EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Packaging and labelling: current & future opportunities

EMA/IFAH-Europe Info Day 2013
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An agency of the European Union

Overview of presentation

- Background to QRD/CMDv PI template v.8
  - Changes and opportunities
- Facilitating multi-lingual packaging
- Future of packaging/labelling requirements

Background to QRD/CMDv template v.8

- Long-term project to harmonise product information template for CP and MR/DCP
  - QRD vet WG held consultation with stakeholders
  - Subsequent consultation with CVMP on more difficult issues
- Final harmonised template adopted in Q3 2012
- Different implementation plans for CP and MRP/DCP
  - Published on EMA and CMDv websites, respectively

Changes & opportunities in QRD/CMDv PI template v.8

- It's all in the brackets! {:-) and grey shading
- Annotated template differentiates between:

  {compulsory text}

  < and text that can be deleted if N/A >
- Boxed template headings should not to be printed
- Annotated template suggests ways to reduce text e.g.
  - 10 x 50 ml (not 'ten vials with 50 ml each')
  - *Special* warnings, not contraindications
  - Disposal advice: choice of long or short text in annotated template

Changes & opportunities in QRD/CMDv PI template v.8

- For the outer and immediate labelling:
  - Indications not mandatory for immunologicals; only for OTC
  - No requirement to state excipients, including adjuvants
  - Target sp. displayed "close to" name, can add pictogram
  - Strength, *if applicable*
    - N/A for many vaccines where 'strength' would lead to entire paragraphs
    - Ongoing issue for products with several a.i. → can lead to confusion
- For small, single-dose containers:
  - Pictograms can replace target species text (case-by-case)
  - Use EDQM standard short terms *i.e. pharmaceutical form*

What is standardised in template v.8 (1/2)

- Target species terminology
  - Use template link to 'telematics controlled terms' (EUTCT) list
- EDQM full and short standard terms
  - for pharmaceutical form, route of administration
- EMA document with accepted terms in EU languages for batch no. & expiry date
- QRD reference doc: tables of non-standard abbrev.
  - e.g. 'GMO' in EU languages

What is standardised in template v.8 (2/2)

- Standard special warnings for some products
  - VMPs with mineral oil or live vaccines
- Subheadings introduced for special warnings in PL

Not so popular…

- Keep out of the sight and reach ~~and sight~~ of children
  - Comes from human side due to results of user testing
  - Pragmatic approach on the timeline for this particular change
  - Does not affect the translated template in all countries

Labelling: what can be done now to facilitate multi-lingual packs? 1/2

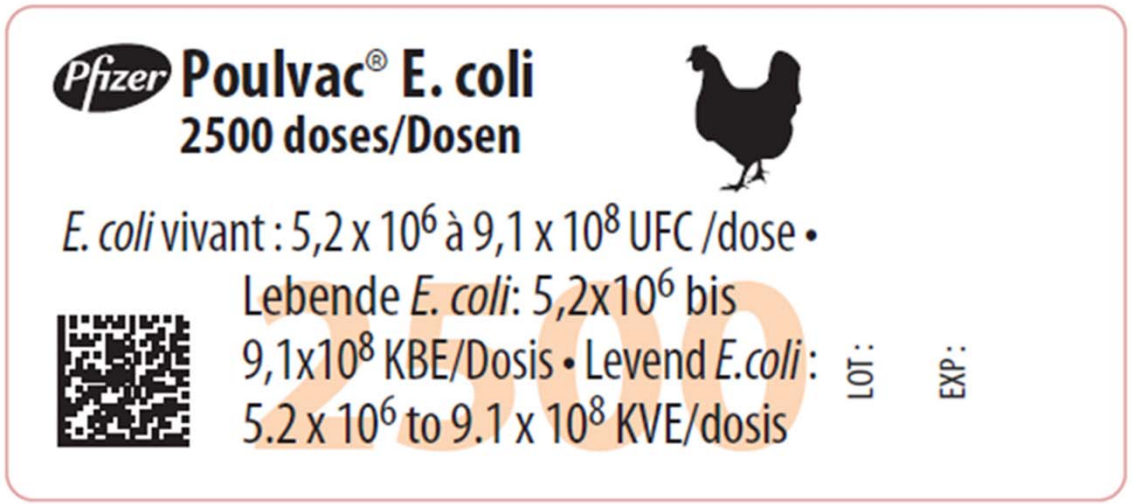
- Plan for multi-lingual packs at initial MAA submission
  - What will be the maximum number of languages?
  - Raise intention early with RMS and CMS so space restrictions discussed during assessment, not in national phase when disharmonisation is then introduced
  - Harmonise standard abbrev. for MSs sharing packaging
  - Advise translators to use as short a translation as possible
- Better understanding from marketing dept. that less is more!

Labelling: what can be done now to facilitate multi-lingual packs? 2/2

Example immediate label of CAP from 2012

43 mm

19 mm

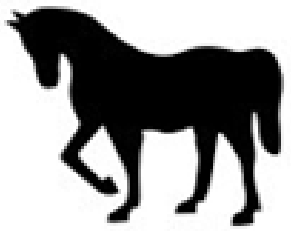


With thanks to Sally John, Zoetis

Future packaging & labelling requirements

- Review of vet legislation = opportunity to simplify
- CMDv/stakeholder initiative sent resulting proposals from two workshops for EU Commission review
  - Much common ground
    - Role of immediate & outer label → move onus onto reading leaflet
    - Increased use of pictograms & abbrev. → standardised library?
  - Some remaining areas of disagreement
    - How to convey 'For animal treatment only' with a pictogram
    - Details of local representative
    - Requirement for withdrawal periods on outer label
    - Blue-box (retain vs eliminate)

Dairy cow



Beef cattle

State of play with review of labelling requirements

- Within the context of the vet legislation review…
  - EC's ideas for future labelling & packaging provisions presented to the Standing Committee in September 2012
  - The drafting continues with clear goal of simplifying and reducing labelling & packaging requirements to remove obstacles to the availability of VMPs across the EEA

Points identified for further discussion this year

- Blue-box requirements
  - Discrepancies between requirements for CP and MR/DCP
  - MR/DCP blue-box requirements now transferred to CMDv website
  - Industry would prefer to eliminate blue-box altogether
  - Regulators constrained by national laws to maintain it
  - As interim measure, both CMDv and industry support to present CP and MR/DCP blue-box requirements **in one single GL**
- Single product name in MR/DCP (checking proc.)
- QR codes: Need to establish main principles in order to develop harmonised EU policy

Conclusions

To simplify labelling, focus on:

- Traceability & identification, safe and efficacious use of product
- Product differentiation (marketing) can lead to proposing more text than required ⇒ obstacle to multi-lingual packs
- Need to break down cost barrier of labelling for smaller markets
- Need to develop the possibilities of new QRD template

THANK YOU

Correct terminology…

Definition of equidae*: "horses, donkeys, including Asian wild asses, **zebras and their crossings**"

* From EU webpage on the EU trade and import of equines (Dir. 90/426/EEC)