EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures

1. Introduction

The safe and correct use of veterinary medicines depends on users being able to accurately read and understand the information on the packaging. Therefore, the main purposes of the labelling are the unambiguous identification, traceability and correct use of the veterinary medicinal product. Marketing authorisation holders (MAH) must make best use of the available space on the packaging to ensure that all the information is clear and legible, taking into consideration the typical environments or situations in which the product will be used. The use of pictograms in general is optional. Pictograms can be useful as long as the meaning and size of the graphic are clear.

Pursuant to Article 10(2) and Article 11(3) of Regulation (EU) 2019/6, the information to be contained on the labelling of the immediate packaging or on the outer packaging shall appear in easily legible and clearly comprehensible characters or in abbreviations or pictograms common throughout the Union. In accordance with Article 17(2) of that Regulation, a list of such abbreviations and pictograms has been adopted and, from 11 May 2024, Regulation (EU) 2024/875[1] allows replacing the information on the immediate and outer packaging with the adopted abbreviations or pictograms listed in this Regulation for existing and new veterinary medicinal products.

The aim of this guidance is to provide practical advice on how to implement the adopted abbreviations and pictograms listed in Regulation (EU) 2024/875 in the labelling of authorised veterinary medicinal products. The aim is also to offer a procedure through which the industry can propose new abbreviations and pictograms to be added to the legal act, which is referred to in section 5.

[1] Commission Implementing Regulation (EU) 2024/875 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council – link

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2. Definitions

Within this guidance, pictograms are defined as standard approved symbols that unambiguously convey a piece of information or an instruction. These pictograms are distinguished from any other images/graphic representations defining a marketing authorisation holder e.g. logo, brand-specific images.

3. Implementation of the adopted abbreviations and pictograms for authorised veterinary medicinal products

Transitional period

Commission Implementing Regulation (EU) 2024/875 gives a transitional period for the replacing of existing abbreviations or pictograms on the immediate or outer packaging that are not compliant with the new approved ones. No other substitutions of labelling text are permissible other than the use of the pictograms/abbreviations in the Implementing Regulation.

Pursuant to Article 3 of the Implementing Regulation, veterinary medicinal products authorised before 11 May 2024, or which are subject to an ongoing application for a marketing authorisation on 11 May 2024, once authorised, may be placed on the market until 11 April 2029 even if the pictograms and abbreviations used in their labelling to replace required text do not comply with this Regulation.

During the transition period, the MAH shall submit, through the dedicated variations indicated below, a change to align the information on the immediate or outer packaging with the requirements of the legal act.

Use of Variation not requiring assessment (VNRA) for the introduction, deletion or update of abbreviations and pictograms

To facilitate any changes resulting from the above mentioned legal act, the European Commission adopted an update of the list of VNRAs[2].

The purpose of the variation not requiring assessment C.10.d, is to be used when introducing abbreviations or pictograms or when replacing the required information on the immediate or outer packaging with an abbreviation or pictogram, as well as when replacing an existing abbreviation or pictogram that is not compliant with the legal act by another adopted abbreviation or pictogram.

The abbreviations and pictograms set out in the Annexes of the Implementing Regulation (EU) 2024/875 shall only be used on the immediate and outer packaging instead of written text and not together with written text.

For new marketing authorisation applications, any proposed use of abbreviations or pictograms from Annex I or II of the Commission Implementing Regulation (EU) 2024/875 should be indicated in the product information within the initial submission or as soon as possible during the ongoing procedure.

Deletion of non-compliant abbreviations or pictograms can be made via VNRA C.10.b.

Explanation of the abbreviation and pictograms in the package leaflet

According to Article 2(2) of the Commission Implementing Regulation (EU) 2024/875 abbreviations and pictograms used on the labelling must be explained in full text in the package leaflet. The aim is to

[2] Consolidated version of Commission Implementing Regulation (EU) 2021/17 establishing a list of variations not requiring assessment – link

ensure that stakeholders (e.g. animal owners, vets, pharmacists or distributors) who have doubts on the meaning of an abbreviation or pictogram can retrieve the information about their meaning from the package leaflet. To achieve this goal, the corresponding abbreviation/pictogram should be included next to the explanatory text in the relevant section of the package leaflet.

4. Use of additional pictograms than those included in the legal act

Additional pictograms for the purpose of reinforcing significant written safety warnings included in the SPC and package leaflet can be used on the immediate and/or outer packaging on a case-by-case basis, if the inclusion of a written warning in the package leaflet alone is not considered sufficient for risk mitigation purposes. Examples of such safety warning pictograms are listed in Annex I of this guidance. The corresponding pictograms should be included next to the explanatory text in the relevant section of the package leaflet.

Furthermore, additional pictograms reflecting the routes of administration, where appropriate can be used on the immediate and/or outer packaging next to the explanatory text for the purposes of correct and safe administration of the product.

5. Updating the list of abbreviations and pictograms in Commission Implementing Regulation (EU) 2024/875

New pictograms or abbreviations may be proposed by industry for endorsement by the CMDv and QRD group. For this purpose, the proposed new pictograms/abbreviations can be submitted to both secretariats: CMDv@ema.europa.eu and qrd@ema.europa.eu. A request from EMA can be made to the European Commission once a year for the inclusion of the new endorsed pictograms/abbreviations.

Annex I –

Pictogram	Explanatory text
	Do not use in cats
	Do not use in rabbits
	The veterinary medicinal product should not be administered by pregnant women.