Public consultation paper 'Review of the Variations Regulation' (Review of Commission Regulation (EC) No. 1234/2008)

Comments from UK/MHRA (human medicines)

General comments:

(a) We think that any changes should respect 'Better Regulation' principles bearing in mind that any added complexity is likely to have a negative impact on both industry and regulators. Our comments on each of the proposals below are made with this principle in mind.

(b) The rules for the variation of purely national authorisations should, wherever possible, be identical to those for variation of DC/MR or Commission authorisations and this particular change should be implemented as soon as possible.

(c) Extension of the rules to purely national authorisations will require a different definition of global marketing authorisation. For operating grouping, worksharing and extension applications in centralised and decentralised procedures this is defined at present using the product number. Purely national marketing authorisations in many MS do not have a single product number encompassing all of the forms and strengths of the product(s).

2.1 Extension to purely national marketing authorisations

Consultation item no. 1:

Do you agree that where dossiers are not harmonised difficulties could raise for worksharing when accepting the assessment carried out by one member state by other member states?

Worksharing is an option at the choice of the company who should bear in mind the differences when making that choice. Such difficulties that may arise for the Reference Authority should not be insurmountable as the experience with informal worksharing procedures has already shown.

Consultation item no. 2:

Which option a) or b) mentioned above do you consider that should be adopted to allow worksharing ?

Neither of the possibilities (a) or (b) described by the Commission are necessary. Prior harmonisation (full or partial) should not be a prerequisite. Article 7 should make clear that worksharing can be chosen where all or some of the authorisations were granted in purely national procedures. If all of the authorisations are purely national it may be necessary to adapt Article 20 to allow for the appointment of a Reference Authority in those cases but this may be better done in procedural or 'best practice' guidance than in legislation. In addition, in the light of experience, the opportunity should be taken to review the role of the coordination group in the existing process in establishing the Reference Authority and consequently the relevant wording in the Regulation (Article 20, 2 (b) and 3).

2.2 Focusing public resources on the procedures with most impact on public health

Consultation item no. 3:

Do you agree with the principle that the deadline for adoption of Commission Decisions amending marketing authorisations must be driven by public health considerations?

We agree that, if there are difficulties for Commission services in meeting the deadline for adoption, then public health considerations should be paramount. However, public health considerations should not be interpreted as meaning only those changes affecting safety information. For example, in those circumstances where changes to Module 3 details are urgently needed to maintain the supply of a product to the market we would not be serving public health if delay meant that product was not available at all.

An alternative solution to variable deadlines could be legislative change to allow for delegated authority such that the Commission no longer needs to adopt the decisions for any, or at least for certain types, of variation.

Consultation item no. 4:

Which category of variations do you consider that should be adopted within shorter deadlines?

If the variable adoption deadline approach is taken then any changes to section 4 of the SmPC or urgent changes to Module 3 (with acceptable justification) should have the shorter deadlines.

Consultation item no. 5:

Do you agree to extent the current system that allows holders to implement certain variations prior to the adoption of the Commission Decision (to the exclusion of those changes with most impact for public health)?

We agree but repeat our suggestion that delegated authority may be a better way forward to avoid delays for some or all types and categories of variation.

Consultation item no. 6:

Do you consider appropriate to introduce a deadline for the implementation of changes to product information significant from a public health standpoint?

Where the flexibility already available for urgent safety restrictions (Article 24(5)) is not available then we agree that an implementation deadline should be agreed for product information changes based on our suggested wider definition of ‘public health

considerations'. Where those changes are part of a group of changes the same agreed implementation deadline should be applied to all changes in the Group submission in order to avoid difficulties in the subsequent monitoring and inspection of compliance with the authorisation.

(ii) More stable SmPC

Consultation item no. 7:

Do you agree with the above analysis?

We agree that encouragement should be provided for use of grouping and worksharing both in national and pan-European procedures, instead of submission of separate concurrent changes or mutiple changes to the SmPC, within a short timeframe.

2.3 Addressing some workability concerns identified

Consultation item no. 8:

Do you consider appropriate to extend the time limits for assessment of complex grouped applications to enable a larger amount of cases where grouping under one single application could be agreed by the competent authority?

We assume this concerns the need for multiple groups of Type IB changes rather than complex Type II changes where extended procedure times are already possible. We do not think that extended procedure times should be needed for Type IB changes. Instead we consider that changes in the classification guideline could allow for a single submission to be made as Type II with safeguards (applied at validation) against inappropriate grouping. We do not agree that multiple groups of Type IB changes should be procedurally handled as major variations because, even collectively, they may not meet the definition in Article 2(3).

2.4 Procedure for authorisation of human influenza vaccines in a pandemic setting

Consultation item no. 9:

Do you think that changes to the procedure in Article 21 of the Variations Regulation are necessary?

A high degree of flexibility is necessary with regard to the amount of data needed at submission and at authorisation depending upon the lead time between identification of a pandemic and its impact on the Community. In that respect, flexibility to allow for derogation from Articles 12, 18 and 19, prior to confirmation of a pandemic situation by WHO, may be considered. Changes to the guidance for influenza vaccines are already under consideration.