HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Joint-labelling for Veterinary Medicinal Products for use in Ireland and the UK

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

1 ELIGIBLE MARKETING AUTHORISATIONS AND CRITERIA

Joint-labelling allows for a single label/leaflet to be used on veterinary medicinal products marketed in both Ireland (IE) and the United Kingdom (UK).

Joint-labelling can be used between IE and Great Britain (GB), IE and UK Northern Ireland (NI), or all three – IE, GB, and UK (NI). The products eligible for joint labelling must:

- hold existing marketing authorisations (MAs) in both IE and the UK, or part of,
- be held by the same marketing authorisation holder (MAH), or MAHs belonging to the same parent company, or,
- have an identical summary of product characteristics (SPC) and identical product labelling texts (hereafter referred to as 'product information') in both territories.

Mock-ups in support of any veterinary medicinal product application type are not routinely required for assessment by the Health Products Regulatory Authority (HPRA) and consequently, a formal application for joint labelling is not necessary (either at the end of a new MA procedure or retrospectively for existing MAs). This applies irrespective of whether the mock-ups / joint labelling application is required by the UK's Veterinary Medicines Directorate (VMD). Instead, where the eligibility criteria, as listed above, are met applicants can prepare mock-ups ensuring that:

- The mock-ups accurately reflect the agreed Quality Review of Documents (QRD) texts and national requirements (all IE national-specific information should be identified as 'IE only').
- The font size used is appropriate and that all elements of the mock-ups are legible.
- The mock-ups comply to the HPRA 'Guide to Preparation of Mock-ups for Veterinary Medicinal Products' available on the HPRA website.

Applicants are advised to also consult the VMD's guidance on joint-labelling for veterinary medicines for use in the UK and IE available on the UK Government website at www.gov.uk.

A MAH may, on a voluntary basis, submit a G.I.15z VRA, for review and approval of mock-ups and where a joint label with the UK is intended, the procedure as outlined under section 2 of this guide will apply.

2 JOINT-LABELLING PROCEDURE

For mutually recognised or nationally authorised products for which formal review of mock-ups is requested, applicants are required to submit simultaneously a G.I.15.z VRA to the HPRA and the VMD. The application should make it clear that the purpose of the variation is to obtain a joint label for a mutually recognised or nationally authorised product. The application should include both the currently authorised QRD text/mock-ups in IE and the UK, along with the proposed QRD text and joint mock-ups.

Upon receipt of the application, the HPRA and VMD will decide who will take the lead. The lead country draws up the timetable and emails it to the applicant and the other country. The following is an outline of the timelines associated with the application.

- Day 0 – Timetable begins.
- Day 11 – The lead country sends their comments to the other country using the agreed pro forma.
- Day 17 – The other country adds their comments to the pro forma and sends it back to the lead country.
- Day 20 – The lead country sends the consolidated list of comments to the applicant, copied to the other country and requests revised mock-ups, if needed. These should be submitted to both countries. The clock stops and enters the company response period.
- Company Response (within 20 days) – The pro forma and revised mock-ups should be returned to both countries indicating agreement or disagreement with the comments. The procedure restarts with the lead country issuing a timetable.

If there are no comments, or the mock-ups can be approved with minor annotations, the application goes into the national phase for final approval.

3 MAINTAINING A JOINT-LABEL

Following a regulatory procedure that changes the product information of a joint-labelled product, it will be assumed that existing joint-labelling status is to remain unchanged if both IE and UK (NI) are involved. The HPRA does not require assessment of mock-ups following a post-authorisation regulatory procedure, unless specifically requested by the MAH and in which case requires the submission of a G.I.15z variation with appropriate fee.

4 HOW TO 'UNDO' A JOINT-LABEL

If you no longer wish to have a joint-label, please send an email to the HPRA and VMD and we will update our records. A variation to review the resultant revisions to the mock-ups will not be requested by the HPRA.

5 CONTACT US

All joint-labelling queries should be sent via email to vetcoordination@hpra.ie.