Joint-labelling of product literature between the UK and Ireland for Nationally Authorised & Mutually Recognised Veterinary Products: Guidance for the Pharmaceutical Industry

Produced by the VMD & HPRA

Revised 9th January 2015

This document replaces the previously published clarification papers on
'The harmonisation of SPCs and product literature (for nationally authorised products) between the UK and IE'
and
'Co-ordinating the joint assessment of product literature by the UK and IE for veterinary products authorised through mutual recognition and decentralised procedures'

UK Ref: VMD/L4/Authorisations/027/C - #584503

INDEX

ANNEXES:

INTRODUCTION

1. To obtain an authorised joint-label for use in the UK and Ireland (IE) you should follow the steps set out below.

2. You are still permitted to use "unofficial" dual labelling but, unless the product literature has been formally joint-labelled in accordance with the procedure set out in this document, the UK and IE will not help you maintain the harmonised nature of the labels / leaflets, and co-ordination of changes to the labels / leaflets remain your responsibility.

3. There are two ways to obtain joint-labelling. For mutually recognised[1] products, this may be achieved at the end of a new application procedure, or via a separate 'joint-labelling' variation later on. For nationally authorised products, this may only be achieved via a 'harmonisation' variation.

OBTAINING JOINT-LABELLING AT THE END OF A NEW MRP OR DCP

4. The UK and IE will assume that you require joint-labelling unless you say otherwise when submitting mock-ups to us.

5. If joint labelling is required, the UK and IE will liaise to decide which country will lead on the joint labelling procedure; if either country has acted as RMS it will be assumed that they will take the lead. If both countries were a CMS a decision will be made when the mock-ups are submitted and you will be informed which country will lead on the assessment.

6. You should submit mock-ups to both the UK and IE within 20 - 30[2] days of the end of the procedure. An extension of 60 days may be granted, but it is your responsibility to request an extension. If not submitted within 20 - 30 days, and no extension is requested, co-ordination of the assessment of mock-ups will not be carried out and timelines detailed for this procedure will not apply.

7. If mock-ups are not submitted on time, the MA will be automatically issued with a condition that you submit a variation to approve mock-ups prior to placing the product on the market for sale and supply.

8. Following completion of a joint-labelling procedure, the product will be considered joint-labelled.

[1] Authorised via MRP or DCP

[2] In the UK mock-ups should be submitted within 20 days, but in Ireland applicants have 30 days to provide mock-ups; therefore, you should aim for 20 days, but ensure mock-ups are submitted to both countries within a maximum of 30 days.

OBTAINING JOINT-LABELLING FOR MUTUALLY RECOGNISED PRODUCTS AS A STAND-ALONE PROCEDURE

9. Once a new MRP or DCP application has been completed without joint-labelled mock-ups you may apply for joint-labelling at a later date by submitting a joint-labelling variation (refer to Annex 2). The application package should include a copy of the mock-ups currently authorised in both countries. If the MA has been issued in the absence of mock-ups, a copy of the agreed QRD text should be provided.

10. A joint-labelling variation should be submitted as an unforeseen Type IB variation (category C.1.z) in the UK and as a Type IB variation (category C.II.6.b) in IE. **You should make it clear in your covering email / letter that the purpose of the variation is to obtain joint-labelling for a mutually recognised product**. The joint-labelling variation procedure is outlined in Annex 2.

11. Following completion of a joint-labelling variation, the product will be considered joint-labelled.

OBTAINING JOINT-LABELLING FOR NATIONALLY AUTHORISED PRODUCTS

12. To obtain a joint-label for a nationally authorised product, you should submit a harmonisation variation to the UK and IE.

13. For nationally authorised products the harmonisation variation will involve harmonising the SPCs[3] of the products as well as the product literature, so the first round of discussions will concern the SPC only. The harmonised wording of the SPC will be agreed using the most conservative view. Once a joint-SPC has been agreed, the mock-ups will be discussed.

14. The harmonisation variation is not intended to update SPCs and / or product literature, but to simply harmonise them, so if any changes to parts of the SPC 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. If it is found during the assessment phase that such changes have been proposed, the harmonisation variation will be refused and you will be required to resubmit it once the appropriate variation to make the necessary changes has been submitted and assessed.

15. A harmonisation variation should be submitted as an unforeseen Type IB variation (category C.1.z) in the UK and Type IB variation (category C.I.z) in IE. **You should make it clear in your covering email / letter that the purpose of the variation is to obtain harmonisation for a nationally authorised product**. The harmonisation variation procedure is outlined in Annex 3.

[3] For mutually recognised products the SPC would already have been harmonised as part of the application procedure to obtain an authorisation.

16. The application package should include a copy of the SPCs currently authorised in the UK and IE, and a proposed joint-SPC with a copy of the mock-ups currently authorised in both countries.

17. The date of renewal (if applicable) should be agreed between the UK and IE at the end of the harmonisation variation. This will ensure that the renewal is submitted in both countries simultaneously, and is progressed at the same time in each country, which will help maintain the joint-labelled status of the product.

18. Following completion of a harmonisation variation, the product will be considered joint-labelled. The term 'harmonised' is no longer used.

MAINTENANCE OF JOINT-LABELLED PRODUCTS

19. The procedure for maintaining the joint-label of a mutually recognised product, i.e. following an EU renewal or variation procedure, will be the same as the one used for obtaining a joint-label. Following completion of a variation or renewal, that results in changes to the mock-ups, a joint-labelling procedure will be instigated (refer to the joint-labelling procedure as outlined in Annex 1).

20. The procedure for maintaining the joint-label (& SPC) of a nationally authorised product is as follows: Once joint-labelling has been achieved, the UK and IE will communicate during any future variation and renewal procedures about any proposed changes to the SPC and / or mock-ups to ensure the continued joint-labelled status of the product[4]; this may mean suspending normal timescales to achieve this (refer to maintenance procedure outlined in Annexes 4a and 4b). You should ensure that you submit any future applications to the UK and IE at the same time with the joint-labelled status of the product clearly stated in the covering letter / email. **It is strongly recommended that applications on joint-labelled, nationally authorised products are submitted using the worksharing procedure, particularly if the application is a type II variation or complex grouped variation. In these cases, the procedure outlined in Annex 4a will not apply as communication will happen automatically as part of the worksharing procedure.**

21. In the **UK** if you consider that a change to the package leaflet / labelling concerns only IE-specific information within the boxed area, e.g. legal category, distributor, etc, the final Irish approved mock-ups must also be submitted to the VMD for information; no fee necessary. This will ensure the VMD has the current packaging that is on the UK market at all times.

22. However, if you consider that a change to the leaflet / labelling concerns only IE specific information within the boxed area, but other changes are also necessary to accommodate the IE specific changes, e.g. reformatting of text,

[4] Questions may be asked in relation to other aspects of the application, but it is only necessary for the countries to communicate and agree questions in relation to SPC and mock-up changes to ensure their continued joint status.

font size, design etc, you should submit a variation to the VMD in parallel to submitting the mock-ups to IE

23. In **IE** if you consider that a change to the package leaflet / labelling concerns only UK-specific information within the boxed area, e.g. legal category, distributor, etc, the final UK approved mock-ups must also be submitted to the HPRA for information; no fee necessary. This will ensure the HPRA has the current packaging that is on the Irish market at all times.

24. However, if you consider that a change to the leaflet / labelling concerns only UK-specific information within the boxed area, but other changes are also necessary to accommodate the UK-specific changes, e.g. reformatting of text, font size, design etc, you should submit mock-ups in parallel to both countries. In IE a Type IB C.II.6.b variation should be submitted.

25. Refer to Annex 4c for further information regarding changes to country-specific information.

SPECIFIC LABELLING REQUIREMENTS

26. Please refer to the Product Literature Standard (PLS), which is available on the VMD and HPRA websites.

FURTHER INFORMATION

27. For further information please contact :

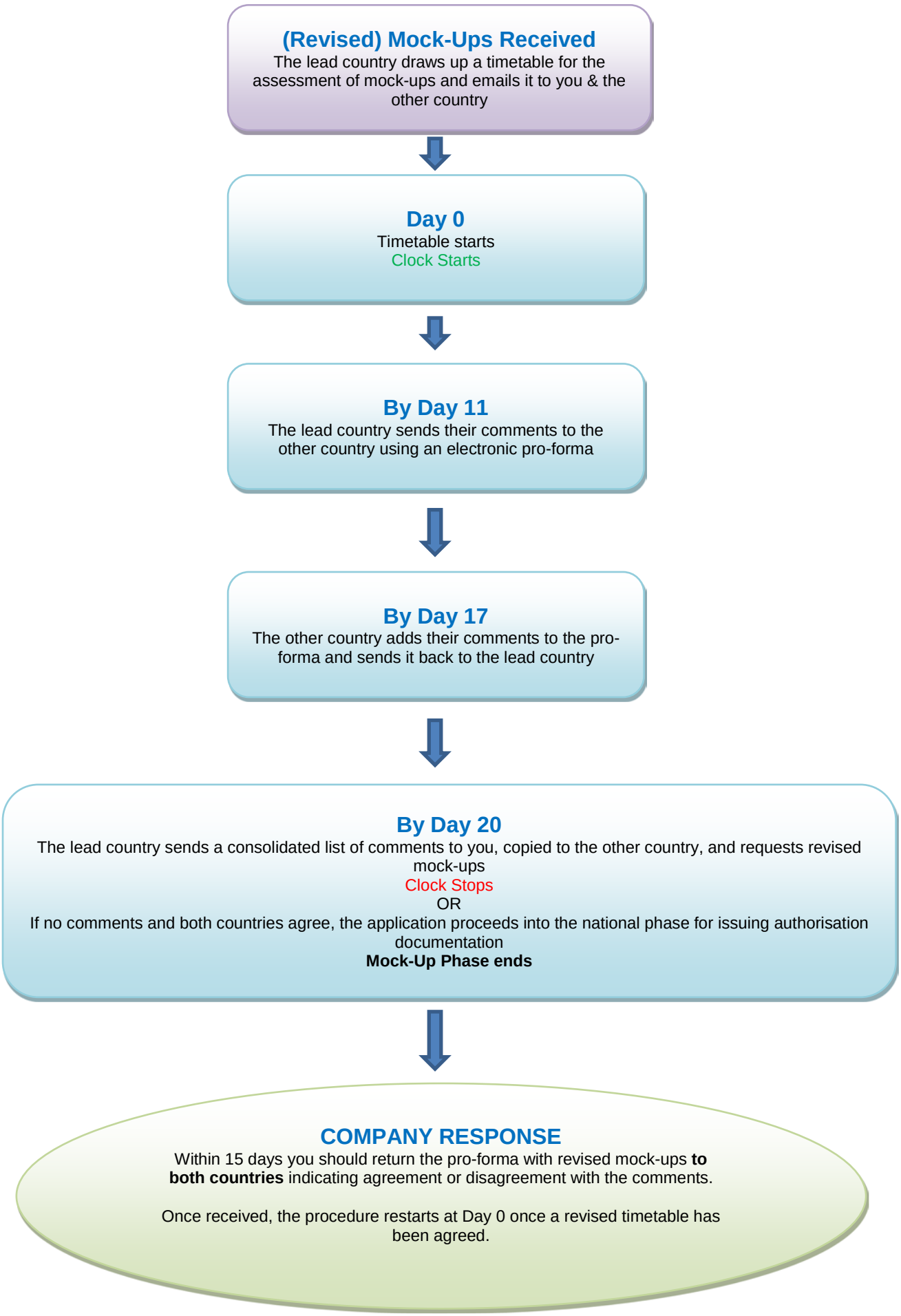
UK

- Obtaining joint-labelling following completion of a new EU procedure: Jo Young at j.young@vmd.defra.gsi.gov.uk
- Maintenance of joint-labelling following completion of an EU or national renewal procedure: Jo Young at j.young@vmd.defra.gsi.gov.uk
- Maintenance of joint-labelling following completion of an EU or national variation procedure: Nicky Sturgess at n.sturgess@vmd.defra.gsi.gov.uk
- Stand-alone joint-labelling / harmonisation variations: Nicky Sturgess at n.sturgess@vmd.defra.gsi.gov.uk

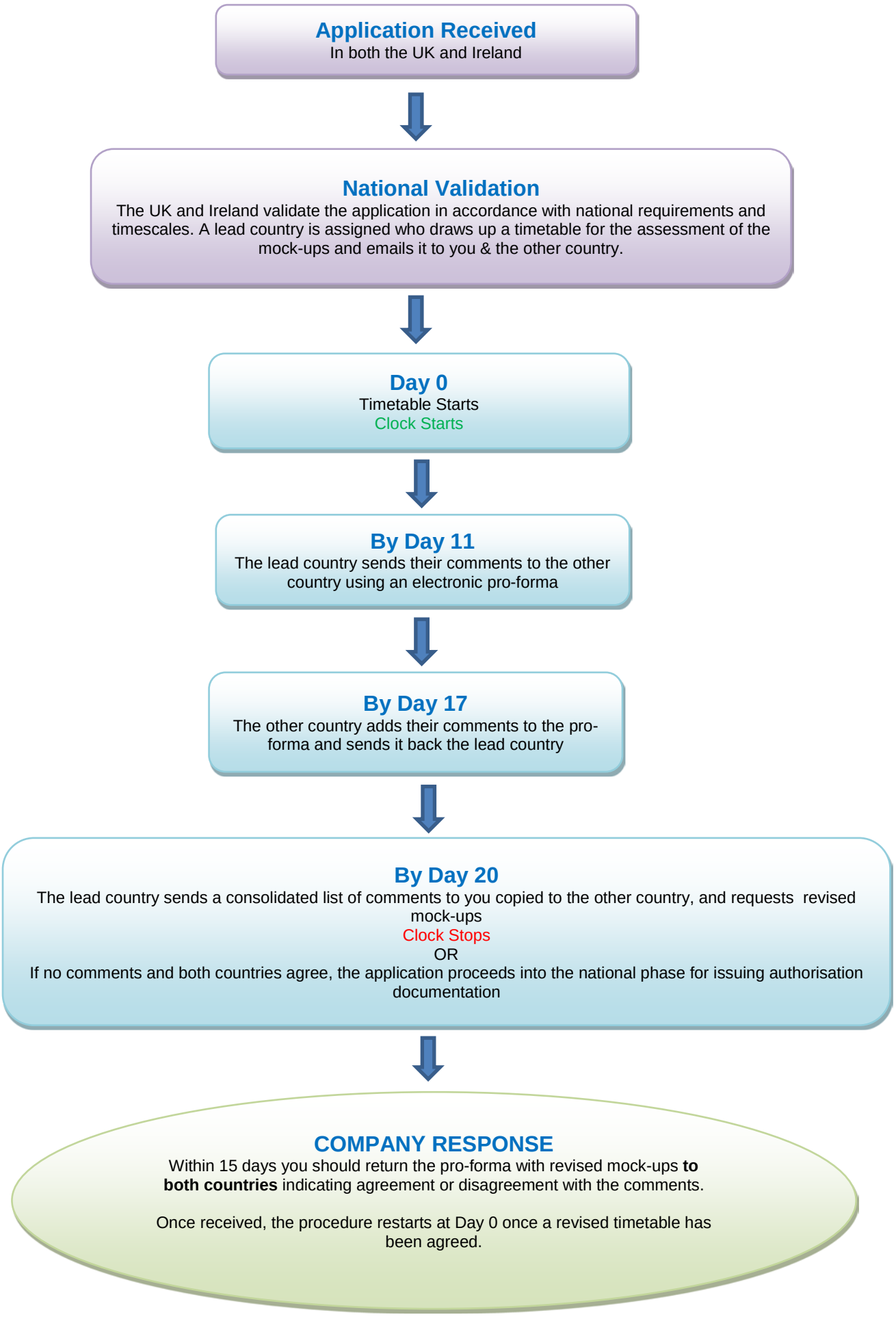
IE

- All joint-labelling queries 01 6764971, or via email at VetCoordination@hpra.ie

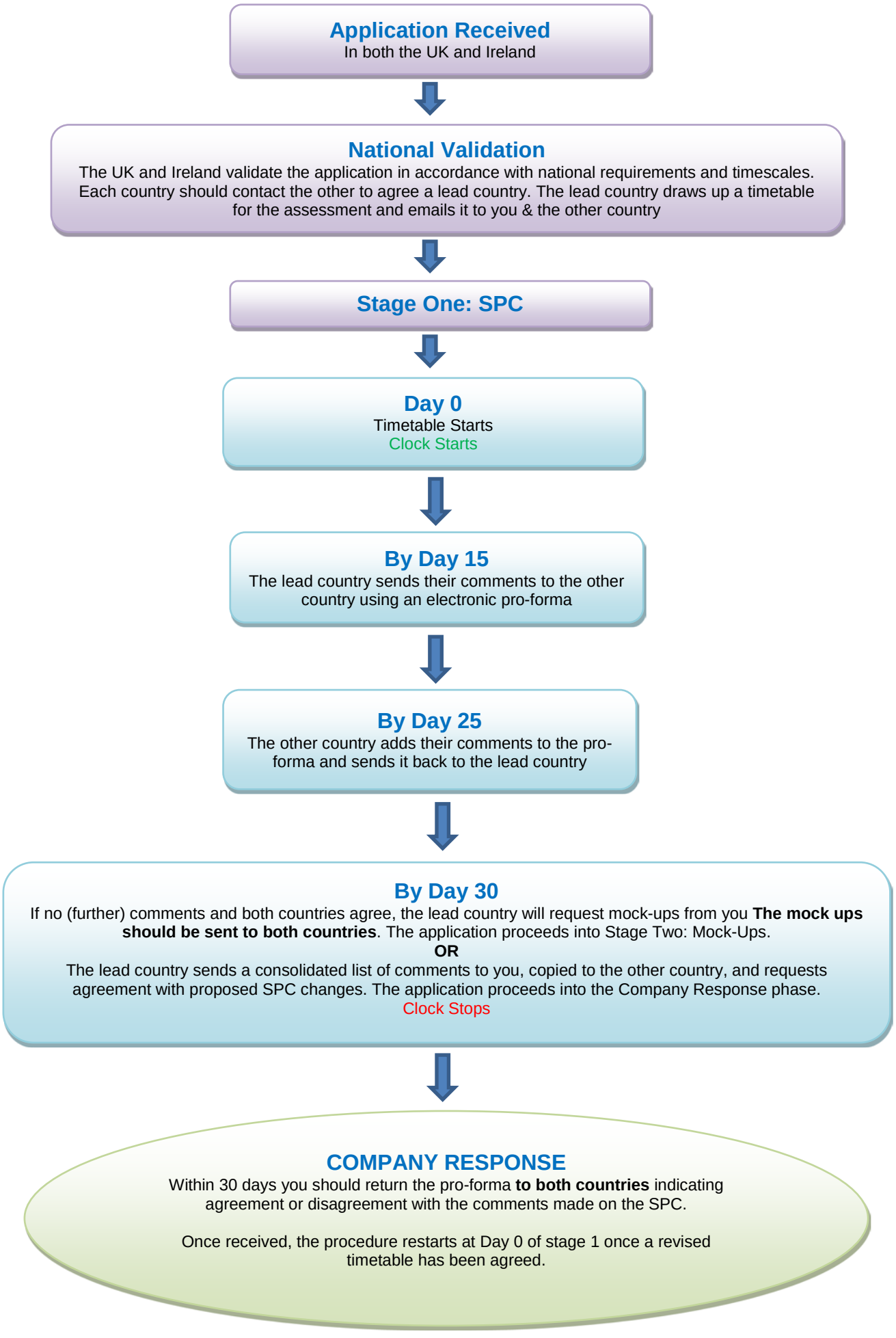
ANNEX 1: JOINT-LABELLING PROCEDURE FOR MUTUALLY RECOGNISED PRODUCTS



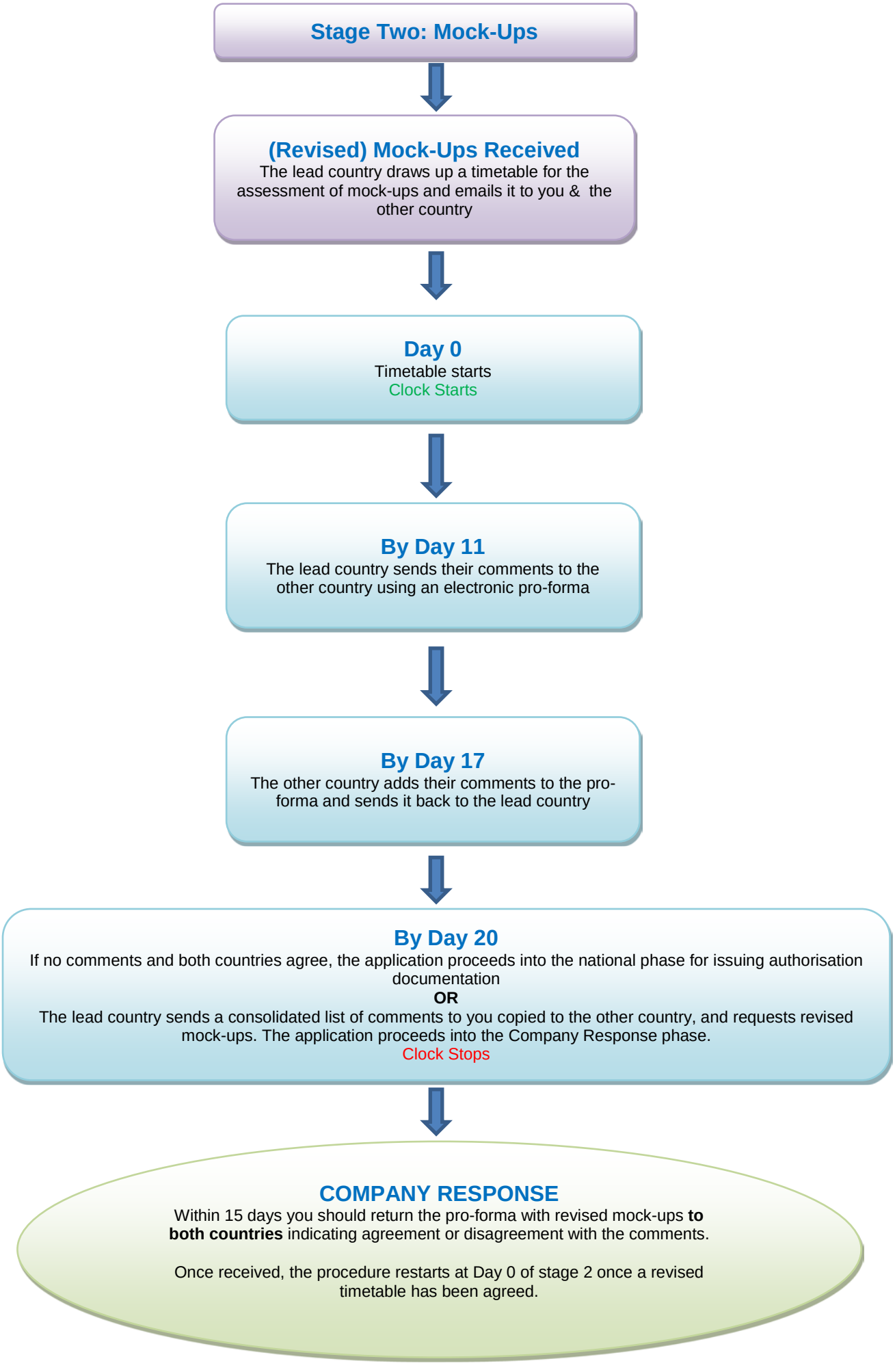
ANNEX 2: JOINT-LABELLING VARIATION FOR MUTUALLY RECOGNISED PRODUCTS



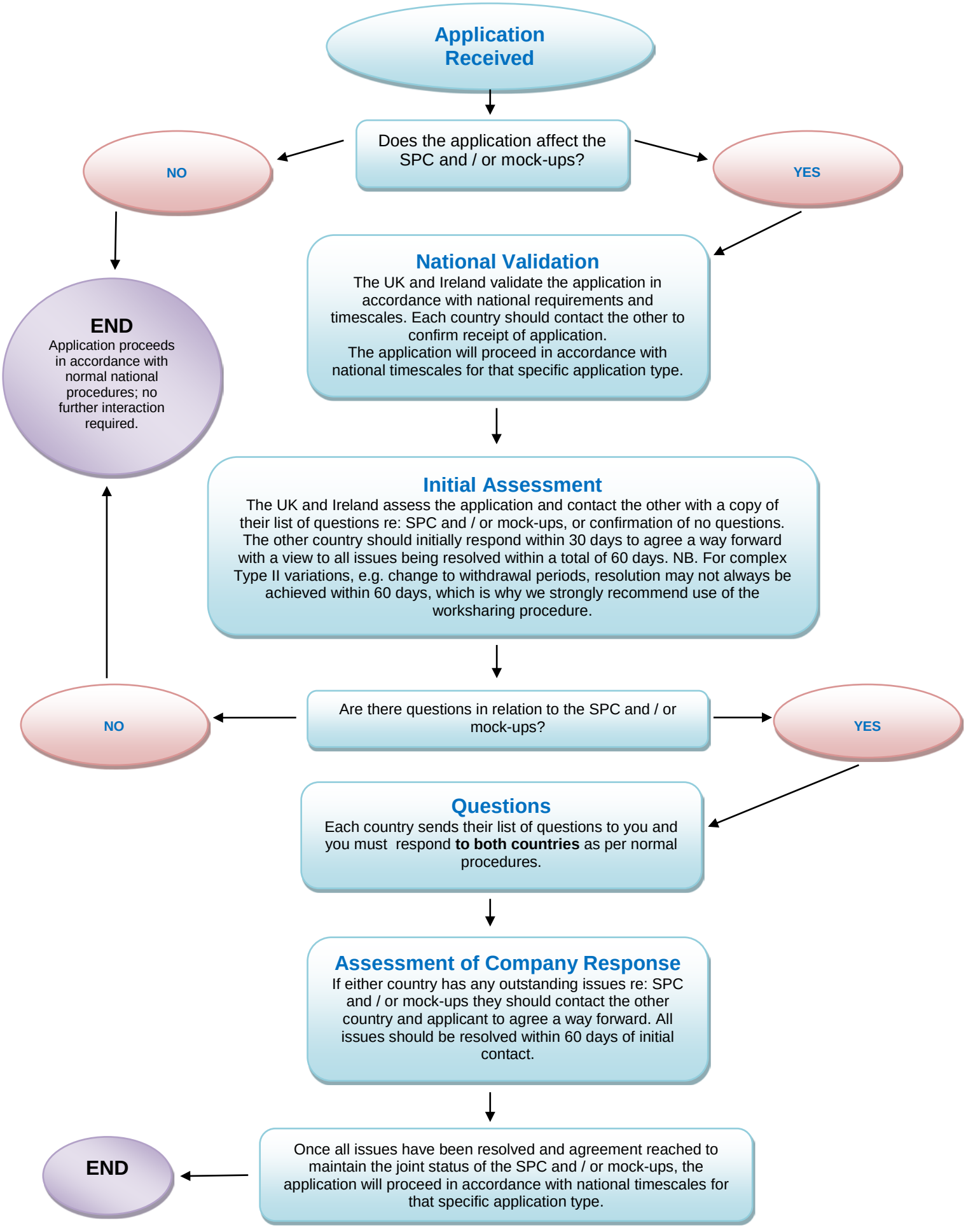
ANNEX 3: HARMONISATION VARIATION FOR NATIONAL PRODUCTS



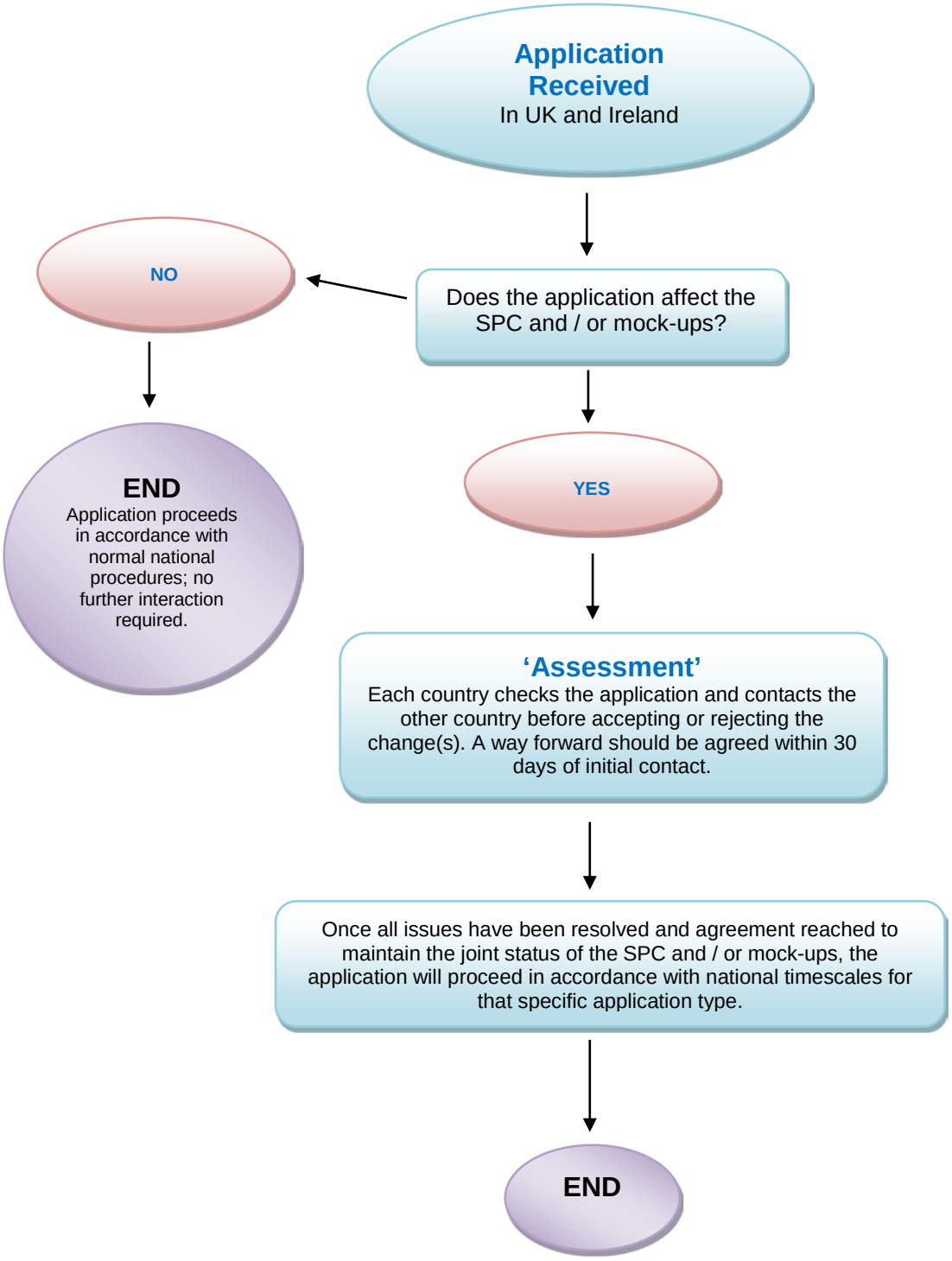
ANNEX 3 CONTINUED: HARMONISATION VARIATION



ANNEX 4A: MAINTAINING JOINT-LABELLING / SPC FOR NATIONAL PRODUCTS – RENEWALS, TYPE IB, TYPE II AND EXTENSION-VARIATIONS



ANNEX 4B: MAINTAINING JOINT-LABELLING / SPC FOR NATIONAL PRODUCTS – TYPE IA VARIATIONS



ANNEX 4c: MAINTAINING JOINT-LABELLING / SPC FOR NATIONAL PRODUCTS – CHANGES TO COUNTRY-SPECIFIC INFORMATION