EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Packaging and labelling

QRDvet template, opportunities for reduced label text and multi-lingual labels, recent examples

EMA/IFAH-Europe Info Day 2014

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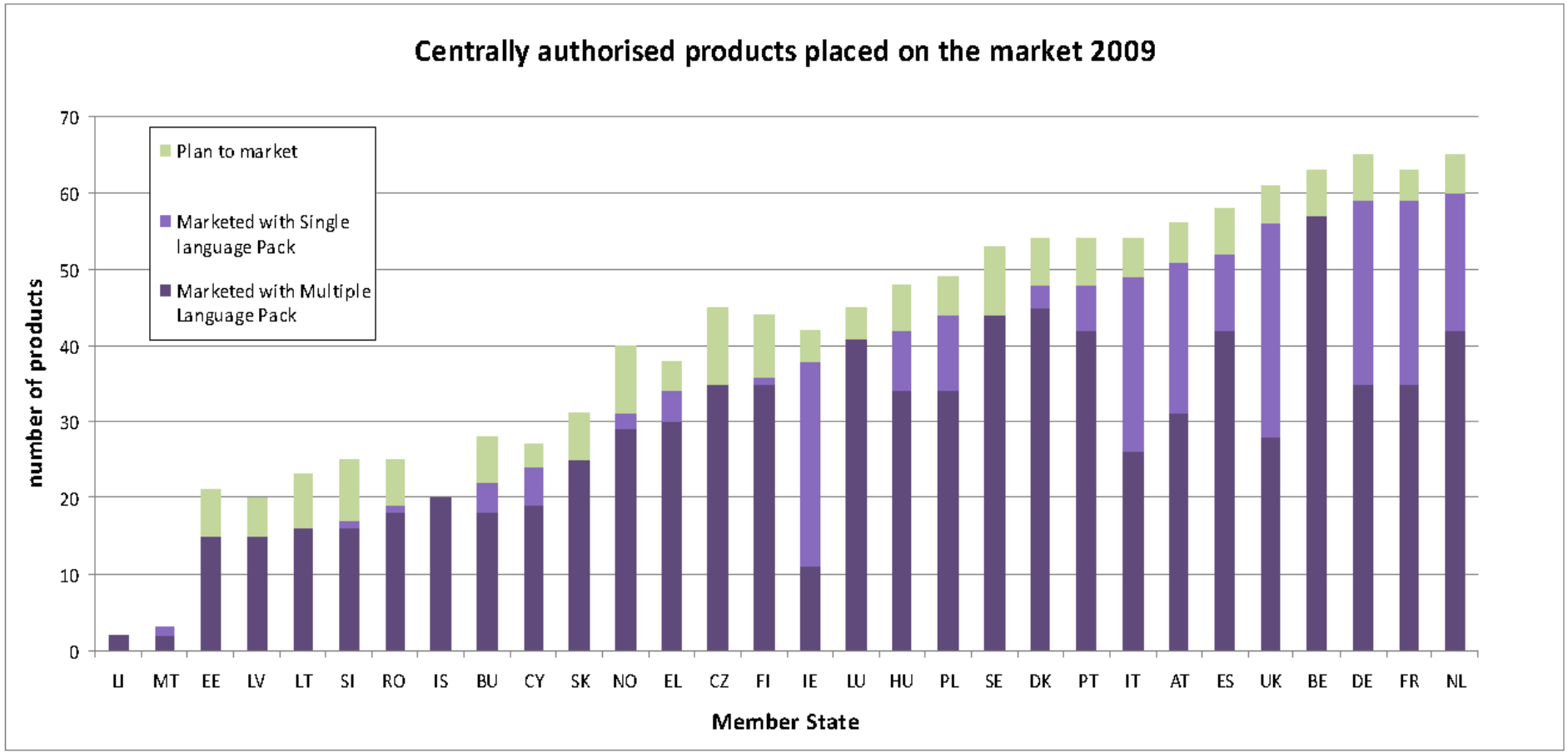
The past – industry and authorities

"The cost of the packaging operations for small batches can mean that it is not financially viable to supply product to some small markets as the unit costs are too high. The use of multi-lingual packaging can overcome this issue… Unfortunately the current legislation requires a large quantity of text to appear on pack labels, making the use of multi-lingual labels difficult." 2010

"Biggest hurdle to small markets = packaging – Proposals: • Minimise info on immediate pack label • Move info to outer carton/box • Put all info on pack insert" March 2011

"The goal of having multilingual packages is seen as pivotal to reduce costs of supplying medicines to smaller markets. The QRDvet should continue to strive to reduce requirements even to less than those of applicants where feasible." April 2011

Figure 13: Graph on availability of centrally authorised products across EU 2009



IFAH-Europe Impact Assessment Data Package

The revised QRDvet template

Implementation plan

Rapporteurs

Project managers – EMA review

CVMP members

CVMP

Success !!!

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form ~~<target species>~~}
{active substance(s)}

[Name of the veterinary medicinal product, followed by its strength (if applicable) and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name, as it appears in the SPC under section 1.]

By name we mean the invented name or the generic name plus the MA-Holder‘s logo or name.

The target species – not any more – specifically deleted from section 1, based on Directive 2001/82 – see section 5.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

[Expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names. Where the active substance is present as a salt, this should be clearly indicated e.g.: "mg X" or "mg Y-hydrochloride (equivalent to mg Y)".]

~~*[Express qualitatively those excipients known to have a recognised action or effect. See theEuropean Pharmacopoeia monograph for vaccines for those excipients which should be mentioned on the label]*~~

The requirement for excipients to be stated has been specifically deleted. This also includes vaccines. Adjuvants, just like other excipients should not be stated. If considered necessary, well then it has to be justified. As always, throughout the update of the template the goal was to reduce labelling.

4. PACKAGE SIZE

[By weight, by volume or by number of doses of the veterinary medicinal product (i.e. pack size, including a reference to any ancillary items included in the pack such as needles, swabs; content of bottle etc...).]

[A short statement should be used to describe the pack size:

e.g.

"10 ml"(not "10 ml vial")

"10 x 50 ml" (not "10 vials with 50 ml of solution for injection")]

[In case of a combined labelling text covering different pack-sizes of the same strength, further pack-size(s) should be included in grey shading.

e.g.

28 tablets

56 tablets

100 tablets]

10 x 1 dose of lyophilisate
10 x 1 dose of solvent
or
10 x [I + II]

By all means, avoid text which needs translation – make this simple – "10 x 50 ml" – not "10 vials with 50 ml of solution for injection".

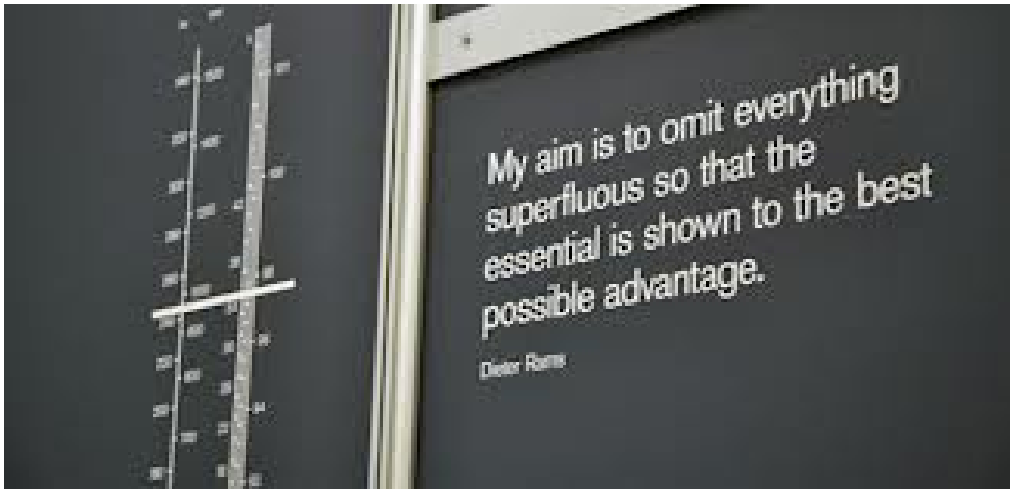
6. INDICATION(S)

*[Indication to be included **only** for medicinal products **not** subject to medical prescription.]*

~~*[Information to be included for immunologicals only. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]*~~

What more can we ask for☺

- Gaining space



7. METHOD AND ROUTE(S) OF ADMINISTRATION

[Method of administration: directions for proper use of the veterinary medicinal product; e.g. "Shake well before use". In all cases, and especially if full details cannot be included on the outer packaging itself, a reference to the package leaflet must be included. If the route of administration is already mentioned in the name of the veterinary medicinal product, it should be repeated here in grey shading (i.e. it will appear in the template text but NOT on the mock-ups and on the final printed materials, e.g Oral solution).]

Read the package leaflet before use.

[Space shall be provided for the prescribed dose to be indicated on the label/outer carton. Route(s) of administration should be mentioned according to "Standard terms" published by the Council of Europe. If the information exceeds the size of the label, reduced text is acceptable.]

If the route of administration is obvious, based on the pharmaceutical form, well then grey shade it here.

This should anyway be a very simple text – the EDQM route of administration – not a detailed description on how to and how much to administer.

9. SPECIAL WARNING(S), IF NECESSARY

[Indicate any particulars essential for safety or health protection, including any special precautions relating to use and any other warnings.]

<Read the package leaflet before use.> *[Unless already included under section 7 or in case of space limitation.]*

[For certain veterinary medicinal products e.g. injectables containing mineral oil or live vaccines, the following statement should be included:]

<Accidental injection is dangerous. ~~read package leaflet before use~~>

<Accidental administration> <~~e~~Contact with the mucosa> is dangerous. ~~see package leaflet before use~~>

Be VERY careful in this section. The heading says “SPECIAL” not “ALL”. Normally the SPC and package leaflet cover the warnings, including contraindications. One might assume that a warning ON THE BOX would refer to something one must know when handling the package, not the animal.

The standard warning sentences have been shortened.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

{(Invented) name of veterinary medicinal product <strength> pharmaceutical form <target species>}
{active substance(s)}
[Pharmaceutical form: short terms according to "Standard terms" published by the Council of Europe may be used in case of space limitation, if consistently used in all language versions.
Target species : according to the target species CTL on the EUTCT website
http://eutct.ema.europa.eu/eutct/displayWelcome.do
Target ~~animal~~ species: a clear pictogram of the target ~~animal~~ species might be used to replace mentioning the target species (to be discussed case-by-case)]

- Remember the user friendly EDQM term for the pharmaceutical form – Can be very helpful to reduce labelling and facilitate multilingual packages – saving money☺
- Note the pictogram option☺

4. ROUTE(S) OF ADMINISTRATION

[According to "Standard terms" published by the Council of Europe. See also QRD reference document "Tables of non-standard abbreviations".]

Consider if it is necessary to mention the route of administration. If the pharmaceutical form is a tablet, eye ointment … then the route of administration may be obvious, hence grey shaded here.

Remember the abbreviations IV, SC, IM – Much shorter than the full term – need not be repeated – most countries accept either "IV", or "i.v." and same for the other abbreviations.

The QRDvet annotated template

There are many more options than covered in this short presentation.

Proposed labelling is getting better.

We are getting better.

We are getting more used to the revised template.

Proposed and approved labelling

Primary package - characters: 869

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Primary package - characters: 161 (18.5% of the original text)

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Proposed and approved labelling

Primary package – characters - 746

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Primary package - characters: - 553 (74% of the original text)

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Proposed and approved labelling

Outer package - characters - 965

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Outer package – characters - 389 (40% of the current text)

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Nothing is impossible, the word itself says 'I'm possible'! Audrey Hepburn