Questions and answers about the placement of medicinal products on the market

Q 1: Is the marketing authorisation holder of product "XY" which was placed on the market prior to the effective date of Act No. 378/2007 on Pharmaceuticals (prior to 31 December 2007) obliged to notify the State Institute for Drug Control (SÚKL) in case of suspension, termination or resumption of placement of the medicinal product on the market in the Czech Republic?

A: Yes, it must. The notification requirement applies to all changes to placement of all medicinal products on the market in the Czech Republic regardless of the date upon which the subject medicinal product was initially placed on the market in the Czech Republic.

Q 2: What does placement of a medicinal product on the market mean? Is this term defined somewhere?

A: Pursuant to Section 3a (10) of the Act on Pharmaceuticals, placement of a medicinal product on the market is considered transfer of the medicinal product after manufacturing has been completed, delivery from another Member State or import conducted for the purposes of distributing the medicinal product excluding its use in clinical trials.

In layman terms, it is the moment when the manufacturer completes manufacturing and it transfers the medicinal product to the distributor.

Q 3: In the case of a consignment warehouse, where the goods remain the property of the marketing authorisation holder, is placement on the market considered the moment of delivery of the goods from the EU to the consignment warehouse?

A: The delivery to the consignment warehouse itself is not considered placement on the market. Placement on the market is the moment of "offtake of the medicinal product" from the consignment warehouse.

Q 4: What does suspension of supply to the market mean? Is this term defined somewhere?

A: Pursuant to Section 19 (1) of Decree No. 228/2008 Coll., on Marketing Authorisation of Medicinal Products, suspension of placement on the market (marketing) is considered to be the moment when the marketing authorisation holder ceases to supply the human medicinal product to the distribution chain.

Q 5: If the product is supplied to the Czech Republic regularly, in monthly intervals and in some of the months the supply is insufficient, is this situation subject to notification of suspended marketing to SÚKL?

A: The marketing authorisation holder is obliged to provide the subject medicinal product, after its placement on the market, for the needs of patients in the Czech Republic by supplying it in adequate quantities and adequate time intervals (Section 33 (3g), item 3 of the Act on Pharmaceuticals). With respect to the nature of the product, the method of its use and the expected number of patients in need of the product the marketing authorisation holder is obliged to plan and realise supplies in a manner which ensures that the needs of patients in the Czech Republic are met.

Where the supplies of the subject medicinal product are provided in monthly intervals and in certain months the supply is insufficient, the situation cannot be characterised as suspended marketing. In some cases, however, the situation may be considered a breach of Section 33 (3g), item 3 of the Act on Pharmaceuticals.
Where, however, a long-term decrease of the regular monthly supplies of the given medicinal product to the distribution chain is concerned, it shall be considered suspended marketing subject to notification to SÚKL.

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

A: Yes, if the variation to the marketing authorisation is of such nature that it results in suspended supply of the concerned medicinal product to the distribution chain, the marketing authorisation holder should, at least two months before the marketing is suspended, notify SÚKL of this fact. In exceptional circumstances the notification may be made no later than concurrently with the suspension of marketing of the medicinal product in the Czech Republic.

Q 7: Is it necessary to report termination of marketing if the marketing authorisation is revoked?

A: Yes, in the case of marketing authorisation revocation, either requested by the marketing authorisation holder or by a SÚKL decision (*ex-officio*), the marketing authorisation holder should report the termination of marketing of the medicinal product. In the *ex-officio* case, the exceptional circumstances scenario may be used and notification of termination of marketing authorisation can be made concurrently with the effective date of legal force of the concerned revocation.
SÚKL furthermore draws attention to the obligation stipulated by Section 34 (8) of the Act on Pharmaceuticals applicable to persons who were the marketing authorisation holders of a medicinal product. Upon the effective date of legal force of the marketing authorisation revocation or if the marketing authorisation has expired, such persons shall be obliged to recall the medicinal product from the market immediately.

Q 8: In the case of a transfer of marketing authorisation to a new marketing authorisation holder, is the former marketing authorisation holder obliged to report termination of marketing?

A: No, not if the transfer of the marketing authorisation does not result in a change to the marketing of the concerned product.

Q 9: In the case of a transfer of marketing authorisation to a new marketing authorisation holder, is the new marketing authorisation holder obliged to report termination of marketing?

A: No, not if the transfer of the marketing authorisation does not result in a change to the marketing of the concerned product.

Q 10: In the case of a transfer of marketing authorisation to a new marketing authorisation holder, which results in suspended marketing, is the new or former marketing authorisation holder obliged to report suspension of marketing?

A: If marketing is suspended prior to the effective date of legal force of the marketing authorisation transfer, the existing (former) marketing authorisation holder shall be obliged to inform SÚKL of this fact. If marketing is suspended after the effective date of legal force of the marketing authorisation transfer, the new marketing authorisation holder should report the suspended marketing.

Q 11: Is the situation where the marketing authorisation holder has supplied the complete stock of medicinal product "XY" to distributors and does not have any product in its own stores considered suspended marketing?

A: Suspended marketing shall mean a situation when the marketing authorisation holder ceases to supply the product to the distribution chain with respect to the situation in the distribution chain in a manner compliant with the conditions stipulated by Section 33 (3g), item 3 of the Act on Pharmaceuticals.

Q 12: Is the marketing authorisation holder obliged, in such situation, to regularly obtain information on the current level of stock at distributors, i.e. on the product availability?

A: The marketing authorisation holder is obliged to safeguard the concerned medicinal product after its placement on the market for the needs of patients in the Czech Republic by means of its supplies in adequate quantities and adequate time intervals (Section 33 (3g), item 3 of the Act on Pharmaceuticals). With respect to the nature of the product, the method of its use and the expected number of patients in need of the product the marketing authorisation holder is obliged to plan and realise supplies in a manner which ensures that the needs of patients in the Czech Republic are met.