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

AUT-G0162-2
14 FEBRUARY 2022
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 IE and GB, IE and UK (NI), or all three – IE, GB, and UK (NI). This guidance document should be read alongside the HPRA 'Guide to Product Literature Standard for Veterinary Medicinal Products' (available on the HPRA website).

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 HPRA and the VMD 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. 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 IE and the UK are permissible without a formal joint-labelling procedure, in these situations the product information is assessed independently by the respective competent authorities. The responsibility of maintaining a 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 the EU and GB, or for national MA applications submitted to IE and the UK (or part of), joint-labelling may be requested as part of these applications. However, no assurances can be made that IE and the UK will arrive at the same conclusion on the assessment of the data provided in support of the application and product information approved may not be identical in the relevant territories. In such instances, joint-labelling will not be possible. Refer to the assessment timetables in section 5 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 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 product.

Applicants are requested to submit a G.I.15 variation in IE and the corresponding variation in the UK, which includes both the currently authorised QRD text/mock-ups in IE and the UK, along with the proposed QRD text and joint mock-ups. Refer to the assessment timetables in section 5 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 IE and the UK. 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 variation to the relevant authority prior to submission.

Applicants are requested to submit a G.I.z (Variation Requiring Assessment with reduced timetable) in IE and the corresponding variation in the UK which includes both the currently authorised SPC in IE and the UK 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 in section 5 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 existing joint-labelling status is to remain unchanged if both IE and UK (NI) are involved. Where the regulatory procedure does not impact on the layout or design of the labelling and package leaflet, then no mock-ups are required to accompany the submission to the HPRA. The procedure will be closed out on the basis of the revised QRD text. This applies irrespective of whether or not the mock-ups are required by the UK. If there are any subsequent amendments to layout or design following review by the UK, the mock-ups should be submitted to the HPRA via a G.I.15 variation for review.

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. As for the case with mutually recognised MAs (see section 4.1 above), mock-ups of the labelling and package leaflet are not routinely required by the HPRA unless the design or readability is affected. The procedure will be closed out on the basis of the revised QRD text. This applies irrespective of whether or not the mock-ups are required by the UK. If there are any subsequent amendments to layout or design following review by the UK, the mock-ups should be submitted to the HPRA via a G.I.15 variation for review.

5 ASSESSMENT TIMETABLES

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

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 procedure will be closed in the absence of mock-ups and the applicant will be requested to submit a G.I.15 variation in IE to facilitate the joint-labelling procedure prior to marketing the product.

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

The product information texts as agreed within both procedures should be presented to both agencies. If the product information is not the same, then during an initial 20 days, the HPRA and VMD 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 mock-ups if it is not the intention of the applicant to market the product immediately.

If/once the QRD text is aligned, you must provide mock-ups for assessment. 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.

5.3 Centrally authorised products

Mock-ups for centrally authorised products (CAPs) submitted to IE, UK (NI) are not assessed by national competent authorities.

6 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.

7 CONTACT US

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