8 February 2012
EMA/77868/2012
Patient Health Protection

Summary - EMA workshop with EU pharmaceutical industry associations on the implementation of Article 57(2), second subparagraph of Regulation (EC) No. 726/2004

14.00 – 17.00 on Monday, 30th January 2012

BACKGROUND:

On 30 January 2012, members of European pharmaceutical industry associations (EUCOPE, EBE, EFPIA, AESGP, EVM, EGA, EUROPABIO), one observer from HMA (MHRA) and representatives of the European Medicines Agency (EMA) met in order to discuss a revised proposal and the next steps on the implementation of article 57(2), second subparagraph of Regulation (EC) No. 726/2004.

The meeting was chaired by the Head of Patient Health Protection Unit; the European pharmaceutical industry associations welcomed the Agency's constructive and open dialogue to find a way forward to progress.

DISCUSSION and OUTCOME:

The Agency presented the background on Article 57, and the main concerns expressed by pharmaceutical industry following the publication on 1 July 2011 of the Legal Notice and Detailed Guidance. Following a review of pharmaceutical industry's concerns the Agency has developed options to progress, with the respective pros/cons, risks and necessary requirements for the electronic submission of the product information.

The Agency stated that the legal questions raised by certain Industry Associations/individual companies regarding the scope of Article 57(2) second subparagraph were not to be subject of the discussion. To address all questions (including legal questions raised) the Agency has developed proposals as outlined above. The Agency and the European Pharmaceutical Industry Associations agreed that continuing a legal debate would not bring specific value on deciding on the next steps to proceed.

The European pharmaceutical industry associations were requested to provide feedback on the following options (please find details for each of them in the annexed presentation) related to the implementation of the structured substances information:

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1. Further reduce the mandatory data set for the structured substances information
2. As point 1 but restricted to biological medicinal products only
3. Not to request any mandatory data set for structured substance information by the deadline of July 2012

The Agency highlighted to attendees the pros, cons and risks attached to this option. In particular, emphasis was put on the fact that the substance data set will not be compliant with the ISO IDMP standard, with as a consequence that duplication of efforts will be required by MAHs (data entry and re-linking of substances and products) at the time of ISO IDMP implementation. Attendees took note of this consequence, however they also highlighted the potential for duplication of effort if MAHs were to enter the Structured Substance Information (SSI) now prior to agreement by all stakeholders on a collaborative approach and the submission process. In addition, the Agency emphasised that this option will have as a consequence that additional time will be required to implement the agreed changes to the ICT tools and infrastructure. At the latest, the Data Entry Tool will be available on 15 April 2012.

EMA confirmed that the received SPCs will be used for validation purposes only.

After discussion, the European pharmaceutical industry associations indicated that they were in favour of Option 3 above as their preferred way forward. One amendment was requested in relation to option 3, i.e. MAHs would not submit the structured substance information, even on an optional basis, until an agreement is reached on a collaborative way forward to coordinate entry of high quality structured substance information.

EMA presented a proposal for the language requirements for the electronic product submission: details can be found in the annexed presentation. The European pharmaceutical industry associations supported this proposal, however they also indicated that some further clarification was needed (such clarification will be provided at a virtual workshop organised by the Agency on 9 February 2012).

EMA also presented a proposal for the reduction of the mandatory data set for medicinal products compared to the original July 2011 data set: details can be found in the annexed presentation. The European pharmaceutical industry associations supported this proposal.

In summary, this means that the option favoured by the European pharmaceutical industry associations is the following:

- The submission of SPC only for validation purpose
- Clarification of the language requirements depending on the authorisation procedure
- Reduction of the mandatory data set for medicinal products compared to July 2011 i.e. the Agency will not ask the following mandatory data elements/set for medicinal products by July 2012:
  - Additional Monitoring
  - Location of the Pharmacovigilance System Master File
  - Description of packaging information
  - Regulated documents
    - Condition of marketing authorisation
    - Labelling
    - Package Leaflet

- Structured Substance Information: attendees also indicated their preference for the Agency not to accept Structured Substance Information (SSI) in the interim until an agreement is reached on a collaborative way forward to coordinate entry of high quality structured substance information.

The European pharmaceutical industry associations were subsequently requested to express their view on the priorities for the next steps. The European pharmaceutical industry associations supported the following prioritised deliveries:

- Detailed Guidance update
- Allow MAHs to perform gateway connection testing and message submission testing and in parallel allow the companies to be part of the User Acceptance Testing (UAT) of the XEVMPD and SSI Data Entry Tool before they are released. Each pharmaceutical industry association was invited to nominate to the Agency one representative each to participate in the gateway connection and message submission testing and one representative each to participate in the UAT process once the testing environment will be available (please send the nomination to eudravigilance@ema.europa.eu).

It was agreed that the Agency will work on the revision of the Legal Notice, whereby the possibility of including the revised language requirements and requirements on SPC text (i.e. common agreed text for MRP, DCP) should be investigated.

The Agency and the European pharmaceutical industry associations agreed to hold a dedicated virtual follow-up workshop in the week starting 6 February 2012 to clarify remaining specific questions on the XEVPRM format not addressed during this meeting. The list of questions shall be submitted to the Agency by the pharmaceutical industry associations by 3 February 2012, 1pm (please send the questions to eudravigilance@ema.europa.eu); the agreed answers following this workshop will be included in the revised Detailed Guidance or in the Questions & Answers document.

It was agreed that the Agency shall also organise a follow-up workshop to discuss handling of variations, business process on collaborative effort to submit structured substance information (SSI) and the roadmap towards international standards implementation in the next months (Q2 2012).

At regular intervals the Agency will also inform through its website on the progress made, including the release date of the data entry tool and the initiation of the testing.

Replying to a question from the European pharmaceutical industry associations on the EMA approach on the publication of commercial confidential information (cci), in particular manufacturing information, the Agency informed that this will be handled in accordance with the HMA/EMA Guidance document on the identification of commercially confidential information and protection of personal data within the structure of the marketing authorisation (MA) dossier – release of information after granting of a marketing authorisation'. Manufacturing information will be regarded as cci and not be published as per the aforementioned guidance document.

The next steps and actions can be summarised as follows:

- The EMA to provide as soon as possible a summary of the outcome of the discussion, and European pharmaceutical industry associations to provide feedback in writing within a short timeframe (Post-meeting note: the dates are respectively 2 February 2012 and 6 February 2012 close of business).
- Once the summary has been agreed upon, EMA will inform the EC and HMA on the outcome of the meeting.

- EMA will communicate the outcome of the workshop with the European pharmaceutical industry associations together with the updated Legal Notice within the coming weeks.
- The remaining specific questions on the XEVPRM format that have not been addressed during this meeting shall be submitted to the Agency by the pharmaceutical industry associations by 3 February 2012, 1pm, in order for the Agency to organise a virtual workshop the following week (6 -10 February 2012) to address them; *Post Meeting Note: Date confirmed for the 9 February 2012.*
- The Agency will update the Detailed Technical guidance in line with the way forward agreed at this workshop, if possible prior to the DIA Information Day on the 21 February 2012.
- The Agency will consult with all stakeholders over the next months to develop a long-term strategic vision towards implementing the IDMP standards and ICH M5. The Agency will organise follow-up workshops to discuss maintenance of data held in EVMPD, the business process on a collaborative effort to submit structured substance information (SSI) and the roadmap towards international standards implementation in the next months. Ongoing, regular collaboration with stakeholders will be necessary to finalise and implement the agreed roadmap.
- At regular intervals, the Agency will inform through its website on the progress made, including the release date of the data entry tool and the initiation of the UAT and testing for the gateway submission.
- Each European pharmaceutical industry association was invited to nominate to the Agency the name of one representative each to participate in the gateway connection and message submission testing and one representative each to participate in the UAT process once the testing environment will be available by the end of week starting the 6 February 2012.
- Agency to make available the data entry tool for structured information on medicinal products by 15 April 2012 at the latest.
- The Agency will promptly communicate to stakeholders if the data entry tool or gateway should be temporarily unavailable due to technical reasons (e.g. overload due to large amount of data being submitted at the same time) including the time period the data entry tool or gateway might not be available.