EGGVP position on Mock-ups

Today, the regulatory process for the approval of product packaging largely differs in the different EU Member States (MS), in particular when it concerns to mock-ups.
The different approaches range from some MS requiring an approval of the mock-ups prior to the marketing of the product to other MS in which the submission and/or approval of mock-ups is not requested as a pre-condition for granting a marketing authorization (MA).

EGGVP is concerned by the first type of procedures, in which MS operate an extensive checking of the mock-ups before the product is launched. Experience shows that this is the cause of **major administrative burden and delays in authorisation procedures**.
Furthermore, the value of submitting mock-ups as a pre-condition for the granting of the MA has many times been put into question. The fact that the competent authority is reviewing the mock-ups prior to product launch does not give full guarantees of the company's liability for compliance.

EGGVP's position on this subject is fully aligned with the "Revised Checking Process of Mock-Ups and Specimens of outer/immediate labelling and package leaflets in the Centralised Procedure for Veterinary Medicinal Products" (EMA/14522/2007-Rev.1), which endorses the following principles:

- It is the **responsibility of the marketing authorisation holder** to ensure that the approved labelling is appropriately reflected on the mock-ups and that the design ensures legibility, in line with the relevant EU and national legislation. This means that the applicant is responsible to ensure that their packaging is correct from the outset and does not need to seek confirmation from the competent authority and that their mock-ups are acceptable.
- There should be **no requirement to submit mock-ups systematically** to the National Competent Authorities (NCAs), which would not routinely perform checks of mock-ups but could instead request **random post-authorisation checks**, taking into account a risk-based approach.

This procedure would ensure that all mock-ups may be checked, rather than only those specifically submitted for checking.

Moreover, in order to reduce the administrative burden linked to mock-ups, harmonize the existing procedures in the different MS and avoid unnecessary delays in the granting of the marketing authorization, EGGVP urges all NCAs to adopt pragmatic approaches by:

- Abolishing any specific national ("blue box") requirements
- Adopting paperless procedures ("e-procedures") only
- Enhancing cooperation with other MS in cases of multilingual labels, and establishing a procedural calendar for comments for all MS involved
- Promote the use and adherence to current issue of the QRD template among regulators and industry
- Allow the use of pictograms for use in immediate label, outer package and leaflet in replacement of text (after assessment and approval from competent authorities). The use of pictograms is a valuable tool for multilingual labels, and therefore increases the availability of veterinary medicines in the MS