UST-46 version 1 Reporting Supplies of Medicinal Products on the Market (REG-13)

This guideline supersedes the guideline UST-46 with effect from June 22, 2026.

The Guideline governing the reporting of supplies of medicinal products (hereinafter referred to as "MP(s)") 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 marketing authorisation holders (hereinafter referred to as "MAH(s)") to set up REG-13 reporting processes, with focus upon obligations associated with the reporting of volumes of human medicinal product supplies on the market in the Czech Republic.

The Guideline is of recommendatory nature.

1. Introduction

The proper set-up of processes of medicinal product supplies on the market pursuant to Section 33(2) of Act No 378/2007 Coll., the Act on Pharmaceuticals and on Amendments to Some Related Acts, as amended (hereinafter referred to as the "Act on Pharmaceuticals"), i.e., report REG-13, requires an exact identification of the mode (business, distribution model) in which the medicinal product is being placed (or supplied) on the Czech market, who safeguards this activity, and the proprietary role in relationship to this product such person acts from.

It is necessary to take into account that the distribution models for various medicinal products (various SÚKL codes) in the portfolio of the pharmaceuticals company may differ. For instance, the pharmaceutical company supplies some medicinal products on the Czech market in the mode of supplies from abroad (the MAH is a member of a group), other medicines as the distributor representing foreign MAHs who are not members of the group; in respect of other medicines, the MAH may be directly the Czech subsidiary, etc. In such a case, the pharmaceutical company must take into consideration that in various roles, it submits reports with various logic (Chapter 2 refers).

For the purposes of this Guideline, the term "pharmaceutical company" is intentionally used as a general term, not foreseeing any specific role in the context of definitions described in the Act on Pharmaceuticals. This term covers:

- a company acting as the MAH;
- a company which operates in the Czech Republic and belongs to the same group as the MAH (forming a corporate group) and which
  - either only promotes the medicinal product, without the medicinal product passing through this company proprietarily or physically (a marketing entity), or
  - also trades the medicinal product on the market (the medicinal product passes through this company proprietarily or physically), in which case the company must be a distributor;
- a company which operates in the Czech Republic and is not in the same group as the MAH, but acts as the MAH´s exclusive partner for the placement of pharmaceuticals on the market in the Czech Republic, representing the MAH on a contractual basis both in the

regulatory (e.g., pharmacovigilance) area and in the pricing and reimbursement issues, etc., and in this role, it may act either as a marketing entity or as the distributor;

- a company which is the manufacturer of the medicinal product and releases the product on the market for the purposes of distribution.

2. Obligations Concerning Reporting Supplies on the Market

- What is meant by a supply on the market
- When to report a supply on the market
- How to report a supply on the market
- 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 report supplies on the market

What is meant by a supply on the market

The obligation to report supplies on the market is stipulated by Section 33(2) of the Act on Pharmaceuticals. Sentence five of this provision reads: "*The marketing authorisation holder shall provide the Institute with complete and correct data about the volume of supplies of medicinal products placed on the market in the Czech Republic in electronic format; the provided data shall contain the identification of the marketing authorisation holder, the identification of the medicinal product, information about the price of the medicinal product for which reimbursement from the public health insurance has been determined, and information about whether the medicinal product has been supplied to a pharmacy or to a distributor; the structure, method, form, and time interval of their provision via the electronic report is stipulated by an implementing legal regulation.*"

Pursuant to Section 3a(10) of the Act on Pharmaceuticals, the placement of a medicinal product on the market in the Czech Republic shall mean "*its hand-over after the manufacturing completion or its delivery from another Member State or its import, which are carried out in order to distribute the medicinal product with the exception of its use in clinical trials*".

Pursuant to Section 5(5) of the Act on Pharmaceuticals, distribution shall mean "*all activities consisting of procuring, holding, supplying, including the supplying of pharmaceuticals within the European Union and exporting to countries other than the Member States (hereinafter referred to as "third countries"), including the relevant business transfers irrespective of whether the activity is conducted for consideration or not"*.

The aforementioned implies that REG-13 is intended for the reporting of situations, when a medicinal product meeting the below listed criteria has been (physically) supplied to the Czech Republic:

- ✓ it has been released from manufacture to distribution (from a domestic or foreign manufacturer who has released the medicinal product from manufacture to distribution, it has been handed over to another entity which is authorised to handle the medicinal product as appropriate – e.g., a distributor in the Czech Republic) → the medicinal product has been physically handed over by the manufacturer to the distributor in the Czech Republic and the product has been stocked up by this distributor

  or

- ✓ it has been supplied from a distributor in another Member State (it may be a distributor authorised directly by SÚKL or a distributor authorised by a foreign authority, who has notified SÚKL of its operation pursuant to Section 75(4) of the Act on Pharmaceuticals) → the medicinal product has been physically handed over from another EU country to a distributor in the Czech Republic and this distributor has stocked up the product

  [Note: pursuant to the last sentence of Section 5(5) of the Act on Pharmaceuticals: "*Distribution of medicinal products shall not be considered the import of medicinal products from third*

countries, either." The importer of pharmaceuticals from third countries shall be considered the manufacturer (Section 62 of the Act on Pharmaceuticals) and it must release the concerned medicinal products from manufacture after the particulars stipulated by law are met. For this reason – to be able to properly interpret the requirement set forth by Section 3a(10) of the Act on Pharmaceuticals – the term "*placing the medicinal product on the market in the Czech Republic"* in relation to the subset of "*(carried out) import"* cannot be related to the phase of the receipt of goods from a third country by the entity, which is the holder of the necessary authorisation, as such, but to the phase of release from manufacture]

and, at the same time,

- ✓ the medicinal product is supplied for the purposes of distribution in the Czech Republic (i.e., not for the purposes of export from the Czech Republic, and, also, not for the purposes of use in clinical trials).

The aforementioned overview implies that placement on the market in the Czech Republic may be normally carried out also without cooperation with the MAH. Although it may concern, strictly speaking, a purely distribution activity, the situation when pharmaceuticals intended for the Czech Republic are being supplied, is associated with the MAH´s obligation to report the quantity of the medicinal product which has been supplied on the market in the Czech Republic as mentioned above.

Therefore, it is assumed that, as a general rule, the MAH is aware of supplies of the medicinal product to the Czech Republic or that the MAH directly participates therein (planning of supplies, receipt and coverage of orders from the MAH´s customers, etc.).

The only exception is parallel import, which, pursuant to Section 45 of the Act on Pharmaceuticals, is not safeguarded by the marketing authorisation holder of the medicinal product in the Czech Republic, or in cooperation therewith. Hence the information about the quantity of a medicinal product placed on the market in the parallel import mode is not to be reported by the MAH in REG-13. As a general rule, medicinal products in parallel import are not to be reported in REG-13.

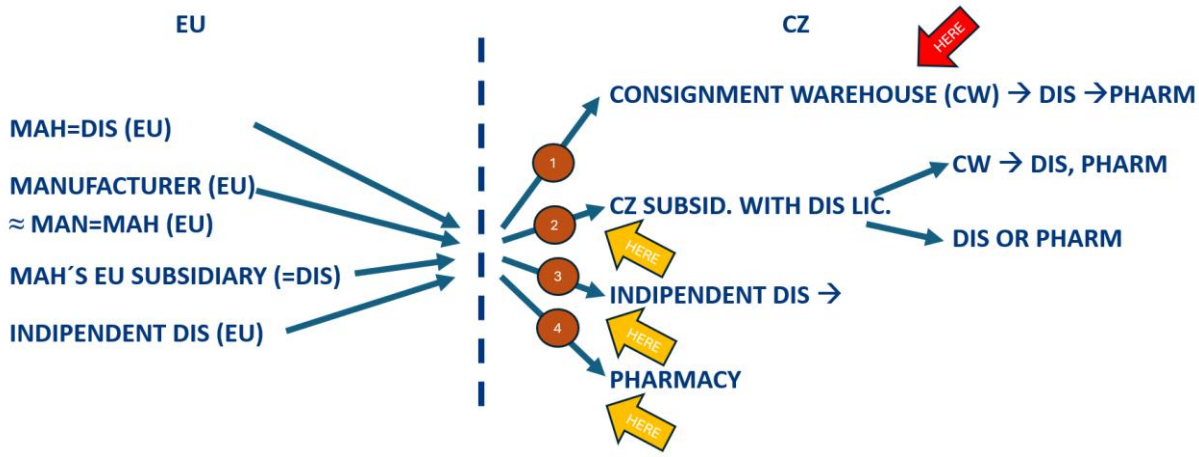
When to report a supply on the market

Essentially, a supply on the market means the physical stock-up of the goods at the premises of a distributor in the Czech Republic (goods intended for further distribution in the Czech Republic). As a general rule, however, rather than the moment (day) when the goods actually arrived in the distributor's storage premises in the Czech Republic, it concerns the day when all of the necessary processes (anticipated by legal regulations) were concluded, as, following physical stock-up, it is necessary to check the goods and also cater for all of the necessary documentation (certificates, release documentation, etc.) in compliance with GDP. Such receipt process then commonly does not take place on the same day as the physical stock-up of the goods in the warehouse. The reference date for the purposes of reporting the volume of supplies of medicinal products placed on the market in the Czech Republic (REG-13) is hence considered to be the date when the receipt process in the warehouse has been completed, i.e., it concerns a medicinal product released by the manufacturer´s qualified person into distribution, in respect of which, at the same time, the check of any and all necessary documentation has been carried out and completed in a manner allowing for further distribution of the medicinal product.

In relation to various possible distribution models of medicinal product supplies, supplies on the market should be reported after the completion of the receipt process following the stock-up of goods in the below-mentioned phases of the supply chain.

The below provided chart illustrates various options of the flow of a medicinal product that arrives in the Czech Republic from abroad (i.e., ownership is transferred from an entity established outside the Czech Republic to an entity established in the Czech Republic) with an indication of the recommended REG-13 reporting time point.

The chart illustrates various combinations of transfers between various entities on the left-hand side and various entities on the right-hand side. Thus it includes 16 various transfer options in total.



In addition to the physical flow of goods, it is also necessary to take into account the transfer of ownership. For some distribution models, this time point is virtually close to the physical hand-over. For other models, however, this may not be necessarily the case, and physical placement (potentially with possession or detention) will in fact differ from the ownership. In such a case, it is necessary to consider the proper time point for the reporting of the supply on the Czech market. The following procedure can be recommended:

Model no. 1, mentioned above, (delivery to the consignment warehouse established by a foreign entity: e.g., foreign MAH or another MAH´s subsidiary established abroad) is the most complicated one. In this model, the goods are physically transferred to the Czech Republic and stocked up in the consignment warehouse, which is managed by a provider on the basis of a contract with the foreign entity, and this provider must be a distribution authorisation holder. The provider (consignee) has the goods in detention or possession, but it is not its owner. The ownership still remains with the foreign entity that has established the consignment warehouse (consigner). In this model, it is recommended to submit the REG-13 report only after the goods removal from the consignment warehouse (by ownership transfer) to a person in the Czech Republic (a distributor in the Czech Republic or a pharmacy in the Czech Republic), regardless of whether this person is the original consignee (a typical distribution model), or someone else, to whom the consignee has handed the goods over on instruction and on account of the consigner (DTP/DTH model). The reason is that pursuant to Section 33(2) of the Act on Pharmaceuticals, the REG-13 report must include also "*information on whether the medicinal product has been supplied to a pharmacy or to a distributor".* Nevertheless, supply to another entity in the chain may occur only by means of sale (transfer of ownership), which will happen only after removal from the consignment warehouse at the moment when it is known to whom this medicinal product will be supplied (not only in terms of the product being supplied to *a* distributor or to *a* pharmacy, but with the mandatory specification of the *particular* distributor or *particular* pharmacy, including the identification code of the site where the goods are to be supplied to). As part of the REG-13 report, it will be also necessary to specify (check the relevant field) whether the concerned distributor is within the MAH´s sphere of influence or not – for further explanation of the "MAH´s sphere of influence", please refer to chapter "How to report a supply on the market".

Model no. 2 to 4, mentioned above, (supply to a Czech subsidiary within the MAH´s group, supply to an independent distributor or supply to a pharmacy) are much more straightforward and they include both the physical and ownership transfer. REG-13 reporting is conducted upon entry (following the completion of the stock-up receipt procedures). In respect of model no. 2, moreover, it is indicated that later on, goods detention in the consignment warehouse may occur, yet in this model is it a consignment warehouse established by a Czech entity (a Czech subsidiary in the MAH´s group), rather

than a foreign entity, so it is certain the goods have already been placed on the market in the Czech Republic.

For completeness´ sake we advise that in addition to reporting supplies of medicinal products on the market, MAHs shall also report the volume of the goods returned from a particular distributor/pharmacy, so called "returns". **In this respect, it is necessary to point out that a return is always a movement of goods from the customer back to the supplier (in this case, the MAH), who shall report this quantity of the returned packages to SÚKL.**

How to report a supply on the market

Pursuant to Section 33(2) of the Act on Pharmaceuticals, the MAH is obliged to provide to SÚKL complete and correct data about the volume of supplies of medicinal products placed on the market in the Czech Republic in electronic format. The provided data shall contain the identification of the marketing authorisation holder, the identification of the medicinal product, information about the price of the medicinal product in respect of which reimbursement from the public health insurance has been determined, information on whether the medicinal product has been supplied to a pharmacy or to a distributor, and identification of the person to whom the medicinal product has been supplied, providing the person´s identification number and the site identification code allocated by SÚKL.

The obligations to provide the reports are applicable to:

- MAHs, who commenced supplies of a medicinal product on the market in the Czech Republic and who notified SÚKL to this effect pursuant to Section 33(2) of the Act on Pharmaceuticals; this obligation shall not apply to medicinal products whose supply on the market in the Czech Republic has not been initiated as yet or whose supply to the Czech Republic has been terminated;
- for the fulfilment of this obligation, it is irrelevant whether the MAH is established in the Czech Republic or abroad.

Reporting data may be submitted only by authenticated and authorised clients on the basis of an allocated certificate.

To be able to report supplies of medicinal products, it is first necessary to apply for access data for SÚKL´s IT systems; the application form is available from: https://pristupy.sukl.cz/ei_forms.html#/form_Reg.

Furthermore, it is necessary to have a generated and properly installed certificate, which may be generated from: https://pristupy.sukl.cz/#portal-externich-identit.

The certificate generation wizard is available from:

https://pristupy.sukl.cz/documents/ei_navod_reg.pdf.

Each marketing authorisation holder is allocated a unique identifier – the site code. This identifier is allocated by SÚKL.

This site code has become important in light of the amended Act on Pharmaceuticals, effective as of 1 January 2024, as it has become part of the report as the piece of information defining the status of the place from where the medicinal products have arrived or where they have been delivered. If the MAH is also a distribution authorisation holder, and, as a MAH, uses several warehouses, it is necessary to specify also the warehouses where the medicinal product has been delivered.

It is necessary to strictly distinguish between the certificates and the access data through which the MAH logs into SÚKL´s systems, particularly in a situation, when a pharmaceutical company in the Czech Republic represents several MAHs (several entities in a corporate group are MAHs – MAHs for various medicinal products in the portfolio of the group are various entities), it is necessary to split this portfolio by MAHs and to submit a report for each MAH separately.

In case a pharmaceutical company in the Czech Republic represents several MAHs, it has to apply for access data to SÚKL´s systems and generate a certificate for each MAH, for which it submits the REG-13 report.

Furthermore, in case a pharmaceutical company in the Czech Republic not only represents a MAH in the Czech Republic (or is a MAH itself), but is also a distribution authorisation holder, it has to have at least one access and certificate for the MAH (for REG-13 report) and one access and certificate for the distributor (for DIS-13) and consistently log in for the reporting purposes via that certificate which is relevant for the role the entity acts from with regard to the medicinal product in question.

The reports shall be submitted for each calendar month. The reports are to be handed over to the Institute by Day 5 of the following calendar month. The structure of the report distinguishes between the reporting of supplies and the reporting of returns (by the pharmacy or distributor). In case no movement of the medicinal product (supply/return) has been registered in the monitored month, a Declaration of non-supply of medicinal products shall be submitted.

The following timelines have been established for the effective provision and uniform reporting of data:

- regular reports shall be submitted by Day 5 of the following calendar month, incl.,
- after Day 5 of the month, the content of the report may be amended only via so called extraordinary correction, which is subject to approval by SÚKL staff,
- from Day 6 of the month on, it is possible to set up a report for the current month,
- the data of the submitted reports are automatically stored in SÚKL´s database; prior to data storage, a basic check of the report form and content takes place; if the report is OK, data are stored, and if the report contains errors, it is not stored in the database and a description of the error is displayed to the submitter,
- in case the report could not be set up by day 5 of the month for serious and objective reasons, it is necessary to send a **written and justified request** containing the MAH´s identification by e-mail to oda@sukl.gov.cz; thereafter, the Declaration of non-supply of medicinal products will be set up for you, and you will have the option to amend it by means of an extraordinary correction; in case the MAH additionally finds out that it has provided incomplete or incorrect data in the report, it shall be obliged to correct the report by means of an extraordinary correction. Only one extraordinary correction may be open/active for the given period. Extraordinary corrections performed after Day 5 of the following month shall be reflected in the OAC application. Nevertheless, as the regular monthly REG-13 data outputs are published as part of open-data on the first business day following the reporting end (typically on Day 6 of the month) and thereafter, the system is closed, such extraordinary corrections will not be reflected in the published data.

The reporting obligation applies to the supplies of:

- authorised medicinal products with an allocated SÚKL code, the supplies of which have already been initiated and have not been terminated by the marketing authorisation holder;
- in the report, the MAH shall specify all SÚKL codes which have been placed/supplied on the market;
- the reporting is done only once, i.e., in case the MAH has placed/supplied at least one medicinal product (SÚKL code) on the market in the Czech Republic, it shall report it via REG-13. Medicinal products (SÚKL codes) with zero values shall not be included in the report. In case the MAH did not place/supply any medicinal product (SÚKL code) on the market in the Czech Republic in the previous month, it shall submit the “Declaration of non-supply”.

Supplies of human medicinal products to the Czech Republic shall be reported with distinction by the type of the customer:

- pharmacy,
- distributor.

a) Structure of the data provided by the MAH via the electronic report

Each report shall be identified by means of the following items:

1. MAH´s site code – the unique identification code of the marketing authorisation holder allocated by the Institute
2. Reporting period – the period for which the report is being submitted
3. Report ID – UUID unique identifier of the report

b) Reporting of supplies of medicinal products on the market in the Czech Republic

Report items:

1. Report type – information on the type of the customer to whom the medicinal products have been supplied:

- reports of supplies of MPs to pharmacies/persons authorised to dispense MPs in the Czech Republic,
- reports of supplies of MPs to distributors in the Czech Republic.

2. Site identification code – identification of the address of the customer´s site as per SÚKL´s index (applies both to supplies and returns).

3. Medicinal product movement type – identifier of goods supply or goods return.

4. SÚKL code – the codes allocated by SÚKL are recorded as per the uniform product index published on SÚKL´s website; SÚKL´s index contains medicinal products authorised by SÚKL´s decision and products authorised via the centralised decision of the European Commission. The index on SÚKL´s website is updated as at Day 1 of each month; no own codes different from SÚKL codes may be used for this report item.

5. Name – the name of the medicinal product.

6. Price – to be specified in Czech crowns (CZK):

a) for medicinal products with determined reimbursement from the public health insurance, the producer price of the medicinal product for which it has been actually placed on the market in the Czech Republic pursuant to the effective Price Regulation of the Ministry of Health on the regulation of prices of medicinal products or foods for special medical purposes, as amended, shall be specified; this price actually applied by the producer is the basis for the application of the mark-up and determination of the sales price of the medicinal product pursuant to effective price regulations; it shall be specified ex. VAT.

b) for medicinal products without determined reimbursement from the public health insurance, the price shall not be specified, but, for technical reasons, the field must be populated with a zero value (0.00 CZK);

- Producer – for authorised medicinal products, this is the marketing authorisation holder.
- Producer price – the price for which the medicinal product is supplied by the producer to the first person authorised to distribute or dispense the medicinal product, ex. mark-up and ex. VAT.
- Price regulation – Price Regulation of the Ministry of Health No 2/2024/OLZP of 29 November 2023, on the regulation of prices of medicinal products or foods for special medical purposes, as amended.
- Specified values – the minimum permissible specified price is 0.00 CZK.

7. Quantity – the number of medicinal product packages for batch and price, which must be greater than zero; the quantity shall be specified in the number of packages per specific customer type, batch, and price. Where the supplied medicinal product has several batches and one batch has several prices,

the medicinal product shall be specified with all of the prices several times, and the codes shall be repeated.

8. Batch – the batch of the medicinal product.

9. Sphere of influence – optional information; for explanation of the sphere of influence, please refer below.

c) Declaration of non-supply of a medicinal product

The report shall be submitted in case the MAH did not supply any package of a medicinal product on the market in the Czech Republic during the calendar month. If, in the previous month, it did not supply any package of any medicinal product in respect of which it is the MAH, it may submit the "**Declaration of non-supply of medicinal products**" form. This applies only to medicinal products the supplies of which on the market in the Czech Republic have been already initiated and have not been terminated.

Report items:

1. **Site code** – the unique identifier of the marketing authorisation holder allocated by the Institute
2. **Reporting period** – the period for which the report is being submitted
3. **Report ID** – UUID unique report identifier

d) Communication interface

1. Reports of supplies of medicinal products and data interface

The reporting system may be used by the marketing authorisation holder via remote access. The marketing authorisation holder shall submit the reports via a communication interface which is available from the production environment at https://api.sukl.cz/, or via a web application for report submission which is available from https://pristupy.sukl.cz/, Reports for SÚKL section, REG13 tile.

It is recommended to complete the web report form using the **Google Chrome** browser.

If submitting reports via API, you can find the complete technical information on the https://testapi.sukl.cz portal, REG13 tile.

The https://pristupy.sukl.cz/ directory contains also FAQs concerning reporting.

2. Data interface

The data interface contains data within the scope defined by the law and by the implementing regulation. The description of the API data interface is implemented via the OpenAPI specification v3.0.3 and the Swagger UI visualisation super-structure.

3. Electronic report identifier

It is recommended to specify the UUID electronic identifier of reports and individual report items in version UUIDv4 or higher.

4. Method of communication with the Institute

The MAH´s information system communicates with the Institute´s report repository via messages defined in the data interface. By sending a message, it is possible to request the Institute´s repository to do the following:

- set up a supply report,
- update a saved supply report,
- load a saved supply report,
- make a correction.

The Institute will send a reply to each of the aforementioned message types.

5. Making a report correction

The Make a correction function, also called an Extraordinary correction, serves for the purposes of making extraordinary changes outside the scope of the predefined monthly timelines. An extraordinary correction set up in this manner is subject to an internal approval by SÚKL staff. The communication interface enables the following correction options:

- set-up of extraordinary correction,
- correction of all report items,
- addition or change of selected report items,
- correction of a single report item,
- correction status retrieval.

6. Customer identification

In the currently effective version of the data interface, it is necessary to identify the customer taking the medicinal products/foods for special medical purposes using the customer´s site code. The site code is allocated by the Institute and it identifies a particular address of a warehouse or pharmacy. The web application allows for full text searches in the customer index by the following attributes:

- by the company registration number (IČO),
- by site code,
- by address,
- by distributor´s company name,
- by pharmacy name.

In v3, API provides a new operation for loading the customer index. The customer index is updated online.

7. Points of access to the Institute´s repository

The access points for the submission of reports of supplies of medicinal products via the MAH´s information system are available with the use of the SSL certificate and are published on the below-listed links:

https://testapi.sukl.cz/reg13/v3

https://api.sukl.cz/reg13/v3/

8. Access and data transfer security

Reports of supplies of medicinal products are submitted via a secured connection created above the public data network (internet). Reports may be submitted only via the electronic authentication certificate issued by SÚKL.

9. Authentication

Access to repository functions is based upon unique identification of the accessing MAH identified via the SSL certificate. The marketing authorisation holder will obtain the SSL certificate on the basis of a completed application located on SÚKL´s website at: https://pristupy.sukl.cz/ei_forms.html#/form_Reg.

10. Authorisation

The authorisation of transactions of the marketing authorisation holder accessing the repository is then conducted upon each call of the function for work with the report. The authorisation verifies

whether the sending MAH calls functions and sends data under their identifier. The registered connection of the certificate with the MAH´s registration in SÚKL is verified. In case of API, consistency of the site code in the body of the sent data message and the used certificate is also being checked.

11. Test environment

The test environment requires its own test accesses, i.e., a certificate and site code of the testing MAH. In this case, the customer index includes only the testing entities who have gained access to the test environment.

12. Transfer protocols and data formats

Reports of supplies of medicinal products are transferred by the MAH´s information system using the REST API and JSON of the data format.

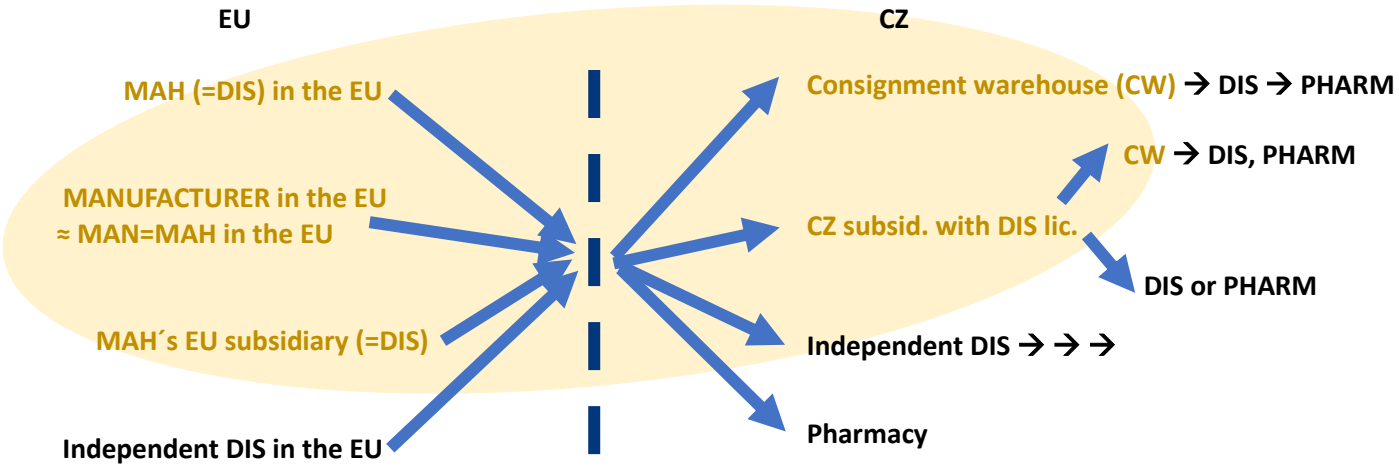
How to determine the quantity of goods available to the MAH – MAH´s sphere of influence

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 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.

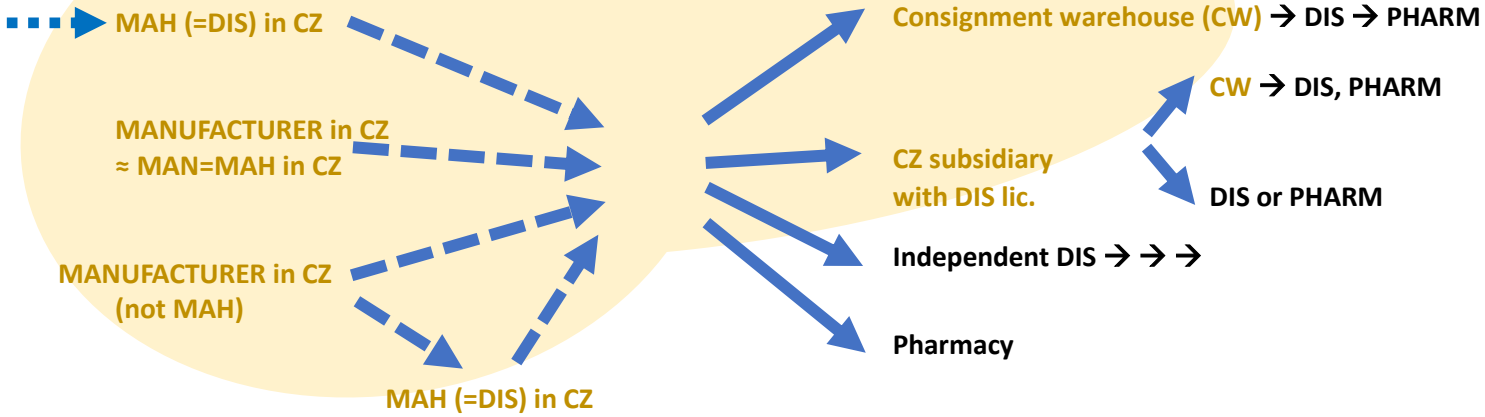
The MAH´s sphere of influence is the ownership or possession or detention of the medicinal product with entities who are directly interconnected with the MAH or who, although not being directly connected (in terms of ownership, staff), will further handle the goods only in accordance with the instructions 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 is, however, that it is a package *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 "suspension 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 observe the obligation to report supplies on the market

The submission of reports forms part of the obligations stipulated by the Act on Pharmaceuticals and it is subjected to regular controls by SÚKL. By failing to meet this obligation, the MAH commits an offence referred to under Section 105(5)(d) 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 the provision of Section 107(1)(e) of the Act on Pharmaceuticals.

3. Additional Information Relevant for the REG-13 Report

Foods for special medical purposes

The obligations of importers or domestic manufacturers of foods for special medical purposes (hereinafter referred to as "FSMP(s)") in respect of which the amount and conditions of reimbursement have been determined, remain in effect without any change as defined by the requirements stipulated by the provisions of Section 39zi of Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts.

The obligation shall mean:

- The obligations to electronically report the date of actual placement, suspension, renewal, and termination of supply of the food for special medical purposes on the market in the Czech Republic (details regarding the report are provided in the guideline UST-45),Reports on the volume of FSMP shipments to the market are submitted via a web application on the https://pristupy.sukl.cz/ portal, which is available at the following link: https://pristupy.sukl.cz/mr-login.html.
- The obligation to file a report lies with the importer or 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 https://pristupy.sukl.cz/.
- The submitted report must be authenticated and authorized based on a certificate assigned to the importer/manufacturer of FSMPs by SÚKL.
- Therefore, the importer/manufacturer of FSMPs must first request access credentials to the SÚKL IT systems (SÚKL Přístupy).

- After being granted access by SÚKL, the importer/manufacturer of FSMPs must have a certificate properly installed, which they can generate on the SÚKL portal.
- If incomplete or incorrect data is reported, the importer/manufacturer is required to submit a corrected report to the Institute without delay.
- Reports on the volume of FSMP shipments shall be submitted by Day 5 of the following calendar month, incl.,
- If a manufacturer/importer has not placed a FSMP supply on the market, they do not submit a report. If they have placed such a product on the market but have carried out no deliveries during the relevant calendar month, a Declaration of non-supply of FSMP shall be submitted.

  FSMP reports are submitted in the same manner as medicinal products reports (see above), with the following differences:
  - Under the "Report Type" field, FSMP deliveries are reported with a distinction based on the customer type:
    - Reporting of FSMP deliveries to distributors in the Czech Republic
    - Reporting FSMP deliveries to pharmacies/persons authorized to dispense in the Czech Republic
    - Reporting FSMP deliveries to inpatient healthcare facilities
    - Reporting FSMP deliveries to other persons
  - In the FSMP report, the "Price" field is optional

Questions

Should you have any questions, you are welcome to avail of the following contacts:

• General questions or expert questions on the content of the report; the MAH did not manage to submit the report within the statutory timeline	oda@sukl.gov.cz
• 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 (reporting methodology)	marketreport@sukl.gov.cz