

Purpose

The purpose of this guidance is to ensure accurate translations from English to Norwegian for substance names and ATC names, as well as translations of terms in the RMS in SPOR, to provide consistent Norwegian naming.

This applies both internally at NoMA and to all relevant external stakeholder.

Target Group

Employees responsible for the substance database and the ATC classification system in the IT solutions at NoMA. This also includes Norwegian Medicines Standards (NLS) and terms from Standard Terms, ST.

Employees involved in tasks where lists from RMS are used in both English and Norwegian.

Any relevant Stakeholder in connection with Norwegian and standard health terms.

Definitions

Athene	DMP's database for drug information
Substance	Common term for all ingredients in Athene
DMP	Norwegian Medical Product Agency
EDLD	"Enhet for Distribusjon av legemiddeldata" Unit for Distribution og drug information
WHOCC	The WHO Collaborating Centre for Drug Statistics Methodology, owner of ATC classification system
INN	International Nonproprietary Names
MedNet	Database for INN terms with information
SmPC	Summary of Product Characteristics
PO	"Preparatomtale", Norwegian name for SmPC
NLS	Norske legemiddelstandarder, the Norwegian part of the Pharmacopoeia
Ph.Eur.	The European Pharmacopoeia
EU-SRS	EU Substance Registration System
SPOR	Solutions at EMA for IDMP, R in RMS is Referentials and S in SMS is Substances.
ST	Standard Terms

The basis for Norwegian nomenclature

The assessment of the Norwegian term for a substance and an ATC name is conducted according to various criteria. The foundation for Norwegian nomenclature is based on in Norwegian orthography; see also the table in section for General guidelines. The same substance/ATC code must have the same Norwegian translation, they cannot differ.

The translation of terms in ST follows the same rules.

Input bases on the English name as the basis for det Norwegian name

- Suggestions for how an English name/term should be translated come from various sources. A comprehensive assessment determines the guiding principles.
 - The English SmPC with a proposed Norwegian translation from the Marketing Authorisation Application.
 - Registration documentation.
 - Guidelines for NLS with input from EDQM.
 - Previous use in similar substance or term.
 - WHOCC and Norwegian translation from INN.
 - EU-SRS substance database where Code system administrator in EDLD ensures correct terms.
 - The Standard terms team for clarification and advice.
- Microorganisms included as substances must always be designated with the microorganism's official name first, followed by type, strain, and characteristics, corresponding to the English format in EU-SRS.
- Characteristics of a substance must be specified after a comma at the end.
- Adjectives must be inflected according to the subject; meanings that plural forms should also be reflected in the characteristics, for example "human," "humant," or "humane."

Sources to be used as reference for a correct naming.

- Guide for Ph.Eur. naming, "Structure/Nomenclature guide"
https://www.edqm.eu/sites/default/files/medias/fichiers/guide_to_the_graphic_representation_and_nomenclatu.pdf (2011)
- WHO publications regarding INN <http://www.who.int/medicines/services/inn/publication/en/>
- Norwegian pharmaceutical standards, (Norske legemiddelstandarder,) NLS
<https://legemiddelverket.no/godkjenning/nls/database-monandrafittler>
- Official Norwegian orthography, dictionaries from the Norwegian language council
<https://ordbok.uib.no/per/ordbok.cgi?&begge=+&OPP=>
- Other sources can be recommendations in "Tidsskrift for den Norske legeforening" as a help. It will consist of medical words and expressions and less of chemical names.
<http://tidsskriftet.no/Innhold/Forfatterveiledningen/Spraak>
- Employees at NoMA using terms from RMS and understand their meaning within the context they are to be used at.
- ISO-standard for Substances ISO 11238 – Norwegian translation must be done in accordance with the standard and in the Norwegian language.
- The Norwegian Chemical Society (Norsk kjemisk selskap) has prepared a nomenclature list for a number of chemicals <http://www.kjemi.no/nomenklaturliste.html>

Decision-making Authority

The Norwegian Pharmacopoeia Commission is the principal advisory authority for decisions regarding the translation of name in case of doubt for approved monographs in Ph.Eur. The entity responsible for NLS work is the guiding authority for what applies in NoMA's database. Other parties that may be consulted include the Standard Terms team, the Pharmacopoeia team, and those responsible for vaccines, both human and veterinary.

General guidelines for Norwegian translations from English:

English	Norwegian	English	Norwegian
Compound chemical names consisting of two or more words in English	Compound chemical names are written as a singel word in Norwegian – Avoid word splitting	Sufentanil citrate Codeine phosphate hemihydrate Dibutyl sebacate Chenodeoxycholic acid Dodecyl gallate Heparin calcium Tetanus antitoxin	Sufentanilsitrat Kodeinfosfathemihydrat Dibutylsebakat Kenodeoksykolsyre Dodekylgallat Heparinkalsium Tetanusanitoksin
X	Ks – exemption for beginning with x	Betadex Bromhexine Infliximab Xylitol Xylazine hydrochloride	Betadeks Bromheksin Inflksimab Xylitol Xylazinhydroklorid
Ch	k	Bromhexine hydrochloride Choriandonadotropin	Bromheksinhydrokloride Koriongonadotropin
-e in the end of the word	-	Acetone Bromhexine Testosterone	Aceton Bromheksin Testosteron
Ph	f	Theophylline Phenazone Phenol Phenolphthaleine	Teofyllin Fenazon Fenol Fenolftalein
c (ikke i «ce», «ci» and «cy»)	k	Aceclofenac Benzocaine Octocand	Aceklufenak Benzokain Oktokand
c (i «ce», «ci» and «cy»)	c – general rule An exception applies when “s” comes before “ce,” “ci,” or “cy,” as the pronunciation will be “k.”	Acemetacin Cefradine Cyproterone acetate Bevacizumab Baricitinib Asciminib	Acemeta ci n Cefradin Cyproteron ac etat Bevacizuamb Bari ci tinib Askiminib
c (i «ce», «ci» and «cy»)	s – exceptionally for certain substances that are listed in Norwegian dictionaries.	Glycerol Glycine Acetylsalicylic acid Paricalcitol	Glyserol Glysin Acetylsalisylsyre Parikalsitol
Cyclo	syklo	Cyclophosphamide Cyclopentolate hydrochloride Dicycloverine hydrochloride	Syklofosamid Syklopentolathydroklorid Disykloverinhydroklorid

English	Norwegian	English	Norwegian
Th	t	Azithromycin Theobromine Azathioprine Thiomersal	Azithromycin Teobromin Azathioprin Tiomersal
Qui (if this is part of a quinoline structure)	ki	Quinapril hydrochloride Quinidine sulfate Quinine hydrochloride Clioquinol	Kinaprilhydroklorid Kinidinsulfat Kininhydroklorid Kliokinol
Qui (if not a quinoline structure) and qu for the rest	kv	Quifenadine Sorbitan sesquioleate Quillaja bark Dequalinium chloride Praziquantel	Kvifenadin (usikker) Sorbitanseskvioleat Kvillajabark Dequaliniumklorid Praziquantel
Io (iodine containing substances)	Jo	Iodixanol Iopromide	Jodixsanol Jopromid
i or y	i or y, as in English/Latin	Betahistine mesilate Gentamicin Azithromycin Oxitropium bromide Oxytocin	Betahistinmesilat Gentamicin Aztromycin Oksitropiumbromid Oksytocin
Succinate	suksinat	Erythromycin ethylsuccinate Metoprolol succinate	Erytromycinetyl suksinat Metoprolol suksinat
Estr (estradienes)	østr	Ethinylestradiol Estradiol hemihydrate	Etinyløstradiol Østradiolhemihydrat

Vaccine standards

- Vaccine standards both human and veterinary, have up to and including NLS 2023.2 been translated starting with
 - Vaksine mot mikrobe... (property)
 - Vaksine mot mikrobe... to «species» (property)
- As of NLS 2024.0 0 a dedicated overview of vaccine standards has been established on the website, where there is also an alternative translation closer to the English monograph.
 - Mikrobe... vaksine (property)
 - Mikrobe... vaksine to «art» (property)

Two equivalent terms will be established in order to, over time, prioritize the use of the Norwegian translation in accordance with the English term.

Standard Terms to Norwegian

DMP has a permanent expert participating in Standard Terms under EDQM. The same person is the team leader in the Standard Terms team. In ST, new terms, including attributes, are established in accordance with ST rules and are subsequently updated in its database. The Standard Terms team decides on the Norwegian translation, the task is delegated to EDLD, via the code system manager by the team leader.

Special rules

Some substances have identical names for the chemical element and the gas/solid form, primarily in English. This creates discrepancies within NoMA, and the solution is to specify the names according to the content.

The list is not exhaustive, new entries are added as needed.

Monograph, EN	Monografi, NO	State of matter	Chemical element EN/NO
Iodine	Jod, I ₂	Gas	<i>Iodine, I</i> - Jod
Nitrogen	Nitrogen, I ₂	Gas	<i>Nitrogen, N</i> - Nitrogen
Oxygen	Oksygen	Gas	This is the O ₂ in gas only
Chlorine	Klorin	Gas	This is Cl ₂ in gas only