

## EMA Workshop: "Outcome of the Evaluation of the EMA"

30<sup>th</sup> June 2010

### 1. Architecture of EMA

Ernst & Young's recent evaluation of the EMA with respect to the effectiveness/efficacy of the marketing authorisation system concludes with regard to the architecture of the EMA:

*" 1. Executive summary, page 10*

*The whole system is progressively attaining its maximum capacity.*

*Main recommendations in this area are focusing on systemic changes in the organisation, roles and responsibilities of the system. Priority is given to the adaptation of the governance and composition of the Committees, by taking into consideration both their political weight and technical inputs in the opinion making process. Some Committees may thus rather be composed by independent experts (PDCO, HMPC and CAT which decision are embedded to CHMP final validation) with more flexibility regarding the Member States representativeness prerequisite. CHMP and CVMP composition relevance will be all the more crucial as they are final opinion-making bodies: the management board may have the opportunities to select one candidate among several presented by each Member State. To overcome CHMP and CVMP workload issues, two dedicated committees may be created to deal with referrals and generics. In addition, working parties organisation should also be also reviewed: some may be removed, others may be created according to their relevance with regards to the evolution of the scientific research and EMEA internal organisation."*

### Summary of main IFAH-Europe points

- The current licensing system is complex, leading to high administrative burden and inefficiencies.
- For the future **a single regulatory procedure** is proposed based on
  - 1 single EU dossier
  - 1 single scientific assessment using the best European competence available to evaluate quality, safety and efficacy
  - 1 decision for marketing authorisation issued by the Central Coordinating Body and this for ALL products: the 1-1-1 concept.
- Setting up even more opinion-making committees would add further complexity to the system.
- The proposed architecture of the future is **a single Central Coordinating Body (CCB)**. It will follow the "Member States model" (one member per Member State) and organise and oversee all work, as well as adopt decisions.
- The members of the CCB will have joint responsibility for the efficient running of procedures and they will assign the **scientific assessment team** from a pool of experts within the European Medicines Regulatory Network.
- The CCB will not do the scientific assessment but it will need the technical competence to transpose the scientific opinion produced by the team of assessors, into the formal

adoption of a decision. To ensure the objective of a true single market is met, the decision would be adopted in the form of a European marketing authorisation (MA).

- The CCB would also be responsible for coordinating the harmonised standard of assessment (*e.g. training/accreditation and peer review*) and coordinating the surveillance/control of products in the market.
- The CCB will not resemble today's CVMP, HMAV or Standing Committee, but rather be something in between, as it must have the competence to make decisions. Its membership would be expected to be composed of high ranking officials from all Member States.
- The CCB would be chaired by a representative of the EU Commission and vice-chairs (elected among its members). The chair or vice-chairs will be entitled to sign the European MA.
- In case of referrals and arbitration the CCB would appoint a second scientific assessment team to do another independent assessment.
- Administratively the CCB will be supported by a central secretariat.
- The central secretariat would report to the CCB and have activities and responsibilities similar to those that exist today:
  - Receiving and validating applications
  - Receiving fees for the single scientific assessment and issuance of the European MA
  - Assisting the CCB in putting together the multinational scientific assessment teams
  - The regulatory management of the scientific assessment process
  - Appointing a national language project manager if so requested by applicant
  - Management of databases
  - Coordination of the pharmacovigilance and inspections, publication of guidelines, secretariat to WGs etc.

In addition it is conceivable for the secretariat to play an important role in ensuring consistency of assessment and of output through e.g. organising peer review of assessments, training of assessors, quality assurance and communication, thus further increasing the confidence of the public into the system.

- The CCB would have the possibility to create sub-committees and appoint expert committees in line with specific needs. To ensure use of the best expertise and the most efficient organisation the composition of those groups would not follow the "Member State model" but the structure called "Expert model" in the E&Y report. Those expert bodies would not be considered permanent.

## 2. European Medicines Network

The first four quotes from the Ernst & Young's evaluation of the EMA with respect to the effectiveness/efficacy of the marketing authorisation system highlight the problems with the network. The final three quotes propose solutions relevant to the network issue:

P. 47 - ... these higher complexity and enlarged scope of responsibility and activities reveal some weaknesses ... The system is progressively attaining its maximum capacity.

P. 48 - The main committees are overwhelmed with work and their agendas could not be extended.

P. 76 - CHMP meetings ... CHMP members are certainly exhausted at the end of the week, raising a certain level of risk .... CHMP agenda is already very heavy.... Considering the increasing workload, the current organisation of this committee's agenda is not perceived as sustainable. In such conditions, the enlargement of the CHMP scope cannot be considered.

P. 91 - ... EMEA may face difficulties coping with the increased demand in the near future, especially since many stakeholders express doubts on the sustainability of the system as it is

P. 48 - However, the shortage of scientific workforce will certainly be a critical concern in the future. A coordinated effort at EU level may attenuate this deficiency. Finally, the process of "Europeanization" leads to a common organisational logic and convergence of outputs by the EU MSs. The settings of normative activity standards between Mss, and a communal approach to communicate between stakeholders on medicines, are suggestions coherent with this European policy orientation.

P. 92 - Some NCAs also have insisted on the importance of sharing good practices, exchanging staff and facilitate multi-national assessment teams. All these initiatives should facilitate the advancement of less experienced agencies, promote trust... and set appropriate standards throughout the system. They should also allow the organisation as a whole to increase its efficiency, by multiplying the number of competent assessors and allowing for the best team to be used, even if it is spread across various agencies.

P. 195 - The EMEA should make a better use of the experts in the network by promoting multinational assessment teams. This should include... allowing the EMEA to directly compensate each contributing NCA in proportion to its involvement in the assessment.

The total number of potential assessors throughout the 44 NCAs of the EU is quite significant, as well as external experts. However, currently, most assessment teams rely only on the resources of one NCA (the one acting as Rapporteur, respectively Co-Rapporteur), and do not tap into resources beyond its MS. This is unfortunate for 2 reasons.

First, sharing assessment across NCAs may allow building a more complete, relevant and experienced assessment team, by allowing access to the best experts in the EU...

Second, it could also facilitate exchange of good practices between NCAs and enhance exposure of smaller NCAs to European procedures by participating directly to specific parts of the evaluation.

### Summary of main IFAH-Europe points

- The regulatory system has become too complex with divergent competences on the national and European level, varying by procedure and leading to administrative burden and inefficiencies.
- There are too many layers involved in evaluation and decision-making.
- It is a waste of resources if applications concerning the same product have to be made to every single MS concerned and are then evaluated in parallel by the NCAs with often different timelines and sometimes different outcomes.
- There is an insufficient degree of NCA alignment in implementing legislation and guidelines. Specific national requirements represent additional bureaucratic hurdles.
- There is a lack of differentiation between human and veterinary medicines in legislation.
- We need to create the single market – a declared aim for veterinary medicinal products ever since the harmonised EU legislation was put in place over 25 years ago.

- A more efficient network will address resource issues within the European Medicines Regulatory Network (EMRN), improve access to veterinary medicinal products across the EU and at the same time create incentives for innovation and industrial development.
- NCAs will continue to be the backbone of the EMRN in which they play an important role as part of a matrix of experts. They would play a major role in provision of resources for project management, assessors/experts, pharmacovigilance and the administrative requirements for placing of products on their market.
- Achieve Better Regulation and Simplification ensuring a fair and equitable regulatory environment proportionate to the needs of veterinary medicine sector.
- Ensure a more harmonised and practical implementation of the legislative objectives leading to predictable, efficient and proportionate regulatory procedures.
- Realise the full potential of the common market via a radical re-think of the current regulatory system by all stakeholders starting from the 1-1-1 Concept.
- The NCA's will be part of a multidisciplinary assessment team assembled by a central coordination group. Experts should be chosen on the basis of their functional discipline and expertise regardless of nationality.
- National agencies would receive the market accession fees which would fund national activities such as setting up market surveillance/control systems directly from the MAH. National agencies would also receive a share of the scientific assessment fee if their experts were involved in the scientific assessment. Fees must be proportionate to the service provided. A more efficient system would remove duplication of effort and cost.

### Focus on the specific "Questions to discuss:"

1. How to assure long-term availability of resources and the highest possible level of expertise?

- increasing the involvement of scientific resources across the network for the Agency
  - *The Ernst & Young (E&Y) report states the financial resources are limited. At the same time, they suggest that more people should be trained. The analysis of the reality and the proposal are in conflict. The way forward is to remove duplication, focus on training and so use the current resources much more efficiently*
- other ways to organise the application review process (cross-border cooperation, splitting dossiers)
  - *The report refers to cross border collaboration that has already occurred. This has been successful. Whilst fee allocation is cited as a problem, this is an administrative issue that needs to be resolved but is not a barrier. Teams should be chosen from across the EU based on their scientific competence. Such a team should assess the dossier on behalf of the 27 member states. This would remove a huge workload that is unnecessary and wasteful duplication today.*
- inspections capacity
  - *If a competent authority inspects a facility, this is accepted by the other competent authorities. The need for a manufacturer to inspect a facility of a contract manufacturer should be removed if the facility has been passed by a competent authority.*

2. Coordination role of the Agency within the network – clarifying roles and responsibilities

- *See the summary of IFAH-Europe's points above.*