MINISTRY OF SOCIAL AFFAIRS AND SENIOR CITIZENS

Minister for Social Affairs and Senior Citizens

Holbergsgade 6
DK-1057 København K

T +45 7226 9000
F +4S 7226 9001
M sum@sum.dk
W sum.dk

Nordic Council
Ved Stranden 1g
1061 København k

Dato: 15-11-Z019
Enhed: MEDINT
Sagsbeh.:
OEPCRV
Sagsnr.:
1908568
Do1. nr.: 1001568

Answers to written questions (E 4/2019) from the Nordic Council's Committee for Growth and Development in the Nordic Region regarding electronic package leaflets for medicinal products for human use

The Nordic Council's Committee for Growth and Development in the Nordic Region has on Iceland's initiative presented the following five questions to the Nordic governments:

1. The Nordic Council's Committee for Growth and Development now asks the health ministers of the Nordic countries if they are willing to work together for a revision of EU Directive 2001/83, in order to change the obligation to insert the package leaflet in the medicine packaging, to an obligation for the pharmacies to print out a package leaflet in accordance with the language knowledge of the customer?

2. If that is not the case, are the governments **willing** to work towards setting requirements on all package leaflets for medicines sold in the Nordic countries to include information in all the Nordic languages?

3. How do the countries now ensure that the patients understand the information in the package leaflets in their medication packaging, in light of the fact that there is no guarantee whatsoever that the patient understands the local language?

4. The Committee has observed that Denmark and Norway collaborate on the joint procurement of expensive medicines. The Committee therefore asks if there is interest on the Finnish, Icelandic and Swedish side to participate in this collaboration, and if the answer is yes, when and how this collaboration can be undertaken, and if the answer is no, what grounds or motives form the basis for such a position?

5. In case the Nordic governments wish to increase their joint procurements of medicines, are the governments then prepared to simultaneously require the pharmaceutical companies to harmonize the packaging, including the labelling with which customers in many countries are familiar with, for instance with the red warning triangle?

Below are the answers to all five questions from Denmark and Finland, since these countries could not reply to the questions earlier due to parliamentary elections. The answers are to supplement the responses by Iceland, Norway and Sweden of 14 June 2019.

Denmark's responses to the questions:

1) Denmark is not affected by the challenges described with regard to language requirements for package leaflets and is as a EU Member State required to implement the requirements in EU legislation with regard to labelling of and information regarding medicinal products for human use. Nonetheless Denmark has a positive stand to exploring the possibilities for solving, through electronic package leaflets, some of the challenges with regard to language knowledge in some of the Nordic countries.

   It should be noted that the European Commission has underlined, in connection with its work on electronic product information, that there is today no obstacle to implementing on a national level electronic leaflets, given that the member state continues to live up to the current requirements of the Directive on medicinal products for human use, regarding having a physical package leaflet within the product packaging.

   If there is to be work on EU level to change the requirements in the legislation on medicinal products for human use regarding having a physical package leaflet within the packaging to a requirement on obligatory electronic product information, it is important for Denmark that work continues with the proposal in order to take patient safety into consideration with regard to the prescription and administration of medicinal products for human use. It should i.a. be ensured that information also reaches more disadvantaged language groups, including for instance patients with limited digital know-how or opportunities.

   The proposal to open for the possibility for pharmacists to print out a package leaflet in the preferred language of the patient would support weaker language groups, but at the same time incur expenses to the pharmacy business. The pharmacies will possibly have to invest in IT-systems and eventually extra printers as well as adjusting their procedures, for instance to prevent the delivery of wrong package leaflets to the patients, as well as instructing the patient with regard to avoiding mixing different leaflets.

   Denmark warns that the proposal can prove to be both expensive and difficult in practice - potential expenses, which are important to uncover in detail, if financing is to be found to implement the proposal.

2) In Article 63 of EU Directive 2001/83/EC there is the possibility for a business to produce the package leaflet in several languages, provided that all the information is conveyed in all the chosen languages. This option is already in use today by pharmaceutical companies wishing to introduce their products in parts of or in the entire Nordic market area.

   If the Nordic countries decide that the package leaflet should be produced in all the Nordic languages, this will probably cause additional expenses for the pharmaceutical companies in the cases where the company does not wish to market the relevant medicinal product for human use in all the Nordic countries. These expenses will at the end of

the day be covered by the consumers through higher prices of the medicinal product, or the company can choose not to introduce the medicinal product at all in the Nordic countries, which in turn is negative with regard to the emergency storing security of medicinal products for human use.

In light of this Denmark prefers the proposal to work towards the implementation of electronic package leaflets in question 1.

3) In case a patient does not understand the Danish labelling and the package leaflet, the patients have the option to get help and advice regarding the pharmaceutical product from the staff in the pharmacy or from their doctor.

4) The question is addressed to the Finnish, Icelandic and Swedish governments, as to why Denmark is not answering the question.

5) Denmark is of the opinion that the proposed harmonization should take place within EU/EEA and in collaboration with the European Medicines Agency (EMA), since harmonized packaging is not necessarily aimed at the Nordic countries, but could also be harmonized with other EU-countries, such as Denmark and Germany.

Finland's responses to the questions:

1) Finland supports the promotion of the use of electronic leaflets and that the requirement for paper package leaflets is eliminated in a controlled manner. It should be possible to use digital package leaflets along with or instead of the paper leaflets. The Member States should be able to choose how and to what extent they start using electronic leaflets.

   The obligation for the pharmacies to print leaflets in a language understood by the customer is a national question which should not be dealt with at EU-level.
   The Member States must be able to decide how they present the information in a package leaflet to the customer. This change requires national solutions in order for users of medicines to receive information on pharmaceutical products.

2) Finland supports the implementation of the use of electronic leaflets. The requirement for information in all the Nordic languages in the leaflets could increase the risk of disturbances in providing the products and is not supported as such.

3) Staff in Finnish pharmacies have a legal obligation to provide advice with pharmaceutical products so that the customer receives information as to the proper and safe use of the product, in addition the pharmacies must have access to necessary information sources and possess the ability to use those.

4) Finland views Nordic cooperation as important, but the government of Finland cannot act on a national level when it comes to procuring medicinal products for human use. In Finland there is no single body that can represent all the involved actors with organizing

responsibilities. The procurement process concerns primarily the medicinal products acquired for use by hospitals. Finland can participate in the exchange of experience and information on civil servant level and is prepared to participate in the discussion on mapping common operational models.

Finland already participates in the Nordic Medicine Forum (Nordisk Lægemiddel Forum, NLF) collaboration at an operational level (HNS-pharmacy, FinCCHTA) in its role as an observer.

5) The requirements for packaging are to a large extent harmonized in all the EU Member States and labelling of medicines for human use is accepted in all countries concerned in relation to the issue of marketing authorization permits. Furthermore the Nordic countries have harmonized their requirements for the package design and provided joint Nordic instructions regarding the common guidelines. The red warning triangle is part of the national requirements and there are no plans to change the established use of the triangle. Pharmaceutical companies have received instructions with regard to how to proceed when the requirements for a red warning triangle differ between the Nordic countries.

Best regards,

Magnus Heunicke