DIS-13 version 8 Reporting Deliveries and Stocks of Distributed Medicinal Products for Human Use

This guideline supersedes guideline DIS-13 version 7.1 as of 19 January 2024

The guideline is issued on the basis of Section 77(1)(f) 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") and it specifies the procedures to be employed when submitting correct and complete electronic reports on the volume of deliveries and stocks of distributed medicinal products.

The guideline is of a **recommendatory nature.**

One of the main goals of the State Institute for Drug Control (hereinafter referred to as the "Institute") in the area of drug policy is to safeguard effective, safe, and quality pharmaceuticals. Due to the need for state administration to work with up-to-date, correct, and complete data allowing to gain an overall picture of the availability of human medicinal products and foods for special medical purposes (with allocated SÚKL code) in the distribution chain and the fulfilment of tasks imposed upon the Institute by the Act on Pharmaceuticals, the Institute, as a technical aid and means providing for reporting uniformity, publishes recommended procedures for the fulfilment of the obligation imposed upon distributors by Section 77(1)(f) of the Act on Pharmaceuticals.

The scope of data which distributors are obliged to provide to the Institute **is implied by Section 77(1)(f) of the Act on Pharmaceuticals,** as amended, with effect as of 01 January 2024. **The structure of the data, the form, method, and time intervals of their provision via the electronic report are set forth by Section 35b and Section 35e of Decree** No 229/2008 Coll., on the manufacture and distribution of pharmaceuticals, as amended (hereinafter referred to as "Decree No 229/2008 Coll.") **with effect from 01 January 2024** - see https://aplikace.mvcr.cz/sbirka-zakonu/.

Timely access to and availability of information on a medicinal product, on the supplier and its client, including chronological data on the product distribution, form a necessary precondition for the product traceability within the distribution chain and an essential prerequisite for adoption of efficient and effective actions to be taken by the Institute in case the lives or health of people are jeopardised, particularly where serious adverse reactions to the medicinal product or a quality defect thereof is identified, as well as for adoption of actions of the Ministry of Health of the Czech Republic to ensure the product availability for the needs of patients in the Czech Republic.

Deliveries of foods for special medical purposes to pharmacies, healthcare facilities, and to other distributors shall be reported in compliance with the decision-making powers of the Institute in the sphere of determination of maximum prices and reimbursements of medicinal products and foods for special medical purposes as referred to under Act No 48/1997 Coll., on Public Health Insurance and on Amendments to Some Related Acts, as amended (hereinafter referred to as the "Public Health Insurance Act"). **In compliance with the effective Price Regulation of the Czech Ministry of Health, the report shall be applicable to deliveries of foods for special medical purposes with an allocated SÚKL code only**. Foods for special medical purposes without an allocated SÚKL code are not the subject of reporting. In case of failure to report deliveries of foods for special medical purposes, the foods could be considered untraded, which could, pursuant to the provision of Section 39j of the Public Health Insurance Act, result in cancellation of the price and reimbursement.

The obligation set forth under Section 77(1)(f) of the Act is to always provide **complete and accurate data** in the report within the scope stipulated by the Act on Pharmaceuticals and the implementing regulation. A functional system for the submission of reports forms part of Good Distribution Practice and it is subjected to regular inspections by the Institute's inspectors. Failure to provide the data on distributed medicinal products is classified as an offence, the merits of which are defined in Section

105(2)(i) of the Act on Pharmaceuticals. Failure to comply with the obligation imposed upon distributors by Section 77(1)(f) of the Act on Pharmaceuticals may be penalised by a fine in the amount of up to 5,000,000 CZK.

A. Requirements for reporting of deliveries of medicinal products/foods for special medical purposes

Pursuant to Section 77(1)(f) of the Act on Pharmaceuticals, the distributor shall be obliged to:

"f) ensure during deliveries of authorised medicinal products ***that records of deliveries of authorised medicinal products are kept using the codes*** *thereof; these records shall be kept for the period of five years; the distributor shall regularly report to the Institute* ***complete and correct*** *data concerning the volume of human medicinal products distributed thereby to pharmacies and other healthcare service providers, to other distributors, to vendors of selected pharmaceuticals, and to veterinarians and concerning the volume of promotional samples supplied thereby to marketing authorisation holders or to sales representatives…; the provided data shall contain the identification of the distributor, identification of the distributed medicinal product, and identification of the person referred to under letter c) to whom the medicinal product was distributed; in case of a healthcare service provider operating a pharmacy service, distributor, and a blood centre also the site identification code and, for a human medicinal product with established reimbursement from the public health insurance, also information about its price; the structure of the data, format, method, and time interval of their provision via electronic report forms for human medicinal products is stipulated by an implementing legal regulation…;*

The reporting duty shall be applicable to:

- Distributors for whom the authorisation to operate as a distributor was issued by the Institute;
- Manufacturers of medicinal products who distribute medicinal products manufactured thereby or medicinal products imported from third countries;
- Distributors who carry out deliveries of medicinal products in the Czech Republic on the basis of a distribution authorisation issued by the competent authority of another EU Member State.

Reporting data may be submitted solely by authenticated and authorised clients on the basis of an allocated certificate. For **each distribution warehouse, a separate report** shall be submitted. Each warehouse of a distributor must have a unique identifier allocated thereto which shall be sent together with the reported data. The identifier and the certificate are allocated by the Institute.

Reports shall be submitted for each calendar month. Reports shall be forwarded to the Institute no later than within the 5th day of the end of each following calendar month. **Should the distributor find out that they provided incomplete or incorrect data in the report, they shall forthwith submit a report rectification to the Institute.**

The report must be always submitted, i.e., also in case no distribution was carried out during the month in question.

The structure of the report distinguishes between **reporting of deliveries and reporting of medicinal products returned** to the distributor by the pharmacy, doctor, or another distributor.

Decree No 229/2008 Coll., on the manufacture and distribution of pharmaceuticals, stipulates the following timelines for the submission of reports:

- Ordinary reports shall be sent within Day 5 of the following calendar month (incl.).
- After Day 5, it is no longer possible to set up the report.
- A change to a report after Day 5 of the month may be done only via an extraordinary report rectification, which is subject to approval by the Institute staff.
- From Day 6 of the month, it is possible to set up a report for the current month.

Data from the submitted reports are automatically stored in the Institute's database. Prior to their storage, an elementary check of the format and content of the report is conducted. If the report is

correct, data are stored, and a valid reply is returned to the sender. If the report contains errors, it is not stored in the database and an error description is sent to the sender.

Should the distributor or manufacturer thereafter find out that they have provided incomplete or incorrect data in the report, they shall be obliged to request the Institute to correct the report via a message defined in the communication interface.

The reporting duty shall be applicable to the deliveries of:

- authorised medicinal products with an allocated SÚKL code, including promotional samples of medicinal products;
- non-authorised medicinal products supplied within the scope of approved specific therapeutic programmes which have an allocated SÚKL code;
- non-authorised medicinal products without an allocated SÚKL code, supplied by distributors as referred to under Section 8(3) to (5) of the Act on Pharmaceuticals;
- non-authorised medicinal products without an allocated SÚKL code, supplied by distributors to other distributors in the Czech Republic or abroad.

1. The reporting duty shall be applicable to the deliveries of human medicinal products and foods for special medical purposes in the Czech Republic made to:

- **pharmacies**;
- vendors of selected medicinal products (**selected medicinal products**);
- persons providing health care where **gases** used in the provision of health care or **infusion solutions, hemofiltration and dialysis solutions are concerned**;
- healthcare facilities as referred to under Section 82(2)(e) of the Act on Pharmaceuticals, where **radiopharmaceuticals** are concerned;
- doctors, where **immunological products intended for vaccination** are concerned;
- **blood centres**, where blood derivatives are concerned;
- **veterinarians** authorised to perform expert veterinary activities;
- marketing authorisation holders or sales representatives appointed by the marketing authorisation holder (**promotional samples**); and
- other **distributors.**

2. Deliveries of human medicinal products and foods for special medical purposes which are made abroad to:

- **persons authorised for their dispensing abroad** (without distinguishing the type of person authorised for dispensing);
- **distributors.**

Reporting deliveries abroad shall not be applicable to:

- non-authorised medicinal products delivered to persons authorised for dispensing abroad;
- non-authorised medicinal products, which are not intended for the market in the Czech Republic, are stored in the Czech Republic and are, in cooperation with the marketing authorisation holder, delivered to markets in other countries.

For distributors and manufacturers subjected to the reporting duty who cannot connect their information system directly to the communication interface, a **web reporting application** is available, with further communication through an identical interface for medicinal product delivery reporting. The submission of a report also requires authentication.

B. Structure of data on the volume of distributed medicinal products provided by distributors via electronic reports

Each report must be identified via the following items:

1. **Distributor site code** – a unique identification code of the distributor allocated by SÚKL to the distributor for each approved warehousing premise.
2. **Reporting period** – the period for which the report is being submitted.

1. Reporting deliveries of medicinal products to persons authorised for their dispensing

1.1. Items of the report of deliveries of medicinal products with an allocated SÚKL code

Report items:

1. **Report type** – reporting of deliveries of medicinal products with an allocated SÚKL code.
2. **Medicinal product movement type** – the identifier of the delivery or return of goods.
3. **Customer type** – information on the type of the customer to whom the medicinal products have been supplied:
    1. Doctor (immunological products for the purposes of vaccination only)
    2. Pharmacy
    3. Nuclear medicine workplace (radiopharmaceuticals only)
    4. Vendor of selected pharmaceuticals (selected medicinal products only)
    5. Person providing health care (where gases used in the provision of health care and infusion, hemofiltration and dialysis solutions are concerned)
    6. Blood centre (blood derivatives only)
    7. Veterinarian
    8. Marketing authorisation holder or sales representative – promotional samples
    9. Person authorised to dispense abroad (without distinguishing the person who is authorised to dispense medicinal products)
4. **Site identification code** – identification of the address of the customer's workplace as entered in the Institute's records, if the customer is a pharmacy or a blood centre (applies both to deliveries and returns).
5. **SÚKL code** – the codes allocated by SÚKL are recorded in compliance with the uniform Product Index published on the Institute's website. The Institute's Index contains medicinal products authorised by the decision of the Institute, products authorised by the decision of the European Commission through a centralised procedure, non-authorised medicinal products with an allocated SÚKL code which may be supplied as part of approved specific therapeutic programmes, and foods for special medical purposes. The Index on the Institute's website is updated as of Day 1 of each month. No external codes other than the Institute's codes may be used in this report item.
6. **Name** – the name of the medicinal product.
7. **Price** –
    a) The price is stated only for human medicinal products for which reimbursement from the public health insurance has been determined. The producer price of the medicinal product for which the product has been actually placed on the market in the Czech Republic in compliance with the Price Regulation of the Ministry of Health, as amended, 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, shall form the basis for the application of the profit margin and the determination of the sales price of the medicinal product pursuant to effective pricing regulations. It shall be specified ex. VAT.

b) For medicinal products for which reimbursement from public health insurance has not been determined, it is not mandatory to provide the price, but for technical reasons, the field must be filled with zero value (0.00 CZK).

c) For customer type no 8. (promotional samples), the price shall not be specified.

- **Producer** – in case of authorised medicinal products: the marketing authorisation holder; in case of medicinal products used as part of a specific therapeutic programme with an allocated SÚKL code: the importer or domestic manufacturer.
- **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. profit margin and VAT.
- **Pricing regulation** – Price Regulation 2/2024/OLZP of the Ministry of Health 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 value is 0.00 CZK.

8. **Quantity** – the number of packages of the medicinal product per batch and price. The distributed quantity shall be specified as the number of packages per specific customer type, batch and price record. In case there are several batches of the distributed medicinal product, and several prices for a single batch, the medicinal product shall be recorded with all of the prices several times and the codes shall be repeated.
9. **Batch** – the batch of the medicinal product.

1.2. Items of the report of deliveries of medicinal products without an allocated SÚKL code (non-authorised medicinal products)

Report items:

1. **Report type** – reporting of deliveries of non-authorised medicinal products intended for use in specific patients in the Czech Republic in compliance with Section 8(3) of the Act on Pharmaceuticals – so called "individual import".
2. **Medicinal product movement type** – the identifier of the delivery or return of goods.
3. **Medicinal product type** – e.g., homeopathic products.
4. **Name** – the name of the medicinal product.
5. **Supplement** – the name supplement of the medicinal product.
6. **Manufacturer** – text identification of the manufacturer of the medicinal product.
7. **Manufacturer's country** – text identification of the manufacturer's country.
8. **Sales price** – the price for one packaging and batch (including margin and value-added tax) is optional, but for technical reasons, the field must be filled with zero value (0.00 CZK).
   Specified values – the minimum permissible specified value is 0.00 CZK.
9. **Quantity** – the number of packages of the medicinal product per batch and price. The distributed quantity shall be specified as the number of packages per specific customer, batch and price record. In case there are several batches of the distributed medicinal product, and several prices for a single batch, the medicinal product shall be recorded with all of the prices several times and the name of the medicinal product shall be repeated.
10. **Batch** – the batch of the medicinal product.

11. **Quality, quantity, and contents** – the qualitative and quantitative contents of active substances.
12. **Customer type** – pharmacy or person providing health care.
13. **Site identification code** – identification of the address of the customer's workplace as entered in the Institute's records, if the customer is a pharmacy or a blood centre (applies both to deliveries and returns).
14. **Customer identification**, if the customer is a person providing health care:
    a) **Customer name**
    b) **Street**
    c) **Building (red) number**
    d) **Town name**
    e) **Postal Code**

2. Reporting of distribution of medicinal products to other distributors

2.1. Items of the report of distribution of medicinal products with an allocated SÚKL code

Report items:

1. **Report type** – reporting of distribution of medicinal products with an allocated SÚKL code.
2. **Medicinal product movement type** – the identifier of the delivery or return of goods.
3. **Customer type** – information on the type of the customer to whom medicinal products have been delivered:
    a) Distributor warehouse in the Czech Republic
    b) Distributor in the European Union
    c) Distributor outside the European Union
4. **SÚKL code** – codes allocated by the Institute are recorded in compliance with the uniform Product Index published on the Institute's website. The Institute's Index contains medicinal products authorised by the decision of the Institute, products authorised by the decision of the European Commission through a centralised procedure, non-authorised medicinal products with an allocated SÚKL code which may be delivered as part of approved specific therapeutic programmes, and foods for special medical purposes. The Index on the Institute's website is updated as of Day 1 of each month. No external codes other than the Institute's codes may be used in this report item.
5. **Name** – the name of the medicinal product.
6. **Price** –
    a) The price is stated only for human medicinal products with determined reimbursement from public health insurance. The producer price of the medicinal product for which the product has been actually placed on the market in the Czech Republic in compliance with the Price Regulation of the Ministry of Health, as amended, 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, shall form the basis for the application of the profit margin and the determination of the sales price of the medicinal product pursuant to effective pricing regulations. It shall be stated ex. VAT.
    b) For medicinal products for which reimbursement from public health insurance has not been determined, it is not necessary to state the price, but for technical reasons, the field must be filled with zero value (0.00 CZK).

7. **Quantity** – the number of packages of the medicinal product per batch and price. The distributed quantity shall be specified as the number of packages per specific customer type, batch and price record. In case there are several batches of the distributed medicinal product, and several prices for a single batch, the medicinal product shall be recorded with all of the prices several times and the codes shall be repeated.
8. **Batch** – the batch of the medicinal product.
9. **Site identification code** – identification of the address of the customer's warehouse as entered in the Institute's records, if the customer is a distributor's CZ warehouse (applies both to deliveries and returns).

2.2. Items of the report of distribution of medicinal products without an allocated SÚKL code (non-authorised medicinal products)

Report items:

1. **Report type** – reporting of distribution of medicinal products non-authorised in the Czech Republic to other distributors in the Czech Republic or abroad.
2. **Medicinal product movement type** – the identifier of the delivery or return of goods.
3. **Medicinal product type** – e.g., homeopathic products.
4. **Name** – the name of the medicinal product.
5. **Supplement** – the name supplement of the medicinal product.
6. **Manufacturer** – text identification of the manufacturer of the medicinal product.
7. **Manufacturer's country** – text identification of the manufacturer's country.
8. **Quantity** – the number of packages of the medicinal product per batch. The distributed quantity shall be specified as the number of packages per specific customer and batch. In case there are several batches of the distributed medicinal product, it shall be listed several times and the name of the medicinal product shall be repeated.
9. **Batch** – the batch of the medicinal product.
10. **Quality, quantity, and contents** – the qualitative and quantitative contents of active substances.
11. **Customer type:**
    a) Distributor in the Czech Republic
    b) Distributor in the European Union
    c) Distributor outside the European Union
12. **Site identification code** – identification of the address of the customer's warehouse as entered in the Institute's records, if the customer is a distributor's CZ warehouse (applies both to deliveries and returns).

3. Declaration of non-operation of distribution

The report shall be submitted in case the distributor has not performed distribution activities in the course of the calendar month.

C. Reporting amounts of medicinal products for human use

Pursuant to Section 77(1)(f) of the Act on Pharmaceuticals, the distributor is obliged to the following:

"*furthermore, the distributor shall electronically provide the Institute with data about the quantities of a human medicinal product labelled with the "limited availability" flag pursuant to Section 33b available thereto as at the End Of Day of the day preceding the date of labelling with this flag, and, furthermore, electronically and at regular intervals, provide the Institute with data about the quantities of this human medicinal product which is available to the distributor; should the Institute suspect that availability of a human medicinal product could be jeopardised, the distributor shall provide to the*

Institute upon request of the latter electronic data about the quantity of the human medicinal product placed on the market in the Czech Republic which is available to the distributor".

Reports on quantities of human medicinal products labelled with the "limited availability" flag pursuant to Section 33b of the Act on Pharmaceuticals shall be submitted **within 1 working day of the labelling of the medicinal product with this flag and, thereafter, every following day of the period during which this flag is valid.**

Reports on the quantity of the medicinal product for which the Institute published a request due to suspected jeopardy to the product availability shall be submitted **within 3 working days of the publication of this request.**

Should the distributor find out that they provided incomplete or incorrect data in the report, they shall forthwith submit a new report specifying the current amount of the concerned medicinal product to the Institute.

The report must be always submitted, i.e., also in case no distribution of the medicinal product subject to the reporting duty took place or in case it is not currently available to the distributor.

Items of the report on medicinal product quantity:

1. **Distributor site code** – a unique identification code of the distributor allocated by SÚKL to the distributor for each approved warehousing premise.
2. **SÚKL code** – the codes allocated by SÚKL are recorded in compliance with the uniform Product Index published on the Institute's website. In this item, no external codes may be used other than those specified in the Institute's General Measure per Section 33c of the Act on Pharmaceuticals for the purposes of labelling a medicinal product with the limited availability flag or in the Institute's request per Section 77(1)(f) of the Act on Pharmaceuticals.
3. **Quantity** – the number of packages of the medicinal product available to the distributor; or the field will be filled in with "0".

D. Technical and organisational information

1. Means of communication

Distributors shall be authorised to use the reporting system as referred to under Section 35b and Section 35e of Decree No 229/2008 Coll. via remote access. Reports can be submitted via SÚKL's web application or via automated sending from the distributor's information system (API interface client). The interface is accessible with a SÚKL authentication certificate. The authentication certificate must be issued directly for the agenda of the distributor of medicinal products; no other type of SÚKL authentication certificate can be used.

For persons with lower amounts of distributed medicinal products/foods for special medical purposes who are obliged to report and cannot connect their information system directly to the API interface, a web reporting application is available. The web application communicates through an identical interface of reporting of deliveries of medicinal products and authentication by SÚKL certificate is also required when sending the report.

2. Web links

The web application is located at the https://pristupy.sukl.cz signpost, under section "Reports for SÚKL":

https://pristupy.sukl.cz/#anchor_hlaseni_pro_sukl

The abovementioned signposts also contain text and video tutorials for work in the web application, a description of the API interface for automated communication, and instructions how to install the SÚKL certificate.

API is available from the below listed URL addresses:
Interface description
https://testapi.sukl.cz/docs/?url=/dis13.api.json
Production environment
https://api.sukl.cz/dis13/v8
Testing environment
https://testapi.sukl.cz/dis13/v8/

The original API version is still supported via redirect. **The redirect as is, without modification, will no longer be functional for existing clients. A broader customer identification is now required in the reporting. The change to the report content requires incorporation of technical modifications of client solutions and matching of the client's own record system to the record system of SÚKL's workplaces.**

3. Support

DIS-13 reporting support contacts are provided below:

- Regulatory issues concerning the content of the report should be sent by e-mail to oda@sukl.cz.
- If distributor failed to set up the report within the statutory timeline – may be addressed by e-mail at oda@sukl.cz.
- Problems with SÚKL certificates: pristup@sukl.cz.
- General technical issues: itpodporahlaseni@sukl.cz.
- IT questions on automated API reporting can be entered into the contact centre at https://kc.sukl.cz, section DIS13.