



Recent developments in EU tobacco control work

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Cross-border health care and tobacco control

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Content of presentation

1. Where do we stand on tobacco control in EU?
2. What are EU tools?
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1. Where do we stand on tobacco control in the EU?

700 000

premature
deaths in EU
per year

the equivalent of the **whole
population** of Seville



- Tobacco kills 700,000 Europeans every year
- Over 25 billion euros every year spent by EU countries on diseases caused by tobacco
- 26% of EU citizens are smokers, rate rather stable since 2014
- Young people 15-24: rate increased from 25% in 2014 to 29% in 2017

Objectives at EU level

- Achieve a high level of health protection in the single market
- Reduce the number of citizens who take up smoking, with particular focus on young people
- Protect citizens from the hazardous effects of smoking, including second-hand smoke
- Reduce consumption of tobacco by 2% within 5 years (TPD)
- Implement provisions of FCTC
- Help current smokers to quit (discontinued)

Governed by EU competences



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2. What are EU tools for tobacco control?

- **Legal** (Regulation of tobacco products, e.g. packaging, labelling, ingredients; advertising restrictions for tobacco products, tax measures and activities against illicit trade)
- **Political** (Recommendations e.g. on smoke-free environments, monitoring)
- **Financial** (Joint Action, cessation campaigns, grants, research activities)
- **International** (FCTC)



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The new Tobacco Products Directive

Main provisions

- Ingredients
- Labelling
- Tracking and tracing
- E-cigarettes



Expected outcome

- Estimated drop of tobacco consumption of 2% within five years = 2,4 million smokers less in the EU
- Guarantee the proper functioning of the EU internal market, while ensuring a high level of health protection
- Health focus - initiation of tobacco consumption, in particular by young people



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Main elements of TPD (1)

Packaging and labelling

- Mandatory combined health warnings (65%) on both sides of the pack
- Certain pack standardisation
- Ban on promotional and misleading elements

Ingredients

- Regulation of ingredients incl. ban of tobacco products with characterising flavours
- Reporting obligations for all ingredients (electronic format)
- Enhanced reporting for additives on a priority list

Smokeless and novel tobacco

- Continued ban of oral tobacco (snus)
- Stricter labelling rules for other smokeless tobacco products
- Prior notification and enhanced reporting for novel tobacco products





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WARNING 1: Smoking causes 9 out of 10 lung cancers



Smoking causes 9 out of 10 lung cancers

Get help to stop smoking at www.nhs.uk/quit

Set 1 image

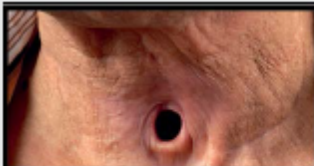


Smoking causes 9 out of 10 lung cancers

Get help to stop smoking at www.nhs.uk/quit

Set 2 image

WARNING 2: Smoking causes mouth and throat cancer



Smoking causes mouth and throat cancer

Get help to stop smoking at www.nhs.uk/quit

Set 1 image



Smoking causes mouth and throat cancer

Get help to stop smoking at www.nhs.uk/quit

Set 2 image

WARNING 3: Smoking damages your lungs



Smoking damages your lungs

Get help to stop smoking at www.nhs.uk/quit

Set 1 image



Smoking damages your lungs

Get help to stop smoking at www.nhs.uk/quit

Set 2 image

WARNING 4: Smoking causes heart attacks



Smoking causes heart attacks

Get help to stop smoking at www.nhs.uk/quit

Set 1 image



Smoking causes heart attacks

Get help to stop smoking at www.nhs.uk/quit

Set 2 image

Main elements of TPD (2)

E-cigarettes

- Safety and quality e.g. nicotine threshold
- Packaging and labelling, including health warning and info leaflet
- 6 months prior notification, market surveillance, extensive reporting obligations
- Advertising restrictions
- Special rules for "refillables"

Fight against illicit trade

- EU-wide traceability system at unit pack level
 - ⇒ Unique identification, full traceability from the manufacturer to the last point before the retail outlet, independent data storage system (= central view of supply chain)
- Obligatory security feature at unit pack level

Cross border distance sale

- Notification and age verification systems, MS may prohibit.

Herbal products for smoking

- Labelling, ingredients reporting.



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Timelines

- Entry into Force: 19 May 2014
- Transposition Deadline: 20 May 2016
- Development of secondary legislation
 - 1st set: 4/2014-5/2016
 - Traceability & Security features: 4/2014-12/2017
 - Input: Studies and discussions with Member States / Expert Group
- Practical implementation of provisions / monitoring: ongoing
- Reporting obligations: 2018 on delegated powers, substantial report in May 2021
- Track and trace system for cigarettes and roll-your-own tobacco by 20 May 2019, for all other tobacco products 20 May 2024



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TPD - practical implementation

Notifications: Compliance checks of national transpositions - ongoing

Packaging and labelling: Combined Health Warnings in all EU languages; clarity on labelling of RYO

Ingredients – Flavours: Independent Advisory Panel established; Technical Group of Sensory and Chemical Assessors

Reporting on Tobacco products and e-cigarettes: Reporting system established and information being sent to MS through the EU-Common Entry Gate (EU-CEG)

Priority Additives: Identification of priority additives and information on methodologies for studies to be requested

E-cigarettes: Technical specifications for a mechanism ensuring refilling without leakage; potential health risks of refillables summarized

Track and trace: setting up of system

Challenges of TPD

- Legal challenges e.g. Court cases
- Transposition and compliance
- Complex and encompassing implementation structure
- New products emerging, e.g. heated tobacco products
- Electronic cigarettes
- Illicit trade in tobacco products: Implementation of track and trace system started

Joint Action on Tobacco Control

- Support EU-Member States in the implementation of the TPD
- Collaboration and exchange of best practices
- Vertical Work Packages (WP 5-9)
 - Extraction and Analysis of reported data (EU-CEG, MS-REP)
 - E-cigarette product evaluation
 - Tobacco Product Evaluation
 - Priority additives subject to enhanced reporting obligations
 - Laboratory verification, collaboration and analyses
- Oct 2017 – Oct 2020, 2.5 Mio Euros (2 Mio from EU Budget)
- Kick-off meeting on 12-13 December 2017 (Athens)
- Partners from 31 countries, including 25 MS

Tracking and tracing of tobacco products

International response

- FCTC Protocol (Art. 8, on traceability)

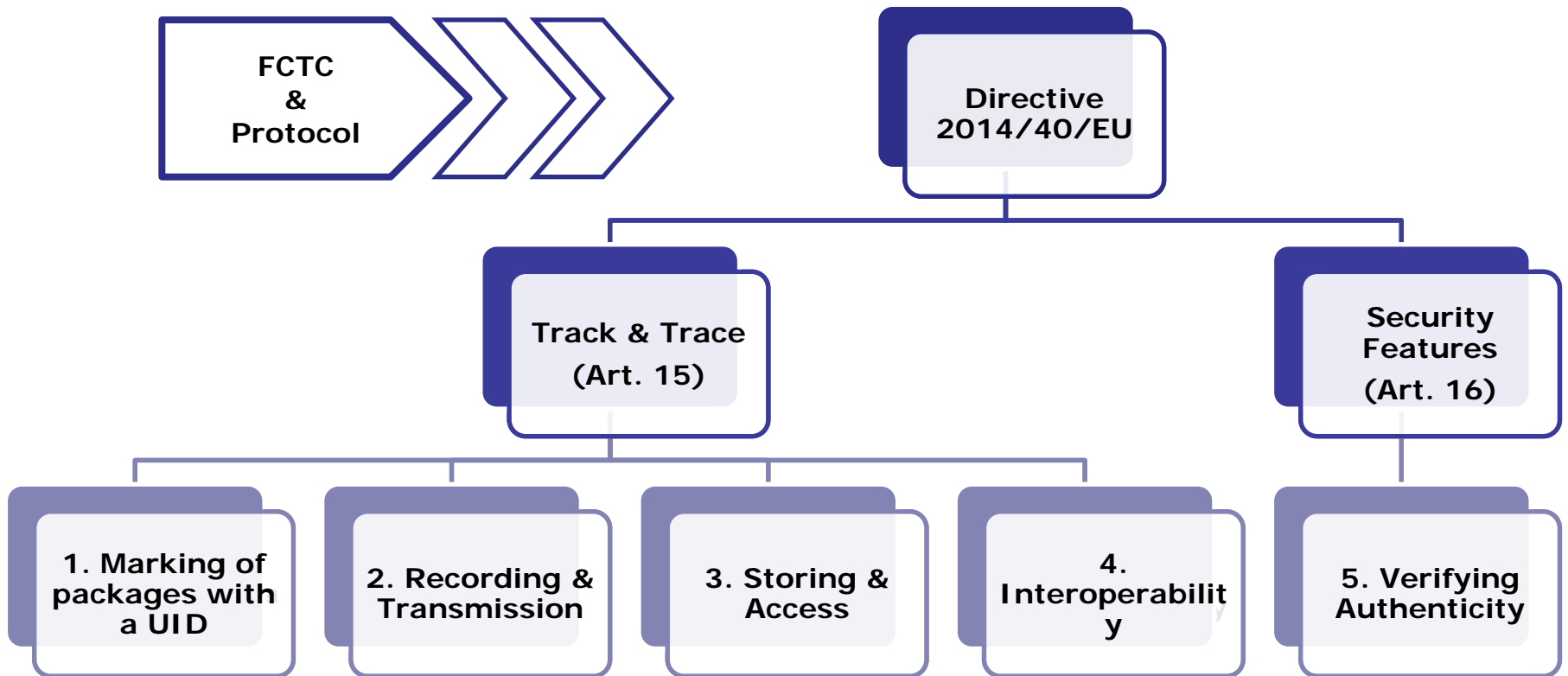
EU response

- Articles 15 and 16 of Tobacco Products Directive 2014/40/EU
 - Implementing and delegated act (traceability)
 - Implementing act (security features)



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Elements of the systems



Future outlook on track and trace

- Secondary legislation in force; supply chain control and fight against counterfeit products
- Systems for traceability and security features are applicable from
 - 20 May 2019 to cigarettes/RYO
 - 20 May 2024 to other tobacco products
- Towards a global tracking & tracing regime...

Tobacco taxation

- **Council Directive 2011/64:** structure and rates of excise duty applied on manufactured tobacco
- 2014/2015: Refit evaluation
- 3/2016: Council conclusions
- **12.1.2018: Commission report:** no proposal now, but e-cigs and heated tobacco products and minimum rates to be reconsidered in next report on directive due in 2019
- 2018: start of evaluation
- **23.5.-3.9.2018: public consultation:** gathers views on current tobacco taxation in EU, novel products, appropriate options for revision of directive



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Advertising and sponsorship

Advertising Directive (2003/33/EC)

- Bans cross-border tobacco advertising and sponsorship in the EU; it covers print media, radio, internet and sponsorship of events such as the Olympic Games and Formula 1 races

Audiovisual Media Directive (2010/13/EU)

- Bans all forms of audiovisual commercial communications, sponsorship and product placement
- **Revision:** formal adoption in autumn 2018



Tobacco Products Directive (2014/40/EU)

- extends above restrictions to e-cigarettes and refill containers

Smoke free environments

Council Recommendation 2009/C 296/02 calls on Member States to

- Provide comprehensive protection against ETS in indoor workplaces, public places and public transport by 2012
- Develop strategies to protect children/adolescents
- Strengthened cooperation at EU level (network of focal points to exchange info and best practice)

Commission Implementation Report in spring 2013:

http://ec.europa.eu/health/tobacco/docs/smoke-free_implementation_report_en.pdf

International: FCTC

- EU very active from the beginning in negotiations and implementation
- Several FCTC guidelines pushed EU actions (e.g. smoke free environments, article 5.3)
- Very active in several WGs (e.g. art. 9/10)
- Very active in Illicit Trade Protocol
- FCTC in NCDs/ FCTC in health SDGs
- COP 8: EU push for a decision on novel tobacco products



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3. What are we currently working on?

Commission currently concentrates on:

- TPD implementation:
 - Further developing/using systems (e.g. IAP and TG, EU-CEG)
 - transposition and compliance checks
- Joint Action on Tobacco Control
- T&T
- FCTC implementation/Illicit Trade Protocol
- Reporting obligations (Art. 27, Preparation for Art. 28 report)

Other issues:

- Tobacco advertising
- Smoke free environments
- Tobacco taxation
- Extended producer responsibility schemes, also for cigarette butts

Stopped:

- Campaigns

Commission 5-year report – May 2021

- **Application** of directive, with a special attention to:
- **Electronic cigarettes and refill containers:** use patterns, role of these products for the initiation of consumption of such products and tobacco products by young people and non-smokers and the impact of such products on cessation efforts, including the role of dual use;
- **Slim cigarettes:** consumer perception of the harmfulness as well as the misleading character of these products;
- **Water pipes:** use patterns and consumer preferences with a particular focus on its flavours, role of dual use;
- Experience gains with **design of package surfaces** (e.g. plain packaging);
- **Market developments:** novel products, e-cigarettes, water pipes, slaims, sales and use by product category
- **Feasibility, benefits, possible impact of a European system** for the regulation of ingredients and of a Union database on ingredients; positive/negative list

4. What are the next steps?

- TPD: making new systems work, compliance, report (art. 28), evaluation on efficiency and effectiveness
- T&T: setting up of system
- E-cigs: market developments, role for initiation and smoking cessation, advertising
- Taxation: public consultation, evaluation, potentially legal proposals
- Plastic strategy: Extended producer responsibility
- FCTC/COP 8/MOP 1 and FCTC in health SDGs



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Thank you!



http://ec.europa.eu/health/tobacco/overview_en