EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Referentials Management Services (RMS)

About RMS

1. Data Content

The RMS Portal contains Lists of Terms required to support a range of processes of a regulatory, scientific and/or procedural nature.

The Lists available via the RMS Portal are broadly divided into:

1.1. Externally Managed Lists

An Externally Managed List contains Terms that are solely managed and maintained by organisations other than EMA.

These Lists will have an identified External List Owner and Terms will include details on their source of information.

The services provided for these Lists may vary depending on the agreements put in place with the List Owner.

In some cases, EMA may accept change requests on these Lists but will only include new/updated Terms if pre-approved by the List Owner.

Examples are:

- Anatomical Therapeutic Chemical classification system - Human from World Health Organisation (WHO)
- Anatomical Therapeutic Chemical classification system - Veterinary from World Health Organisation (WHO)
- Pharmaceutical Dose Form from European Directorate for the Quality of Medicines and Healthcare (EDQM)
- Packaging from European Directorate for the Quality of Medicines and Healthcare (EDQM)
- Routes of administration from European Directorate for the Quality of Medicines and Healthcare (EDQM)
- Units of Presentation from European Directorate for the Quality of Medicines and Healthcare (EDQM)
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In other cases EMA may not accept any change requests and all updates need to be handled by the user directly with the List Owner.

Examples are:

- Medical Dictionary For Regulatory Activities (MedDRA) from Maintenance and Support Service Organisation (MSSO)

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1.2. Internally Managed Lists

An Internally Managed List contains Terms that are solely managed and maintained by EMA.

These Lists are owned by EMA and managed through the Referentials Management Services in consultation with relevant groups. Terms do not include details about their source of information.

Examples are:

- Target species in consultation with CVMP
- Shelf Life Type in consultation with QRD
- Submission Mode in consultation with eSubmission colleagues and their network
- Trial Design in consultation with Clinical Trials colleagues and their network
- etc

2. Licensing

The Lists in the RMS Portal are available to be used free of charge.

Although the content of some Externally Managed Lists are subject to licensing policies, EMA has negotiated agreements to allow the content to be made available to users in the EMRN free of charge.

3. Copyright

The contents made available on **the RMS Portal** are **copyright protected.**

The RMS Portal contains the following contents:

● SPOR documents and other content;

● Referential data which refers to Lists and Terms: 'Externally Managed Lists and Terms' and 'Internally Managed Lists and Terms';

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The rules applicable to each List are described in each List Information Document.

Example:

WHO ATC list has the following copyright: "Use of all or parts of the material requires reference to the WHO Collaborating Centre for Drug Statistics Methodology. Copying and distribution for commercial purposes is not allowed. Changing or manipulating the material is not allowed."

3.1. External List Owners

The EMA would like to express their gratitude to the following List Owners for allowing the content of their Lists to be made available through the RMS Portal.

3.1.1. European Directorate for the Quality of Medicines and Healthcare (EDQM)

The EDQM is a leading organisation in the establishment of high quality standards for human and veterinary medicinal products as well as blood transfusion and organ transplantation recognised throughout Europe

EDQM manages and approves the English version of the standard terms for:

- Pharmaceutical Dose Forms
- Routes of Administration
- Packaging
- Units of Presentation

The translations of these standard terms into the EEA languages are provided by the NCAs to EDQM.

3.1.2. Maintenance and Support Service Organisation (MSSO)

The MSSO serves as the repository, maintainer, and distributor of the Medical Dictionary For Regulatory Activities (MedDRA) as well as the source for the most up-to-date information regarding MedDRA and its application within the biopharmaceutical industry and regulators. The MSSO possesses a wide range of background experiences in the Biopharmaceutical, Regulatory, and IT industries and ensures that daily operational processes and medical reviews of the MedDRA terminology are performed utilizing the highest quality standards in the industry.

3.1.3. International Organization for Standardization (ISO)

ISO is the world largest standards developing organization. Between 1947 and the present day, ISO has published more than 17000 International Standards, ranging from standards for activities such as agriculture and construction, through mechanical engineering, to medical devices, to the newest information technology developments.

ISO manages the Standards for:

- Country
- Language

3.1.4. World Health Organisation (WHO)

The WHO Collaborating Centre for Drug Statistics Methodology was established in 1982. The Centre is situated in Oslo at the Department of Pharmacoepidemiology at the Norwegian Institute of Public Health and funded by the Norwegian government.

The Centre's main activities are development and maintenance of the ATC/DDD system, including:

- To classify drugs according to the ATC system.
- To establish DDDs for drugs which have been assigned an ATC code.
- To review and revise as necessary the ATC classification system and DDDs.
- To stimulate and influence the practical use of the ATC system by co-operating with researchers in the drug utilization field.
- To organize training courses in the ATC/DDD methodology and to lecture such courses and seminars organized by others.
- To provide technical support to countries in setting up their national medicines classification systems and build capacity in the use of medicines consumption information

4. Disclaimer

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