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 that has been agreed by the Health Products Regulatory Authority (HPRA), on behalf of Ireland, and the Veterinary Medicines Directorate (VMD), on behalf of the UK, to be used on veterinary medicinal products marketed in their countries.

Joint labelling can be achieved between GB and IE, UK (NI) and IE, or all three - GB, IE and UK (NI). With reference to Question 6.3 of the 'Notice to Stakeholders - Withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products', multi-country packs with the UK market are only possible if the product information is exactly the same in the United Kingdom as in the EU and the Member State has allowed additional administrative information labelled in the 'blue box'. This guidance document should be read alongside the HPRA 'Guide to Product Literature Standard for Veterinary Medicinal Products' (available on the HPRA website) which lists both general labelling requirements along with the advice on how the additional administrative information as referenced above can be captured on mock-ups.

The products involved in the joint-labelling process must:
- hold existing Marketing Authorisations (MAs) in both Ireland and the UK, or part of, or
- be the subject of new national or EU procedure MA applications submitted to both the VMD and the HPRA at the same time,
- be held by the same Marketing Authorisation Holder (MAHs), or MAHs belonging to the same parent company, or
- have product information which is exactly the same.

An application for joint-labelling can be made either at the end of a new MA procedure or retrospectively for existing MAs, whether authorised by EU or national procedures. To obtain joint-labelling, the Summary of Product Characteristics (SPC) and product labelling texts (hereafter referred to as 'product information') must be identical in the relevant territories. This can be achieved, for existing MAs, by applying for a harmonisation variation in both countries. To maintain joint labelling the product information must remain harmonised.

Applicants are advised to also consult the VMD's guidance on joint-labelling for veterinary medicines for use in the UK and Ireland (https://www.gov.uk/guidance).

Whilst 'dual labels' between the IE and the UK are permissible, the mock-ups are assessed independently by the respective competent authorities. The responsibility of maintaining a harmonised dual label/leaflet lies completely with the applicant.

2 ACHIEVING JOINT-LABELLING FOLLOWING A NEW MA PROCEDURE

For new MRP or DCP applications involving both IE and UK (NI), mock-ups should be submitted within 30 days of the end of the procedure simultaneously to the HPRA and the VMD and should clearly identify a request for the joint-labelling procedure.

For new MA applications submitted in parallel to GB and the EU, or for national MA applications submitted to the UK (or part of) and IE, joint-labelling may be requested as part of these applications. However, no assurances can be made that IE will arrive at the same conclusion as the UK based on the respective assessments of the data provided in support of the application. In such instances joint-labelling will not be possible but mock-ups may still be assessed on a national-only basis. Refer to the assessment timetables below for more information on the procedure once the application has been validated.

3 JOINT-LABELLING VARIATION

A variation application for joint labelling can be made retrospectively for existing MAs, irrespective of whether the MA has been granted by way of an EU or a national procedure. The variation application should include a clear, concise description of the variation under 'scope of change'.

3.1 Mutually recognised MAs

For mutually recognised products, a joint-labelling variation should be submitted simultaneously to the VMD and HPRA. The application should make it clear that the purpose of the variation is to obtain a joint-label for a mutually recognised product.

Applicants are requested to submit a 'Type IB Category C.II.6 (b)' variation in Ireland and a 'Type IB Category C.1.z' variation in the UK, which includes both the currently authorised mock-ups in the UK and Ireland along with the proposed joint mock-ups. Refer to the assessment timetables below for more information on the procedure once the application has been validated.

3.2 Nationally authorised MAs

To obtain joint-labelling for existing nationally authorised products, the product information must be identical in both the UK and IE. This can be achieved by applying for a harmonisation variation in both countries. The harmonisation variation is not intended to update product information texts, but to simply harmonise them. If any changes to parts of the product information require data to be assessed to bring them into line in the two countries, then this must be dealt with by means of a separate variation to the relevant authority prior to submission of the harmonisation variation.

Applicants are requested to submit a 'Type IB Category C.1.z' variation in both the UK and Ireland which includes both the currently authorised SPC in the UK and Ireland along with the proposed joint SPC. Revised labelling QRD texts should additionally be presented. Mock-ups are not required at this stage and will be requested once the joint SPC has been agreed. Refer to the assessment timetables below for more information on the procedure once the application has been validated.

4 MAINTAINING JOINT-LABELLING

4.1 Mutually recognised MAs

Following a regulatory procedure that changes the product information of a mutually recognised product, it will be assumed that the joint-labelling status is to remain unchanged if both UK (NI) and Ireland are involved. If not, this should be made clear when submitting the mock-ups.

4.2 Nationally authorised MAs

Any future applications that affect the product information should be submitted to the HPRA and VMD simultaneously. The application should clearly highlight that the product is joint-labelled. Normal application timescales may be suspended during these applications to allow the agencies to liaise with each other.

5 ASSESSMENT TIMETABLES

5.1 Following the end of a new MRP or DCP in UK (NI) and IE

The HPRA requests the submission of mock-ups within 30 days of the procedure ending. 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.

- 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 where each country issues the authorisation documentation including the agreed joint-label.

If mock-ups are not submitted on time or the revised mock-ups are still incorrect, the MA will be issued with a condition that a variation must be submitted to approve mock-ups (Type IB - C.II.6 (b)) prior to placing the product on the market for sale and supply.

5.2 Following the end of a new national procedure in GB and/or UK (NI) and IE OR following the end of a new GB national procedure submitted in parallel to an EU procedure OR joint-labelling variation

The product information texts as agreed as part of the counter procedure should be presented to the respective agencies. If the product information is not the same, then during an initial 20 days, the VMD and HPRA will consider the differences and whether alignment of the text can be reached. Where product information texts have been agreed in IE by way of an EU procedure, no changes will be permissible to the agreed EU texts. If alignment is not possible, labelling review of IE-only labelling may continue or the existing procedure may be closed without approved packaging.

If/once the QRD text is aligned, you must provide mock-ups for assessment. The VMD and HPRA will decide who will take the lead. The lead country draws up the timetable and emails it to the applicant and the other country.

- 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.

5.3 Centrally authorised products

Mock-ups for Centrally Authorised Products (CAPs) submitted to IE, UK (NI) are not assessed by national competent authorities and no variation is required to introduce changes to the blue box. However, they must reflect the agreed product information texts and observe 'blue box' requirements (the blue-box facilitates inclusion of administrative country-specific information on the mock-ups).

6 HOW TO 'UNDO' A JOINT-LABEL

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

7 CONTACT US

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