Questions and Answers on Issues Regarding the Placement a Medicinal Product onto the Market

Q 1: Does the holder of marketing authorisation for medicinal product XY which had been placed on the market prior to the effective date of Act No 378/2007 Coll. (before 31 December 2007) have to notify SÚKL of suspended or terminated or renewed marketing of the medicinal product in the Czech Republic?

A: Yes, they do. The notification duties apply to all changes to the marketing of all medicinal products in the Czech Republic regardless of the date of the initial placement of the concerned medicinal product onto the market in the Czech Republic.

Q 2: What does "placement of a medicinal product on the market" mean? Is there any definition thereof?

A: Pursuant to Section 3a, paragraph 10 of the Act on Pharmaceuticals, placement of a medicinal product on the market means its hand-over after the completion of manufacture, delivery from another Member State or import thereof, which are carried out for the purposes of distribution of the medicinal product, except its use within the scope of clinical trials.

Q 3: In case of consignment stocks where the ownership of goods remains with the MA holder, does placement on the market mean the moment of the delivery of the goods from another EU Member State to the consignment stocks?

A: Yes, the delivery from another EU Member State to a distributor's consignment stock in the Czech Republic is understood to be the placement of the medicinal product onto the market in the Czech Republic.

Q 4: What do suspended deliveries to the market mean? Is there any definition thereof?

A: The suspension of marketing is considered to be the moment when the MA holder temporarily stops to supply a human medicinal product to the distribution chain.

Q 5: Where deliveries to the Czech Republic are carried out on a monthly basis and in some months they are insufficient, is such a situation subject to notification of SÚKL on suspended deliveries to the market?

A: Following placement of a medicinal product onto the market, the MA holder is obliged to safeguard the respective medicinal product for the needs of patients in the Czech Republic through its deliveries in adequate quantities and necessary time intervals (Section 33, paragraph 3(g), item 3 of the Act on Pharmaceuticals). With a view to the nature of the product, the method of its use, and the anticipated number of patients who will need the product, the MA holder is hence obliged to plan and execute deliveries in a manner covering the needs of patients in the Czech Republic.
If the deliveries of the respective medicinal product are safeguarded on a monthly basis, and in some months the delivery is insufficient, the situation cannot be classified as suspended delivery. Nevertheless, in some cases, such situation could be considered a breach of Section 33, paragraph 3(g), item 3 of the Act on Pharmaceuticals.
In case of a suspension of regular monthly deliveries of the respective medicinal product to the distribution chain, however, in quantities covering patient needs, it concerns suspended deliveries which is subject to notification to SÚKL.

Q 6: Is it necessary to send to SÚKL a notification of suspension in case of a variation to marketing authorisation which results in suspended marketing?

A: Yes, if the variation to marketing authorisation is of such nature which results in suspension of deliveries of the respective medicinal product for the purposes of distribution, the MA holder should, at least 2 months in advance of the suspension of the marketing, notify SÚKL to this effect, specifying the reason for suspension in compliance with Section 33, paragraph 2 of the Act on Pharmaceuticals. Where exceptional circumstances arise, such notification may be made no later than concurrently with the suspension of marketing of the concerned medicinal product in the Czech Republic.
For more details on the method of provision of information on the reasons for suspended/terminated marketing, please refer to:
http://www.sukl.eu/medicines/pripomenuti-zpusobu-poskytovani-informaci-pri-hlaseni

Q 7: Is it necessary to report terminated marketing in cases where the marketing authorisation has been revoked?

A: Yes, in cases of revocation of marketing authorisation upon request of the MA holder, as well as ex officio, the MA holder has to report terminated marketing of the medicinal product in compliance with Section 33, paragraph 2 of the Act on Pharmaceuticals. Where an ex-officio revocation of marketing authorisation of a medicinal product is concerned, it is possible to avail of the option of exceptional circumstances and to report on the terminated marketing upon the expiry of the timeline for filing appeals, or upon waiving the right to file an appeal from the decision concerned.
Furthermore, SÚKL hereby draws attention the obligation set forth by Section 34, paragraph 8 of the Act on Pharmaceuticals for a person who was a holder of marketing authorisation of a medicinal product. Once the revocation of marketing authorisation becomes final, or in case the marketing authorisation ceased to exist by the expiry of its effective period, such person is obliged to withdraw the medicinal product from the market without any delay.

Q 8: In cases where a marketing authorisation is transferred to a new MA holder, does the new MA holder report on the placement of the product on the market?

A: Yes, they do. As a result of the transfer to the new MA holder, the medicinal product is allocated a new SÚKL code for which distributor deliveries and pharmacy dispensing are subsequently reported. The new MA holder therefore has to report on the placement on the market for this new SÚKL code.
The notification of placement of a medicinal product onto the market in case of transfer of the marketing authorisation to a new MA holder does not apply to centrally authorised medicinal products, as SÚKL codes of these products do not change upon a transfer of marketing authorisation to a new MA holder.

Q 9: In case of a transfer of marketing authorisation to a new MA holder, which results in suspended or terminated marketing of the original medicinal product, is it necessary to report the suspension or termination and who should file such report? The new MA holder or the previous one?

A: Yes, suspended or terminated marketing in case of a transfer of marketing authorisation to a new MA holder has to be reported. If marketing is suspended or terminated before the decision on the transfer of marketing authorisation becomes final, the existing (previous) MA holder is obliged to inform SÚKL to this effect. After the finality of the decision on the transfer of marketing authorisation, the suspension or termination of marketing has to be reported by the new MA holder, as in compliance with Section 36, paragraph 4, sentence one and two of the Act on Pharmaceuticals, the new MA holder fully enters into the rights and obligations of the previous MA holder.

The notification on suspended/terminated marketing in case of a transfer of marketing authorisation to a new MA holder does not apply to centrally authorised medicinal products, as SÚKL codes of these medicinal products do not change upon the transfer of marketing authorisation to the new MA holder.

Q 10: Is the case when the MA holder has delivered their complete stock of medicinal product XY to distributors and does not have any product XY available in the warehouse itself, considered to be suspended marketing?

A: Suspended marketing is considered to be a situation when the MA holder stops to secure the medicinal product for the needs of patients in the Czech Republic through its deliveries in adequate quantities and time intervals with a view to the current situation in the distribution chain in a manner compliant with the conditions stipulated by Section 33, paragraph 3(g), item 3 of the Act on Pharmaceuticals.

Q 11: Is the MA holder obliged to regularly ascertain the current state of stock at distributors´, i.e. availability of the product?

A: Following the placement of the medicinal product onto the market, the MA holder is obliged to safeguard the concerned medicinal product for the needs of patients in the Czech Republic through its deliveries in adequate quantities and time intervals (Section 33, paragraph 3(g), item 3 of the Act on Pharmaceuticals). With a view to the nature of the product, the method of its use and the anticipated number of patients who will need the product, the MA holder is obliged to plan and execute deliveries in a manner covering the needs of patients in the Czech Republic.

Q 12: How to proceed in case an error arises in the submitted report? Is it possible to correct or delete an incorrect report?

A: No, reports filed in the database may no longer be deleted or corrected. The report has to be re-submitted and, concurrently, an e-mail requesting invalidation of the original record has to be sent to helena.moravcova@sukl.cz. On the basis of the e-mail, the incorrect report will be labelled as an “Invalid report”.