Department
of Health

From the Rt Hon Jeremy Hunt MP
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To all UK MEPs

Dear colleague,

PROPOSAL FOR A REVISED TOBACCO PRODUCTS DIRECTIVE

Ahead of the plenary vote on the proposal for a revised Tobacco Products Directive on 8 October, I wanted to write to you to set out how important I think this legislation is to improve public health and protect young people from the harms of tobacco.

The UK Government considers the revised Tobacco Products Directive to be crucial to more effective tobacco control across the EU. I believe that it is the duty of all governments to protect children from the harms of smoking and to reduce the burden on our health services from smoking related diseases. The proposal will help to achieve these aims by reducing the uptake of smoking among young people.

I was pleased that Member States were able to agree their position on the Directive in June, following lengthy and complex negotiations. It is now crucial to keep up momentum. I urge you to support the negotiating mandate and give this dossier every chance of becoming law within the term of the current European Parliament.

I welcome the strong stance on public health taken by Member States and the Parliament's Public Health Committee vote in July. I very much hope that the robust approach to the regulation of ingredients and combined health warnings remains intact following the plenary stage.

I would like to bring your attention to two issues in particular.

Firstly, I am aware of the concerns that many of you have about the availability of electronic cigarettes for those who are trying to quit smoking cigarettes. The UK Government supports the regulation of nicotine-containing products, including e-cigarettes, as medicines.

The UK Government wants to see more and better quality products on the market to encourage as many smokers as possible to use these products to reduce the harm to them and to those around them. We want safe, effective products to be available as widely as possible. Medicines regulation – with a light touch approach – can support this and enable innovation in this important, rapidly growing market.

Medicines regulation does *not* amount to a ban. The non-prescription medicines market operates just like the fast moving consumer goods market, highly competitive with large numbers of both branded and generic products. The majority of the market is micro and small business which clearly demonstrates that medicines regulation does not stifle markets; rather it can encourage and support true innovation to create more effective products.

Quality standards for nicotine-containing products are both achievable and proportionate in a market estimated to be worth well over €500M in Europe and growing rapidly.

Secondly, I would ask you to consider how important it is for the final Directive to clearly give Member States the flexibility to make further progress on domestic tobacco control measures if they so wish. The Public Health Committee voted for an amendment which largely achieves this goal, except in one key respect. They opted to retain the Commission power of veto over Member States' domestic measures. I am extremely concerned about giving the Commission this power. In practice it would create uncertainty and additional risk for UK tobacco control legislation. Member States must not be unnecessarily constrained in their ambitions on tobacco control where it is proportionate and compatible with EU law.

Officials from my Department, who I know that some of you have already met, would be happy to provide further information, a summary of which is appended to this letter.

Thank you for your ongoing support on this public health priority. We have an opportunity here to make real improvements to the health of future generations throughout Europe.

Yours sincerely

Jeremy Hunt

JEREMY HUNT

Department
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Annex

UK GOVERNMENT POSITION ON KEY ELEMENTS OF THE TOBACCO PRODUCTS DIRECTIVE PROPOSAL

Nicotine Containing Products and medicines regulation (Article 18)

Key points

The public health priority of reducing the harms of smoking can best be achieved by the regulation nicotine containing products (NCPs), including electronic cigarettes (e-cigs), under the medicines framework.

Medicines regulation does not amount to a ban. Quality standards for NCPs are both achievable and proportionate in a market estimated to be worth well over €500M in Europe and growing rapidly.

The non-prescription medicines market operates just like the fast moving consumer goods market, highly competitive with large numbers of both branded and generic products. The majority of the market is micro and small business[i] which clearly demonstrates that medicines regulation does not stifle markets; rather it can encourage and support true innovation to create more effective products.

Medicines regulation has the tools to manage the risk of poor and ineffective products and to maximise the potential for public health gain. The framework is already in place, with established systems, standards, guidelines and enforcement capability to deliver assurance of safety and quality in the rapidly changing e-cig market. There are well established and enforceable powers to control marketing and advertising, especially important as the tobacco industry moves into this sector.

UK Government position

The UK wants smokers to have access to safe and effective products to help them cut down, quit or as a safer alternative to smoking for smokers and those around them. Medicines regulation can adapt and change to respond to developing markets, as more is learned about the safety of products in use or as new risks emerge.

There have been licensed nicotine products for over 30 years (patches, gum etc). The best available evidence is that e-cigs may be as effective as regulated nicotine

but the lack of safeguards in medicines regulation – including long term safety monitoring - represent a public health concern. E-cigs, and what other forms of nicotine products may follow, have great potential, but the lack of an appropriate regulatory framework can inhibit investment in true innovation.

Some E-cig companies (large and small) support medicines regulation, as do large, small and micro pharma, the public health community (medical Royal Colleges, researchers and academics, Action on Smoking and Health, etc.).

The UK is looking at ways to positively engage with small businesses and further facilitate licensing of NCPs. The MHRA has met with over twenty e-cig companies that are interested in gaining a medicines licence for their products and is working with interested parties in developing an approach to licensing NCPs, within the existing framework.

Opportunities of medicines regulation

Medicines regulation can provide for:

- Wide access to products that meet standards of quality, safety and efficacy outside pharmacy (note ENVI amendments)
- Controlled advertising, in licensed uses, including powers to pre-vet advertising
- Safety monitoring in use, including over the long term, through established reporting systems
- Emerging risks, e.g. of NCPs acting as a gateway to smoking tobacco, including by children, can be effectively managed

Unlicensed NCPs are not risk free. Known and reported risks include acute effects on lung function, possible pneumonia and others risks related to poor product quality.

Targeted and proportionate regulation

Medicines regulation can be targeted and proportionate. One size does not fit all. The medicines regulatory approach is constantly adapting to regulate in proportion to relative risk: requirements for an over the counter cough remedy are very different to those for a tissue engineered medicinal product.

Clinical trials should not be necessary to demonstrate the well-established efficacy of nicotine. Nicotine quality, delivery and the safety of the drug delivery device would be the focus of the licensing process.

A new marketing authorisation is not required each time there is a change to a product; in most cases the marketed authorisation can be varied to reflect changes.

Most member states (23 out of 24 surveyed) already have forms of licensed NRTs widely available as non-prescription medicines. Most Member States (two thirds) already have a legal category of medicines that can be sold outside pharmacy. Member States will be required to amend national laws to transpose the directive. For those member states that do not have a general sale category for sale outside pharmacy, there is a ready opportunity for a nicotine category to be created for sale in retail outlets when national law is changed.

Competitive marketplace and innovation

The medicines industry is one of the most innovative in the world in developing new products. But medicines regulation in the over the counter medicines (OTC) sector also supports a fast moving consumer goods approach. The UK market in over the counter medicines alone is worth around €3Billion annually. The market for licensed OTC NRT is worth €120million. There are many examples of successful innovation and evolution of existing brands, which drive growth and achieve competitive advantage. Nicorette has 21 different medicines in its range of forms – gums in several flavours, invisible patches, nasal sprays, mouth sprays – proving that medicines regulation need not suppress the range of products.

The pharmaceutical industry is extremely innovative. The medicines regulatory framework that can act as a driver for improving manufacturing, effectiveness, safety and consumer acceptability. The current framework does not support the development of quality products, such that the most popular brand of e-cigs on the UK market is likely to be less effective than licensed NRT.

Self-regulation and tobacco regulation are not appropriate

In the six years since products first appeared on the European market, an adequate self- regulatory model has not been developed. Restrictive regulation, as on tobacco, is not appropriate for a product with potential for public health benefit, but strong powers are needed to ensure responsible product development, including by the tobacco industry.

Member State flexibilities (Article 24)

UK position

It is crucial for public health reasons that Member States retain the ability to go further domestically on tobacco control measures if they so wish and that Member States are not unnecessarily constrained in their ambitions on tobacco control where it is proportionate and compatible with EU law. The UK Government wants to retain the option to make further progress on domestic tobacco control legislation in certain key areas in the future, complementing this Directive. There is also a strong argument that Member States should not be forced to consider regressive action to water down existing domestic tobacco control legislation following the adoption of the revised Directive.

Commission proposal

The European Commission appears to have intended to provide for Member State discretion while respecting the internal market treaty base of the proposal. However, the UK Government considers that a re-drafting of Article 24 would better achieve the intended aim. The conditions to be applied to more stringent national measures set out in Article 24(2) such as "grounds relating specific situation of the Member State" are onerous and will create additional litigation risks for Member States and for the institutions. The UK Government believes that Article 34 of the Treaty on the Functioning of the European Union already provides sufficient safeguards to test domestic measures and we do not believe that introduction of another test is appropriate or necessary. In addition, the Commission's power to approve or reject future domestic action is inappropriate as the compatibility of national measures with EU law is for the courts to determine.

Latest Council text

For the reasons set out above, the UK Government welcomes the wording of Article 24 in the compromise text on which a General Approach was agreed in Council on 21 June 2013.

Latest European Parliament text

It is clear that the ENVI position aims to give Member States the flexibility to introduce more stringent domestic measures to better protect public health if they wish to do so. This aligns well with our objectives.

However, we are concerned that ENVI has retained the European Commission's power to veto domestic measures. The UK Government believes that such a

Commission power is inappropriate because it is for the Courts to determine whether Member States have gone too far, not the Commission. In practice, we believe that the retention of the veto will be disadvantageous for the UK. In practice it adds uncertainty and additional risk for UK tobacco control legislation.

Regulation of ingredients (Article 6)

The UK Government does not wish to see an exemption for any characterising flavour, including menthol, from the proposed prohibition, as recommended in the WHO Framework Convention on Tobacco Control (FCTC) guidelines. We note that the ENVI Committee, like the Council, supported a complete ban on characterising flavours with the exception of sugars lost during the manufacturing process.

Combined health warnings (Article 9)

The UK Government supports bigger combined health warnings which evidence demonstrates are more effective. We do not support a reduction in the size of the warnings to below 65% of the front and back of packs.

Cross border distance sales (Article 16)

The UK supports the age verification and notification systems foreseen in the Commission's proposal and supports the General Approach agreed in Council which would give Member States the ability to choose whether or not to prohibit cross border internet sales. However we are not convinced by the evidence to support a mandatory pan-EU ban on cross border sales, as set out in the latest ENVI Committee text.

Tobacco for oral use (Article 15)

The UK strongly supports the current prohibition on tobacco for oral use in all Member States other than Sweden. We cannot support a backwards step for public health by relaxing an existing ban on a category of tobacco. The ENVI Committee voted in favour of retaining the ban on snus (with the exception for Sweden), which we are content with.

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[i] *UK Business Industry and Skills Department statistics suggest that there are 385 businesses in the sector which covers Manufacturers of pharmaceuticals, medicinal chemicals and botanical products, of which 230 are micro and 65 medium sized).*