



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 December 2017
EMA/776723/2017

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

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. The need for a harmonised, approved 'catalogue' of pictograms was identified:

- to improve predictability of approval by regulators when the use of pictograms is proposed;
- to embed and thereby improve the meaning of these harmonised pictograms for users of veterinary medicines.

This guidance has been developed together with industry stakeholders. The use of pictograms from Annex 1 as defined in this guidance will apply to the national authorisation procedures, including MRP and DCP, as well as to the centralised procedure. The aim of the guidance is to outline the approval requirements and process for two situations where either:

- pictograms from Annex 1 may accompany text on the outer and immediate packaging;
- pictograms from **section 1** of Annex 1 may substitute text on small, immediate packaging/blisters.

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. General characteristics of pictograms

As a general requirement, pictograms should be clearly distinguishable from the background i.e. good contrast. Pictograms taken from Annex 1 should specifically be printed in black and white, as shown. However, flexibility for the pictograms to face in either direction will be allowed.

The use of a highly glossy or metallic reflective colour is not recommended as it may affect clarity.

No additional visual effects such as shading should be used in the pictogram.

The size of the pictograms should be proportionate to the overall size of the printed material. Pictograms may not be less than 5 mm in height, which may be waived in exceptional circumstances for very small packs; the approval of pictograms smaller than 5 mm in height will be a matter for assessment on a case-by-case basis.

The location of the pictograms should not negatively affect the readability of the mandatory information on the packaging (e.g. if the pictogram is too close to text it can impact on readability).

Pictograms should exclude any element of a promotional nature.

4. Requirements for pictograms taken from Annex 1

Using pictograms from Annex 1 to substitute text on the packaging

If pictograms are used to substitute text on the packaging, it is compulsory to use those provided in **section 1** of Annex 1 i.e. the use of proprietary pictograms not in this 'catalogue' is not approvable in the case of substitution of text.

The pictograms from **section 1** of Annex 1 of this guidance can only be used to substitute text on small immediate packaging units (as defined in the QRD product information template) and blisters.

Pictograms in **section 2**¹ of Annex 1 may not be used to substitute text i.e. they may only be used in addition to (alongside) the required text.

Further considerations specific to pictograms of target species

In particular for target species, pictograms cannot be used to replace text such as the age, sex or size of the animal, therefore pictograms will always represent the species and not the sub-species.

¹ Section 2 is currently empty at the time of publication

Using pictograms from Annex 1 to accompany text on the packaging

As a general principle, the pictograms in Annex 1 may be included on the outer and immediate packaging in addition to (alongside) the corresponding text that they are representing.

Replacing existing pictograms with agreed pictograms from Annex 1 for approved products

To ensure harmonisation and to establish a common understanding of pictograms by the user, it would be preferable that any existing pictogram currently authorised as a substitution for text is replaced with an approved pictogram from **section 1** of Annex 1. Where existing pictograms are currently used alongside the text that they represent, it is equally encouraged to replace them with an approved pictogram from Annex 1 using the mechanisms described in section 5.

5. Mechanism to introduce pictograms from Annex 1

For new marketing authorisation applications, any proposed use of pictograms from Annex 1 should be indicated in the product information within the initial submission or as soon as possible during the ongoing procedure. For authorised products, requests to make use of pictograms from Annex 1 can be made during a post-authorisation procedure affecting the product information when the product information is 'open' for review. Alternatively, a stand-alone variation application may be introduced using classification C.II.6.b² (Type IB).

In order to indicate its intended use to assessors, any pictogram should be inserted within the product information, as follows:

- If text is to be substituted by a pictogram from **section 1** of Annex 1 insert the pictogram within the respective section of Annex IIIA (Labelling) in the product information (QRD) template without the accompanying text (*N.B. substitution only currently possible for small immediate packaging units/blisters*).
- If a pictogram is intended for use in addition to the text, insert the pictogram with the accompanying text within the respective section(s) of the product information (QRD) template.

6. Maintenance of pictograms in Annex 1

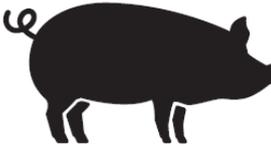
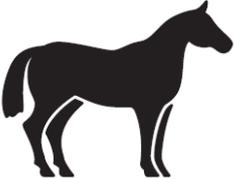
New pictograms (currently limited to the category of target species), should be proposed and endorsed within industry associations where possible and then submitted to both the CMDv and QRD secretariats for regulatory approval: CMDv@ema.europa.eu and qrd@ema.europa.eu. The newly-requested pictogram must be approved by these regulatory bodies before its use in any submission under the terms of this guidance. The new approved pictograms will be added periodically to the annexes of this guidance.

² Variation classification guideline 2013/C 223/01: [link](#)

Annex 1 – Approved pictograms

SECTION 1

Target species:

Species	Pictogram	
1. Pig		Link
2. Cattle		Link
3. Sheep		Link
4. Chicken		Link
5. Rabbit		Link
6. Horse		Link
7. Goat		Link
8. Dog		Link

Species	Pictogram	
9. Cat		Link
10. Turkey		Link
11. Goose		Link
12. Duck		Link
13. Fish		Link

SECTION 2

This section is currently empty at the time of publication.