



Constitutional and Legislative Affairs

European Commission proposal to revise the Tobacco Products Directive (Directive 37/2001/EC)

Briefing

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1. Introduction

On 19 December 2012, the European Commission published a proposal to revise Directive 37/2001/EC ('the Tobacco Products Directive').¹ The Tobacco Products Directive dates back to 2001 and sets down requirements in relation to tobacco products (their manufacture, presentation and sale) in order to align the laws, regulations and administrative provisions of all the EU's members states. The new proposal published by the Commission in December 2012 revises this legal framework and proposes new and strengthened rules on tobacco products.

An Explanatory Memorandum was prepared by the UK Government's Department of Health in response to the Commission's proposal on 21 January 2013.²

2. The proposed Directive

The objectives of the proposed Directive were summarised in a press release issued by the European Commission:

All citizens will benefit from the revision foreseen as they will receive more accurate information about the products. Young people will be discouraged from taking up tobacco consumption, as the possibilities to render the products "attractive" will be limited. Current tobacco users will benefit from the measures proposed in the Directive as they will be in a better position to take informed decisions about the products and on quitting if they so wish and thus benefit in terms of health.

Manufacturers of tobacco products will benefit from clearer rules, an improved functioning of the internal market and a level playing field. The new rules take particular account of the specific needs of small and medium-sized companies.³

In particular, one of the proposed Directive's main aims is to extend the scope of the Tobacco Products Directive to encompass **non-tobacco nicotine-containing products** ('NCP') (e.g. **e-cigarettes**) below a certain nicotine threshold.

Although there is no suggestion that the proposed Directive will seek to ban e-cigarettes, the intention is that NCP products which contain above a certain level of nicotine, will be regulated as 'medicinal products' in a similar way to nicotine replacement therapies ('NRT') which are used as aids in smoking cessation (patches, gum etc.). NRT products are currently available on prescription from GPs and can also be purchased in pharmacies and larger supermarkets. NCP products with nicotine levels below the threshold could continue to be sold as consumer products (but must feature an adapted health warning). The nicotine threshold would be based on nicotine content in medicinal products already authorised for smoking cessation.

¹ EUROPA, [Questions and answers: Towards a new EU law on Tobacco Products](#), 19 December 2012 [accessed 20 February 2013]

² Department of Health, [Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products](#), 21 January 2013 [accessed 20 February 2013]

³ EUROPA, [Questions and answers: Towards a new EU law on Tobacco Products](#), 19 December 2012 [accessed 20 February 2013]

The proposal is expected to reinforce the character of NCP as smoking cessation rather than 'leisure', and aims to make tobacco products and tobacco consumption less attractive, therefore discouraging more young people from starting to smoke.

At present, NCP products fall outside the scope of the Tobacco Products Directive, and Member States have taken different approaches to these products, including regulating them as medicinal products, applying certain provisions that are used for tobacco products, or having no specific legislation. The proposal aims to remove the current legislative divergence between Member States, and the differential treatment of NCP and NRT.

According to the accompanying European Commission Press Release, the proposal has been adopted following extensive consultation with stakeholders, including a public consultation.⁴ It also states that an impact assessment was also carried out and a number of external studies were commissioned.⁵

3. Subsidiarity

The Subsidiarity Protocol provides all national parliaments of the EU's member states with an **eight-week** early warning period to submit a reasoned opinion stating why it considers that the draft legislative proposal in question does not comply with the principle of subsidiarity.

Turning such objections into practice however is dependent on the following procedures:

- **Yellow card procedure:** Triggered if one third of the EU's national parliaments (currently 9 out of the 27 member states) contest the conformity of a draft legislative proposal on grounds of subsidiarity. The procedure requires the EU Commission to re-examine the draft and explain why it is maintaining it. A different threshold of a quarter of member states (either 6 or 7 member states) applies if the draft legislation in question relates to the area of freedom, security and justice.
- **Orange card procedure:** Triggered if a simple majority of the EU's national parliaments (currently 14 member states) challenges the conformity of a draft legislative proposal on grounds of subsidiarity and if the European Commission maintains its original proposal. The procedure requires the matter to be referred to the European Parliament and the Council, which will issue a decision at first reading. If they believe that the legislative proposal is incompatible with the principle of subsidiarity, they may reject it subject to a 55 per cent Council majority or a majority vote in the European Parliament.

In addition to these procedures, the **Committee of the Regions** is also empowered to refer cases where the principle of subsidiarity is breached by one of the main EU institutions directly to the Court of Justice of the European Union.

Because the National Assembly is considered a 'regional' rather than a national parliament at the EU level, it has no direct legal grounds to question EU legislative proposals on the basis of subsidiarity. Nevertheless, the Assembly's Standing Orders enable a 'responsible

⁴ EUROPA, [Tobacco products: towards bigger health warnings and ban of strong flavourings](#), 19 December 2012 [accessed 20 February 2013]

⁵ Ibid

committee' (currently the Constitutional and Legislative Affairs Committee) to raise formal concerns about a draft legislative proposal introduced by the European Commission, within the Assembly's legislative competence or the Welsh Ministers executive powers, on the grounds that it breaches the subsidiarity principle.

If the Committee decides that the draft legislative proposal in question does not comply with the subsidiarity principle, Standing Orders allow it to make written representations on behalf of the National Assembly within the eight week early warning period to the relevant committees in the House of Commons and the House of Lords, who may take account of those representations in reaching their own conclusions.

The eight week deadline for reasoned opinions from national parliaments in relation to the proposed Directive is **4 March 2013**. To date, only two reasoned opinions (by the national parliaments of Italy and the Czech Republic) have been expressed on the proposal.⁶ Possible concerns may also be raised by the Swedish Riksdag.⁷ According to the Committee of the Regions' Subsidiarity Monitoring Network, no concerns have been raised in relation to the proposed Directive by any of the regional or sub-state legislatures of the EU's member states.⁸

3.1. *The role of the Assembly*

Although Welsh Ministers were consulted by the Department of Health in preparing the EM to the proposed Directive,⁹ a copy was not received by the Assembly upon its publication.

The proposed Directive was not initially identified from the 'batch list' (i.e. a list prepared by the Foreign and Commonwealth Office of all the proposals published by the European Commission) as relevant to the work of the Assembly by Assembly officials upon its introduction. This was on the basis that its provisions would fall outside the scope of the Welsh devolutionary settlement as 'Human medicines and medicinal products, including authorisations for use and regulation of prices' is included as an exception to the Assembly's legislative powers, as outlined in Schedule 7 to the *Government of Wales Act 2006*.¹⁰

3.2. *The UK Government's position*

The Department of Health's EM does not provide a specific view on whether the UK Government will oppose the proposal on the grounds of subsidiarity or not, stating instead that:

⁶ IPEX, [Document: COM/2012/0788](#), 3 January 2013 [accessed 20 February 2013]

⁷ Ibid

⁸ See Subsidiarity Monitoring Network, [REGPEX](#) [accessed 20 February 2013]

⁹ Department of Health, [Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products](#), 21 January 2013, paragraph 5 [accessed 20 February 2013]

¹⁰ [Government of Wales Act 2006](#) (Chapter 32)



The UK Government recently consulted on the standardised packaging of tobacco products and retains an open mind on this issue. The Government would wish to see a final text which leaves this option open for Member States.¹¹

No reasoned opinion has been issued by either the House of Commons or the House of Lords in relation to the proposal to date.

4. Next steps

On the basis that no further objections on the grounds of subsidiarity will be made by other member states before 4 March 2013, the proposal will be passed on for discussion in the European Parliament and in the Council of Ministers. It is expected to be adopted in 2014, and would come into force sometime in 2015-2016.

¹¹ Department of Health, [Explanatory Memorandum on European Union legislation: Proposal for a directive of the European Parliament and of the Council on the approximation of the laws, regulation and administrative provisions of the Member States concerning the manufacture, presentation and the sale of tobacco and related products](#), 21 January 2013, paragraph 15 [accessed 20 February 2013]