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Lead committee: ENVI

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Opinion committee: AGRI

## REGULATION ON VETERINARY MEDICINES

### TOPIC: LABELLING AND PACKAGE LEAFLETS

#### What is the issue?

Compliance with labelling rules constitutes the largest segment (34%) of the total administrative burden identified in the EC's Impact Assessment Report. This high figure is driven by the need for national language labelling in each member state. The cost of packaging is a factor preventing marketing of products in small markets.

**Need for multi-lingual packs:** As the largest component of this cost is the manufacturing operation to apply the immediate label to the primary container, the desired solution is to create greater opportunities for multi-lingual packs (avoiding numerous separate small labelling operations) by reducing the quantity of information on the immediate label. The use of standard pictograms and standard abbreviations also helps. All additional information can be included in the package leaflet, including a glossary of pictograms and abbreviations.

#### What is proposed?

The COM proposal reduces the information required on the immediate and outer packaging (art. 9-10). This will facilitate multi-lingual packs and will help to remove hurdles to marketing low-volume products in small member states. But the rules are *unnecessarily restrictive* and inevitably such 'closed' rules will cause problems in individual cases, due to the very wide range of product types in veterinary medicine, ranging from small vials to large 25kg sacks.

#### What needs to be done?

**Support** the general approach taken, but **remove unnecessary restrictions** - additional information, that complies with the summary of product characteristics, should be allowed if there is sufficient space on the immediate and outer packaging (e.g. on large packs).

#### Other issues

**The phrase "animal treatment only"** (art. 10.1(d)) on the outer packaging takes up much space, with all the different translations, preventing the use of multilingual outer packaging, which may lead to products not being placed on the market in small countries; this creates the risk of increased off-label use of veterinary or human medicines in animals (via art. 115 and 116); the risk of accidental use of a veterinary medicine in a human is small.

**Solution:** The phrase "animal treatment only" is redundant with the use of an animal pictogram, and could be stated on the package leaflet, with "read the package leaflet" pictogram included on the outer package.

**"Take-back schemes"** (10.1(f)) vary from country to country; this country specific information will take up a lot of space on the outer packaging, hindering the use of multilingual packaging.

**Solution:** revert to the text used in article 58.1(j) of the current Directive 2001/82/EC as amended "reference to any appropriate [waste] collection system in place;"

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P.T.O.

IFAH-Europe (International Federation for Animal Health Europe) represents manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It represents both corporate members and national animal health associations in Europe, comprise both local and international companies, and covers 90% of the European market.

# Illustrations

## 1. Example of an existing small, tri-lingual label for immediate container



## 2. How a small label might look using pictograms and standard abbreviations

