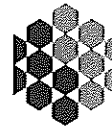


FROM THE MINISTER FOR HEALTH,
SOCIAL SERVICES AND PUBLIC SAFETY



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Our Ref: COR/1862/2015

Date: 5 January 2016

Dear

HEALTH (MISCELLANEOUS PROVISIONS) BILL – SUMMARY OF WRITTEN EVIDENCE

I refer to the summary of written evidence on clauses of the Bill (as introduced) which we received on 16 December 2015.

Please find enclosed the Departmental response to the stakeholder comments.

Yours sincerely

SIMON HAMILTON MLA

HEALTH (MISCELLANEOUS PROVISIONS) BILL

SUMMARY OF EVIDENCE ON CLAUSES OF THE BILL

The summary of written evidence includes only those comments made in relation to the clauses of the Bill as introduced.

Complete written evidence can be accessed at: <http://www.niassembly.gov.uk/assembly-business/committees/health-social-services-and-public-safety/legislation/health-miscellaneous-provisions-bill---call-for-evidence/written-submissions/>

Part 1 consists of 5 clauses and provides for regulations to be made prohibiting the sale of nicotine products both to under 18s and from vending machines.	
Clause 1 Prohibition of sale of nicotine products to persons under 18	
Stakeholder Comments	Departmental response – 22 December 2015
Royal College of Physicians of Edinburgh: The College supports the prohibition of sale of nicotine products to persons under 18, including nicotine vapour products/e-cigarettes. It also supports the creation of an offence in relation to the proxy purchasing of nicotine products, as it believes this is a significant means of obtaining cigarettes for many young smokers.	Noted
British Medical Association NI The BMA Northern Ireland welcomes this Health (miscellaneous provisions) Bill and its focus was on Part 1: sale of nicotine products and tobacco. BMA Northern Ireland has a long history supporting comprehensive tobacco control measures and our goal is for a tobacco	Noted

free society by 2035. It believes that a wide range of measures are needed to achieve this goal and it fully supports the Bill.

- The chief medical officer in his annual report shows that although smoking rates have reduced from 29% in 1998-99 to 22% in 2013-14, it remains the single greatest cause of preventable deaths in Northern Ireland, killing around 2,300 people each year.
- In relation to young people, between 2000 and 2013, the proportion of children aged 11 to 16 years who had ever smoked declined by almost two thirds from 37% to 13% in 2013. There are a number of concerns around the rising popularity of e-cigarettes, namely the aggressive promotion and marketing of e-cigarettes which has led to their increased awareness and use by children and young people. This was highlighted by a recent YouGov survey which found that 10% of young people have tried e-cigarettes (up from 7% in 2013). There is a need for a strong regulatory framework to ensure the necessary controls are in place to protect children and young people.
- It is widely recognised that the health risks associated with e-cigarette use are likely to be significantly lower than the well-established risks associated with smoking tobacco, and BMA Northern Ireland recognises their potential for supporting tobacco harm reduction. There is, however, a lack of robust research and evidence in this area, and any public health benefit is not yet well established. There remains a lack of conclusive evidence as of the effectiveness of e-cigarettes as a smoking cessation aid, and concerns regarding the safety and variability of the components

Noted

Noted

From May 2016, the new EU Tobacco Products Directive will require *all* nicotine-containing products, which contain less than 20mg/ml of nicotine, to be regulated as consumer products. In practice, this means that e-cigarette manufacturers will be obliged to comply with a number of requirements if they wish to sell their products within the EU. These include: a limitation on the nicotine content of e-cigarettes (20mg/ml); obligatory reporting on ingredients in,

of e-cigarette vapour. BMA Northern Ireland supports regulating e-cigarettes as licensed medical products, as this best reflects their use for harm reduction, would bring them in line with existing nicotine replacement therapy products, and ensure their effectiveness, quality, and safety.

- BMA has published, 'Promoting a tobacco-free society,' and this paper summarises our position on the future of tobacco control and what measures are needed to move towards a tobacco-free society in Northern Ireland. Our goals for a tobacco free society are based on: policy and legislative changes; education and information; smoking cessation and tobacco industry accountability.
- It believes the clauses outlined in this Bill will assist in working towards a long term goal of a tobacco free society. It proposed the inclusion of two additional amendments to achieve this goal [see submission]

Fontem Ventures:

Fontem Ventures supports legislation which restricts the access and consumption of nicotine products by anyone under the age of 18, and to make it an offence to proxy purchase nicotine-containing products. Fontem Ventures also supports the introduction of a requirement for retailers of e-cigarettes to have an age verification policy in place to

and emissions resulting from, the use of e-cigarettes, including toxicological data; the provision of information to consumers, including a health warning on packaging; and restrictions on cross-border advertising and promotion.

The BMA's first proposed amendment relates to amending the Tobacco Retailers Act to include those selling e-cigarettes. The Department is in the process of establishing the tobacco retailers register and expects to have it operational from Spring 2016. At present, there are no plans to extend the register to include e-cigarette retailers, however, this will be revisited in future if there are difficulties enforcing the age of sale provisions in relation to e-cigarettes.

The second amendment calls for a ban on smoking in cars in private vehicles carrying children under 18 years. The Minister has already confirmed his intention to table an amendment to this effect.

The Department has no plans at present to introduce a requirement in the Bill for retailers of e-cigarettes to have an age verification process in

prevent anyone under the age of 18 accessing nicotine-containing products. That said, there are clear and substantial differences between nicotine-containing products such as e-cigarettes and tobacco products. E-cigarettes do not contain tobacco, do not burn, and do not smoulder unlike tobacco products. For this reason, Fontem Ventures does not agree that e-cigarette legislation should take the form of extended tobacco legislation. Fontem Ventures believes the Northern Irish authorities should embody a regulatory approach aimed at preventing uptake of e-cigarettes by under 18s while encouraging tobacco smokers to shift to e-cigarettes as a smoking-cessation tool and a means of reducing the number of tobacco-related illnesses.

JTI

JTI fully supports both the Northern Ireland Executive’s decision to make it an offence to sell e-cigarettes to under-18s and the introduction of a ban on proxy purchases. It believes that these measures could make a significant contribution to reducing young people’s access to nicotine containing products. JTI does not market electronic cigarettes, or any other nicotine containing product, to under-18s or to non-users of tobacco or nicotine-containing products. In line with its core principle that children should not smoke, or have access to tobacco products, we also believe that children should not have access to electronic cigarettes or other nicotine containing products. As such it supports the proposal to introduce legislation that would make it an offence to sell electronic cigarettes to under-18s. JTI also supports the introduction of legislation making it an offence to allow a person under the age of 18 to sell nicotine products, unless specifically authorised to do so by a responsible person.

National Federation for Retail Newsagents

The NFRN strongly supports age regulation of sale of nicotine products to persons under the age of 18, including the use of e-cigarettes and

place. This would place an additional burden on retailers and has not been consulted on.

To date, two novel nicotine products have been granted licences by MHRA and can be marketed as a smoking cessation aid. As with all licensed products, it is then a matter for the prescribing practitioner who is assessing the client accessing smoking cessation services, to decide on which licensed product is most appropriate to that particular client's needs.

The Department has no plans at present to make it an offence to allow a person under the age of 18 to sell nicotine products. Such legislation may have a negative impact on the employment prospects of young people, particularly in rural areas where part-time employment is limited.

Noted

<p>other vapour products. In addition, the NFRN supports the addition of an offence of obtaining nicotine / nicotine products through proxy purchasing, further preventing minors obtaining nicotine products.</p>	
<p>British Dental Association In relation to Part 1 of the Bill, BDA supports the proposal to restrict the sale of nicotine products to people over 18 years of age.</p>	<p>Noted</p>
<p>Cancer Focus NI Cancer Focus NI supports regulations that will prohibit the sale of nicotine products to under 18s (Clause 1), and from vending machines (Clause 2). It is also satisfied with the proposal to create an offence for proxy purchasing of nicotine products (Clause 1). The proposals within Part 1 will be important practical instruments to assist in making it more difficult for young people to access nicotine products, including e-cigarettes, either directly, or through a proxy.</p>	<p>Noted</p>
<p>Imperial Tobacco Clause 1 of the Bill provides a regulation-making power for the Department of Health, Social Services and Public Safety (the “Department”) to prohibit the sale of nicotine products to a person under the age of 18. The clause provides an exemption for persons employed in the industry and a due diligence defence. In addition, the clause also includes a regulation-making power for the creation of an offence in relation to the proxy purchasing of nicotine products. Imperial Tobacco agrees with the provisions set out in this clause and believes that nicotine products and tobacco should not be sold or marketed to under 18s. It would like to draw the Committee’s attention to existing retailer programmes designed to discourage under-age sales to children such as the ‘No ID, No Sale’ retailer awareness campaign and the ‘CitizenCard’ proof-of-age scheme. It would encourage the inclusion of nicotine products, such as e-cigarettes, within these</p>	<p>Noted</p>

<p>successful initiatives. Imperial Tobacco would be happy to meet with Committee officials to discuss how the use and take-up of such initiatives could prevent the under-age sales of e-cigarettes.</p>	
<p>Clause 2 Prohibition of sale of nicotine products from vending machines</p>	
<p>Royal College of Physicians of Edinburgh: The College supports the prohibition of sale of nicotine products from vending machines, meaning that nicotine vapour products are subject to the same restriction as traditional cigarettes, whose purchase from vending machines was banned a number of years ago. This prohibition is important in preventing young people from accessing nicotine products.</p> <p>Fontem Ventures: Fontem Ventures does not agree with the prohibition of sale of e-cigarettes from vending machines. Fontem Ventures believes that by placing vending machines in over 18 establishments or limiting access to vending machines through interaction with staff first, the age of vending machine users can be controlled. Allowing access to e-cigarettes in over 18 establishments helps encourage a switch from traditional tobacco products to e-cigarettes, which have been found to be 95% safer than conventional tobacco products by Public Health England. Provided that effective age verification can be guaranteed, it generally believes e-cigarettes should be accessible as possible in order to encourage smokers to switch as much and often possible. Fontem is not alone in this conclusion. In an open letter to the WHO, more than fifty health and tobacco specialists stated that “it</p>	<p>Noted</p> <p>While the Department is not aware of any premises where e-cigarettes can be sold by vending machines, it wishes to future-proof the legislation. Before sales of tobacco from vending machines were banned, they were a regular source of tobacco for under 18s. The Department would only intend to make regulations in relation to vending machines if there was evidence to suggest that young people were able to obtain e-cigarettes from them.</p>

would be unethical and harmful to inhibit the option to switch to tobacco harm reduction products”. Therefore, an outright ban on e-cigarette sales via vending machines would not be proportionate to the goal of restricting sales to under 18s. Instead, a clear requirement to have effective age verification tools in place will be fit for purpose.

JTI:

JTI is fundamentally opposed to a ban on electronic cigarette vending machines. Adults who choose to use electronic cigarettes are entitled to be treated fairly and equally, and have the right to choose and to obtain the products they prefer. It believes that under-18s should not be able to obtain electronic cigarettes either via vending machines or any other sales channels, and therefore access to vending machines should be strictly controlled by, for example:

- Introducing adult identification functions in vending machines, either by electronic age verification means, ID coin mechanisms or remote control operation, in line with various international precedents. JTI has experience of introducing such systems in other countries around the world, including Austria, Germany and Japan, and JTI would be willing to share further information on the costs, timings and technicalities of the different types of adult identification functions available;
- Where vending machines are not equipped with adult identification functions, requiring them to be located solely in areas where only adults are permitted; or
- Requiring vending machines to be located within sight of employees of the venues in which they are located so that their use can be monitored.

As above.

<p>In its opinion, a very clear and convincing justification needs to be present before restricting the means by which adult users can access electronic cigarettes. In addition, the Northern Ireland Executive must show that there are no more proportionate methods of achieving the goal of preventing under-18s from accessing electronic cigarettes via vending machines. As no such justification has been presented, and as it believes that strictly controlling access to vending machines is a more proportionate method, it does not support an extension of the vending machine prohibition to include electronic cigarettes.</p>	
<p>National Federation for Retail Newsagents The NFRN supports the prohibition of the sale of nicotine and nicotine related products from vending machines.</p>	Noted
<p>Cancer Focus NI See Comments under Clause 1</p>	Noted
<p>Imperial Tobacco Clause 2 provides a regulation-making power for the Department to prohibit the sale of nicotine products from automatic vending machines. It notes that an amendment was made to Part 1 of the Bill following the consultation process yet the proposal to prohibit the sale of nicotine products from automatic vending machines was not formally included in the 2014 public consultation. It is disappointed to note that the Department has included an amendment without formal consultation on this issue. Imperial Tobacco does not support this clause. We believe that by placing vending machines in over 18 establishments or limiting access to vending machines through interaction with staff first, the minimum age of vending machine users can be controlled. Furthermore, during a recent Second Stage debate on the Bill (8 December 2015), the Minister for Health, Social Services and Public Safety stated that:“While there is no evidence of that happening at this</p>	The amendment in relation to vending machines was included as a result of comments received during the consultation on the Health (Miscellaneous Provisions) Bill. The Department would only intend to use these powers if it became apparent that there was an issue around access of e-cigarette products by young people from vending machines.

stage [nicotine products being sold from vending machines], I believe that it is important that we have measures in place to prevent such an eventuality.”

Imperial Tobacco calls on the Committee to ensure that all clauses within the Bill are supported by evidence and are proportionate to the issue being addressed.

<p>Clause 3: Amendments consequential on sections 1 and 2: makes consequential amendments to integrate the new age of sale offence for nicotine products into the existing age of sale legislation for tobacco products.</p>	
<p>British Medical Association NI BMA Northern Ireland believes that e-cigarettes and their refills should be an age restricted product and therefore an additional clause is needed in this Bill to amend the Tobacco Retailers Act (NI) 2014 to include those selling e-cigarettes. This enables support and advice to be directed at those trading these items to avoid illegal sales and enable easier enforcement of the law.</p> <p>National Federation for Retail Newsagents The NFRN supports these amendments.</p>	<p>The Department is in the process of establishing the tobacco retailers' register and expects to have it operational from Spring 2016. At present, there are no plans to extend the register to include e-cigarette retailers, however, this will be revisited in future if there are difficulties enforcing the age of sale provisions in relation to e-cigarettes.</p> <p>Noted</p>
<p>Clause 4: Amendment of the Order of 1991: increases the penalty for selling tobacco from automatic vending machines in line with similar offences for underage sales of tobacco products.</p>	

<p>Royal College of Physicians of Edinburgh: The College supports these changes to prohibit the sale of nicotine products to those under 18, and to standardise the penalty for doing so.</p> <p>National Federation for Retail Newsagents The NFRN supports these amendments.</p>	<p>Noted</p> <p>Noted</p>
<p>Clause 5: Interpretation of Part 1: definition of “ nicotine product”</p>	
<p>Royal College of Physicians of Edinburgh: The College supports this clause which defines nicotine products to include e-cigarettes and other nicotine vapour products.</p> <p>National Federation for Retail Newsagents The NFRN supports this clause which expands the definition in the inclusion of e-cigarettes and other nicotine related vapour products.</p> <p>Imperial Tobacco Clause 5 of the Bill defines a “nicotine product” as: a) a device which is intended to enable nicotine to be consumed by an individual or otherwise to be delivered into the human body; b) an item which is intended to form part of a device within paragraph (a); or c) a substance or item which consists of or contains nicotine and which is intended for human consumption or otherwise to be delivered into the</p>	<p>Noted</p> <p>Noted</p> <p>The Department notes the concerns expressed by Imperial Tobacco around “heat, not burn” products. However, the main purpose of the provisions in Part 1 of the Health (Miscellaneous Provisions) Bill is to prevent the sale of nicotine-containing products to persons under the age of</p>

human body.

The Bill goes on to state that the following are not nicotine products:

- a) tobacco;
- b) cigarette papers;
- c) any device which is intended to be used for the consumption of lit tobacco.

Imperial Tobacco believes that the wording in the Bill does not cover new and emerging products sufficiently. A number of multi-national tobacco companies have launched and are promoting new tobacco products where the tobacco is reportedly “heated” rather than burnt. The current wording of the Bill creates ambiguity which may allow these so-called heated tobacco products to remain outside legislation in Northern Ireland. Heated tobacco products use tobacco just like conventional cigarettes and some even use cigarette branding. Manufacturers claim these products work by heating tobacco sufficiently to release nicotine and aroma compounds into an inhalable vapour, but not sufficiently high enough to burn the tobacco. These products are available in a number of EU countries and are also available online, so could therefore conceivably appear in Northern Ireland.

Heated tobacco products contain less tobacco than conventional cigarettes and so smoke emissions from these products are reduced in comparison with conventional cigarettes; however, many of the harmful and potentially harmful constituents found in tobacco smoke, which have been reported to cause smoking-related diseases, are still produced.

It has been claimed by some manufacturers that heated tobacco products may offer a “reduced risk” of developing tobacco-related diseases and may be considered a “harm reduction” product. Such claims are yet to be demonstrated scientifically and have not been endorsed by any regulatory body. We believe society and regulators should keep a clear, distinct line between products that contain tobacco e.g. heated tobacco products and those which do not e.g. e-cigarettes.

18. The “heat, not burn” products referred to by Imperial Tobacco will not be available for sale to under 18s as they contain tobacco and under the Health and Personal Social Services (Northern Ireland) Order 1978, “a person who sells to a person under the age of 18 any tobacco or cigarette papers, whether for his own use or not, shall be guilty of an offence.

Imperial Tobacco believes that heated tobacco products do not fit the description of “nicotine products” - as set out in Clause 5 of the Bill - as they contain tobacco. Neither do they fit the description of “lit tobacco” as these products are not “lit” if used as intended and are claimed to heat rather than burn tobacco. As heated tobacco products contain tobacco we believe the Committee should act in this area and ensure these novel heated tobacco products are regulated to the same standard as conventional cigarettes.

In this regard, Imperial Tobacco proposes the following amendment to Part 1, Section 5(3) of the Bill:

Current clause	Proposed amendment
<p>Interpretation of Part 1</p> <p>Section 5(3) The following are not nicotine products for the purposes of this Part—</p> <p>(a) tobacco; (b) cigarette papers; (c) any device which is intended to be used for the consumption of lit tobacco.</p>	<p>Interpretation of Part 1</p> <p>Section 5(3) The following are not nicotine products for the purposes of this Part—</p> <p>(a) any product which contains tobacco; (b) cigarette papers; (c) any device which is intended to be used for the consumption of lit.</p>

Part 2 consists of 6 clauses to amend the 2008 Act provisions in respect of primary dental services, general ophthalmic services, pharmaceutical services and charges for services provided to persons not ordinarily resident

Clause 6: Persons performing primary dental service

British Dental Association
 The Bill provides the Department with the regulatory powers to introduce a new contract for dental services, including the creation of a performers list. BDA is content that the proposed technical amendments outlined in Clause 6, 9 and 10 are necessary to ensure that the correct

Departmental Response:
 The Department notes that the British Dental Association is content with the technical amendments required to allow for the introduction

<p>wording and legislative references are in place to enable the creation of contractual legislation.</p> <p>The proposed amendments to give the Department powers to introduce a performers list, requires further detail and consideration of the potential impacts. The term ‘performer’ is not currently used in Northern Ireland and in the absence of a definition in the Bill, there must be an impact assessment on the practical implications and outturns of the introduction of a performers list. In particular, further clarity is required on listing requirements, the ability to engage a ‘performer’, service provision and the potential impact on payments such as practice allowance and pensions.</p> <p>BDA recognises that much of the detail on how performers lists will be introduced in NI is not contained in this primary legislation and will be covered in subsequent subordinate legislation. BDA expects that this will be subject to full impact assessments and consultation.</p> <p>It should also be noted that a new contract for GDS is a considerable time away and is dependent on progress and evaluation of GDS pilots in the first instance, before further negotiations between the BDA and DHSSPS.</p>	<p>of primary dental services.</p> <p>As already acknowledged by the BDA, the detail of how primary dental services will operate in practice (including how performers’ lists will operate) will be contained the subordinate legislation.</p> <p>That legislation will be subject to detailed assessment and consultation.</p>
<p>Clause 7: Ophthalmic services: revokes the provisions in the 2008 Act and restores the pre 2008 listing provisions</p>	
<p>General Optical Council: The General Optical Council is content with the provisions that relate to ophthalmic services.</p>	<p>Departmental Response: The Department notes the General Ophthalmic Council is content with the provisions relating to ophthalmic services.</p>
<p>Clause 8: Pharmaceutical services: revokes the provisions in the 2008 Act and restores the pre 2008 listing</p>	

provisions	
No comments	
Clause 9: Disqualification by the Tribunal	
British Dental Association See comments under Clause 6	
Clause 10: Provision of medical or dental services: Article 15B arrangements	
British Dental Association See comments under Clause 6	
Clause 11: Charges for services provided to persons not ordinarily resident in Northern Ireland	
No comments	
Part 3 consists of 5 clauses and makes provision in respect of interpretation of the Bill, subordinate legislation and repeals, and sets out the title and commencement dates.	
Clause 12: Interpretation	
No comments	

Clause 13: Regulations and Orders	
<p>Imperial Tobacco Section 13(2) states that regulations and orders made by the Department under this Act may contain such incidental, supplementary, transitional, transitory or saving provisions as appear to the Department to be necessary or expedient. Imperial Tobacco calls on the Committee to ensure that any such changes to the regulations and orders under this Act are evidence-based and subject to scrutiny of the Northern Ireland Assembly. It notes that the Department has committed to hold a further consultation on draft regulations relating to nicotine products and it welcomes the opportunity to participate in these discussions.</p>	Noted.
Clause 14: Repeals	
No comments	
Clause 15: Commencement	
No comments	
Clause 16: Short Title	
No comments	