DIS 13 - version 5

Reporting Deliveries of Distributed Medicinal Products for Human Use

Adopted on: 1 May 2017; effective date: 1 June 2017

The Guideline is issued with reference to and in compliance with the provision of Section 77, paragraph 1(f) of Act No 378/2007 Coll., on Pharmaceuticals, as amended at the time of effect of Guideline DIS-13, version 5.

The Guideline is legally binding.

Guideline DIS-13, version 5 supersedes Guideline DIS-13, version 4, effective as of 1 April 2011, including its Amendment effective as of 2 March 2016.

Changes to the previous version of the Guideline:

- In respect of medicinal products not authorised in the Czech Republic, deliveries thereof to another distributor and deliveries of medicinal products not authorised in the Czech Republic to foreign clients shall be newly also reported.
- In respect of non-regulated medicinal products (neither the maximum ex-factory price, nor the profit margin are subject to regulation – please refer to the Price Regulation of the Ministry of Health 1/2013/FAR of 7 December 2012, on the regulation of prices of medicinal products or foods for special medical purposes, as amended), the purchase price of the medicinal products ex. VAT shall be newly reported.
- Deliveries to marketing authorisation holders or sales representatives (promotion samples of medicinal products) shall be reported without producer price. In the communication interface, please enter "Price not specified".
- Deliveries to blood centres, where blood derivatives are concerned, shall be reported.
- The subject of reporting has been extended by foods for special medical purposes.
- In respect of deliveries to other distributors, the producer price shall be newly reported for regulated medicinal products, and the purchase price ex. VAT for non-regulated medicinal products.

Introduction
With a view to the need of state administration to work with current and accurate data allowing to obtain a general overview of human medicinal products and foods for special medical purposes in the distribution chain, the State Institute for Drug Control hereby revises its guideline on the reporting of deliveries of human medicinal products and foods for special medical purposes from distributors, foreign distributors, and final manufacturers (distribution of medicinal products manufactured by the manufacturer) to pharmacies, other healthcare facilities, other distributors, and to veterinarians authorised to conduct expert veterinary activities.

The reporting duty of distributors of medicinal products in respect of the State Institute for Drug Control (hereinafter referred to as the "Institute") is stipulated for distributors by Section 77, paragraph 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"). The Act authorises the Institute to publish the scope of data and the method of their provision in the information media of the Institute.

The scope of data subject to mandatory reporting is implied by the obligations and tasks defined for the Institute by the Act (**Section 13, paragraph 3(b)** of the Act – "*The Institute shall populate and maintain the pool of expert information on pharmaceuticals, including data on the consumption of medicinal products"*) and by the requirements for safeguarding constant and effective surveillance over the sphere of handling of medicinal products at all levels of the distribution chain (**item 35 of Preamble to Directive No 2001/83/EC:** *"It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will*

considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.").

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 adopted by the Institute in case the lives or health of people is jeopardised, particularly where serious adverse reactions to the medicinal product or a quality defect thereof is identified.

Each delivery of a medicinal product shall be accompanied by documentation allowing to trace the distribution route of each individual batch of the medicinal product **(Section 77, paragraph 3 of the Act**).

Deliveries of foods for special medical purposes to pharmacies, healthcare facilities, and to other distributors shall be reported in compliance with the decision-making power of the Institute in the area 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, as amended, particularly with a view to the provisions of Section 39a, Section 39c, paragraph 2(a), Section 39c, paragraph 5, Section 39j, paragraph 1 of this Act.

If deliveries of foods for special medical purposes were not reported, the foods could be considered untraded, which could, pursuant to the provision of Section 39j of Act No 48/1997 Coll., result in cancellation of the price and reimbursement.

The obligation set forth under Section 77, paragraph 1(f) of the Act stipulates that complete and accurate data in the full scope defined by this Guideline must be always reported. A functional system for the submission of reports forms part of Good Distribution Practice and is subject to regular inspections by the Institute´s inspectors. Failure of the operator to observe this obligation shall be classified as an administrative offence referred to under Section 105, paragraph 2(i) of the Act and the Institute shall take the course of action outlined under Section 107, paragraph 1(d) of the Act.

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

Pursuant to Section 77, paragraph 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"), the distributor shall be obliged to:

f) ensure that **records of deliveries of the delivered 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 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, and to the Veterinary Institute complete and correct data concerning the volume of medicinal products distributed thereby to pharmacies, veterinarians, breeders, and manufacturers of medicated feedingstuffs; the scope of particulars and the method of their provision by means of a report shall be published by the Institute or the Veterinary Institute in its information media.

The reporting duty shall be applicable to:

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

Reporting data may be submitted solely by authenticated and authorised clients on the basis of an issued certificate. The reports shall be submitted **for each distribution warehouse separately**. 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 provided by the Institute.

Reports shall be submitted for each calendar month. Reports shall be forwarded to the Institute no later than within the 10th day of the end of each following calendar month.

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 other another distributor.

In respect of reporting the data, the Institute hereby stipulates the following in order to make the reporting more effective and to unify the form of reporting:

- The regular report shall be submitted by the 10th day of the following calendar month, inclusive.
- From the 10th to the 20th day of the following calendar month, updates to a previously submitted report may be made.
- After the 20th day of the month, no further amendments may be made to the content of the report.
- Data from the submitted reports are automatically stored in the Institute´s database. Prior to their storage, the form and content of the report are subjected to an elementary check. 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.
- If the distributor or manufacturer additionally find out that they have specified 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, paragraphs 3 to 5 of the Act;
- Non-authorised medicinal products without an allocated SÚKL code, supplied by distributors to other distributors in the Czech Republic or abroad;
- Non-authorised medicinal products without an allocated SÚKL code, which are not intended for the market in the Czech Republic, supplied by distributors in cooperation with the marketing authorisation holders to eligible clients 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, paragraph 2(f) of the Act, where **radiopharmaceuticals** are concerned;
- Facilities referred to under Section 82, paragraph 2(c) of the Act, where **immunological products** are concerned;
- Doctors, where **immunological products intended for vaccination** are concerned;

- **Blood centres,** where blood derivatives are concerned;
- **Veterinarians** authorised to exercise 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 made to distributors and final entities (without distinguishing the type of person authorised for dispensing) in the EU Member States and countries outside the EU shall be reported.

Where the marketing authorisation holder supplies, via its distribution warehouses in the Czech Republic, medicinal products not intended for the Czech market also onto markets in other countries, these deliveries shall be specified in the part of the report intended for deliveries of non-authorised medicinal products without allocated SÚKL codes.

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

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

Each report has to be identified through these items:

1. **Distributor's site code** – a unique identification code of the distributor and its dispatch warehouse allocated by SÚKL
2. **Reporting period** – the period for which the report is being submitted
3. **Report ID** – UUID – a unique identifier of the report

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 medicinal products with an allocated SÚKL code
2. Medicinal product movement type – the identifier of the delivery or return of goods
3. Client type – information on the type of the client 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. Hygienic station (immunological products for the purposes of vaccination only)
5. Vendor of selected pharmaceuticals (selected medicinal products only)
6. Person providing health care (where gases used in the provision of health care and infusion, hemofiltration, and dialysis solutions are concerned)
7. Blood centre (blood derivatives only)
8. Veterinarian
9. Marketing authorisation holders or sales representatives – promotional samples
10. Person authorised to dispense abroad (without distinguishing the person who is authorised to dispense medicinal products)

4. 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 through 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 the first day of each month. No external codes different from the Institute´s codes may be used in this item.
5. Name – the name of the medicinal product
6. Price –

a) In respect of medicinal products regulated by the determination of the maximum producer price and maximum profit margin or by the profit margin only, 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 1/2013/FAR of 7 December 2012, 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) In respect of non-regulated medicinal products, the purchase price of the medicinal product ex. VAT shall be specified.

c) For client type no 9. (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, without profit margin and value-added tax.
- **Price regulation** – the Price Regulation of the Ministry of Health 1/2013/FAR of 7 December 2012, on the regulation of prices of medicinal products or foods for special medical purposes, as amended.
- **Specified values** – non-zero values shall be provided; the minimum permissible specified price shall be 0.01 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 client 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.

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, paragraph 3 of the Act – 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. The price of the medicinal product specified by the distributor for medicinal products on the delivery note, including margin and value-added tax.
   Specified values – non-zero values shall be provided; the minimum permissible specified price shall be 0.01 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 client, 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.
10. **Batch** – the batch of the medicinal product.
11. **Quality, quantity, and contents** – the qualitative and quantitative contents of active substances.
12. **Client type –** pharmacy or person providing health care.
13. **Client name**
14. **Street**
15. **Building number**
16. **Town**
17. **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. Client type – information on the type of the client to whom medicinal products have been supplied:

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 SÚKL are recorded in compliance with the uniform Product Index published on the Institute´s website. The Institute´s Index contains medicinal products authorised through 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 the first day of each month. No external codes different from the Institute´s codes may be used in this report item.

5. Name – the name of the medicinal product

6. Price –

a) In respect of regulated medicinal products, the producer price of the medicinal product for which the medicinal product was actually placed on the market in the Czech Republic in compliance with the Price Regulation of the Ministry of Health 1/2013/FAR of 7 December 2012, on the regulation of prices of medicinal products or foods for special medical purposes, as amended, shall be specified. It shall be specified ex. VAT.

b) In respect of non-regulated medicinal products, the purchase price of the medicinal product ex. VAT shall be specified.

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 client 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.

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

a) to other distributors in the Czech Republic or abroad

b) in cooperation with the marketing authorisation holder to distributors 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 client 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. Client type:

a) Distributor in the Czech Republic – only for reports a)

b) Distributor in the European Union

c) Distributor outside the European Union

3. Declaration of non-execution of distribution

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

Report items

1. **Distributor's site code** – a unique identification code of the distributor and its dispatch warehouse allocated by SÚKL
2. **Reporting period** – the period for which the report is being submitted
3. **Report ID** – a unique identifier of the report allocated by the Institute's repository

4. **Declaration** – the following statement shall be entered: “No distribution activities have been carried out in the reporting period.”

C. Communication interface

1. Reporting of deliveries of medicinal products and the data interface

Distributors shall be authorised to use the reporting system as referred to under Guideline DIS-13 via remote access.

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 communication interface, a web reporting form is available, which further communicates through an identical interface for the reporting of deliveries of medicinal products; the submission of such reports shall also require authentication.

2. Data interface

The data interface contains data in the scope defined by law and by this Guideline. The definition of the report items for hand-over is provided in the data interface published by the Institute at https://api.sukl.cz/dis13, or https://testapi.sukl.cz/dis13. The data interface forms part of the DIS-13 information system the use of which in reporting is mandatory for distributors.

3. Electronic report identifier

It is advisable to specify the electronic report identifier and individual UUID report items in the UUIDv4 version.

4. Method of communication with the Institute

The distributor´s information system communicates with the Institute’s repository via messages defined in the data interface. By sending a message, the repository may be requested to:

- Enter reports of deliveries
- Update a stored report of deliveries
- Cancel a stored report of deliveries
- Download a stored report of deliveries
- Make a correction

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

5. Report correction

The report correction function serves for the purposes of making extraordinary changes outside the predefined monthly timelines. A report entered in this manner shall be subject to internal approval by the employees of the Institute. The communication interface allows for the following correction options:

- Report entry
- Correction of all of the report items
- Addition of or amendment to selected report items
- Correction of a single report item
- Download of the correction status

6. Access points to the Institute’s repository

Access points for the submission of reports of deliveries of medicinal products via the distributor´s information system are available via the SSL certificate and are published at the addresses specified below:

https://testapi.sukl.cz/dis13/v5/{operation name}

https://api.sukl.cz/dis13/v5/{operation name}

7. Securing access to and transfer of data

Reporting of deliveries of medicinal products is conducted via a secured connection created over the public data network (Internet). The submission may be done using a new electronic certificate issued by the Institute.

8. Authentication

Access to the repository functions is based upon an unequivocal identification of the accessing distributor site identified via a SSL certificate. The distributor will obtain the SSL certificate upon completion of a request available on the Institute´s website. The Institute shall allow larger distributors to use a single certificate for all of their sites.

9. Authorisation

The authorisation of transactions of the accessing distributor site is thereafter conducted upon each call of the function to work with the report of medicinal product deliveries.

The authorisation verifies that the submitting distributor site calls functions and submits data under its identifier. The code from the received certificate and the code of the warehouse site in the body of the submitted report are checked in order to make sure that the distributor´s site submits data on its own behalf.

10. Transfer protocols and data formats

The transfer of reports of deliveries of medicinal products shall be conducted by the distributor´s information system using the HTTP transfer protocol and its standard operations (GET/POST/PUT/DELETE). The data format of the report shall be JSON.