FDA/IMSN Summit on Labeling & Packaging June 19 and 20, 2018

- Goals of the meeting:
  - to create a minimum set of best practices for labelling and packaging aimed at reducing medication errors.
  - to promote the use of technologies to reduce medication errors

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- Participants agreed that guidelines are needed regarding the presentation of critical label information to deal with look-alike labels, noting that logos and highly stylized graphics detract from readability of the label.
- They also suggested review of existing guidelines and consideration of the following best practices related to drug labelling and packaging.

Best Practice 1

- Include both the per mL and the per container quantity, not the per mL quantity alone, when presenting the concentration for injectables.

EMA feedback: this is already reflected in our 'expression of strength policy document' (https://www.ema.europa.eu/documents/regulatory-procedural-guideline/quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf)

Best Practice 2

- Use metric units for products, and eliminate ratio expressions.

EMA feedback: this is already reflected in our 'expression of strength policy document' (https://www.ema.europa.eu/documents/regulatory-procedural-guideline/quality-review-documents-recommendations-expression-strength-name-centrally-authorised-human_en.pdf)

Best Practice 3

- Eliminate potentially error-prone abbreviations and dose designations on labels, such as U for units, IU for international units, or trailing zeros (e.g., 1.0) to express strength.

EMA feedback: In the European context with multilingual/multi-country packs and the associated space constraints, it is rather difficult to ban completely abbreviations. We have to balance between availability of the medicine and potential risk of medication errors. Therefore, we consider each labelling proposal involving, e.g. IU, on a case by case basis. We have also issued a table with preferences per Member State for this particular abbreviation. (https://www.ema.europa.eu/documents/other/acceptability-iu-abbreviation-international-units-strength-human-medicinal-products_en.pdf).

However, the policy to avoid trailing zeros is already reflected in our SmPC (your Prescribing Information) guideline (page 3): (https://ec.europa.eu/health//sites/health/files/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf)

Best Practice 4

- Prominently display cautionary statements on carton and immediate container labels of neuromuscular blockers, potassium chloride concentrate injection, methotrexate, and other selected error-prone medications.

EMA feedback: The inclusion of special warnings is reflected in the guidance of our so called 'QRD product information template' (the instrument that provides the skeleton of standard headings, statements etc.) where under Section 7 [OTHER SPECIAL WARNINGS, IF NECESSARY] of the Outer Packaging, it states 'Special warnings on labelling should be reserved to cases where they are considered very important in order to fulfil a risk minimisation objective (e.g. "Cytotoxic: Handle with caution", "May cause birth defects", etc.' (https://www.ema.europa.eu/documents/template-form/qrd-product-information-annotated-template-english-version-10_en.pdf)

Then it is up to our packaging reviewers to evaluate the best way of display/design of such warning. In the specific case of Methotrexate our scientific committee (PRAC) is currently evaluating all possible measures to be taken to mitigate the occurrence of medications errors, we discussed in Washington.

Jylamvo (the 1st centrally authorized methotrexate product with both indications) reflects clearly this principle; this particular label was part of my presentation in Washington.

Best Practice 5

- Use contrasting label backgrounds for the printing on glass ampules, and recommend font size and label orientation, to improve readability.

EMA feedback: This aspect is being routinely taken care during the standard mockups and specimens check by our internal packaging specialist reviewers.

Best Practice 6

- Physically link or integrate diluents with drugs that are powders.

EMA feedback: This out of the scope of EMA's regulatory remit.

Best Practice 7

- Increase the adoption of ready-to-use/ready-to-administer syringes, premixed IV solutions, unit-dose packaging, and other more efficient, safer packaging, while considering the overall cost of implementation.

EMA feedback: This action could potentially be reflected as a guidance at the level of development that we could consider. It is something we need to investigate further internally how it can be taken forward. It is currently not possible to refuse authorization on these grounds.

Best Practice 8

- Develop product-specific world safety standards; for example, standard packaging for non-oncologic methotrexate to prevent accidental daily use and overdoses.

EMA feedback: See reply above. It is part of the ongoing referral procedure for Methotrexate containing products. (https://www.ema.europa.eu/medicines/human/referrals/methotrexate-containing-medicinal-products).

Best Practice 9

- Include barcodes on packages so they can be scanned at the bedside or other locations where medications are dispensed or administered by healthcare providers.

EMA feedback: This out of the scope of EMA's regulatory remit. It is in the national responsibility of each EU Member State to implement in their health care system.