IP-11-250

25 October 2011

international plasma fractionation association

To: European Commission/DG Sanco Pharmaceuticals
SANCO-PHARMACEUTICALS@ec.europa.eu

C.c. ipfa@sanquin.nl

Subject: IPFA responses on the paper of the European Commission DG Sanco on the extension of Regulation (EC) 1234/2008 to the handling of variations to purely national marketing authorisations

2.1 Worksharing Procedure

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?

IPFA Response:

Yes.
Although the Worksharing procedure does bring advantages, the MAH agrees that assessing a variation via a Worksharing procedure where no harmonised dossier exists could pose some difficulties, if extended to a purely national marketing authorisation.

It is generally accepted that the same product can be nationally registered/authorised in several EU markets with different indications or other registered details depending on the member state granting the marketing authorisation. Taking this into account, it will be difficult for one MS to accept the assessment of a non-harmonised dossier by another MS.

From an MAH's perspective, this has the potential to cause delay to the assessment of national variations.

2.1 Worksharing Procedure

Consultation item no. 2:
Which option a) or b) mentioned above do you consider that should be adopted to allow Worksharing?

IPFA Response:
b)
The MAH will ask for WS when parts of the MAs are harmonised. It should be the MAH's choice to go for WS or not.

2.2 i) Deadlines for the adoption of the Commission Decision adjusted to the public health implications.

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?

IPFA Response:

IPFA agrees that public health consideration should be the driver for setting Commission shorter deadlines.

2.2 i) Deadlines for the adoption of the Commission Decision adjusted to the public health implications

Consultation item no. 4:

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

IPFA Response:

The MAH proposes the following variation categories for shorter deadline:

- Changes to the SmPC, labelling or Package Leaflet following the issuing of Articles 30 & 31, for products not covered in the defined scope of the referral (currently listed as IB variation)

- Implementation of changes requested following the assessment of a PSUR, Risk Management Plan where the wording is agreed with the Health Authority (Currently listed as Type IB variation) (safety issue)

The MAH's proposal is based on the principle that both of the listed variations require the implementation of agreed wording to the SmPC, labelling and Package Leaflet. The assessment of the Product Information should be minimal as the wording has been pre-agreed by Health Authorities.

2.2i) Deadlines for the adoption of the Commission Decision adjusted to the public health implications

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)?

IPFA Response:

Yes, IPFA agrees with this proposal which is to be encouraged.

2.2 i)Deadlines for the adoption of the Commission Decision adjusted to the public health implications

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 standpoints?

IPFA Response:

Yes
The MAH is open to setting deadlines to protect public health but these deadlines should be realistic. They must allow time for generation of new artwork and packaging e.g. Patient Information Leaflets which require 'user testing' prior to approval and introduction.

2.2 ii) More stable "Summary of Product Characteristics"

Consultation item no. 7:

Do you agree with the proposed analysis?

IPFA Response:

IPFA partially agrees with this analysis. MAH should be encouraged to group minor changes whenever possible but Authorities have also to respect deadlines in assessing SPC proposed changes. To date some Member State national authorities take more than 2 years to assess a renewal which makes it particularly difficult for the MAH to have an up to date SPC (variations approved in an order different than that of submission) and globally detrimental for practitioners and patients (they do not have access to an up to date SPC)
Couldn't we think of a system (exchange zone) that could enable MAH and Authorities to have a permanent access to the current SPC with a quicker assessment for minor changes?

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 application to enable a larger amount of cases where grouping under one single application could be agreed by the competent authority?

IPFA Response:

IPFA agrees in principle with the proposal to extend the time limits for assessment of complex grouped applications.
However, it needs to be made clear to industry what the expected timelines will be for the assessment of complex grouped variations, that the time limit should not exceed the deadlines implied in case of submission of separate variations and that the assessing Agency must keep to their applicable timelines for completion of assessment and issue of decision.

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

Consultation item no. 9:

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

IPFA Response:

This section is not relevant to IPFA activities.