UST-45 version 1 Reporting Launch, Interruption, Renewal or Cessation of a Medicine on the Market with Focus upon Obligations Associated with the Notification of Supply Interruption and Quantities of Goods Available to the MAH

This guideline supersedes the guideline UST-45 with effect from July 11, 2025.

The Guideline governing the reporting of supplies of medicinal products on the market has been drafted through collaboration involving the State Institute for Drug Control (hereinafter referred to as "SÚKL" or the "Institute"), the Ministry of Health of the Czech Republic, the Czech Association of Pharmaceutical Companies (ČAFF), and the Association of Innovative Pharmaceutical Industry (AIFP).

The Guideline is issued in an effort to make it easier for the marketing authorisation holder (hereinafter referred to as "MAH(s)") to set up the processes of reporting the launch, interruption, renewal, and cessation of placement of a medicinal product on the market, with focus upon obligations associated with the notification of supply suspension and the quantity of goods available to the MAH.

The Guideline is of recommendatory nature.

1. Introduction

The MAH has a statutory obligation to report the launch, interruption or cessation and subsequent renewal of placement of a medicinal product on the market in the Czech Republic.

The provisions of Section 33(2) of Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts (Act on Pharmaceuticals), as amended (hereinafter referred to as the "Act on Pharmaceuticals") stipulate, *inter alia,* the MAH´s obligation to notify SÚKL of the following:

- the date of actual launch of the medicinal product on the market in the Czech Republic by pack size and type of packaging, no later than within 2 months of its actual placement on the market,
- the date of interruption or cessation of placement of a medicinal product on the market in the Czech Republic at least 2 months in advance; in exceptional circumstances, such notification may be made at the time of the interruption or cessation of placement of the medicinal product on the market in the Czech Republic, incl. reasons for such interruption or cessation,
- the date of renewal of placement of the medicinal product on the market, which shall be notified forthwith.

Reports on the launch, interruption or cessation and renewal of placement of a medicinal product on the market in the Czech Republic are published by SÚKL on an ongoing basis (Launch, interruption, renewal or cessation of a medicine on the market – SÚKL) in order to provide for availability of information concerning supplies of medicinal products. These data are important particularly for doctors to be able to safeguard the treatment of patients in clinical practice, for pharmacists in the dispensing of medicinal products and provision of relevant information to patients.

2. Obligations Concerning the Notification of Supply Interruption and Quantity of Goods Available to the MAH

- What is meant by supply interruption
- What information is required in the supply interruption notification
- Quantity of goods available to the MAH
- How to determine the quantity of goods available to the MAH – MAH´s sphere of influence

- What are the penalties for failure to comply with the obligation to notify supply interruption

Pursuant to sentence one of Section 33(2) of the Act on Pharmaceuticals, the MAH is obliged to notify "*the Institute of the interruption or termination of the placement of the medicinal product on the market in the Czech Republic no later than two months in advance thereof. Where exceptional circumstances arise, such notification may be made no later than concurrently with the actual interruption or termination of the placement of the medicinal product on the market in the Czech Republic.*"

What is meant by supply interruption

In terms of the linguistic as well as systematic interpretation of this provision, it is obvious that interruption of placement of a medicinal product on the market in the Czech Republic means a situation when an unexpected circumstance with a potential to affect the availability of the medicinal product arises in the scheduled (or established) supply intervals. Essentially, the situation between two scheduled supplies, in circumstances where the current stock of the medicinal product on the market will, according to the MAH´s expectations based upon objective historical data and the currently available information, cover the anticipated demand until the date of the next scheduled supply, does not constitute suspension of placement on the market. Interruption of placement on the market is only a situation when an objective event (in the manufacturing or supply chain) or market development (such as the development of the demand or consumption) has a fundamental impact upon the anticipated demand coverage with the current stock of the medicine on the market until the next scheduled supply time point, or a situation when the date of the next scheduled supply has become rather uncertain (again, however, when the current stock on the market is not sufficient to cover the reasonably anticipated demand within a time horizon of less than several months, optimally three to four months). Even if the date of the next supply is rather uncertain, but the goods, with regard to the historical development of its consumption and reasonable anticipation, is within the Czech Republic in a volume covering the demand for e.g. one year, there is, in principle, no reason to immediately submit the supply suspension notification. On the other hand, it is appropriate to notify of supply interruption at a moment when:

1) the quantity of goods drops under a three- to four-month volume of consumption, and, at the same time,
2) the date of the next supply is still rather uncertain (the order has not been confirmed by the supplier or it has been suddenly cancelled or the delivery date has been unilaterally postponed; or the interval between scheduled supply dates is too long and most of the interval falls within a period when the current stock of the medicinal product is likely to be already used up, etc.).

It is necessary to have regard to Section 33(3)(g)(3) of the Act on Pharmaceuticals, which stipulates that the MAH is obliged to "*ensure, following the placement of the medicinal product on the market, that the medicinal product is available as needed by patients in the Czech Republic by supplying it in adequate quantities and time intervals*".

If the MAH meets this statutory obligation and the medicinal product is constantly available to patients, it is then irrelevant in what time intervals and in what quantities the medicinal product is supplied to the Czech Republic in individual deliveries. This is the MAH´s responsibility. Suspension of placement on the market is hence an instrument that may be used by the MAH when it anticipates that, on objective grounds, it will not be able to fulfil this obligation for reasons that are beyond the MAH´s control. It is essential to realize that the reporting of supply interruptions always relates to a specific variant of the medicinal product (SÚKL code). Therefore, it is necessary to submit a report in cases where the medicinal product is not continuously available to patients, even if the MAH has sufficient substituting alternative packages (e.g., different package sizes, etc.)

The aforementioned implies that a suspension of supplies for a few days, interruption of supplies due to stock taking, etc., does not in fact constitute a situation that should be notified in compliance with Section 33(2) of the Act on Pharmaceuticals as a "interruption of placement on the market".

What information is required in the supply interruption notification and how to submit it

Pursuant to Section 33(2) of the Act on Pharmaceuticals, the notification of supply suspension must include also "*information on the reasons for such suspension or termination as well as information on the current quantity of the human medicinal product available to the marketing authorisation holder as of the date of the notification, which is intended thereby for the market in the Czech Republic.*"

For the reporting purposes, SÚKL has prepared an application available at the link: SÚKL Accesses. There is detailed instruction on how to use the application are provided.

The obligation to submit the notification lies with the MAH. Nevertheless, the MAH may appoint another person to do so. Most often, it is the domestic subsidiary of the corporate group the MAH belongs to that acts on behalf of the foreign MAH (on the basis of a Power of Attorney).

The electronic reporting is carried out via SÚKL´s communication interface accessible in the remote-access mode in an open-data format. Hence it is not possible to report by e-mail, post or data mailbox. The data file has to be sent via the communication interface, which is either by a direct connection via the application program interface (API) requiring software solution on the part of the MAH communicating with SÚKL servers (https://api.sukl.cz), or by sending an open-data format via SÚKL´s portal (SÚKL Accesses).

Submitted report has to be authenticated and authorised on the basis of a certificate which is allocated to the MAH by SÚKL. Initially, the MAH has to apply for access data to SÚKL´s IT systems, and thereafter it has to have a properly installed certificate which the MAH may generate from SÚKL´s portal.

In case the person submitting the report does not have any allocated certificate, it is possible to log into the application via citizen´s electronic identity (NIA = an identification instrument allowing for advanced proof of identity when logging into online services). In such a case, however, it is necessary to deliver to SÚKL a Power of Attorney from the MAH (unless the report is submitted directly by the MAH) and an authorisation for a particular person to enter the report (this does not concern a situation when the report is submitted directly by the executive officer of the authorised company). Both documents are subjected to control and confirmation by SÚKL and the report is published only afterwards.

This method of logging into the application should be used only in exceptional cases.

It is possible to edit or cancel only the last valid report for a specific variant of the product designated by the SÚKL code.

Detailed explanation of specific items

Interruption without publication

A selection option to indicate the level of supply suspension within the supply chain. Through this option, SÚKL intends to help MAHs to provide valid and non-misleading information about unavailability of medicines for the public in a manner ensuring that only relevant notifications that may actually affect the availability of the concerned medicinal product for patients are included in the list of notifications about suspensions of supplies on the market, which is available to the general public from Report on the placing, interruption, resumption or cessation of the medical product marketing. In case the MAH send this type of notification, this notification will not be included in the list of notifications of supply suspensions intended for the general public. By sending this type of notification, the MAH indicates that this action is purely administrative, and that, according to the information available to the MAH, the MAH believes that it has sufficient quantity of the medicinal product under its control (MAH´s sphere of influence) and that no shortage of the medicinal product will occur on the market, as the MAH managed significant quantity of the concerned medicinal product within the supply chain, which will cover the anticipated demand until the expected renewal date or it has a sufficient

quantity of a replaceable medicinal product. This is to prevent unnecessary confusion, misinterpretation or massive purchases and stockpiling that could only worsen the situation with the medicinal product availability.

- It is necessary to bear in mind that the aforementioned field is only a super-structure, optional item and it **does not replace the standard "interruption"** , as only by completing reporting the "interruption" , the MAH foresees a situation of actually running out of stock on the wholesale distributor level or on the MAH´s sphere of influence level (as explained below). And in such a case, this report will be included also in the list intended for the public.
- The possibility of interruption without publication has been set up especially for those cases where a large quantity of goods is being transferred (for approx. quarter of a year or more) between the manufacture/MAH and the distributor or MAH´s consignment warehouse within the MAH´s sphere of influence. This hence concerns the fulfilment of the MAH´s obligation without publication, in order to avoid the provision of misleading information to the public, which, however, at the same time, binds the MAH to ensure continuity of supplies and meet the proper reporting obligations from its sphere of influence.
- Renewal in the situation of "interruption without publication" shall not be reported; it is automatically cancelled/overwritten by any following standard report.
- The obligation to ensure supplies as referred to under Section 33(1) of the Act on Pharmaceuticals will, in case of the regular reporting process "interruption without publication" followed by "interruption", apply to the date specified in the "interruption" report. For completeness sake, it is necessary to point out that the volume needed to ensure supplies referred to under Section 33(1) of the Act on Pharmaceuticals and under Section 33(2) of the Act on Pharmaceuticals will be related by SÚKL to the supply suspension date specified in the first report, and, in the evaluation of these obligations, SÚKL will take into account supplies from the MAH´s sphere of influence.

Quantity of goods available to the MAH

The current quantity of the medicinal product (intended for the Czech market) which is available to the MAH as at the date of notification:

- in the MAH´s warehouse, and, at the same time,
- in a particular distributor´s warehouse within the MAH´s sphere of influence, which will be identified by the distributor´s site code.

Notification of the quantity of the medicinal product intended for the Czech market which is available to the MAH, forms a compulsory part of the supply interruption notification.

This information shall be entered in the relevant field of the application, which allows for numeric entries (numerals) only. The numeral specified in the field is to indicate the number of packages of the medicinal product available to the MAH as at the date of the submission of the supply interruption (or termination) notification. In this respect, it is necessary to specify the number of packages of the particular medicinal product (SÚKL code) for which the concerned report is being filled in.

Please not that although Section 33a of the Act on Pharmaceuticals provides also the option to meet the obligation to ensure the supply of a particular quantity of a medicinal product that is subject to reimbursement or price regulation after its notified supply interruption by supplying an alternative medicinal product (under certain conditions), it does not prejudice the notification of the quantity of goods available to the MAH in association with the submission of the supply interruption notification. For example, the MAH may specify that it has little or even no quantity of the medicinal product in respect of which supply interruption is notified, and yet it can, in parallel, supply an alternative medicinal product (another SÚKL code) meeting the conditions of Section 33a of the Act on Pharmaceuticals, and thus fulfil the obligation to ensure the supply of the medicinal product even after

supply interruption. In other words, the quantity of goods available to the MAH which is to be notified thereby pursuant to Section 33(2) of the Act on Pharmaceuticals along with supply interruption is not directly linked to the obligation to forthwith ensure a certain quantity of pharmaceuticals upon supply interruption as referred to under Section 33a of the Act on Pharmaceuticals.

Zero stock as at the date of supply interruption notification may hence be notified without any fear of penalty, as, in addition to the aforementioned circumstance, there may be also a situation when:

- The actual quantity available to the MAH at present, as at the supply interruption date, is zero, but there is a scheduled supply from the manufacture or from a distribution warehouse in the nearest future after the supply interruption date (within days or few weeks), and hence it may be reasonably assumed that the patients will not be affected by the shortage during the period stipulated by law.
- As at the supply interruption date, the quantity of the medicinal product, in respect of which supply interruption is notified, available to the MAH is indeed zero, nevertheless, the MAH has a sufficient quantity of an alternative medicinal product (another SÚKL code, e.g., another pack size or strength) to meet the obligation set forth by Section 33a of the Act on Pharmaceuticals.
- The supply interruption is notified for a medicinal product which is not subject to price regulation or reimbursement from health insurance, or which is listed under Decree No 457/2023 Coll., on the list of human medicinal products not subjected to the obligation of the marketing authorisation holder to ensure supply thereof after notified supply interruption or termination date (hereinafter referred to as "Decree No 457/2023 Coll.), and the MAH is therefore not obliged to ensure the supply pursuant to Section 33a of the Act on Pharmaceuticals.

It should be also noted that medicinal products available to the MAH which have not yet been referred to in any report (i.e., via REG-13 and DIS-13) are also considered to be stock; this may, for instance, concern stock of medicinal products stored in a consignment warehouse outside the Czech Republic or stock located with the manufacturer outside the Czech Republic or stock that will be released from manufacture in the coming days, i.e., goods that are prepared for placement on the market in the Czech Republic, etc.

How to determine the required quantity of goods the MAH is obliged to supply after the notified interruption

The calculation of the quantity required by the provision of Section 33a(1) of the Act on Pharmaceuticals is based upon the reports of the medicinal product supplies on the market (REG-13). The law requires that one or two average monthly supplies be provided for. One average monthly supply is calculated from twelve consecutive calendar months in which this product was not labelled with the "limited availability" flag.

If, to date, the medicinal product has never been labelled with the "limited availability" flag, or it has not been labelled therewith in the last 12 calendar months, one average monthly supply will equal the arithmetic mean of the supplies reported in the 12 calendar months prior to the supply interruption date. According to the standard rules for the calculation of time represented by a calendar month, it is understood that the number of days in the calendar month is not relevant. This is consistent also with the concept of the REG-13 report, which is based on a full calendar month. Furthermore, Section 33(2) of the Act on Pharmaceuticals specifies an average supply as that for "*the last 12 consecutive calendar months"*. It is hence understood that the last data entering the calculation process is the report of the quantity from the month preceding the supply interruption.

It is not necessary to evidence the delivery of the required quantity of the medicinal product the MAH was obliged to supply after the notified supply interruption date. It is not necessary to report the quantity of the supplied goods after a notified shortage. Nevertheless, the MAH´s obligation to report

supplies to the Czech Republic via the REG-13 continues. And the obligation of distributors (both those within and outside the sphere of influence) to report supplies to pharmacies via the DIS-13 report also continues.

Controls of deliveries of the required quantities are performed by SÚKL randomly, on the basis of data provided by the MAH (supplies on the market, REG-13 report) and data provided by distributors within the MAH´s sphere of influence (supplies to pharmacies and to other distributors in the Czech Republic, DIS-13 report). To help the MAH more easily fulfil this obligation, SÚKL regularly, on a monthly basis and beyond its obligations, publishes in the open data catalogue (Katalog otevřených dat | Otevřená data) the calculated quantities of medicinal products for individual SÚKL codes, which the MAH is required to ensure for the needs of patients in the Czech Republic from the perspective of the Institute and the data available to it after the reported interruption or termination of supplies.

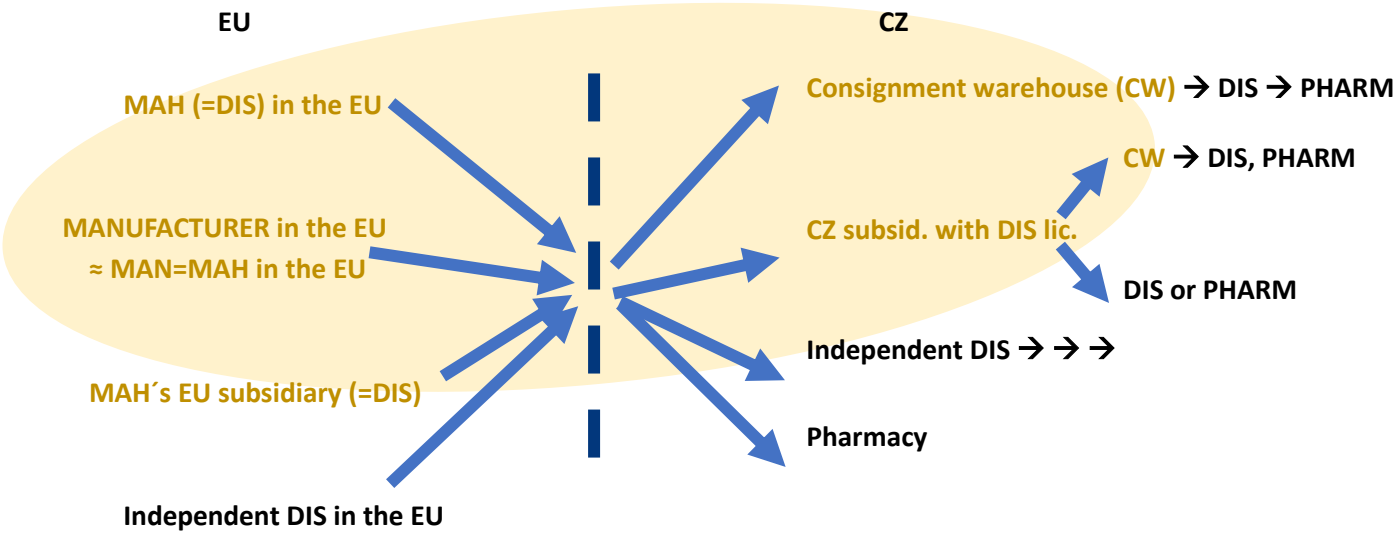
How to determine the quantity of goods available to the MAH – MAH´s sphere of influence

In many cases, the MAH certainly does not have to be directly involved in supplies of medicinal products to the Czech Republic. In majority of cases, however, the MAH is aware of the supplies and participates in their coordination (or coordination by the parent company within the corporate group where the MAH belongs). At the operational level, coordination is often provided for by the Czech representation which is either the distribution authorisation holder itself, and the medicinal product passes via it in terms of ownership, or it coordinates supplies to contractual partners, i.e., other distributors. In many cases, it therefore does not involve a situation where the medicinal product is in fact available directly to the MAH, and it is necessary to take into account other circumstances and other entities with whom the MAH coordinates the supplies to and within the Czech Republic. In this respect, it is possible to talk about the “MAH´s sphere of influence”. In the REG-13 report, the “MAH´s sphere of influence” is an optional item.

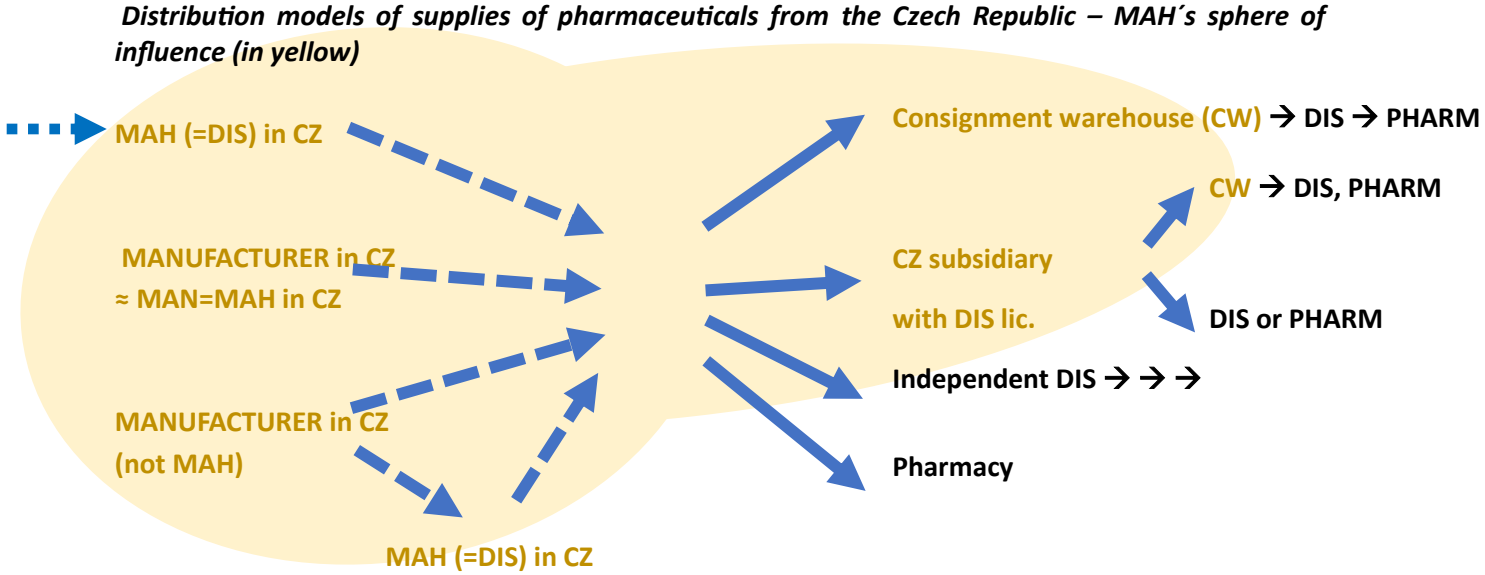
The MAH´s sphere of influence is the ownership or possession or detention of the medicinal product with entities who are directly interconnected with the MAH or who, although not being directly connected (in terms of ownership, staff), will further handle the goods only in accordance with the instructions of the MAH or entities which are connected with the MAH.

The MAH´s sphere of influence may be depicted in business models approximately as follows:

Distribution models of supplies of pharmaceuticals from abroad – MAH´s sphere of influence (in yellow)



Distribution models of supplies of pharmaceuticals from the Czech Republic – MAH´s sphere of influence (in yellow)



If the goods are in the ownership/possession/detention with the aforementioned entities, they are deemed to be in the MAH´s sphere of influence, as the MAH (or the corporate group where the MAH belongs) can influence further distribution of the concerned medicinal product within the distribution chain, it exerts a (direct or indirect) influence on the volume and dates of further releases of the concerned medicinal product to other entities, and hence also on the supplies to other distributors and to pharmacies.

It must always concern an actually existing package of the medicinal product which has been released from manufacture and placed on the market (or prepared to be placed on the market) for the purposes

of distribution in the Czech Republic. It may therefore concern goods physically deposited e.g., in a MAH´s distribution hub on a territory outside the Czech Republic (a hub for several EU countries), the essential aspect, however, is that it is a package that is *a-priori* allocated for subsequent supplies to the Czech Republic.

The aforementioned implies that the quantity of the medicinal product, available to the MAH as at the date of reporting supply suspension, to be entered is the sum total of the quantities of the concerned medicinal product (SÚKL code) with all entities within the MAH´s sphere of influence, i.e., the sum total of the quantity of the concerned medicinal product which already physically exists, has been released from manufacture and is intended for supplies to the Czech Republic (regardless of the place where it is located – the fact that it is located within the sphere of influence of the MAH´s corporate group is sufficient).

In case of the "interruption without publication" report type, it is mandatory to specify the current quantity within the MAH´s sphere of influence separately for:

- particular warehouses of the distributor within the MAH´s sphere of influence, which will be identified by the distributor´s site code, and, at the same time,
- warehouses of the manufacturer within the MAH´s sphere of influence.

What are the penalties for failure to comply with the obligation to notify supply interruption

The submission of supply interruption notification is an obligation imposed by Section 33(2) of the Act on Pharmaceuticals and it will be subject to controls by SÚKL, particularly in cases of retrospective investigation following the occurrence of a shortage of a medicinal product. By failing to meet this obligation, the MAH commits an offence referred to under Section 105(5)(c) of the Act on Pharmaceuticals, for which the marketing authorisation holder may be penalised with a fine in the amount of up to 2,000,000 CZK as referred to under Section 107(1)(c) of the Act on Pharmaceuticals.

3. Obligation to Ensure Delivery of Goods after Notified Supply Interruption

- What is meant by the obligation to ensure delivery of goods after a notified supply interruption
- How to evidence the delivery of the required quantity of goods the MAH was obliged to supply
- By when is it necessary to deliver the required quantity of goods the MAH is obliged to supply
- Linking supplies reported under REG-13 and under DIS-13 that can be offset against the MAH´s obligation to ensure the delivery of goods after a notified supply interruption
- What are the penalties for failure to meet the obligation to ensure goods following a notified supply interruption

The provision of Section 33a(1) of the Act on Pharmaceuticals stipulates: "*To cover the needs of patients in the Czech Republic, the marketing authorisation holder shall be obliged to ensure a human medicinal product with a determined reimbursement from the public health insurance or a maximum price, except for human medicinal products referred to under paragraph 4, so as to be able to supply on the market in the Czech Republic, without unnecessary delay after the notified supply interruption or termination date as per Section 33(2), this human medicinal product or another human medicinal product with a determined reimbursement from the public health insurance or maximum price, which may, taking into account the posology, replace the former, in quantity equivalent to at least*

a) twice the average monthly supply of the human medicinal product for which supply interruption or termination as per Section 33(2) has been notified; or

b) *the average monthly supply of the human medicinal product for which supply interruption or termination as per Section 33(2) has been notified if, in the last two years prior to this notification, the marketing authorisation holder was placing this human medicinal product on the market in the Czech Republic without any supply interruption or if such supply interruption in the last two years lasted no longer than 20 days in total."*

The aforementioned provision of the Act on Pharmaceuticals implies that the MAH is obliged to ensure the supply of a medicinal product reimbursed from health insurance or with a determined maximum price (except for medicinal products listed under Decree No 457/2023 Coll.) as follows: after the date of interruption, the MAH shall supply this medicinal product or its adequate replacement in the volume equal to the average two-month supplies of this product, whose supplies have been interrupted, or in the volume of average one-month supply of a product, whose supplies have been interrupted, if in the last two years, there was no supply interruption exceeding 20 days it total in respect of the such product.

What is meant by the obligation to ensure delivery of goods after a notified supply interruption

The terminology of Section 33a(1) of the Act on Pharmaceuticals is intentionally inconsistent with the terms defined in the introductory provisions of the Act on Pharmaceuticals, so as to be able to interpret the methods of complying with the concerned obligations in more general terms and in a broader context.

The terms "ensure" or "ensure delivery" have been chosen by the legislator so as to emphasise that the MAH can choose how to fulfil the obligation. Delivery may be ensured not only by the existence of domestic or foreign stock of the concerned medicinal product or its alternative replacement, but also by supplying newly released medicines from the manufacture or medicines from other markets (foreign-language batches).

The important thing is that this volume will be delivered "after the notified date of interruption". In other words, delivery to other elements of the supply chain the Czech Republic should occur after the date which is associated with the supply interruption notification. At the same time, the Act on Pharmaceuticals assumes that supply interruption should be reported in advance (2 months before), although exceptions are permissible. If the notification is submitted in time, it is necessary to take into account the fact that the required volume of the medicinal product must be delivered only after the effective date of the supply interruption.

How to evidence the delivery of the required quantity of goods the MAH was obliged to supply

It is not necessary to evidence the delivery of the required quantity of the medicinal product the MAH was obliged to supply after the notified supply interruptiondate. The MAH´s obligation to report supplies to the Czech Republic via the REG-13 report still lasts and so does the obligation of distributors (those within as well as outside the sphere of influence) to report supplies to pharmacies via the DIS-13 report.

Controls of deliveries of the required quantities are performed by SÚKL randomly, on the basis of data provided by the MAH (supplies on the market, REG-13 report) and data provided by distributors within the MAH´s sphere of influence (supplies to pharmacies and to other distributors in the Czech Republic, DIS-13 report).

In other words, the quantity of goods available to the MAH includes also goods that are in the ownership or possession/detention with distributors who are within the so-called MAH´s sphere of influence. The release of such goods further to the distribution chain (to other distributors in the Czech Republic, and, consequently to pharmacies in the Czech Republic) is the very delivery the MAH is obliged to "ensure" after the supply interruption referred to under Section 33a of the Act on

Pharmaceuticals. Therefore, not only the supplies reported via REG-13 after the notified supply interruption date but also supplies to distributors in the Czech Republic and to pharmacies in the Czech Republic reported via DIS-13 by distributors within the MAH´s sphere of influence will be recognised by SÚKL for the MAH.

By when is it necessary to deliver the required quantity of goods the MAH is obliged to supply pursuant to Section 33a of the Act on Pharmaceuticals

The MAH is obliged to ensure delivery "without unnecessary delay", so as to continuously cover the needs of the patients for the period of 1 or 2 months following the supply interruption, which is to prevent the patients from being affected by the supply interruption. This essentially means within days or weeks.

Linking supplies reported under REG-13 and under DIS-13 that can be offset against the MAH´s obligation to ensure the delivery of goods after a notified supply interruption

For SÚKL to be able to verify the fulfilment of the obligation stipulated by the provision of Section 33a of the Act on Pharmaceuticals, it must link the MAH with its sphere of influence (see above).

A MAH who will not actively notify the sphere of its influence, will subsequently have the possibility to justify the admissibility of adding deliveries made to distributors or to pharmacies reported by other distributors the MAH considers to be the sphere of its influence, within an administrative procedure that could be initiated upon suspicion of an offence. As part of such procedure, SÚKL will then verify whether the distributor in question indeed meets the conditions for being included in the MAH´s sphere of influence as described above.

What are the penalties for failure to meet the obligation to ensure the delivery of goods following a notified supply interruption

The obligation to ensure the delivery of the defined volume of the medicinal product after the notified supply interruption is enforceable under the threat of imposition of penalties. By failing to fulfil this obligation, the MAH commits an offence referred to under Section 105(5)(j) of the Act on Pharmaceuticals, for which a fine in the amount of up to 20,000,000 CZK may be imposed upon the marketing authorisation holder as per Section 107(1)(e) of the Act on Pharmaceuticals.

4. Additional Information Relevant for the Reporting of Launch, Interruption, Renewal, and Cessation of Placement of a Medicinal Product on the Market

Medicinal Products in a Specific Therapeutic Program

Medicinal products whose distribution, dispensing, and use have been approved within a Specific Therapeutic Program are available in the application after logging within the distributor's certificate. If the submitter is different from the distributor, the Ministry of Health's decision may impose an obligation on the submitter to ensure that the distributor notifies the Institute of the launch, interruption, resumption, and cessation of supplies.

Foods for special medical purposes

The obligations of importers or domestic manufacturers of foods for special medical purposes (FSMPs) in respect of which the quantity and conditions of reimbursement have been determined, as defined by the requirements stipulated by the provisions of Section 39m of Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended.

The importer or domestic manufacturers of FSMPs, after the decision on the determination of the amount and conditions of reimbursement of FSMPs becomes reimbursed, has a legal obligation to notify the launch, interruption, resumption, and cessation of supplies of the marketing of FSMPs in the Czech Republic. The above provision also establishes the obligation to notify SÚKL on the following:

- the date of actual placement of FSMPs on the market in the Czech Republic by pack size and type of packaging, no later than within 2 months of its actual placement on the market,
- the date of interruption or termination of placement of FSMPs on the market in the Czech Republic at least 2 months in advance; in exceptional circumstances, such notification may be made at the time of the interruption or cessation of placement of FSMPs on the market in the Czech Republic, incl. reasons for such s interruption or cessation,
- the date of renewal of placement of FSMPs on the market, which shall be notified forthwith.

SÚKL continuously publishes reports on the launch, interruption, cessation, and resumption of the marketing of FSMPs in the Czech Republic (see Launch, interruption, renewal or cessation of a medicine on the market – SÚKL) to ensure the availability of information regarding FSMP supplies.

- The report on the launch, interruption, resumption, or cessation of the marketing of FSMPs is submitted via the web application on the portal SÚKL Accesses, which is available at the link: Market report - Login to the application.
- The obligation to submit the notification is responsibility of the importer or domestic manufacturer of FSMPs.
- The electronic report is carried out through the SÚKL communication interface accessible in an open data format. It is not possible to report via email, mail, or data box. The data file must be sent through the communication interface, either by direct connection through the application programming interface (API) requiring a software solution on the part of the MAH communicating with the SÚKL servers https://api.sukl.cz, or by sending the open data format through the web application on the portal SÚKL Accesses.
- The submitted report must be authenticated and authorized based on a certificate assigned to the importer/domestic manufacturer of FSMPs by SÚKL. Therefore, the importer/domestic manufacturer of FSMPs must first request access credentials to the SÚKL IT systems and then have the certificate correctly installed, which can be generated on the SÚKL portal."

Questions

Questions and answers regarding the issue of reporting are published on the website Launch, interruption, renewal or cessation of a medicine on the market. For any further inquiries please use the following contacts:

• Technical questions, problems associated with the submission of the report	itpodporahlaseni@sukl.gov.cz
• Creation of test accesses, basic questions and problems with the use and generation of the certificate	pristup@sukl.gov.cz
• Other questions	marketreport@sukl.gov.cz