Country	Are you aware of such products being placed on the market in your country? Please provide details.	How are these products currently regulated? (e.g. as	5. Have you considered the applicability of the medicinal products legislation for such products?	Do you consider that the medicinal product definition for such products, in particular from a view of their capacity to modify physiological functions by exerting a pharmacological, immunological or metabolic action? (assuming similar or higher nicotine concentrations than authorised nicotine replacement therapies for smoking cessation ?	Would you like to provide any additional comment regarding the possible role of such products in national tobacco cessation policies and their intecfarance with the authorised nicotine raplacement therapies in the light af mounting “harm reduction” daims and what is, in your view, the bast regulatory way to address the risks related to these products?
CZ State Institute for Drug Control	Yes, such products are placed on the market in our country.	general products safety	Yes, we have. These products have not been classified as medicinal products for the below mentioned reasons: a) They are not presented as having properties for treating or preventing disease so they are not considered medicinal products by presentation. b) There is a shortage of information on nicotine absorption from nicotine pouches, based on some literature (Lunell E, Fagerström K, Hughes J, Pendrill R. Pharmacokinetic Comparison of a Novel Non-tobacco- Based Nicotine Pouch (ZYN) With Conventional, Tobacco-Based Swedish Snus and American Moist Snuff. Nicotine Tob Res. 2020 Oct 8;22(10):1757-1763), it is reasonable to suppose that nicotine absorption from nicotine pouches is comparable with or higher than that from ordinary cigarettes, other tobacco-based products and nicotine-containing medicinal products. Nevertheless, we have not proved that modifying physiological functions by nicotine in nicotine pouches is higher than that during use of ordinary cigarettes, other tobacco-based products or foodstuffs. c) According to the ruling in 2014 [Markus D. (C-358/13) and G. (C-181/14)], Article 1(2)(b) of Directive 2001/83/EC must be interpreted as not covering substances which produce effects that merely modify physiological functions, but not having any beneficial effects, either immediately or in the long term, on human health, and are consumed solely to induce a state of intoxication and are, as such, harmful to human health. Based on the paragraphs b) and c), nicotine pouches are not considered medicinal products by function.	See the answer to Question 5 please.	Aware that oral nicotine suppresses nicotin withdrawal symptoms and that efforts are being made to use these products as part of harm reduction, please note that there are a couple of issues that have to be explored in case the nicotine pouches are considered in smoking cessation. 1) Chemical composition of the products - especially deeper analysis of additives and flavouring 2) Level of nicotine content - in some products the amount of nicotine is many times higher compared to oral nicotine replacements. Recommended dose and the limit of nicotine should be quantified. 3) Pharmacokinetics of nicotine - nicotine absorption varies depending on amout of nicotine and other additives in the pouches, salivary pH, pattern of use and other factors. These factors should be studied to determine recommended dose for nicotine replacement therapy purposes. 4) Legal conditions - legal age restriction for buying over the counter products (nicotine pouches as an NRT) should be fixed. The Czech Republic would prefer a common approach within the EU.
ES Spanish Agency of medicinal products and medical devices - AEMPS	Theve ae no mach products on fhe restet in Spain	We do not have specific legislation provisions at national	The AEMPS considers nicotine pouches should be considered as medicinal products, wich would mean that for these products the legislation concerning medicinal products applies and a marketing authorization is required to enter the market legally in Spain These products fulfill the definition of a medicinal product, they modify physiological functions by exerting a pharmacological effect. In addition, we understand nicotine pouches will be used for smoking cessation.	Please, see the answer to Question 5	No additional comment

FI Finnish Medicines Agency - Fimea	There are no such products on market in Finland. These products are classified as medicinal products, thus they would require a marketing authorization to enter the market legally in Finland. Finland has granted one marketing authorization to medicinal product called Zonnic (available in 2mg and 4mg) for smoking cessation. However, unauthorized products are illegally marketed and sold for Finnish users online from other member states where they are not classified as medicinal products.	Finland classifies these as medicinal products, which mea	Medicinal products legislation is already applied to these Medicinal products legislation is already applied to these Nicotine pouches containing over 4mg of nicotine per dose/pouch are regarded as prescription medicinal products and pouches with 4mg or less as OTC medicinal products.	The Finnish Medicines Agency Fimea is the national authority who is responsible of classifying products as medicinal products in Finland. Fimea has interpreted that these products fulfill the definition of a medicinal product, they modify physiological functions by exerting a pharmacological effect. When these products are illegally marketed to Finnish users online from abroad, they are also often stated to be used as a nicotine replacement therapy. This means they are marketed as having a medicinal indication although they are not authorized medicinal products. Finland has granted a marketing authorization to one similar product (Zonnic, available in 2mg and 4mg and sold as a OTC product in normal grocery stores in Finland), which can be used as a benchmarking product regarding these products. Without exception, the unauthorized products marketed to Finnish people online from abroad contain more than 2mg of nicotine per pouch/dose, sometimes even more than 20mg. The dossier of Zonnic contains reliable information about the effects and adverse effects of nicotine.	The Finnish Medicines Agency sees the current situation with these products in the union complicated because of the different policies between the member states. Fimea hopes for clear guidelines/regulation on these products to be applied in all member states. In general, if these products are to be used for the purpose of smoking cessation (they might have potential for that), their quality, nicotine concentration and mandatory instructions attached to these products, occurrence of adverse effects etc. should be regulated and controlled somehow. At the moment, Fimea sees that public health concerns require these products to be treated as medicinal products. The unauthorized products possess e.g. a risk of nicotine overdoses and increased risk that the users become addicted to these products and they are not used only as a temporary nicotine replacement therapy as authorized medicinal products are intended to be used.
HU The National Institute of Pharmacy and Nutrition (OGYÉI)	Yes, these products are placed on the market in Hungary. Https://www.bat.hu/group/sites/BAT_ABLKYM.nsf/vwPagesWebLive/DOBJKKRS httpw://www.vimpexdrink.hu/index.php?menu=product_list&pt 1=CIG.KELL&pt 2=NIK%20P%C1RNA	Nicotine pouches are considered to smoking-substitute n	Nicotine is the active substance of the authorized medicinal product Niquitin in Hungary.	Nicotine pouches are considered as smoking-substitute nicotine-containing tobacco product in Hungary. The definition of smoking-substitute nicotine-containing tobacco product was introduced into the Hungarian legislation with the amendment of the Act XLII of 1999 on the Protection of Non-Smokers and Certain Regulations on the Consumption and Distribution of Tobacco Products in 2020: "1. § y) smking-substitute nicotine-containing tobacco product shall mean a product, other than an electronic cigarette, refill container or cartridge, that contains nicotine, but no tobacco, that is not considered as a medicinal product and whose active substance is inhaled or ingested or penetrated the mucous membrane."	The best regulatory way to address the risks related to these products should be a clear regulation at the EU level (e.g., amendments in the Tobacco Products Directie) limiting the amount of nicotine, specifying age restrictions, restrictions on advertising etc. for these nicotine containing products.

IE Health Products Regulatory Authority (HPRA)	We understand that these products have been supplied to the Irish market over the past year mainly via online sales from other countries.	This is currently under consideration at national level as t	Yes, but in general recognising the non-medicinal uses of nicotine and noting that nicotine itself does not have any recognised health benefits, we generally only classify products containing nicotine as medicinal products when they make medicinal claims such as claims relating to smoking cessation. In our experience to date we have not identified any nicotine pouches making such claims.	It is our understanding based on European case law (e.g. Markus D. and G. C-358/13 & C-181/14), that it is not in itself sufficient for a product to have pharmacological actions that modify physiological functions to be classified as a medicinal product ,but that the product should also have beneficial effects (either immediately or in the long term) on human health and should not be harmful to human health. We do not feel that nicotine is beneficial to human health and therefore believe that nicotine products should only be classified as medicinal products when they make claims and are intended to be used for smoking cessation.	In the event that companies marketing nicotine pouches wish to make claims relating to smoking cessation, we believe that such products should be regulated as medicinal products to enable such claims to be appropriately evaluated. In the absence of such claims, we believe that European tobacco legislation should be updated to clearly provide for the regulation of nicotine pouches. While we appreciate that nicotine pouches do not contain tobacco, the same situation applies to E-cigarettes, which are now regulated under tobacco legislation provided that they do not make medicinal claims. We believe that a similar approach for nicotine pouches would be the most appropriate way to ensure appropriate regulation and put in place appropriate safeguards relating to the safety of such products (e.g. limit the concentration of nicotine, packs sizes). Please be advised that this response has been prepared from the perspective of the HPRA, which is the competent authority for medicinal products in Ireland. Food products, tobacco control and national tobacco cessation policies do not fall within our remit and therefore we cannot comment on those aspects.
LV The State Agency of Medicines of Latvia	Nicotine pouches are available on the market in Latvia. Information about these products is available from websites, press releases, social media, industry sources etc.. There also has been communication between the Agency and other national competent authorities regarding possible changes in the national legislation (Low On the Handling of Tobacco Products, Herbal Products for Smoking, Electronic Smoking Devices andTheir Liquids) regarding these products.	Nicotine pouches currently are not subject to any specific product regulation. It is planned to define nicotine pouches as a product of tobacco substitution, which will be regulated by Law On the Handling of Tobacco Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids. Discussion regarding possible changes in the national legislation (Low On the Handling of Tobacco Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids) regarding tobacco substitutes is ongoing.	Currently no. However, there is a proposal to limit the amount of nicotine in these products, taking into account dose of nicotine in medicinal products containing nicotine, which are authorised for the nicotine replacement therapy for smoking cessation treatment.	The definition of medicinal product cannot be directly applied to all these products without scientific and market research, especially for products containing lower or higher nicotine concentrations than authorised nicotine containing medicinal products for replacement therapies for smoking cessation.	The best regulatory way to address the risks related to these products should be a clear regulation at the EU level (e.g., amendments in the Tobacco Products Directive) limiting the amount of nicotine, specifying age restrictions, restrictions on advertising etc. for these nicotine containing products.
NL	yes, it is a product with an increasing popularity and a wide vaiety of brands with flavours is available on our market. The Dutch national institute on Public health and the environment has been looking onto these products on our market and published areport with an Enlish summary : https://www.rivm.nl/publicaties/nicotineproducten-zonder-tabak-voor-recreatief-gebruik	Currently these products fall under the Commodities Act but are not specifically regulated. We are looking into regulating them more specifically under the Commodity act for the short term and also under our tobacco control legislation for the long term. A political decision needs to be made on the regulation of these products.	no, we do not think is suitable	no, see below	Our government is of the opinion that there is no room for these products in tobacco cessation policiy. These products are detrimental to health and addictive, made highly aftractive to younsgsters and non smokers by the way eg the products are designed, marketed and the availabilty of all the flavours and the invisibility of their use.. The best way to treat these products in my opinion would be by banning them. Existing and Proven strategies and products for tobacco cessation are available.

PT	There have been several attempts to place some brands in the Portuguese market. However, considering the high risk profile of this kind of products, Infarmed response wasthat they should be considered medicinal products and needed to submit a dossierfor evaluation of their quality, safety and efficacy. Until now there was no submission.	As explained in the question above, they are considered	Yes, see above	Yes. Nicotine has an undeniable and very well-known pharmacological action, with also very well-known side-effects including the high addictive potential so, in our oppinion, the risk/benefit balance of this products should be caretully assessed and the medicinal products legislation is the one that provides the highest level of protection for consumers	Regarding the national tobacco cessation policies there are several authorised medicinal products containing nicotine that can be used and prescribed by medical doctors so, there is no special need in this context. However, we have no objection against the evaluation of an eventual market authorisation request for a nicotine pouch supported by a complete dossier
SL Agency for Medicinal Products and Medical Devices of the Republic of Slovenia	There are some web sides, which offer such products to customers from Republic of Slovenia, like: • https://www.haypp.com/eu/slovenija/ (company HayppABB from Sweden), • https://www.kompasshop.si/sl/Price_list_tobacco_products/Nicotine_Pouches/ (seller Kompas shop, d.d., based in Slovenia), • https://www.velo.com/si/si/#o-velu (seller Velo, based inSlovenia), …	Any final decision regarding classification of nicotine pouches hasn't been taken in Slovenia yet due to the fact they do not contain tobacco. Notwithstanding the foregoing, advertising of such products was prohibited, based on paragraph 6 of Article 29 of Restriction on the Use of Tobacco Products and Related Products Act (ZOUTPI, Official Gazette, no. 9/17 and 29/17, English version is available at http://www.pisrs.si/Pis.web/cm?idStrani=prevodi), in which is stipulated: "It shall be prohibited to advertise products that could encourage the consumption of tobacco, tobacco products and related products by their appearance and intended use." This legal basis was considered appropriate because such products are similar to chewing tobacco, and once you become addicted to nicotine, you can easily switch between different products, if by chance one is not available, you can use electronic or classic cigarettes. The Office of Chemicals is currently investigating whether they could be classified under chemical legislation. For the time being, except from Article 29 of the ZOUTPI, they are considered as general products in accordance with the general provisions of the General Product SafetyAct.	In opinion of our agency, they should be considered as medicinal products, if they are used as aids for smoking cessation and/or if they contain 2 mg of nicotine or more (medicinal product by function according to proven pharmacological effect). If they are used as alternative tobacco products, as substitute for smoking, and contain less than 1,8 mg of nicotine (this is an amount of nicotine smoker inhales with a single cigarette according to: https://www.healthline.com/health/how-much-nicotine-isin- a-cigarette#nicotine-in-cigarettes), they wouldn't be considered as medicinal products in Slovenia.	See the answer to question no. 3.	In the view of common EU market a common EU legislation should cover these products with clear definition of: - quality requirements (including the maximum allowed quantities of nicotine contained in one pouch), - safety warnings and precautions needed to prevent use these products by non-smokers, children and other vulnerable groups of people, - advertising, -etc.