Prague 28 January 2021

Information for marketing authorisation holders regarding the possibility to request issuance of a provisional measure by the Ministry of Health of the Czech Republic according to the provision 11 (r) Act no. 378/2007 Coll., Act on Pharmaceuticals ("Act on Pharmaceuticals")

To ensure the availability of medicinal products for patients in the Czech Republic the Ministry of Health of the Czech Republic informs marketing authorization holders that:

In accordance with the provision 11 (r) of the Act on Pharmaceuticals the Ministry of Health of the Czech Republic may in the situation when a verification of safety features appearing on the packaging of the medicinal product is not possible within Article 10 of the Regulation on safety features[1] exceptionally temporarily allow distribution and dispensing of such medicinal product by the decision issued at the request of the marketing authorisation holder ("request") due to the fact that this medicinal product does not comply with the requirements of this Regulation after completion of the production of the medicinal product.

In such case marketing authorization holders, manufacturers of medicinal products, distributors and people authorized to supply medicinal products fulfil the obligations arising from the Regulation on safety features adequately. The use of medicinal products within providing health services is not affected by the Regulation on safety features.

The liability for defects of medicinal products of marketing authorization holders stated by the specific legislation[2] is not affected. The Ministry of Health of the Czech Republic informs the State Institute for Drug Control about the issued provisional measure.

The request may be submitted only for medicinal products which's production has already been completed i.e. medicinal products have been released by a qualified person of the manufacturer for sale and distribution. The request cannot be submitted for medicinal products which have not yet been certified and released from production by a qualified person of the manufacturer.

The Ministry of Health of the Czech Republic will publish the issued provisional measure on its notice board and the State Institute for Drug Control will publish it in a way that allows remote access. The State Institute for Drug Control maintains on its website the list of medicinal products that have been granted the provisional measure.

The request may be submitted by the marketing authorization holder that identified that medicinal products:

- are not provided with the 2D code, the carrier of the unique identifier, and should be provided with it because they are a subject to the requirements of the Regulation on safety features (eg. medicinal products listed in the Annex II of the Regulation on safety features),
- are provided with the 2D code, the carrier of the unique identifier, which contains incorrect, incomplete data that prevent its correct upload to the storage system and successful verification,

[1] COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use

[2] Act no. 59/1998 Coll.

- are provided with the 2D code, the carrier of the unique identifier, which contains correct and complete data, however no data are available on the storage system to successfully verify the unique identifier,
- are provided with the 2D code, the carrier of the unique identifier, without this obligation applying to them (eg. medicinal products listed in the Annex I of the Regulation on safety features),
- are provided with the 2D code, the carrier of the unique identifier, according to the legislation of a third country and the marketing authorization holder has not yet been exempted from this obligation.

The web application for submitting requests named *MAH11r* (available at https://pristupy.sukl.cz/#anchor_hlaseni_pro_sukl) was created to speed up the administrative proceedings and reduce the administrative burden. To access the web application, it is necessary to use a certificate held by marketing authorization holders for purposes of reporting information according to the instruction of the State Institute for Drug Control REG-13. After entering the data listed in the table below and designating the contact person authorized to communicate in the matters related to the request the web application will generate the request (in .pdf format).

Particulars of the request	
Medicinal product information	• SUKL code • Name of the medicinal product • Identification of the discrepancy with the Regulation on safety features • Batch number • Expiration date • Amount of the medicinal product
Annexes	It is further required to submit for each batch: • Certificate of analysis • Batch release certificate • Pictures of medicinal product packaging from all sides
Justification of the request	The applicant shall state reasons for the request and describe the facts and causes that caused the discrepancy with the requirements of the Regulation on safety features (ie. precise description of the error or defect which caused the discrepancy). The applicant may also indicate the person representing the marketing authorization holder.
Corrective measures applicant adopted by the applicant	The applicant shall state information regarding the measures taken or to be taken to ensure that the medicinal product will comply with the requirements of the Regulation on safety features. It is appropriate to state the time assumption.

It is necessary to send the generated request officially to the Ministry of Health of the Czech Republic by the data box (pv8aaxd), electronically to mzcr@mzcr.cz with a qualified electronic signature or in paper form. If neither of the mentioned approaches are possible, please contact us (opatreni11r@sukl.cz).

Further communication regarding the submitted request will take place through e-mails with the contact person and through the web application.

Please send questions regarding the content of the request to opatreni11r@sukl.cz.

Please send questions regarding the technical issues of the web application to the email addresses below:

- technical questions about the web application - itpodporahlaseni@sukl.cz
- problems with access certificates – pristup@sukl.cz