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

Q 1: Is the marketing authorisation holder of product "XY" which has been placed on the market before the new Act on Pharmaceuticals has come into force (prior to December 31 2007) obliged to notify SÚKL of suspended or terminated or resumed marketing of the medicinal product in the Czech Republic?
A: Yes they are. The notification duties are applicable to any changes to the marketing of medicinal products in the Czech Republic regardless of the date of the first placement of the concerned medicinal product on the market in the Czech Republic.

Q 2: What does the suspension of supply to the market mean? Is it defined anywhere?
A: Pursuant to Section 19, paragraph 1 of Decree No 228/2008 Coll., on marketing authorisation of medicinal products, the suspension of marketing is considered to be the moment as of which the marketing authorisation holder ceases to supply the human medicinal product to the distribution chain.

Q 3: 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 safeguard the concerned medicinal product after its launch for the needs of patients in the Czech Republic by means of its supplies in adequate quantities and in adequate time intervals (Section 33, paragraph 3(g), item 4 of the Act on Pharmaceuticals). With respect to the nature of the product, the method of its use and expected number of patients in need of the product the marketing authorisation holder is hence 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 concerned medicinal product are provided in monthly intervals and in certain months the supply is not sufficient, the situation cannot be characterised as suspended marketing. In some cases, however, the situation could be considered a breach of Section 33, paragraph 3(g), item 4 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 subjected to notification to SÚKL.

Q 4: Is it necessary to send a notification to SÚKL where a variation to marketing authorisation which results in suspended marketing is concerned?
A: Yes, if the variation to 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 5: Is it necessary to report termination of marketing if marketing authorisation is revoked?
A: Yes, in the case of marketing authorisation revocation, either requested by the marketing authorisation holder or by the decision of SÚKL (*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 termination of marketing

authorisation notified concurrently with the coming legally into force of the concerned revocation.

SÚKL furthermore draws attention to the obligation stipulated by Section 34, paragraph 9 of the Act on Pharmaceuticals applicable to the persons who were the marketing authorisation holders of medicinal products. Upon the coming legally into force of the revocation of marketing authorisation or if the marketing authorisation expires, these persons shall be obliged to forthwith recall the medicinal product from the market.

Q 6: 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 7: 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 8: 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 coming legally into force of the marketing authorisation transfer, the existing (former) marketing authorisation holder shall be obliged to inform SÚKL to this effect. If marketing is suspended after the coming legally into force of the marketing authorisation transfer, the new marketing authorisation holder should report the suspended marketing.

Q 9: 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 their 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, paragraph 3(g), item 4 of the Act on Pharmaceuticals.

Q 10: 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 launch for the needs of patients in the Czech Republic by means of its supplies in adequate quantities and in adequate time intervals (Section 33, paragraph 3(g), item 4 of the Act on Pharmaceuticals). With respect to the nature of the product, the method of its use and 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.