LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Questions and Answers about the National Substance Register for Medicinal Products (NSL)

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April 2016

1. File Information

1.1. How to search the register

There is no search engine provided by the Medical Products Agency, only the file containing the substance register. It is possible to open the files in a text program such as Notes. To use the information properly, the file should be implemented in another application or database. Information on substances is available through Search for medicines (Läkemedelsfakta) at the Medical Products Agency website. This service is only available in Swedish but there is an entrance also from the English version of the website.

1.2. What is an xml file?

xml is a standard technique used to structure and organize information. xml files presents data in text format readable by the human eye. Also, the structured form makes it readable for computers. The main purpose of an xml file is to exchange information between IT systems.

1.3. Is a special program required to open the xml file?

It is possible to open the file in a text program such as Notes. The information is presented in between <tags> in a long text document and can be difficult to interpret. To use the information properly, the file should be implemented in another application or database. Such applications or databases will not be provided by the Medical Products Agency. Information on substances is available through Search for medicines (Läkemedelsfakta) at the Medical Products Agency website.

1.4. How to open the zipped link? How to download an xml-file?

Click ”Download NSL (xml file)”. A download pop-up will open. Click Save and choose the directory, or choose Open to view the files.

1.5. How is the file structured?

The structure for substance information in NSL is derived from the European Medicines Evaluation Agency’s (EMA) xml scheme for substance information, which is based on the ISO standard 11238. A simplified version of this structure is the basis for NSL. A small amount of national information (substance relation, narcotic classification, Swedish recommended name and selected English name in Sweden) without counterpart in the ISO standard is included in a separate structure. For detailed information of the structure, see nsl.mpa.se.

1.6. What are the contents of the zip file?

The zip file contains 16 different files. The files SEnsl-ssi.xsd and SEnsl-ssi.xml contain substance information in accordance with the ISO structure. Additional substance information, not compatible with the ISO structure, is included in the files SEnsl-other.xsd and SEnsl-other.xml, while schemes for management of lexicon tables are available through SEnsl-lexicon.xsd. Eleven schemes with lexicon tables required for the substance register are included, including Swedish translations of texts for ATC codes (atc-code-lx.xsd). For further description of the structure, view nsl.mpa.se.

1.7. How can the file be used?

The file contains information open to the public and is free to use. No registration is required.

1.8. How often is the xml file updated with NSL?

The xml file of the substance register is updated every night in together with the files for NPL. The Permanent URL for the xml file is http://nsl.mpa.se/sensl.zip.

1.9. Who is the owner of NSL?

The Medical Products Agency owns the information in NSL and is responsible for ongoing maintenance. The information in NSL is generated from the Medical Products Agency's internal source database.

2. Substance Information

2.1. What is included in NSL?

NSL comprises quality assured information on substances from the Medical Products Agency's database. Substances included are:

- Active substances in all approved medicinal products, traditional herbal medicinal products, natural remedies and certain medicinal products for external use.
- Active substances in medicinal products withdrawn from the Swedish market after June 2004.
- Substances that have been assigned an International non-proprietary name (INN) by WHO since 2006.
- Active substances in most of the medicinal products with special permission (license).
- Active ingredients in extemporaneous pharmaceuticals.
- A limited number of excipients.

2.2. Which excipients are included?

The selection of excipients consists mainly of the substances included in the Commission's guideline on excipients in the label and package leaflet of medicinal products for human use. It should be noted that excipients are not distinguished in NSL. The function of a substance in a medicinal product is product specific and is specified in the National Repository for Medicinal Products (NPL) and in Läkemedelsfakta for each medicinal product. Some substances can occur as excipients as well as active substances in different medicinal products.

See the Commission's guideline: Notice to applicants Volume 3B, Guidelines, Medicinal products for human use, Safety, environment and information, Excipients in the label and package leaflet of medicinal products for human use, July 2003.
http://www.lakemedelsverket.se/upload/foretag/humanlakemedel/Excipientlistan.pdf

2.3. What substance information is available in NSL?

All substances have a Swedish recommended name, possible narcotic classification and a selected English name in Sweden. Also synonyms, external codes (CAS, SnomedCT, ATC and UNII) as well as substance relationships may be included.

2.4. What is a Swedish recommended name?

All substances have been given a Swedish recommended name. The guidelines for naming substances have been prepared in consultation with interested parties and are published on the Medical Products Agency webpage (http://www.lakemedelsverket.se/overgripande/Publikationer/Rapporter/). The recommended Swedish names are developed in accordance with EMA guidelines and are principally names from the European Pharmacopeia or INN. Some substances, e.g. vaccine substances, have been given more scientifically descriptive names since they lack a European Pharmacopeia name or INN.

2.5. How should the Swedish recommended name be used?

The Swedish recommended name should be used whenever the substance is described, e.g. in product information and treatment recommendations. An alternative recommended name applicable on some substances, e.g. a reversed word order which is preferred in written text. The Swedish recommended name is shown in SEnsl-other.xsd and SEnsl-other.xml.

2.6. Where is information about Swedish recommended name for a substance found?

The files SEnsl-ssi.xsd and SEnsl-ssi.xml include all names for a certain substance. Since specifying Swedish recommended name not is possible in the ISO standard, this information is shown in SEnsl-other.xsd and SEnsl-other.xml although the name itself is included with all names in SEnsl-ssi.xsd and SEnsl-ssi.xml.

2.7. What is a selected English name in Sweden?

All substances in NSL have been given a selected English name in Sweden. The selected English names in Sweden are principally names from the European Pharmacopeia or INN and is the English equivalent to the Swedish recommended name. Some substances, e.g. vaccine substances, have been given more scientifically descriptive names since they lack a European Pharmacopeia name or INN.

2.8. Where is information about selected English name in Sweden for a substance found?

The files SEnsl-ssi.xsd and SEnsl-ssi.xml include all names for a certain substance. Since specifying selected English name in Sweden not is possible in the ISO standard, this information is shown in SEnsl-other.xsd and SEnsl-other.xml although the name itself is included with all names in SEnsl-ssi.xsd and SEnsl-ssi.xml.

2.9. Which synonyms appear?

Synonyms included are alternative names, alternative spellings, conventional abbreviations, certain chemical hybrid names and reversed word order.

2.10. What does substance relationship mean?

The active substance of many medicinal products exists as a salt or a solvate. These salts or solvates have been connected to their mother substances to show substance relationships in the database. This connection information is stored in a defined connection table. This will facilitate implementation of regulations based on properties of mother substances for e.g. constructors of knowledge support.

2.11. Is Swedish narcotic classification included?

Details of any narcotic classification on the substances have been introduced in NSL according to LVFS 2011:10.

2.12. Which substance codes are included?

Each substance in NSL has a unique identifier (SeNSLid) that consists of the prefix "ID", followed by 16 random digits and/or letters. The same ID is used for the substances in the National Repository for Medicinal Products (NPL).

External codes from the following sources have been included in NSL so far:

- Systematized Nomenclature of Medicine (Snomed CT), from the National Board of Health and Welfare.
- Chemical Abstracts Service (CAS), from the American Chemical Society.
- UNique Ingredient Identifier (UNII), from the Food and Drug Administration.
- Anatomic Therapeutic Chemical classification system (ATC), from the World Health Organization.

2.13. What are substance codes used for?

Substance information is available in a number of national and international registers. The substance codes enable users to combine information from several different registers.

2.14. ATC codes on substances?

ATC codes are WHO: s tripartite classification of medicinal products based on one anatomical level of the product's use, one level of therapeutic kind, and one level considering the chemical structure of the active substances. The substances in NSL are assigned both human and veterinary ATC codes at level 5 (chemical substance). Only codes where the substance is expressly in the description are included. This is to avoid codes which are product dependent. It should be noted that ATC codes for products are shown in NPL.

2.15. What is the difference between ATC codes in NSL and NPL?

The ATC codes in NSL are for substances while the ATC codes in NPL are for products. In NPL, the ATC codes are determined when companies apply for certain indications of their products. In NSL, the ATC codes have been assigned by WHO on the 5th level (chemical substance).

2.16. What is the difference between NSL and NPL?

NSL and NPL complement each other and are intended to be used together. Information about the role of substances in medicinal products is not available in NSL - only in NPL. In analogy with NSL, NPL contains a substance file. This file only contains basic information about substances. By using the same substance identifier in NSL and NPL, the interested parties can develop services which combine information in these registers. One possibility is to show the role of a substance (e.g. active or excipient) in a product.

2.17. Is the information in NSL and NPL synchronized?

The information in NSL and NPL has the same source database. Additionally, they are both updated simultaneously once daily.