COMMITTEE FOR THE SAFETYFEATURES OF MEDICINAL PRODUCTS

Responses to queries from SFEE/PEF (document ref. no. 75/31.01.2017)

1. TIME FRAME

SFEE/PEF: Please officially confirm that the **date of full application** of the Delegated Regulation will be, as we have agreed, **two years after its application in other Member States.**

EOF: We have no objection to defining as the date of full application of the Delegated Regulation two (2) years after its application by the other EU Member States, i.e. under the current regime, on 9 February 2021.

2. SCOPE

SFEE/PEF: How and when will the derogations are specified? (based on Annexes III and IV to the Delegated Regulation, we as an industry can request exclusions both from the list of prescription medicines which shall not bear the safety features and from the list of OTC medicines which shall bear the safety features).

Given that the derogations will have to be agreed upon with the National Organisation for Medicines (EOF), please inform us:

- *How shall we submit our proposals and within which time frame will the final lists be adopted by EOF?*

EOF: Proposals for derogations form part of the procedure described in Chapter X of the Delegated Regulation. They will be compiled in due course, along with the discussion of whether or not the authenticity tag should be maintained.

3. GLOBAL TRADE ITEM NUMBER (GTIN)

SFEE/PEF: For the Product Code, we intend to follow the GTIN coding scheme (Blueprint). ***Does EOF agree?***

EOF: The technical specifications for the unique identifier in general and the product code in particular are laid down in the individual provisions of the Delegated Regulation, including Article 4: *"The manufacturer shall place on the packaging of a medicinal product a unique identifier*" and Article 5(5) *"When encoded in a Data Matrix as data element of a unique identifier, the product code shall follow a coding scheme and begin with characters specific to the coding scheme used. It shall also contain characters or character sequences identifying the product as a medicinal product. The resulting code shall be less than 50 characters and be globally unique. Product codes which conform to the ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014 shall be presumed to fulfil the requirements set out in this paragraph*".

EOF does not intend to intervene in this process and specify the system to be followed by MAHs/manufacturers of medicinal products.

4. HUMAN READABLE FORMAT (HRF)

SFEE/PEF: Language to be used:

According to the QRD template, the words "batch/lot" and "expiry" are accepted in both language versions, Greek and English). Please confirm.

EOF: Article 7 of the Delegated Regulation specifies the data elements of the unique identifier that are required to be printed on the packaging in human-readable format as follows:

"(a) the product code;

(b) the serial number;

(c) the national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market and not printed elsewhere on the packaging".

Moreover, under Article 77 of Joint Ministerial Decision No. DY3a/32221/2013 "Harmonization of Greek legislation with relevant EU legislation in the field of production and circulation of medicinal products for human use, in compliance with Directive 2001/83/EC on the Community code relating to medicinal products for human use (L 311/28.11.2001), as currently in force", the expiry date shall be indicated in a clear manner (month/year), together with the batch number, on the outer packaging of medicinal products.

We have no reason to deviate from QRD, according to which the terms "batch" and "expiry" are accepted in Greek and English. This point does not imply any change in the current practice.

5. NATIONAL HEALTH REIMBURSEMENT NUMBER (NHRN)

SFEE/PEF: EOF has orally indicated that the NHRN will be required. Please confirm. Please also clarify whether the **NHRN** will be the current **13-digit EAN code** used on the authenticity tag. We suggest that the NHRN should not appear on the packaging in human readable format or be incorporated as a fifth element in the UI, but instead the database look-up option should be preferred, which would also accommodate the requirements of IDIKA.

Explanation: An option that has emerged from EMVO is to have NHRNs stored in the system directly by the MAH rather than in the UI. The national repository (NMVS) could retrieve them at any time (database look-up). Thus, NHRNs could also be fed into the electronic prescription system if designed so by the developer. This option ensures that the size of the UI does not increase, which would be a problem in small packs and multi-market packs.

EOF: We confirm that the national health reimbursement number (NHRN) for medicinal products shall be maintained and linked to the unique identifier. NHRN shall mean the 13-digit code that all medicinal products are required to bear and which identifies them at pack level.

At this stage, we have no objection to the **database look-up** option, provided that the response time is in line with the response time specified in the Delegated Regulation for the repository, i.e. lower than 300 milliseconds in at least 95 % of queries, and this does not hamper the smooth functioning, without significant delays, of the e-prescription system or any other interface as may be required by the competent authorities.

6. PROCEDURE FOR THE SUBMISSION OF NEW PACKS

SFEE/PEF: Please specify the procedure to be followed by companies for submitting **the 2D code**. We suggest that we should closely follow the guidance of CMDh.

Explanation: Guidance on the submission procedure is already available, both from EMA in respect of centrally authorised products and from CMDh in respect of national/MRP/DCP products. Implementation plan CMDh/345/2016 states that Greece, having a longer transition period for the implementation of the safety features, will inform MAHs of any additional instructions.

EOF: The guidance to be followed is contained in the documents available through the following links:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/02/WC500201413.pdf

http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Falsified_Medicines/CMDh_345_2016_R ev00_02_2016_1.pdf.

The submission of package mock ups shall not be required.

7. ADMINISTRATIVE FEES

SFEE/PEF: According to the "**Implementation plan for the introduction of the safety features on the packaging of nationally authorised medicinal products for human use**" (CMDh/345/2016), MAHs can re-label their products on the occasion of an upcoming regulatory procedure (e.g. variations or renewal); if no such regulatory procedure is expected within the envisaged timeframe, they should submit a notification pursuant to Article 61(3) of Directive 2001/83/EC.

Please note that no administrative fees are envisaged for this latter case, given that notifications do not entail an assessment procedure. In view of the large expected volume of submissions, we suggest that mass submission should also be permitted.

EOF: No administrative fee shall be required for notifications pursuant to Article 61 (3) (type P) in the cases where ONLY fields 17 & 18 of the safety features are notified (in all other cases an administrative fee shall normally be payable).

8. SMALL PACKS

SFEE/PEF: In view of:

• the implementation of the Delegated Regulation two years after the rest of the EU (including Cyprus);

• the placing of an authenticity tag on our packs; and

• the addition of the 2D code, which has already begun to be added, even symbolically, to our labelling,

a space problem is likely to arise in the case of small packs. What solution will EOF prefer until the authenticity tag is abolished?

EOF: The requirement to place the authenticity tag, just as the other requirements laid down in the legislation and relating to the authenticity tag, is not in any way cancelled. In all cases, it remains compulsory to avoid concealing important elements of product labelling. EOF does not intend, for the time being, to change something in this respect.