic impacts of tobacco.

As Party to this treaty, the [country] is under a positive legal duty to implement the measures stated therein.

1 Obtained from Toolkit for policy makers and advocates: Preventing tobacco industry interference. A publication by South East Asia Tobacco Control Alliance (SEATCA) and Health Justice, Inc. 2010; pages 63-68.

2 Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control https://www.who.int/fctc/guidelines/article_5_3.pdf

The WHO FCTC recognizes that tobacco interference poses the single greatest threat to tobacco control. It has been documented that the tobacco industry has used strategies to subvert, hinder and prevent tobacco control efforts. Article 5.3 of the treaty obligates the Parties to protect public health policies with respect to tobacco control from the commercial and other vested interest of the tobacco industry.

II. Objectives

A. To establish a set of rules to guide officials and employees of the agency in dealing with the tobacco industry; and

B. To promote accountability and transparency in the government.

III. Definition of Terms

A. Conflict of interest - arises from a situation in which public officials have private interest which may influence, or appear to influence, the impartial and objective performance of their official duties. Conflict of interest is created when an official or employee has interest in the tobacco industry.

B. Divestment - the transfer of title or disposal of interest in property by voluntarily, completely and actually depriving or dispossessing oneself of his right or title to it in favour of a person or persons other than his spouse and relatives within the fourth degree of consanguinity or affinity.

C. Gift - a thing or a right to dispose of gratuitously, or any act or liberality, in favour of another who accepts it, and shall include a simulated sale or an ostensibly onerous disposition thereof. It shall not include an unsolicited gift of nominal or insignificant value not given in anticipation of, or in exchange for, a favor from a public official or employee.

D. Tobacco Industry - organizations, entities, associations, and individuals that work for or in behalf or the tobacco industry, such as, but not limited to, tobacco manufacturers, wholesale distributors, importers of tobacco products, tobacco retailers, lawyers, scientists, lobbyists, front groups and any other individual or organization that work to further the interests of the tobacco industry (including pharmaceutical or medical devices industry owned by tobacco companies: this is a growing problem as they are investing at this sector in their attempt to sell harm reduction products).

E. Whistleblower - any person believing that an employee or group of employees and/or officials of the agency is or has engaged in improper conduct that constitutes violation of these rules makes a disclosure, in good faith, through the filing of a complaint against the respondents.

IV. Specific Guidelines

A. Interactions with the tobacco industry must be transparent and limited to instances when strictly necessary for its effective regulation.

"Officials, employees and representatives of the relevant ministries/institutions/agencies/organizations shall interact with the tobacco industry only when strictly necessary for its effective regulation. They shall exercise transparency in all interaction with the tobacco industry."

Proposed sanction under Revised Uniform Rules on Administrative Cases in the Civil Service

*Insubordination [*cite relevant section*]*

*OR Simple Misconduct [*cite relevant section*]*

B. No preferential treatment to the tobacco industry

"Officials and employees shall serve the public interest and are prohibited from providing incentives, privileges, benefits or exemptions to the tobacco industry."

Proposed sanction under the Revised Uniform Rules on Administrative Cases in the Civil Service

*Conduct prejudicial to the best interest of the service [*cite relevant section*]*

*OR Unfair discrimination in rendering public service due to party affiliation or preference. [*cite relevant section*]*

C. Prohibition against receipt of gifts, donations and sponsorship

"Officials and employees shall not take advantage of their position for their own private interests. They shall not demand or receive any contributions from the tobacco industry for themselves, their families, relatives, friends, or any other persons or organizations. Contributions shall include, but are not limited to, payments, gifts and services, monetary or in-kind, research funding, financial aid, policy drafts and legal advice."

Proposed sanction under the Revised Uniform Rules on Administrative Cases in the Civil Service

*Soliciting or accepting directly or indirectly, any gift, gratuity, favour, entertainment, loan or anything of monetary value which in the course of his official duties or in connection with any operation being regulated by, or any transaction which may be affected by the functions of his office. The propriety or impropriety of the foregoing shall be determined by its value, kinship, or relationship between giver and receiver and the motivation. A thing of monetary value is one which is evidently or manifestly excessive by its very nature. [*cite relevant section*]*

OR *Receiving payments, gift or other valuable thing in the course of official duties or in connection therewith when such fee, gift or other valuable thing is given by any person in the hope or expectation of receiving a favour or better treatment than that accorded to other persons, or committing acts punishable under the anti-graft laws. [*cite relevant section*]*

D. Divestment of interest in the tobacco industry

Officials and employees shall declare and divest themselves of their direct or indirect interest in the tobacco industry.

For the purpose of this rule, interest in the tobacco industry means personal, financial or other interest, including, but not limited to:

1. having an existing ownership or investment

2. receiving any contribution from the tobacco industry

3. being a member of the Board of Directors, an officer of the corporation or a partner in a partnership.

Proposed sanction under the Revised Uniform Rules on Administrative Cases in the Civil Service

Failure to resign from his position in the private business enterprise within thirty (30) days from assumption of public office when conflict of interest arises, and/or failure to divest himself of his shareholdings or interest in private business enterprise within sixty (60) days from assumption of public office when conflict of interest arises; Provided, however, that for those who are already in the service and conflict of interest arises, the official or employee must either resign or divest himself of said interest within the periods hereinabove; provided, reckoned from the date when the conflict of

*interest had arisen. [*cite relevant section*]*

V. Reporting of Violations

A. Complaint

1. Formal Requirements. A **complaint against a civil service official or employee** shall not be given due course unless it is in writing, subscribed and sworn to by the complainant. However, in cases initiated by the proper disciplining authority, the complaint need not to be under oath. In some local cases complaint can be verbally accepted by a specific officer of the supervisory committee.

Anonymous complaints may be entertained provided there is obvious truth or merit to the allegations therein or supported by documentary or direct evidence.

The complaint should be written in a clear, simple and concise language and in a systematic manner as to apprise the civil servant concerned of the nature and cause of the accusation against him and to enable him to intelligently prepare his defence or answer.

The complaint shall contain the following:

(a) full name and address of the complainant;

(b) full name and address of the person complained of as well as his position and office of employment;

(c) a narration of the relevant and material facts which shows the acts or

(d) omissions allegedly committed by the civil servant; and

(e) If available, the complainant may also submit certified true copies of documentary evidence and affidavits of his witnesses.

2. *Venue.* The complaint shall be filed in the [X Department]. Upon receipt of the complaint, it shall be acted upon within three (3) working days. If the [X Department] finds that the complaint is sufficient in form and substance, it shall require the person complained of to submit a Counter-Affidavit/ Comment under oath within three (3) days from receipt.

B. Investigation

1. *Conference.* The parties may be summoned to a conference where the investigator may propound clarificatory questions.

2. *Fact-Finding Investigation.* A fact-finding investigation may be conducted further or prior to the preliminary investigation for the purpose of ascertaining the truth.

3. *Preliminary Investigation.*

(a) The preliminary investigation shall commence not later than five (5) days from receipt of the complaint by the disciplining authority and shall be terminated within thirty (30) days thereafter.

(b) Within five (5) days from the termination of the preliminary investigation, the investigating officer shall submit the Investigation Report and the complete records of the case to the disciplining authority.

(c) If a prima facie case is established during the investigation, the disciplining authority shall issue a formal charge and a formal investigation shall follow.

(d) In the absence of a prima facie case, the complaint shall be dismissed.

C. Formal Investigation and Hearing of the Case

1. *Notice*. The respondent shall be provided a copy of the formal charge including all evidences supporting the formal charge. He/ She shall be informed of his right to formal investigation and counsel of his/her choice and shall be required to submit a sworn answer within five (5) days from receipt of formal charge.

2. *Failure or Refusal to Answer*. If the respondent fails or refuses to file his answer to the formal charge within five (5) days from receipt thereof, he shall be considered to have waived his right thereto and formal investigation may commence.

3. *Pre-Hearing Conference*. A pre-hearing conference may be conducted for the parties to appear, consider and agree on any of the following:

a. Stipulation of facts;

b. Simplification of issues;

c. Identification and marking of evidence of the parties;

d. Waiver of objections to admissibility of evidence;

e. Limiting the number of witnesses, and their names;

f. Dates of subsequent hearings; and

g. Such other matters as may aid in the prompt and just resolution of the case.

The parties may submit their position papers and memoranda and submit the case for resolution without need of further hearings.

4. *Formal Investigation*. Although the respondent does not request a formal investigation, one shall nevertheless be conducted by the disciplining authority where from the allegations of the complaint and the answer of the respondent, including the supporting documents of both parties, the merits of the case cannot be decided judiciously without conducting such investigation. The investigation shall be held not earlier than five (5) days nor later than ten (10) days from receipt of the respondent's answer. Said investigation shall be finished within thirty (30) days from the issuance of the formal charge or the receipt of the answer unless the period is extended by the disciplining authority in meritorious cases.

Continuous hearings shall be conducted until the case is terminated. Where no pre-hearing conference is conducted, the parties, their counsel and witnesses, if any, shall be given a notice of at least five (5) days before the first scheduled hearing specifying the time, date and place of the said hearing and subsequent hearings. Thereafter, the schedule of hearings previously set shall be strictly followed without further notice.

If the respondent fails or refuses to appear during the scheduled hearings despite due notice, the investigation shall proceed ex parte and the respondent is deemed to have waived his right to be present and to submit evidence in his favour during those hearings.

Unless directed otherwise by the hearing officer, the order of the hearing may be as follows:

The prosecution shall present its evidence subject to the pre-hearing agreement;

a. Cross-examination by the party;

b. There may be redirect and re-cross examination;

c. The respondent shall then offer evidence in support of his defense following the same order;

d. Rebuttal and sur-rebuttal, if any.

When the presentation of evidence has been concluded, the parties shall formally offer their evidence either orally or in writing and thereafter objections thereto may also be made either orally or in writing. After which, both parties may be given time to submit their respective memorandum which in no case shall be beyond five (5) days after the termination of the investigation.

Failure to submit the same within the given period shall be considered a waiver thereof.

5. *Decision.* Within fifteen (15) days after the conclusion of the formal investigation, a report containing a narration of the material facts established during the investigation, the findings and the evidence supporting said findings, as well as the recommendations, shall be submitted by the Hearing Officer with the disciplining authority. The complete records of the case shall be attached to the Report of Investigation.

The disciplining authority shall render his decision on the case within thirty (30) days from receipt of the Report of Investigation.

6. *Penalty.* A decision rendered by heads of agencies whereby a penalty of suspension for not more than thirty (30) days or a fine in an amount not exceeding thirty (30) days' salary is imposed, shall be final and executory. However, if the penalty imposed is suspension exceeding thirty (30) days, or fine in an amount exceeding thirty (30) days salary the same shall be final and executory after the lapse of the regulative period for filing a motion for reconsideration or an appeal and no such pleading has been filed.

D. Remedies

1. *Motion for Reconsideration.* The party adversely affected by the decision may file a motion for reconsideration with the disciplining authority who rendered the same within fifteen (15) days from receipt thereof.

2. *Appeal.* Decisions of heads of departments, agencies, provinces, cities, municipalities and other instrumentalities imposing a penalty exceeding thirty (30) days suspension or fine in an amount exceeding thirty days salary, may be appealed to the Commission Proper within a period of fifteen (15) days from receipt thereof.

In case the decision rendered by a bureau or office head is appealable to the Commission, the same may be initially appealed to the department head and finally to the Commission Proper. Pending appeal, the same shall be executory except where the penalty is removal, in which case the same shall be executory only after confirmation by the Secretary concerned.

VI. Whistleblower Protection

A. Protected Disclosure

1. Reporting of a violation of any provision of these rules shall be considered protected disclosure and the whistleblower shall be accorded protection from intimidation and reprisals.

2. The protection provided by this rule does not require that the whistleblower's report/complaint lead to final determination by the agency that a violation has occurred.

3. To be considered a whistleblower and accorded with the rights and privileges under this act, the complainant:

a. Shall execute a statement outlining, in sufficient detail, the participation of the respondent/s and the act committed constituting violation of the rules. The disclosure must be made voluntarily, in writing and under oath.

b. In the event that he or she has taken part in the violation, he/she must not be the most guilty of all the respondents concerned or in instances where he or she is, such disclosure is compelling against one in higher authority.

c. The information provided leads to successful conduct of investigation and gathering of evidence sufficient to sustain a finding of probable cause for filing of either a formal charge in the agency or for filing of criminal case before the court of competent jurisdiction.

d. Has not been previously convicted by final decision of a criminal or administrative offense involving moral turpitude.

B. Requisites of Protected Disclosure

1. A disclosure must meet the following requirements to qualify as protected disclosure:

a. The disclosure is not yet the subject of an existing or filed complaint or inquiry, or it introduces new evidence of a case earlier dismissed/archived, or it strengthens the case or the conduct of an investigation or inquiry.

b. The disclosure is made before persons, offices, or agencies designated or mandated to receive the complaint (ex. officials of the agency, Heads of other public offices [name relevant regulator]

c. The whistleblower assists or participates in the proceedings commenced to enforce the provisions of the rules in connection with the subject matter of his disclosure.

d. The information provided can be supported by other material evidence.

2. The head of the agency, upon the recommendation of X Committee (committee or supervisory authority established to implement the rules) and after proper evaluation shall certify that the person, having fulfilled all the requirements, is qualified to be a whistleblower and entitled to whatever rights and privileges attributed thereto.

C. Protection Accorded to Whistleblowers

1. Retaliatory acts against the whistleblower, such as but not limited to discriminatory actions, reprimand, punitive transfer, and undue poor performance reviews, are prohibited. The proper administrative action shall be taken against the person/s committing such retaliatory act/s.

Retaliation shall mean any direct or indirect detrimental action recommended, threatened, or taken because the protected disclosure.

2. He/she shall not be subject to any liability, whether administrative, civil, criminal or any other proceedings, for making a protected disclosure and no action, claim or demand may be taken or made of, or against the whistleblower for making the disclosure.

3. He/she shall have as defence in any other inquiry or proceeding, the absolute privilege with respect to the subject matter of the disclosure or information given to a qualified person, office or agency.

4. If he/she has made a protected disclosure and a provision of law, regulation, issuance, practice or other convention, imposes a duty on him/her to maintain confidentiality with respect to any information disclosed, he/she is considered not to have committed a breach thereof.

D. Rights and Benefits of a Protected Whistleblower

1. He/she shall not be liable to disciplinary action for making such protected disclosure. Refusal

to follow orders of his/her immediate superior/supervisor outside of his/her regular functions that would cause him/her to violate any provision of these rules shall likewise be protected from reprisals and retaliatory action in the workplace.

2. The whistleblower and his/her immediate family shall be given free medical treatment, hospitalization and medicines for any harm, injury and illness incurred or suffered by reason of the protected disclosure.

3. The agency shall assist the whistleblower in relocation and/or in obtaining means of livelihood.

4. For the whistleblower who is also an employee of the agency, possible reassignment to other place of work with his/her consent.

5. The whistleblower shall be accorded interim protection as necessary during the course of review or investigation regarding the violation of these rules.

6. The whistleblower shall be informed of the outcome of the investigation including whether disciplinary measures or sanctions have been imposed.

E. Malicious allegations.

In case the appropriate unit determines, after investigation, that the complaint made by the whistleblower has baseless, untruthful, fabricated, malicious or vexatious allegations, the whistleblower shall lose all benefits or protection under the rules, without prejudice to the filing of administrative or criminal case against him/her.

VII. Funding.

All costs incident to the implementation of this Administrative Order shall be sourced from the budget of [X Department].

VIII. Review of the Rules

The rules shall be subjected to periodical review to assess the necessity for amendments taking into consideration new information or strategies in dealing with the tobacco industry.

IX. Repealing Clause

Other related issuances inconsistent with the provisions of this _____ are hereby revised, modified or rescinded accordingly. All other provisions of existing issuances which are not affected by this order shall remain valid and in effect.

X. Effectivity Clause

This _____ shall take effect fifteen (15) days following the date of its publication in a newspaper of general circulation.

5. Examples of Tobacco Industry tactics

Some examples of TI tactics are given below, as well as some useful resources for a more in-depth knowledge of the issue, in order to focus on the reasons why it is highly needed to implement recommendations, sign a DoI and adopt a CoC to counteract TI interference.

TI uses a wide range of tactics to subvert, undermine and prevent proven tobacco control efforts, policies and programs so they can keep and expand their business. The sphere of their influence extends to different fields such as scientific research, politics, law, education and the media (Gannon, 2022).

The tactics used include, but are not limited to, discrediting proven science by sponsoring and promoting research; using lawyers and front groups to aggressively lobby for pro-industry measures, influence the political and legislative process, and intimidate governments with the threat of litigation; promoting misinformation, either directly or through front groups, to exaggerate the economic importance of the industry and its positive role in society (WHO, 2019).

Another issue is that TI targets low-income and middle-income countries (LMICs) which are already facing a growing burden of tobacco-related disease. For example, especially in LMICs, TI has also moved to distance itself from tobacco cultivation through establishing "leaf partnerships" with third-party companies. Instead of direct contracts with farmers, by transferring responsibility for monitoring and addressing problems from TI to leaf companies, TI has continued to reap the benefits of cheap leaf products and to escape responsibility for harmful practices (Gilmore et al., 2015).

In the 9th WHO *Report on the global tobacco epidemic* (WHO, 2023) the following 9 tobacco tactics are reported:

1. Building increasingly elaborate alliances and front groups to represent its case the "third party technique",
2. Attempting to fragment and weaken the public health community,
3. Disputing and suppressing public health information,
4. Producing and disseminating misleading research and information,
5. Directly lobbying and influencing policymaking,
6. Influencing "upstream" policies, including trade and investment agreements, to make it harder to pass public health regulations,
7. Litigating or threatening litigation,
8. Facilitating and causing confusion around tobacco smuggling, and using this confusion to undermine tobacco control,
9. Seeking to manage and enhance its own reputation by rebranding themselves as environmentally and socially responsible to increase the ability to influence policy.

Other specific TI tactics to undermine smoke-free environments are outlined in the same WHO report.

For a more comprehensive view of TI tactics refer to the dedicated parts on the websites of organizations such as: SEATCA, University of Bath (Tobacco Tactics), STOP (Stopping Tobacco Organizations and Products), Tobacco-Free Kids, and Truth Initiative (SEATCA, 2020; University of Bath, 2023; STOP, 2023; Tobacco-Free Kids, 2023; Truth Initiative, 2023).

5.1 Influence targeted to policy-making and political lobbying

To achieve their aims, TI manipulates the media often by recruiting and providing financial and other incentives to journalists to be in line with TI goals (Rowell et al., 2014).

Legal challenges is one of the strategies with a long history and is aimed at challenging different policies from tax policies to Tobacco Advertising, Promotion & Sponsorship (TAPS) restrictions,

often using the argument that cigarettes are legal products like any other and that punitive control measures are in breach of international trade and intellectual property law. This legal challenge is initiated even when a positive outcome is foreseen (Gannon, 2022).

TI not only sells a defective product that kills half of its consumers, but they also have a long history of pressuring governments to block and delay lifesaving regulations, thus costing the world millions of lives and huge spending every year (ASH USA, 2017).

In fact, political lobbying is the widespread TI strategy to persuade a member of the government to support laws or rules in favor of maintaining and expanding TI business. It involves financial donations to political parties or candidates or covering travel or other costs to obtain support for the TI business (Gannon, 2022). TI utilizes third party collaborations to interfere with tobacco control policy making, or to gain legitimacy as a "stakeholder" and to white wash their reputation (ASH USA, 2017).

The SFP, which aims to promote tobacco control advocacy and policy research at EU and national levels, has been monitoring the EU Transparency Register to identify and measure the representation of TI interests, in order to shed light on the human and economic resources of the TI and its allies, who are lobbying the EU institutions.

SFP published a briefing (in 2022, referring to 2021 data) about TI presence in the EU policy-making environment, reporting TI direct and indirect lobbying spending and the number of TI accreditations to EU institutions, highlighting the fact that no meetings with the European Commission are declared in the Transparency Register (SFP, 2022). It is highly recommended an active surveillance on this issue possibly from DGSante.

In the preliminary opinion of the EU Ombudsman (released on April 18, 2023), regarding its own-initiative inquiry on the transparency of meetings between the European Commission and TI representatives (in 2020 and 2021), it has been highlighted a "maladministration" in the European Commission's approach to meeting with tobacco lobbyists. SFP consider of utmost importance that EU Commission implement the proactive transparency policy put in place by the Directorate-General for Health and Food Safety (DG SANTE) across all departments, following the 2016 EU Ombudsman recommendations (SFP, 2016), as well as that all departments publish online all meetings with TI and the related minutes, and that public health policies are always protected (SFP, 2023).

5.2 Scientific research and front groups

TI knowingly hid the truth about the impact of cigarette smoking for decades and funded research undermining objective scientific findings to protect profits (Briggs & Vallone, 2022).

While some tactics are aimed at youth and minors (WHO, 2020), others, such as the use of front groups and funding scientific research, are specifically aimed to researchers and public officials.

The TI has a long history of influencing the scientific community through tactics mostly related to information management: creating doubt about scientific evidence, funding scientists and commissioning research and reviews, using ghost writing technique (e.g. writing articles or scientific reports which are officially credited to another person).

Practical examples of TI influencing science and funding scientists are sustaining controversy on secondhand smoke (SHS), or providing the US Duke University a multi-million dollar funding to establish the Duke Center for Nicotine and Smoking Cessation Research (University of Bath, 2020).

TI attempted to counter the scientific evidence on the harms of passive smoking, even using the label of "junk science" (Samet & Burke, 2001) and contested the evidence (epidemiological and biological) that SHS increases cardiovascular disease (CVD) risk, by affecting the design and interpretation of their own cardiovascular studies (Tong & Glantz, 2007). Moreover, TI persuaded a researcher to

change his conclusion that SHS is an independent risk factor for Sudden Infant Death Syndrome (SIDS) to state that the role of SHS is "less well established". The integrity of the scientific process is definitely compromised by TI funding (Tong et al., 2005).

To undermine smoke-free policies in multi-unit housing, TI used the tactics of distortion (funding studies that downplayed the link between SHS and asthma among low-income residents) and deflection (engaging in corporate responsibility for youth programs) (Miller & Vijayaraghavan, 2022).

The public reporting of 5 clinical trials funded by Juul Labs (US electronic cigarette company) was found to have specific outcome reporting biases (of 61 specified outcomes, 28 were CONSORT compliant). No full results of these trials were published on the Clinicaltrials.org website. The lack of transparency of the results reporting cannot support public health professionals, clinicians, and the public in making informed choices about the benefits or harms of electronic cigarettes (DeVito et al., 2023).

TI has created websites to promote their own science, and used them to report their approaches to the science on newer products nicotine and tobacco products for alleged harm reduction purposes (University of Bath, 2023).

Moreover, TI uses front groups such as FOREST (The Freedom Organization for the Right to Enjoy Smoking Tobacco) for mobilizing support and many other front groups to lobby health organizations with recent examples of this being the Foundation for a Smoke-Free World (FSFW). FSFW is a self-declared "independent and non-profit organization" but whose sole funder is actually PMI (Gannon, 2022).

TI is infiltrating scientific spaces: FSFW published articles in established journals (e.g. *International Journal of Environmental Research and Public Health* and *Drugs and Alcohol Today*), by circumventing conflict-of-interest documentation and policies or by hiding their role in funding (Briggs & Vallone, 2022).

TI aims also at influencing scientific conferences: for example, the Society of Research on Nicotine and Tobacco (SRNT) used to allow the participation of TI researchers in the annual meetings, but after many researchers started to complain about this excessive overwhelming presence, SNRT decided to ban the TI participation (Briggs & Vallone, 2022).

It is particularly important for scientists and experts to be aware of the TI practice of funding scientific research which is documented in TI documents that are available since the 1990s (Schick & Glantz, 2007). Presently, this practice continues as was also seen during the COVID-19 pandemic (Gallus, 2022; STOP, 2022; Hagen & Dorado, 2023).

5.3 Harm reduction

TI uses the "harm reduction" (term used since 1999) concept to gain access and (re)start a dialogue with policy-makers, scientists and the public health community and to rebuild its reputation as a responsible industry (Peeters & Gilmore, 2015). TI has been promoting their research and development efforts in developing potentially reduced harm tobacco/nicotine products defining them as "one of the biggest public health opportunities of this generation" (STOP, 2020). Actually, the tobacco and nicotine industries work strategically to delay and defeat policy measures worldwide in order to promote and protect the viability of their business, employing various tactics that interfere with government efforts for public health protection (SEATCA, 2020).

In a recent analysis by Edwards et al. (2022), no evidence was found for any tobacco company rapidly progressing towards eliminating conventional tobacco products, ceasing to obstruct effective tobacco control measures and taking action to minimise smoking uptake and disparities. TI actions are more consistent with profit maximisation than eliminating conventional product use, which is best described as 'pseudo-transformation', designed to delay implementation of effective tobacco

control policies (Edwards et al. 2022).

In a context of interference in policy-making, TI argues that Heated Tobacco Products (HTP) should be subject to lighter regulation than conventional cigarettes. In fact, TI emphasizes that HTPs heat tobacco without combustion, in order to claim that HTP are "reduced risk" products compared to conventional cigarettes. The approach that HTP aerosols do not constitute tobacco smoke is being used as part of the tobacco harm reduction concept promoted by TI (WHO FCTC, 2021). TI uses a number of tactics in pursuing relatively light regulation for HTP, including downplaying and ignoring health risks from HTP, lobbying parliamentarians directly in order to bypass health authorities, and funding front groups to push a "harm reduction" narrative (WHO FCTC, 2021).

TI sponsors the so-called "smoke-free" policies at holiday destinations which appear to encourage tourists and locals to stop smoking cigarettes, while heavily promoting its HTP (e.g. Astypalea in Greece or Canary Islands with "La Graciosa Smoke Free Initiative", which received a Smoke-Free Culture certification from TUV Austria for its campaign to encourage either "quitting" cigarettes or switching to alternatives such as HTP (University of Bath, 2022).

5.4 Corporate Social Responsibility (CSR) and Greenwashing

Corporate Social Responsibility (CSR) is "The idea that a company should be interested in and willing to help society and the environment as well as be concerned about the products and profits it makes". TI implements a variety of environment/sustainability-themed CSR programs across the world in order to enhance their corporate image. CSR is part of the TI greenwashing efforts (e.g. charitable donations, donations to disaster relief efforts, funding various environmental sustainability organizations). TI uses CSR programs around sustainability to pre-empt regulation and influence policymakers. TI CSR activities are now very relevant in the environmental sector, where regulators are not so well aware of the WHO FCTC (STOP, 2021). TI should not be allowed to communicate to the public at all.

They have also used environmental impact disclosure processes and sustainability awards from external bodies to try to create a sense of legitimacy and present their industry as socially and environmentally friendly. TI states that reducing the environmental impact of their operations is a key part of their visions for corporate sustainability (e.g. by downplaying the amount of water needed to produce tobacco by comparing it with the amounts necessary to produce tea or chocolate, per weight of finished product, ignoring the differentiator that these other products do not damage health, as tobacco does) (University of Bath, 2022).

The TI widespread strategic use of misleading CSR and sustainability reporting to facilitate tobacco promotion, requires urgent regulatory attention (Greenland at al., 2020).

TI tactics also include offering scholarships to high school, college and graduate students (such as in US, Israel and UK) and sponsoring school programs and youth camps (WHO, 2020; Baler et al., 2020), as well as cultural events and sports (for example in Europe: Italy, Romania, Spain, etc.) (Jackler et al., 2020), despite sponsorship by TI in sports being widely banned with the notable exception of motorsports and Formula 1 (Freeman at al., 2022; STOP, 2020; Blum, 2005).

It is also worth of note that especially in the past ten years, TI is seeking to transform itself towards wellness and health care areas by investing and acquiring pharmaceutical companies (WHO, 2023; Sy, 2023). These pharmaceutical acquisitions are part of a CSR strategy. Paradoxically, tobacco companies profit from selling medicines for health conditions, many of which are caused by tobacco products themselves (Sy, 2023).

Some important CSR activities of TI also include contribution of millions in annual funding to charities such as donations to the Red Cross (University of Bath, 2021). Also TI utilized the COVID-19 pandemic for their CSR activities. Many governments, made vulnerable by the pandemic, freely

accepted and endorsed charity from the TI, when such donations often come with strings attached, and compromised on tobacco control policies (GGTC, 2021b).

CSR include the practice of "Greenwashing", used by industries to market their goods and/or image as environmentally friendly in an effort to increase product sales and divert public attention from their own environmentally damaging practices. Reporting environmental impact and funding environmental CSR projects and organizations, serves to "greenwash" tobacco companies, and detract from the harms the industry inflicts on the environment and environmental health. TI has historically greenwashed its reputation and products through programmes such as beach clean-ups, marketing of new products as "eco-friendly" and funding environmental organisations, especially in LMICs (University of Bath, 2022).

TI continues to use so-called CSR to access high-level policy-makers, including those in non-health sectors (WHO, 2019).

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7. List of acronyms

ASH	Action on Smoking and Health
CoC	Code of Conduct
CoI	Conflict of Interest
CONSORT	CONsolidated Standards of Reporting Trials
COP	Conference of the Parties of WHO FCTC
COVID-19	Coronavirus disease 2019
CSR	Corporate Social Responsibility
DHA	Danish Health Agency
DIHR	Danish Institute for Human Rights
DG SANTE	Directorate-General for Health and Food Safety (of the EU Commission)
DoI	Declaration of Interest
EU	European Union
FCTC	Framework Convention on Tobacco Control
FOREST	Freedom Organization for the Right to Enjoy Smoking Tobacco
FSFW	Foundation for a Smoke-Free World
GGTC	Global Center for Good Governance in Tobacco Control
HSE	Health Service Executive
HTP	Heated Tobacco Products
JATC2	Joint Action on Tobacco Control 2
LMIC	Low-income and Middle-Income Countries
MS	Member State
PMI	Philip Morris International
RIA	Regulatory Impact Analysis
SEATCA	Southeast Asia Tobacco Control Alliance
SFP	Smoke Free Partnership
SHS	Secondhand smoke
SIDS	Sudden Infant Death Syndrome
SNRT	Society of Research on Nicotine and Tobacco
STOP	Stopping Tobacco Organizations and Products
TAD	Tobacco Advertising Directive
TAPS	Tobacco Advertising, Promotion & Sponsorship
TPD	Tobacco Products Directive

TI	Tobacco Industry
UN	United Nations
WHO	World Health Organization
WHO FCTC	World Health Organization Framework Convention on Tobacco Control
WP	Work Package