Clarification Paper:

Partnership Initiative between the UK, Ireland and Belgium for National application procedures

Produced by the UK, Ireland and Belgium

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(Updated 24th September 2010 to include BE in the initiative)

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BACKGROUND

1. One component of the new Variation Regulations 1234/2008 is worksharing for the assessment of variations dealt with on a national basis, which will have significant implications for the future operation of individual agencies. It is anticipated that this major change to the system of variations will not be implemented before July 2012. In 2008 the UK and Ireland (IE) took the opportunity to develop a national worksharing scheme known as the Partnership Initiative. In 2010 the Belgian (BE) authorities were invited to be included in the scheme, so the Partnership Initiative now involves the UK, IE and BE.

2. MAHs often submit the same national variation applications to a number of countries. Where the supporting data are identical, and the underlying data for the MA are very similar, it should be possible to conduct a single assessment rather than each national authority assessing the data individually. MAHs would benefit from receiving basically the same questions from the involved countries and doing so in a similar timeframe.

3. Agencies have resource constraints, and at times these can be particularly severe in one or two areas of specialism. By being aware of these it should be possible to provide/receive assistance at certain times.

4. In the first 18 months operation of the scheme 47 applications were made under this procedure.

SCOPE

5. From 24th September 2010 the scope will be as follows:

   - UK, Ireland and Belgium
   - Variations which are classified as Type II variations under both the previous classification system and the new classification system introduced by Regulation 1234/2008 (excluding those dealing with national label changes), e.g. variations involving:
     - Addition of a new source of active substance relying upon an active substance master file
     - Addition of non-food species
     - Addition of an indication
     - Change of withdrawal period

6. Further types of applications may also potentially be progressed as partnership applications with the agreement of the relevant countries. For example, if a variation is classified as a Type IB in Ireland, then the assessment of this application could be subject to this procedure under a Type II timetable at the request of the company. The possibility of dealing with national extensions under this scheme also exists but this will need the prior agreement of the involved countries.

7. It is anticipated that the scheme will be further revised on 1 October 2010 when the UK expects to apply the new Variation Regulation to national Marketing Authorisations.

8. In order for an application to be progressed in accordance with the Partnership Initiative at least two out of three countries must be involved in the application procedure. As the UK will oversee the scheme and provide summary data on its operation to all involved countries, it is important the UK is informed of any applications being progressed under the scheme in Belgium and Ireland, but not the UK.

IMPACT ON INDUSTRY

9. The scheme offers a number of advantages to industry; in particular they will receive a single set of questions and a single decision according to the same timescale.

10. When a MAH confirms that they are content for a variation to be included in this partnership exercise it is important that they are also aware of the following points:

- The national fees will be set at the usual level
- The overall timescale from receipt of an application to issue of the variation may be slightly longer than in entirely national procedures, because it is necessary to have a common start date for the applications.
- In accordance with the European system for Type II variations, and the VMD systems for Type II variations, the MAH has only one opportunity to provide a complete and satisfactory response. The Irish and Belgian national system permits several rounds of questions and answers. However, this possibility will **not** exist for partnership variations. (*The VMD has operated their current system for several years and this indicates that this leads to only a very small proportion of variations being refused and the MAH having to re-apply). Similarly experience in the partnership initiative to date is that very small numbers of variations are refused.*

PROCEDURE

Pre-Submission

11. Where an MAH wishes to use this procedure for a Type II variation, if there are significant differences between the SPCs authorised in the involved countries, which they believe might be relevant to the planned variation, they should first contact either the UK (Validator), IE (Planning and Licensing Manager), or BE (Project Manager), who will liaise and reach a quick decision on whether or not the variation can be progressed using this procedure.

Validation

12. The MAH must clearly indicate in the covering letter that they wish the application to be assessed under the Partnership Initiative. The MAH should

indicate in the covering letter if the same application/data are being submitted to the UK, IE and BE. The MAH should also indicate if the original data held by the involved countries and the corresponding SPCs differ in any major regard which would be relevant to the particular variation application. For example, if the posology in the SPCs differ then it may not be possible to perform a joint assessment if a change in withdrawal period is proposed. If there are major differences a decision will be made whether sharing of the assessment work is viable. The applicant should indicate that they are aware of the partnership procedure and are happy for the application to be assessed in line with it.

13. If the cover letter does not include a request for assessment under the Partnership Initiative, but it is subsequently decided that it is appropriate to do so, for example following communication between the applicant and one of the involved countries, the relevant country will immediately inform the other countries of the change in status of the application.

14. The applications will be validated in accordance with the normal national requirements and timetables. As these differ between the three countries, once one country has validated the application the usual clock periods and performance standards will be suspended until the second and/or third country has validated the application.

15. Following receipt of a valid application in all involved countries the relevant administrative personnel will contact each other via a designated mailing list and establish the suitability of the application for the procedure. If deemed suitable for the partnership procedure a lead country will be assigned and the applicant will be informed. The lead role will be allocated in rotation between the three countries with appropriate grouping of related applications. If one of the countries is not in a position to take the lead for a particular application, it will be allocated to the next country.

16. The lead country will set up a timetable and copy it to the applicant and all involved countries. The timetable will ensure that the initial assessment is completed within 60 days of passing validation in all involved countries, the company provides responses to questions within no more than 120 days, and that responses are assessed and a decision is reached within 60 days following receipt of a complete response. The timetable will be prepared so as to ensure as far as possible key dates/periods do not fall on public holidays or weekends. The administrators will exchange the contact details for the assigned assessors. Once the timetable is agreed, the assessors will wherever possible communicate directly with each other as required. Please note, for the UK, all emails sent to the assessors should also be copied to the following email address: worksharing@vmd.defra.gsi.gov.uk.

Initial assessment

17. The lead country will assess the data and prepare a list of questions. In all cases an assessment report will be prepared. Where the supporting data are not extensive the assessment report may take the form of a simple worksheet

in which the proposed change and data are summarised together with the rationale for approval/refusal.

18. The lead country will send the draft list of questions and assessment report to the other involved country/countries. Where necessary, for reasons of confidentiality, these documents will be sent via Eudralink. This will be done according to the timetable (usually by 40 clock days – although, with the prior agreement of the involved countries, for complicated applications with extensive supporting data at the time of establishing the timetable a maximum of 50 days for the initial assessment by the leading country may be agreed).

19. The other countries' assessors will review the documents and, according to the timetable (usually by no later than 55 clock days), forward to their counterpart(s) an email confirming they are content, or the list of questions with suggested changes tracked. Following a reminder, and in the absence of comments, the leading country will issue the questions to the MAH.

20. If there are different views on the need for certain questions or wording, this will be resolved between the assessors, usually by phone.

21. The lead country will send the agreed list of questions to the MAH and to the other involved country/countries by day 60.

22. The MAH will be asked to submit their responses to questions to each of the involved countries at the same time.

Receipt of Responses

23. On receipt of the responses, the administrative personnel in each country will inform each other of this and the clock will only start once all countries have received the complete response. A timetable for response assessment and sign off will be distributed by the lead country to the other countries and the applicant.

24. If an MAH fails to provide a response to the questions according to the specified deadline, and following a reminder, the variation will be refused.

Assessment of responses

25. The lead country will assess the responses, according to the timetable (usually within 40 days of receipt of the response). An assessment of the responses will be provided except where no additional data/studies have been provided and the MAH have simply agreed to certain changes or made commitments.

26. The assessment of the responses will be forwarded to the other country/countries who will be asked to provide their comments according to the timetable (usually by day 55).

27. If all assessors are satisfied with the responses they will inform their counterpart(s) of this and the variation will be signed off within 60 days of receipt of the response.

28. If the assessors consider that minor issues remain to be resolved and this can be done whilst the clock continues to run, the leading country assessor will email the MAH and cc the other country/countries with the questions, asking the MAH to provide responses to all involved countries.

29. Also, if the assessors are not content with the responses and the issues can not be resolved in the time available, the variation will be refused.

30. Should the assessors have different opinions on the responses, these should be discussed, usually by phone, and should be resolved to reach an agreed decision. In exceptional circumstances it may be necessary that divergent positions are reached in each country.

MONITORING

31. The UK validation team will maintain a record of applications each country has led for. This information will be distributed to the relevant staff at each Agency and initially reviewed on a monthly basis. The operation of the scheme can be reviewed by any Agency at any point.

EVALUATION OF THE PARTNERSHIP INITIATIVE

32. The extended partnership initiative will be evaluated following the initial six month pilot period, which commenced on 24th September 2010. If all parties are content, the partnership initiative will continue for a further two years. This two year period will start immediately following the end of the initial term of six months.

33. At the end of the two year period the partnership initiative may be terminated by any of the involved member states. The terminating member state should send a written notice to the other member states 90 days before the end of the two-year period. If all parties are content, the partnership initiative will continue for a further two years. The effectiveness of the partnership initiative will be reviewed on a two yearly basis.

FURTHER INFORMATION

34. Enquiries about using the partnership initiative should be directed to:

UK

- A member of the VMD validation team on 01932 338484, or via email at: initial.surname@vmd.defra.gsi.gov.uk
- General enquiries about the partnership initiative should be sent via email to Nicky Free at: n.free@vmd.defra.gsi.gov.uk

IE

- The planning and licensing manager, Elaine Hynes, on ++353 1 6764971, or via email at elaine.hynes@imb.ie

BE

- The Project Manager, Valérie Van Merris, on ++32 2 524 81 31, or via email at: valerie.vanmerris@fagg.be