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Conference on the outcome of the evaluation of the European Medicines Agency

Joint European Commission-European Medicines Agency conference, held on 30 June 2010 at the European Medicines Agency, London.



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Disclaimer: Participants’ views presented in this document do not represent the views of the European Commission or the Agency.

Abbreviations list

Abbreviation	Definition
ATMP	Advanced Therapy Medicinal Product
CMD(h)	The Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human
DCP	Decentralised procedure
EEA-EFTA	European Economic Area–European Free Trade Area
EMA	European Medicines Agency
EU	European Union
CAT	Committee for Advanced Therapies
CHMP	Committee for Human Medicinal Products
COMP	Committee for Orphan Medicinal Products
CVMP	Committee for Veterinary Medicinal Products
HMA	Heads of Medicines Agencies
HMPC	Herbal Medicines Committee
IT	Information Technology
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedure
MUMS	Minor Use And Minor Species
NCA	National Competent Authority
PDCO	Paediatrics Committee
PIPs	Paediatric Investigation Plans
SAWP	Scientific Advice Working Party
SME	Small and Medium sized Enterprises
SPCs	Summary of Product Characteristics

1. Executive summary

The European Medicines Agency's (EMA) founding regulation requires that the Agency is evaluated every ten years. Such evaluation was carried out in 2009 with a view to assessing the effectiveness and efficiency of the system dedicated to the provision of marketing authorisations for human and veterinary medicinal products. Following the completion of the evaluation, the European Commission together with the Agency organised a joint conference to discuss the outcomes of the report with partners and stakeholders.

The evaluation report emphasised that the current system performed well in achieving its objectives and demonstrated high predictability. A number of improvements were suggested for the future in order to address the complexity of the architecture of the system and the high volume of workload. Conference participants exchanged views on recommendations proposed in the evaluation report.

The evaluators suggested that inter-linkages and collaboration among committees and related working parties need to be further streamlined to assure consistency of the Agency's scientific committees' opinions. The report also raised an issue of the sustainability of the architectural capacity of the committees taking into account high workload. The participants exchanged views on those proposals. As part of the discussion, the conference reflected on the need to increase the accessibility and continuity of the Committee for Human Medicinal Products (CHMP) scientific advice.

The evaluation report also raised the issue of long-term ability of the network to provide scientific resources for the centralised procedure. Conference participants reflected how to ensure the ability of national competent authorities to continue providing scientific resources for the centralised activities long-term while maintaining their ability to carry out their responsibilities at the national level. In this context, a separate session was dedicated to the sustainability of financing of the Agency. The conference also looked at issues seen within the field of veterinary medicines regulation and suggested possible ways forward to address identified weaknesses. Overall, participants agreed that veterinary specific issues exist in the area of medicines and in the work of the European Medicines Agency. Taking into account the identified issues, participants felt that future veterinary legislation should sufficiently account for the differences between human and veterinary fields and provide for a fair and equitable regulatory environment proportionate to the needs of the veterinary medicines sector.

2. Background

The European medicines regulatory system is a network of the European Commission, national competent authorities and the European Medicines Agency. The European Medicines Agency is entrusted with tasks for which centralised evaluation and decision making can bring added value. The European system for the evaluation of medicinal products is based on the notion of the network of European Medicines Agency, national competent authorities (NCAs) and European Union (EU) institutions and relies on collective knowledge. The network ensures the availability of expertise and the existence of necessary capacity. The system based on aggregate expertise is more reliable and robust. The Agency and the network have consistently managed assessment of the benefit/risk of medicinal products.

The founding regulation (Regulation (EC) No 726/2004) requires that the Agency is evaluated every ten years after the entry into force of the regulation. The objective of the present evaluation was to assess the effectiveness and efficiency of the system dedicated to the provision of marketing authorisations for human and veterinary medicinal products. In 2009 the European Commission commissioned this evaluation. The evaluation was conducted by Ernst & Young between January and December 2009. Agency stakeholders from Member States, pharmaceutical industry, patient organisations and representatives of health care professionals contributed to the evaluation by completing a survey or answering questions during interviews, which formed part of the assessment.

The assessment report was published by the European Commission on 12 April 2010:

http://ec.europa.eu/enterprise/dg/files/evaluation/final_report_emea_january_2010_en.pdf

Following publication of the assessment report, the European Commission asked the Agency to organise a joint conference to discuss the outcomes of the report with partners and stakeholders.

A steering committee, with a representative from the European Commission, the European Medicines Agency, Management Board, Member States and industry was formed to prepare the conference (*see [Conference steering committee](#)*). The steering committee decided on the main focus areas from the report for discussion at the conference based on the importance of the recommendations given in the report. Sustainability of the current set up of the system for authorisation of medicinal products featured as one of the main topics on the agenda. Chosen topics were the architecture of the Agency's scientific forums, long term availability of resources in the network, coordinating role of the Agency within the network and issues specific for veterinary medicines. Reflection on the funding of the system and impact of the fees concluded the programme (*see [Annex A Agenda](#)*).

The steering committee identified representatives from the various interested parties to participate as session chair, speakers or panel members. Sessions were structured to start with a presentation by the speaker followed by a tour de table of panel members and an open floor discussion.

To prepare the conference, the steering committee held 11 teleconferences. After the general conference format and Agenda was agreed, preparatory teleconferences with the chairs, speakers and panels for each session were held.

After the conference, the steering committee discussed outcomes during a follow-up teleconference, followed by a teleconference on the draft report.

Since the outcomes of the Agency's evaluation provided important ideas for the future of the Agency and the system, the conference participants also discussed the outcome of the public consultation on the draft EMA road map to 2015, impact of concepts proposed in the road map on the regulatory model for the licensing of medicines and the role of the Agency in the interaction with health technology assessment bodies.

The conference took place in London on 30 June 2010 and was attended by 171 participants from national competent authorities, European Parliament, industry, patient, healthcare professional organisations and journalists (see [Annex B List of registered attendees](#)).

The slides of all presentations given during the conference, plus other documents relating to the conference, are available through the 'Conferences & Events' section of the European Medicines Agency's [website](#)¹.

The conference programme is included in Annex A.

3. Key issues discussed at the conference

The report evaluating the activities of the Agency and views expressed by stakeholders during the conference confirmed that the European Union (EU) system has a high degree of predictability. Participants saw it very encouraging that in spite of high complexity, the Agency remains focused on science for the benefit of European patients.

The evaluation report emphasised that the current system performed well and achieved its objectives to the highest standards and demonstrated high predictability. The report states that "the European Medicines Agency, as a whole including the contribution of 44 national competent authorities throughout the 27 EU Member States and the 3 European Economic Area – European Free Trade Area (EEA-EFTA) countries and the EMA secretariat, is the archetype of an effective Community model with concrete and regular outputs". The Agency "provides with complete, clear and highly valued opinions within regulatory tight deadlines and allows the contribution of the best available experts in Europe". The evaluation confirmed the operational effectiveness of the system as a whole which was maintained despite its growing complexity.

However, a number of improvements can be introduced in the system to address some issues created by high complexity of the architecture of the system and high volume of workload at both centralised and national levels. Conference participants exchanged views on recommendations proposed in the Agency's evaluation report as well as considering other ideas that would help to ensure long-term sustainability of the system.

This chapter presents topics that were discussed at the conference.

Each topic includes the background and relevant recommendations from the Ernst & Young evaluation report (text of recommendations from the Ernst & Young report is included in Annex D), the discussions during the conference on the identified topics and reflections on possible future actions. The latter distinguish between actions that would require or not require changes in the legislation.

3.1. Effectiveness of the architecture of EMA's committees

Background from the evaluation report

Scientific Committees

Currently the Agency has six scientific committees (and a seventh committee proposed in the new pharmacovigilance legislation) and 35 working parties.

The report in particular highlighted the challenges to ensure consistency among the Paediatric Committee (PDCO), the Scientific Advice Working Party (SAWP) and the CHMP. The evaluation report observed "that the regulation does not ensure the consistency between opinions of these two

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2010/12/event_detail_000370.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

committees [CHMP and PDCO] with two committees being opinion-making committees potentially for the same product at two different periods of its life-cycle. The industry outlined this situation as a specific concern. Thus, the organisation should provide effective measures to reduce the risk of incoherence between the opinions produced by the PDCO, and, later in the drug development process, by the CHMP, and potentially by the SAWP as well.”

The evaluation report and conference participants summarised challenges arising from the ‘complex’ organisation of the committees:

- Complex organisation creates challenges to ensure consistency of opinions and guidelines, and continuity of decisions, and increase the potential for duplication of work
- Significant efforts are needed to ensure high level of coordination among committees, and between committees and working parties

Working parties

Linked to the committees is the topic related to working parties, their membership, dynamics of establishing and closing working parties in line with the actual and changing needs of the committees and the Agency. In addition to the coordination of the work of the six committees described above, the Agency needs to ensure the coordination among the committees and scientific working parties. There are 35 scientific working parties which add to the complexity described above. The report concluded on this matter that a regular review of working party mandates and discontinuation of those that have completed theirs should lead to a more focused and relevant coordination workload (recommendation 6).

Ernst & Young recommendations

The evaluators looked in detail in this domain and concluded that committees’ roles and responsibilities, interdependence between committees as well as governance rules between committees have to be more clearly communicated (recommendation 1).

The complexity of interaction of the scientific committees is somewhat influenced by the fact that all six committees are rather independent from each others. The evaluation suggests establishing an “opinion-making committee” and “pre-committee” structure which would help to clarify the roles, would improve linkages between committees and add to consistency of the Agency decisions. The report proposes to distinguish between two types of committees:

- Opinion-making committees: those which deliver opinions directly followed by the European Commission decision, and
- Pre-committees: those committees which prepare scientific opinions to be agreed by the CHMP (recommendations 1, 3).

The report also suggests reviewing membership arrangements for committees and proposes to establish two models: Member State based membership (which is the currently the case for all committees) and expert based membership. In the latter case the membership would not be on a basis of one member per each Member States but would be based on expertise. As a consequence of such a change, there could be a smaller number of members in the committees, which would reduce the use of NCA resources (Recommendations 2, 4).

Discussion at the conference

Interaction among scientific committees

The participants agreed that there is an issue with the complexity of the system, particularly when the interaction of Committee for Medicinal Products for Human Use (CHMP), Paediatric Committee (PDCO)

and Scientific Advice Working Party (SAWP) are concerned. There is indeed a risk that the three bodies may produce inconsistent views on the same issues, for example mandatory paediatric investigation plans (PIPs) may not always meet the requirements of the CHMP which is the body making final opinion for granting a marketing authorisation. Participants were uniform in their views that the system needs to be streamlined to ensure that there are no discrepancies between the bodies.

Other examples of areas that are subject to complex interactions include the coordination of work between the COMP and CHMP, and between the Committee for Advanced Therapies (CAT) and CHMP. The relative roles and responsibilities of these committees can overlap due to independence of the committees, which originate either in the legislation or in the working procedures of the Agency. The imminent establishment of the pharmacovigilance committee by the new legislation will further add to the above challenges.

The Agency dedicates a lot of attention and work to maintain consistency among the committees and ensure good linkages. The coordinating role of the Agency is established in the legislation. The interactions, collaboration and consistency of committees' opinions are foreseen in the legislation. More specifically, for the committees established after 1995, the legislation provides that CHMP representatives serve as members on those committees. However, this task remains challenging and not without pitfalls. The participants acknowledged that streamlining of such interactions and linkages is needed and can be achieved within the current legislation. The clarity of roles and responsibilities as well as interdependencies of the committees is therefore very important in ensuring continued high quality and consistent (from scientific and regulatory point of view) output of the scientific committees (recommendations 13,16). The Agency's secretariat needs to continue strengthening its role in ensuring this scientific and regulatory consistency.

Working parties

The conference participants discussed the issue of working parties and stressed that the working parties are an important element of the scientific work of the Agency. The parties also require significant resources from the national competent authorities and the Agency. In addition having working parties as a more dynamic tool in terms of their creation, closure and membership, a more rational look at the working parties may mean that a working party should provide its support not only to the committee that established it but also to the other committees and the Agency's fora requiring its expertise.

Scientific advice

The participants highlighted the interaction between the SAWP and the CHMP as one that requires more immediate attention. They also addressed the issue that the CHMP scientific advice does not have a binding role on the committee. The scientific advice is given early in the process of medicine development and the advances in science and technology warrant a different look at medicines at the time of application for marketing authorisation. However, the 'decreasing compliance' was seen as an important issue and it was recognised that work is needed to ensure more consistency and better predictability of decisions. The committee and working party chairs agreed that the level of CHMP commitment should increase and measures have been taken in this direction.

The participants were of the opinion that scientific advice provided by the national competent authorities is easier to access. The industry expressed its views that the Agency's scientific advice needs to be made more accessible for applicants. In spite of the fact that sponsors of orphan medicinal products and small and medium sized enterprises (SMEs) benefit of reduced EMA fees, industry considers that EMA's advice is too expensive particularly in view that a number of national competent authorities provide free scientific advice or at lower price. It was noted that industry sometimes applies for scientific advice both at a national competent authority and the European Medicines Agency.

The conference participants agreed with the views that the scientific advice should not be compulsory for the industry. It is recognised that CHMP scientific advice is the way to obtain a European scientific advice that has been shown, if followed, to result in a higher predictability of regulatory decisions.

Opinion-making committees and subcommittees, committee membership

The report proposed that CHMP, CVMP and COMP remain as 'opinion-making' committees with full Member States membership while PDCO, CAT and Committee on Herbal Medicinal Products (HMPC) evolve into 'pre-committees' with expert based membership.

The conference participants discussed that it is essential to ensure the balance between the involvement of Member States in the decision making and the rational composition of bodies of the Agency. Participants discussed that the Member State participation (current model) in decision-making process is essential in cases where committees take opinions on benefit/risk.

Overall, participants were not in favour of proposed change of status of some existing committees to pre-committees and to expert based membership. More specifically participants discussed that, for example, the HMPC's role is different compared to other 'more conventional' committees. This Committee's core task is to develop European harmonised scientific standards, in particular Community herbal monographs and list entries, for use by companies and national competent authorities. Similarly, it was discussed that the CAT committee should remain as 'opinion-making' committee since it proposes opinions on benefit risk balance of advanced therapy medicinal products which is then adopted by the CHMP. Another scenario could be - disconnecting the CAT committee from CHMP and allowing it to conduct a full benefit/risk assessment. However the latter change can only be implemented through revision of legislation. Currently, CAT is a committee composed of experts (albeit with an expert from each Member State) in accordance with legislation that states areas of expertise that have to be present in the committee.

A member of European Parliament recalled that the role of EMA is defined in the legislation and that the Commission, the Council and the European Parliament are responsible for developing policy. As regards the architecture and the high number of subcommittees sometimes with overlapping membership, a leaner organisation would improve efficiency and make cost-savings.

Another issue is the so called "bridging membership" among the committees (where a member in one committee is simultaneously a member in another committee). The model has benefits and drawbacks. The benefit is possible contribution to consistency between the work and output of related committees. However, the fact that the same members cannot fully participate in the work of two committees given the volume of activities is seen by some as a shortfall of this model. More reliance could be placed on the secretariat, since the legislation provides that EMA secretariat's role is to ensure the consistency among committees and stronger interactions between the committees and the secretariat would help to ensure better consistency.

The Agency also works to embrace the needs emerging in the societal developments such as responding to patients' requirements and opinions on what information is needed for them and patients' willingness to participate in making healthcare choices. Patient representatives thanked the Agency for close and productive interaction with their organisations. The Agency will further develop this interaction to increase ways in which representatives can contribute and participate in the process of communication and provision of information to patients as well as in their willingness to take part in the assessment process. Patient representatives expressed their willingness to contribute to the work of the CHMP in a way which is similar to such a contribution provided when working with other scientific committees.

Compilation of reflections on possible ways forward

Actions not requiring the review of legislation

Interactions between committees

- Clarify roles and responsibilities as well as interdependencies of the committees to improve linkages and consistency of opinions between the scientific committees. Work in this area has started.
- Further streamline interactions between the process of paediatric investigation plans and scientific advice.
- Review ways to ensure continuity between the scientific advice given and the CHMP assessment and consider to what degree scientific advice can be 'binding' on the CHMP.
- Consider whether for some procedures such as referrals it could be possible to set up drafting groups per therapeutic area with final agreement by the CHMP.

Working parties

- Consider mandating the working parties to work for different committees to enable more efficient use of working party resources.
- Monitor, amend or clarify mandates and corresponding composition of working parties, as needed.

Assessment process

- Reinforce the "therapeutic pathway" from scientific advice and guidelines to rapporteurship to improve continuity during the whole assessment process (recommendation 17).
- Develop further the model for scientific advice to make it more accessible (recommendation 19).

Actions requiring the review of legislation

- Explore the proposal for pre-committee structure.
- Explore the proposal for Member State vs expert based membership in scientific committees.
- Assess options for streamlining the approval process of clinical trials.
- Inclusion of patients' and healthcare professionals' representatives in the work of the CHMP.

3.2. Workload and the sustainability of the architectural capacity of the committees

Background from the evaluation report

The evaluators concluded that the architectural capacity of some scientific committees is reaching maximum capacity in its ability to manage the growing number of applications. The main opinion making committees, CHMP and CVMP, are overloaded with work and their agendas could hardly be extended.

Part of this trend can be attributed to the workload created by generic and referral applications. During the recent years, generic and biosimilar products have accounted for an increasing proportion of

marketing authorisation applications in the centralised procedure which consume an increasing part of the Agency's resources and have become a significant workload for the scientific committees.

Some of the reasons accounting for this increase relate to the fact that data exclusivity for a number of centrally authorised medicinal products has expired, in which case the generic industry has an option to apply for authorisation of medicines either through the centralised procedure or through the decentralised procedures. Even if the proportion of generics using the centralised procedure is limited, the industry saw the centralised procedure as an opportunity to avoid waiting for 'slots' in the decentralised procedure.

Ernst & Young recommendations

To address the architectural capacity to deal with workload, the evaluation report suggests creating additional temporary subcommittees for referrals and for generic products with a view to decreasing the CHMP and CVMP workload. The assessment work would be carried out by these subcommittees and the outcomes of those assessments would be validated by the CHMP and CVMP respectively to ensure the consistency of opinions (recommendation 5).

The report touches on models of how experts from NCA can work on behalf of the Agency including building a capacity of seconded experts at the European Medicines Agency. The report highlights a number of drawbacks of such a model (recommendation 7) including insufficient flexibility of a system to draw on relevant expertise and difficulties to exchange best practices between the European Medicines Agency and national competent authorities.

Discussion at the conference

Establishing subcommittees to deal with specific types of applications

Participants' views on the subcommittees subject were diverse, with some representatives arguing that the sub-committees will not increase the effectiveness of the system, since the same individuals and the same resources within NCAs would be used to evaluate applications.

The industry representatives stressed that establishment of additional committees should not become an extra burden for applicants, consistency should be ensured and any changes should make procedures smoother. With regards to generic medicines and referral procedures, other options were also mentioned: for example delegating work to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMD(h)) and handling the issues through the decentralised procedure.

Also, the referral work can be increasingly done by those Member States which may not have enough resources to take up full applications which usually require significant resources. The issue of compensation would need to be addressed for this and other non-compensated activities.

There is ongoing work to review the structure of the committee agendas in order to allow the committee more time to focus on complex issues.

The monthly cycle of activities and frequency of meetings need to be revised. Some committees should meet more than once a month while others may consider reducing the frequency of meetings. New meeting technologies need to be introduced more widely. The meetings should increasingly take a combination of physical meetings and distance meetings. Working parties in particular could move to distance meeting practices. Distance working would enable more outside experts to join in the meetings.

The concept of 'full time' membership

The participants discussed some options enabling members to allocate more of their time for the work in the committees and the centralised procedure. Currently members have also responsibilities at the national level.

One of the options raised in the report includes inviting committee members to work at the Agency for a prolonged period of time. In practice, this would mean extending the currently run national expert programme to committee members. The positive side of the above model would allow focusing experts' time solely on centralised procedures as well as further contributing to stronger links between the Agency and the national authorities. This option would be possible for experts and delegates already dedicating most of their time to European Medicines Agency activities while for others that would represent a lost capacity for national competent authorities and their ability to carry out their national responsibilities.

Another option would be the establishment of 'full time' members. 'Full time' membership would mean that the experts concerned would continue to reside in their national agencies, however would dedicate all their time only to tasks of the Agency, thus increasing the capacity and effectiveness of the committees, and forego national responsibilities.

The conference participants responded with mixed views on the 'full time' membership concept since any new approach needs to be balanced with the availability of resources for the national competent authorities.

Compilation of reflections on possible ways forward

Actions not requiring the review of legislation

Committee working practices

- Review the structure of scientific committees' agendas to find alternative ways to address committees' workload using different approaches.
- Increase the use of alternative meeting solutions to reduce the number of topics to be dealt with at scientific committees meetings.
- Explore the concept of "full time" membership and/or expanding the national experts' programme run at the Agency.

Sub-committees

- Further consider with scientific committees the proposal to establish sub-committees in certain domains of scientific committee work.

NCA cooperation

- Further develop and implement targeted training to respond to long term needs for expertise and resources.

3.3. Workload and the sustained availability of scientific resources of the European medicines network

Background from the evaluation report

In addition to the architectural capacity of the scientific committees described earlier, the evaluation report also noted that national competent authorities are experiencing increasing difficulties to find

relevant resources for work at the EMA level and communicated their concern that increase in activity may lead in the near-future to a shortage of resources.

The evaluation extensively examined the role and achievements of the Agency's secretariat in coordinating the European regulatory network. The report highlighted the importance of effective and efficient EMA secretariat as a prerequisite for effective European regulatory network.

Ernst & Young recommendations

With regard to the availability of national resources to contribute to the work at the EMA level, the report suggested to:

- Find ways to increase exposure of experts at NCAs to European procedures (recommendation 7),
- Use multi-national assessment teams (recommendation 8),
- Ensure the right balance between the need to ensure independent assessment (conflicts of interest) and the availability of the highest level of expertise (recommendation 10) and
- Ensure adequate funding for NCAs contributing to activities at the EMA level.

The evaluators have provided a number of statements and proposals to reinforce the role of the secretariat. These include: the EMA secretariat should strengthen its ability to monitor the consistency of the European Medicines Agency's outputs (recommendation 13), put in place specific support for NCAs that need it, focusing on EMA secretariat areas of excellence (recommendation 14), alleviate the administrative burden for scientific assessors when scientific complexity of a dossier justifies it (recommendation 15), continue specific efforts in quality assurance procedures, to guarantee the appropriate level of quality and consistency of EMA outputs (recommendation 16), EMA and NCAs should reinforce their coordination in all IT-related projects in order to facilitate the emergence of a European IT architecture (recommendation 24), keep the lead on harmonising pharmacovigilance procedures and tools at the European level (recommendation 28).

Discussion at the conference

The conference confirmed that the main challenge relates to increasing demand on scarce scientific resources in the network while there is little possibility to increase the number of resources due both to strict budgetary policies in public sectors of many countries and to limitations affecting the availability of external expertise (shortages in some scientific areas, tightening of rules pertaining to conflicts of interests). However, members of the European Parliament emphasised that EMA should not compromise on conflict of interest criteria especially because perception of the public in this area is very important.

A number of responsibilities vested on NCAs compete for national resources. These include contribution to EMA activities, work in the area of non-centralised procedures such as the Mutual Recognition Procedure and the Decentralised Procedure (MRP/DCP) or clinical trials and national responsibilities in the medicinal products area. The balance between EU and national responsibilities, which together form the entire system, is essential since both centralised and decentralised procedures rely on the same resources.

At the same time, new tasks have been added for the network. Those were not matched with financial resources (examples include legislation on paediatric and herbal medicines). National authorities shared a concern that, if the issue remained unaddressed, in future it may become difficult to find (co) rapporteurs on a voluntary basis for certain activities.

The participants stressed that it is important to maintain a balanced, efficient and predictable "twin engine" system of the centralised procedure and the decentralised procedure while improving weak

points of both marketing authorisation routes. Both routes of marketing authorisation have advantages, which have to be explored and reinforced. One of the challenges to be addressed in the near future is the requirement for the network to ensure the consistency in the final outcome of assessment, independent of which route of marketing authorisation is chosen. Such consistency can be improved through the training of assessors. The participants also agreed that a regulatory process catering for personalised medicines needs to be established long term. The current legislation will need to be looked at and developed to ensure that this goal is achieved.

Ways to ensure the availability of scientific resources of the network

The conference participants stated that the following would help to ensure long-term availability of resources in the network:

- Avoiding duplication of work. The network needs to review critically the areas where duplication may occur (for example clinical trials, scientific advice) and review its processes to eliminate such duplication and free resources.
- More work-sharing is needed to free resource. New areas need to be identified in this context (for example increased coordination and better recognition of inspections in the EU, one assessment of the Active Substance Master Files, assessment of clinical trials applications and other)
- Developing explicit and planned resource management. This activity has to encompass the whole of the network and has strong links with the training strategy for the European regulatory network.
- Conducting prioritisation of activities based on relative risk and, more broadly, on relative added value for public health.
- Developing joint assessment teams for rapporteurships which would enable the involvement of additional NCAs that have the necessary skills to undertake a part of the assessment for which another NCA is not well equipped or has no available resources at a particular time.

However for this approach to work and to be sustainable two conditions would have to be met:

- One NCA must be responsible for the coordination of the assessment and accountable for the work done;
- Clear responsibilities must be defined in relation to post-authorisation activities.
- Using virtual meetings more frequently and in a larger variety of situations.
- Cooperation arrangements between NCAs are also an option. In this case one NCA would be mandated to represent one or two other NCAs during some scientific meetings and would share the information.

Compensation for certain activities that are currently not compensated

At the outset of the current regulatory system which was put into operation in 1995, the work mainly consisted of the evaluation of applications for marketing authorisation. Over the years, the work at the EMA level has expanded.

A considerable number of activities are not paid for by fees and, at present, national competent authorities are not compensated for that work. At the same time, the proportion of non-paid activities has grown significantly. Some of those activities include: designation of orphan medicinal products, review of paediatric investigation plans, preparation of herbal monographs and list entries, and referral procedures. However, a European Parliament representative stressed that it was not the intention of the legislator to preclude that NCAs be compensated for such activities in the interest of public health.

Conference participants strongly felt that there is an increasing need to compensate NCAs for currently non-paid activities in order to ensure sustainability of scientific resources dedicated to the EU system in Member States long term and warrants resolution over time. A future review of the Agency's fee legislation could provide a platform for a further debate on this topic.

Role of EMA secretariat

The participants discussed the role of the Agency's secretariat and stressed that it has been developing and growing over the years. Some of the current activities include acting as a hub of the European regulatory network, providing administrative support for the evaluation process, developing and managing information technology, facilitating scientific process, and coordinating the scientific network.

Participants also highlighted that progress has been achieved overall in the development of IT systems that support the work of the EU regulatory network. However, more work needs to be done in this area to further increase the effectiveness and efficiency of the network. The systems should be fit for purpose and take account of technological advancements.

It was stressed that the Agency needs to look for further ways to alleviate the administrative burden of assessors (recommendations 14, 15).

Compilation of reflections on possible ways forward

Not requiring changes in legislation

NCA cooperation

- Identify areas in the network where duplication of work takes place and change working practices to remove such duplication.
- Increase the number of areas which benefit from work-sharing arrangements within the network
- Develop cross border cooperation (joint teams for rapporteurship) for the evaluation of centralised applications and put in place infrastructure that would support that approach (fee sharing) (recommendation 8). To safeguard accountability, clear roles and responsibilities would need to be established.

Resources

- Further develop and implement targeted training to respond to long term needs for expertise and resources.
- Develop explicit and planned resource management within the network.
- Reflect on mechanisms for compensation for identified activities done by national competent authorities for the European Medicines Agency which are currently not compensated.
- Assess the adequacy of compensation for civil society representatives.

EMA secretariat

- Further develop the role of the secretariat to alleviate the tasks carried out by the scientific committees (recommendations 14,15)
- Pay particular attention at the development of IT systems that increase the effectiveness and efficiency of the network.

3.4. Topics specific to veterinary medicinal products

Background from the evaluation report

Veterinary specific issues exist in the area of medicines and in the work of the European Medicines Agency. The veterinary market for medicines is small (only 2.5 % of the human market value) and is privately funded (no reimbursement schemes). The number of different species adds fragmentation to the veterinary market as well as further complexity, and the scope of issues to be considered with respect to safe use of products includes both safety of consumers and the environment. In addition, product availability varies highly between the Member States of the EU. Finally, resources are a compelling issue due to the small markets for many products.

At present, the most important opportunity for the veterinary sector is the ongoing reflection on the legal framework for veterinary medicines. The consideration on the role of the Agency and the role of its scientific Committee for Veterinary Medicinal Products (CVMP) was very timely, considering the consultation by the European Commission concerning better regulation of veterinary medicines. This consultation asks for input by stakeholders and the general public on how to put in place a simpler legal framework, continuing to safeguard public and animal health while increasing the competitiveness of companies. The consultation closed on 15 July for the Commission to consider and analyse the responses and the conclusions from this session on veterinary medicines will be fed into the discussions to follow thereafter.

A number of other topics raised in the report are relevant to the veterinary medicines area, including amongst other issues, finding ways to address workload, particularly in the field of referrals, and an overall shortage of resources.

Ernst & Young recommendations

The report provides the following conclusions:

- Consider the authorisation of veterinary medicines as leading to highly specific issues that cannot always be solved through simply mirroring solutions developed in the context of human medicines;
- Contribute to the reflection launched by the Commission on the necessity for amending the veterinary legislative framework with respect to specific aspects including consideration by the Commission of the appropriateness of market exclusivity or other incentives for minor use and minor species (MUMS) products and how best to cater for different species in terms of data exclusivity and generics.

Discussion at the conference

The conference participants reflected on the architecture of the Agency committees in support of veterinary medicines, initiatives to support the product development pipeline and the veterinary dimensions to the European medicines network in the context of ensuring the availability of products for this different market.

Experience with the current system

Conference participants agreed that there is a lack of differentiation between the legislation governing human and veterinary medicines. Participants were concerned that the regulatory system for veterinary medicines has become complex with multiple procedures at the national and European level, leading to a lack of predictability, administrative burden and inefficiencies. In general, a fair and equitable regulatory environment proportionate to the needs of the veterinary medicines sector was called for.

There are many layers involved in evaluation and decision-making. The fact that applications concerning the same product have to be made to every single Member State concerned and are then evaluated in parallel by the NCAs, sometimes with different outcomes, was seen as an inefficient use of resources. Industry considered that there is an insufficient degree of NCA alignment in implementing legislation and guidelines and that specific national requirements represent additional bureaucratic hurdles.

A more efficient network would address resource issues within the European Medicines Regulatory Network, improve access to veterinary medicinal products across the EU and at the same time create incentives for innovation and investment. The way forward would be to remove duplication, focus on training and use the current resources more efficiently.

In relation to availability, the single internal market is not yet a reality with respect to veterinary medicines as there are pricing differences and differences in the availability of the same product between Member States. Further harmonisation of existing products is still required and slow progress in this area prevents the fulfilment of a common market and leads to a high number of referrals.

Proposal for a future system

Participants discussed ways to achieve better regulation and simplification ensuring a fair and equitable regulatory environment proportionate to the needs of veterinary medicine sector. There was discussion on how to ensure a more harmonised and practical implementation of the legislative objectives leading to predictable, efficient and proportionate regulatory procedures.

IFAH – Europe proposed that there should be a single regulatory procedure (1-1-1 concept) based on 1 single EU dossier, 1 single scientific assessment using the best European competence available to evaluate quality, safety and efficacy, and 1 decision for marketing authorisation issued by a central coordinating body (CBB) and that this should be open for all products. The proposed architecture of the future would be a single central coordinating body. It would follow the “Member States model” (one member per Member State) and organise and oversee all work, as well as adopting decisions in the form of a European marketing authorisation to ensure that the objective of a true single market is met.

For generics equally a system of one application, one assessment resulting in one EU authorisation could be established, where the assessments would be carried out by teams of experts from Member States. However the generic industry was concerned that further strengthening of central coordinating and scientific role of the Agency could lead to potentially significant increases in development and authorisation costs, for example for translation of product literature.

A radical change in the role of the Agency to become a central coordinating and scientific body with expanded decision making powers (the committee would not only decide on whether or not to authorise a product but also its conditions of use) would require a change in the legislation, and it was questioned whether such a model would be more efficient than a modification of the existing system. Instead of a radical change, it may be more efficient to raise more initiatives to share the workload to cope with demand by for example applying a cross-national team approach. The CVMP has at present an essential role in harmonisation, which should be maintained. For this aspect of harmonisation, training of assessors is of key importance.

Other topics: availability of veterinary medicines, data exclusivity, committee structure, One World One Health concept

For many the critical issue in the veterinary field remains the availability of products in practice. Availability of medicines is a continued concern and there is a need for continuous research and development of products for both minor species and minor use, and for the major species. A critical

factor for success relates to the effective involvement of interested parties of which there is already good experience.

Improved data protection may be a key element in any solution to availability. This would be an issue requiring a legal change and it would be necessary to ensure that the protection provided by data exclusivity should be balanced and fair, considering the needs both of the generic and the innovative industry.

Further measures to promote availability are clearly needed, and it could be considered if it would be helpful to establish a separate (pre)committee for MUMS/limited markets.

Concerning the proposal of the creation of subpanels/subcommittees or expert committees under the current legislation, further reflections are needed on for example the use of a pre-committee for certain types of referrals such as those for harmonisation of the summary of product characteristics (SPCs). Participants suggested, however, that it may be more efficient for the CVMP to continue to be responsible for the more complex issues, such as referrals under Article 35 of the Directive 2001/82. Moreover, the current problem related to the lack of compensation for assessment of referral procedures would need to be overcome.

For generics, such a pre-committee may be less necessary on the veterinary than the human side, considering that there are a very low number of generics for centrally authorised veterinary products at the present time. In addition, the view of most regulators was that the input from the Committee should be reserved mainly for innovative medicines.

Participants were also reminded about the concept of "One World One Health", which emphasises the close connection between animal health and public health. Under this concept it is important that veterinary issues are not considered in isolation but that close links are maintained with the human medicines sector to ensure cooperation and collaboration. The Agency, with its dual responsibility for human and veterinary medicines, is ideally placed to promote such cooperation.

Compilation of reflections on possible ways forward

Not requiring changes in legislation

- Focus on best use of resources, to ensure high quality scientific assessment; make use of worksharing and cross-border teams, and consider the concept and definitions of benefit/risk assessment.
- Ensure appropriate involvement by stakeholders in guideline development from an early stage.

Requiring changes in legislation

- Adapt the legislative framework for veterinary medicines to the needs of the sector.
- Consider the architecture of the committees, ensuring that the structure is proportionate and adapted to the needs of the veterinary area.
- Facilitate scientific advice on the development of products, and consider the benefits and drawbacks of phased assessments or similar initiatives.
- Further reflect on data exclusivity ensuring that it is proportionate, adapted to the specific realities of the veterinary sector and able to benefit both generics market and innovators in a fair way.
- Explore other initiatives to facilitate the availability of necessary products for the veterinary area, for example a reduction in requirements concerning labelling.

3.5. Fee system of the European medicines agency

Background from the evaluation report

The Agency has a dual source of financing – fees for evaluation of medicinal products and contribution of the EU budget. Currently, on average 80% of the Agency's activities are financed by fees. The evaluation showed that overall the fees paid by applicants compare favourably to other regulatory agencies. However, the fact that the Agency is largely financed by fees also makes it vulnerable due to high dependency on fees for applications. The evaluation also showed that stakeholders consider that the current fee system is rather complex and could be simplified.

The national competent authorities are compensated by the Agency for the scientific work. The Agency pays around 47% of its fee revenue to national competent authorities (around 75 million Euro per year). However, the evaluation report also stressed the fact that a number of activities carried out by the national competent authorities for the European Medicines Agency are not compensated. This is the case for those areas where fees are not provided for in the legislation, for example evaluation of paediatric investigation plans, designation of orphan medicinal products, and work in the area of herbal medicinal products. However, since the amount of resources required for the non-paid activities has grown significantly, the absence of compensation challenges the long term ability of national competent authorities to contribute to these activities.

Ernst & Young recommendations

The evaluators suggested that the Agency should clarify the compensation system and identify a funding system for activities that are currently not compensated (recommendation 12). The report concluded that careful consideration of the funding of non-fee paid activities is crucial to ensure the sustainability of the whole system.

Discussion at the conference

The Agency has reviewed its experience with the fee system and submitted a report to the European Commission. The current fee system follows the model established fifteen years ago. Over the years new fees and incentives have been added which contributed to increasing the number of fee types. The Agency currently has 131 different fees, which also adds to the complexity of the administration of such a system. A product can go through a combination of stages when different fees and incentives are applied. Some of those stages include a consideration whether a product is an orphan medicinal product, relevant or not for paediatric populations, a product developed by an SME, that was subject to a scientific advice, pre and post authorisation evaluation procedures, which may be an advanced therapy medicinal product, etc.

Over the period of time, the actual fee level for various activities remained largely unchanged, however there were further developments impacting on fee related workload, such as enlargement of the EU which increased resources needed for maintenance activities.

Participants pointed out that there are instances when the fee system needs to be more flexible, so as to enable the introduction of fees for new activities, when appropriate. For example, the ATMP certification procedure does not have a fee for site visits and this cannot be introduced under the current legislation.

Taking the above into account, the Agency put forward its own reflection on the current fee system for discussion at the conference with suggestions for example on how to ensure long-term sustainability whilst reducing complexity.

The conference participants stressed that the fee system is an essential part of the European medicines network, it should provide for sustainability for the European Medicines Agency and should enable the

compensation for activities that national competent authorities do on behalf of the Agency. In addition the system should be simple to operate and transparent towards the stakeholders. The work which is unfunded creates a risk to the long term sustainability of the system, since national competent authorities are experiencing increasing difficulty to finance their contribution to the tasks of the European Medicines Agency. Some participants emphasised that any revision of the fee structure should focus on ensuring that fees are proportionate to the actual work carried out rather than on simplification.

European Parliament representatives pointed out that the increasing dependence of the European Medicines Agency on fee income will carry a financing risk due to possible fluctuations in fee income. The industry representatives asked to ensure that fee levels would reflect the amount of work that the Agency and assessors make to evaluate products, and as a consequence should remain transparent and fair. A future fee system should maintain those principles and representatives were not certain whether substantial grouping of fees would fulfil that expectation. Industry representatives also felt that the current fee system also needs some fine tuning, for example in the areas of type IA variations, informed consent, duplicate applications and, as discussed earlier, applications for scientific advice.

SME representatives supported the findings of the evaluation report with regards to the need to simplify the fee system. It is important for SMEs to have a fee system that would reduce an overall administrative burden. Any new fee structure should not increase the overall amount of fees to be paid by SMEs and should safeguard the incentives reflected in the current system since SMEs remain sensitive to any increase in fee levels.

SME representatives also raised a concern that some companies as development proceeds lose their SME status and the corresponding loss of incentives can adversely affect the companies. Moreover, the SME criteria applied to biotech companies seem to be inadequate to the size of investment needed in this type of industry.

Similar expectations were raised by the representatives of the veterinary industry. In addition, the participants noted that the specificity of the veterinary sectors involves the fact that the veterinary industry bears a double administrative burden – that related to satisfying the needs and expectations of veterinarians and users of medicines on one hand, and the additional public health measures directed to safeguarding the food chain and public health on the other.

Representatives of the self-medication industry also pointed out that, when reassessing the fees, it should be taken into account that the assessment of well established substances entails a lesser workload.

The Agency and the network continuously work to identify areas where gains in efficiency can be achieved. This includes the work-sharing and cooperation in different procedures, capacity building, and developing IT systems which would contribute to better efficiency of procedures. Considering the high number of committees and sub-committees that meet regularly, it was suggested that cost savings could be made by using more virtual meetings. Finally, it was suggested that cost savings could be made by better integrating the IT systems of the European Medicines Agency and those of the national competent authorities.

The participants concluded that work should continue to achieve savings, which would contribute to sustainability of the system, would enable a continuous provision of incentives as foreseen in the legislation and would contribute to the ability of the Agency to compensate for the work carried out by the national competent authorities.

Compilation of reflections on possible ways forward

Actions requiring the review of legislation

- The European Commission will launch a reflection process for the future review of the fee legislation.

Acknowledgements

Meeting-organisation team

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Conference steering committee

Name	Representing
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Matus Ferech	European Commission
Aginus Kalis	Heads of Medicines Agencies
Christine-Lise Julou	European Federation of Pharmaceutical Industries and Associations (EFPIA)
Isabelle Moulon	European Medicines Agency
Arielle North	European Medicines Agency
Pat O'Mahony	Management Board
Nerimantas Steikunas	European Medicines Agency

Annexes

Annex A – Conference agenda

Annex B – List of registered attendees

Annex C – Further conference-related documents

Annex D – Text of recommendations from the evaluation report prepared by Ernst & Young

Annex A – Conference agenda

30 June 2010, 8.30 to 18.00

Room 2A

Time	Chairs/Panel members/Topics	Speakers
9.00 -9.15 15 min	Opening of the conference	Nils Behrndt (European Commission)
9.15-9.30 15 min	Preparing the Agency for tomorrow's challenges	Thomas Lönngren (EMA)
9.30-10.15 45 min	Presentation of outcomes of the evaluation	Pascale Augé, Florent Gomez-Bonnet (Ernst & Young)
10.15-11.45 1 hr 30 min	<p>Session 1: Architecture of the European medicines agency</p> <p>Session chair Patrick Le Courtois (EMA)</p> <p>Panel: Daniel Brasseur (PDCO), Kerstin Westermark (COMP), Bruno Flamion (SAWP), Jan Mazag (HMA), Christoph Thalheim (EMSP), Michael Doherty (EFPIA)</p> <p>Topic: Improving the architecture of the EMA to make it better equipped for the future</p> <ul style="list-style-type: none"> - structure and organisation of the CHMP - addressing the complexities of interaction between committees - assuring capacity and capability to deal with current workload - interaction with the industry throughout lifecycle of medicines <p>Discussion Conclusions of the session</p>	<p>Eric Abadie (CHMP)</p> <p>All Arielle North (EMA)</p>
11.45-12.05 20 min	Break	
12.05-13.35 1 hr 30 min	<p>Session 2: European medicines network</p> <p>Session chair Aginus Kalis (HMA)</p> <p>Panel: Martina Cvelbar (HMA), Martin Schneidereit (International Federation for Animal Health Europe (IFAH-Europe)), Beata</p>	

Time	Chairs/Panel members/Topics	Speakers
	<p>Stepniewska (EGA), Michael Wilks (CPME)</p> <p>Topics:</p> <p>1. Assure long-term availability of resources and the highest possible level of expertise</p> <ul style="list-style-type: none"> - increasing the involvement of scientific resources across the network for the Agency - other ways to organise the application review process (cross-border cooperation, splitting dossiers) <p>Discussion</p> <p>2. Coordinating role of the Agency within the network – clarifying roles and responsibilities</p> <p>Discussion</p> <p>Conclusions of the session</p>	<p>Jean Marimbert (HMA)</p> <p>All</p> <p>Peter Arlett (EMA)</p> <p>All</p> <p>Martin Terberger (European Commission)</p>
<p>13.35-14.35 1 hr</p>	<p>Lunch</p>	
<p>14.35-15.20 45 min</p>	<p>Session 3: Topics specific to veterinary medicinal products</p> <p>Chair: David Mackay (EMA)</p> <p>Panel: Anja Holm (CVMP), Frank Verheijen (Netherlands), Kornelia Grein (EMA), Brigitte Boenisch (International Federation for Animal Health Europe (IFAH-Europe)), Inge Sandberg (EGGVP), Jan Vaarten (FVE)</p> <p>Topics: Architecture of the Agency committees in support of veterinary medicines Supporting the product development pipeline Veterinary dimensions to the European Medicines Network</p> <p>Discussion</p> <p>Conclusions of the session</p>	<p>Brigitte Boenisch (International Federation for Animal Health Europe (IFAH-Europe))</p> <p>All</p> <p>Fia Westerholm (EMA)</p>
<p>15.20-16.45 1 hr 25 min</p>	<p>Session 4: Fee system of the European medicines agency</p> <p>Session chair Andrzej Ryś (European Commission)</p> <p>Panel:</p>	

Time	Chairs/Panel members/Topics	Speakers
	<p>Andreas Pott (EMA), Pat O'Mahony (Management Board), Christa Wirthumer-Hoche (HMA), Edwin Ruighaver (EFPIA), Emmanuel Chantelot (EBE), Neil Craven (International Federation for Animal Health Europe (IFAH-Europe))</p> <p>Topic: Ensuring long-term sustainability</p> <p>Discussion</p> <p>Conclusions of the session</p>	<p>Ulrike Nagl (EMA)</p> <p>All</p> <p>Zaide Frias (EMA)</p>
<p>16.45-17.00 15 min</p>	<p>Break</p>	
<p>17.00-17.55 55 min</p>	<p>Session 5: Road map</p> <p>Session chair Thomas Lönnngren (EMA)</p> <p>Panel Dagmar Roth-Behrendt (European Parliament), Kent Woods (HMA), Hubertus Cranz (AESGP), Wills Hughes-Wilson (EuropaBio), Brigitte Boenisch (IFAH- Europe)</p> <p>Topic: High-level Overview of the Outcome of the Public Consultation</p> <p>Discussion</p>	<p>Noël Wathion (EMA)</p> <p>All</p>
<p>17.55-18.00 5 min</p>	<p>Closure</p>	<p>Thomas Lönnngren (EMA)</p>

Annex B – Organisations and countries represented at the conference

AGE Platform Europe (The European Older People's Platform)
Association of the European Self-Medication Industry (AESGP)
Austria
Belgium
Bulgaria
Bureau Européen des Unions de Consommateurs (BEUC)
Committee for Herbal Medicinal Products (HMPC)
Committee for Medicinal Products for Veterinary Use (CVMP)
Committee for Orphan Medicinal Products (COMP)
COPA-COGECA
Cyprus
Czech Republic
Denmark
Ernst & Young
European AIDS Treatment Group (EATG)
European Biopharmaceutical Enterprises (EBE)
European Cancer Patient Coalition (ECPC)
European Commission
European Federation of Pharmaceutical Industries and Associations (EFPIA)
European Generics Medicines Association (EGA)
European Genetic Alliances' Network (EGAN)
European Group for Generic Veterinary Products (EGGVP)
European Institute of Women's Health (Eurohealth)
European Medicines Agency
European Multiple Sclerosis Platform (EMSP)
European Organisation for Rare Diseases (EURORDIS)
European Parliament
European Patients Forum (EPF)
European Union Geriatric Medicine Society (EUGMS)
Federation of Veterinarians of Europe (FVE)
Finland
France
France
Germany
Groupement Pharmaceutique de la Communauté Européenne (GPUE)
Hungary
Iceland
International Alliance of Patients' Organizations (IAPO)
International Federation for Animal Health Europe (IFAH-Europe)
International Federation for Animal Health Europe (International Federation for Animal Health Europe (IFAH-Europe))
International Patient Organisation for Patients with Primary Immunodeficiencies (IPOPI)
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Malta
Management Board (European Medicines Agency)
Netherlands
Norway
Plasma Protein Therapeutics Association (PPTA)
Poland
Portugal
Romania
Scientific Advice Working Party (SAWP)
Slovakia
Slovenia
Spain

Standing Committee of European Doctors (CPME)
Sweden
The European Association for Bioindustries (EuropaBio)
The Organisation for Professionals in Regulatory Affairs (TOPRA)
United Kingdom
Animal Pharma
Agence de Presse Medicale
Financial Times
MedNous
Regulatory Affairs Journal

Annex C – Further conference-related documents

More documents relating to the conference are available through the 'Conferences & Events' section of the European Medicines Agency's [website](#).²

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http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2010/12/event_detail_000370.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1

Annex D – Recommendations from the evaluation report prepared by Ernst & Young

1. Committees roles and responsibilities, interdependence between committees as well as governance rules between committees and in particular between opinion-making committee and pre-committees have to be more clearly communicated
2. The Member States representativeness prerequisite should be considered mostly in opinion-making committees.
3. PDCO should evolve towards a Pre-committee model to reinforce consistency of the whole system.
4. Some committees could rather evolve towards an expert model to improve the reactivity of the opinion process.
5. The creation of additional temporary targeted pre-committees for referrals and for generic products could decrease the CHMP and CVMP workload.
6. A regular review of the working groups nebula should lead to a more focused and relevant coordination workload.
7. EMEA and NCAs should encourage more experts at the NCA level to be exposed to European procedures, so as to foster harmonisation in evaluation practices and increase the number of knowledgeable experts that could be solicited for any given assessment.
8. The EMEA should make a better use of the experts in the network by promoting multinational assessment teams. This should include removing administrative burdens and allowing the EMEA to directly compensate each contributing NCA in proportion to its involvement in the assessment.
9. The EMEA should facilitate NCAs' ability to identify relevant assessors at the EU level by improving the experts' database.
10. While maintaining strong rules for experts involved in opinion-making committees, selection criteria should be more flexible for experts contributing to assessment teams, in order to facilitate access to experienced assessors.
11. The Management Board should be able to choose between multiple candidates when selecting a member of a Committee.
12. The compensation system should be clarified, and a funding system identified for non-fee paid activities.
13. The EMEA Secretariat should strengthen its ability to monitor the consistency of EMEA outputs.
14. EMEA Secretariat should put in place specific support for NCAs that need it, focusing on EMEA Secretariat areas of excellence.
15. EMEA Secretariat should alleviate the administrative burden for scientific assessors when the scientific complexity of a dossier justifies it.
16. EMEA Secretariat should continue putting specific efforts in quality assurance procedures, to guarantee the appropriate level of quality and consistency of EMEA outputs.
17. The Centralised procedure could be further streamlined (...).
18. Implement minor improvements to guidelines preparation process to further strengthen their impact.

19. Make the Scientific Advice a more streamlined and easily accessed procedure.
20. EMEA should pursue its efforts in order to provide clearer, more coherent and targeted messages.
21. EMEA should facilitate the understanding of its fee structure.
22. EMEA should simplify its fee structure.
23. EMEA Secretariat should continue promoting teleconference tools whenever relevant.
24. EMEA and NCAs should reinforce their coordination in all IT-related projects in order to facilitate the emergence of a European IT architecture. EMEA and Member States should also encourage NCA's involvement in the appropriation of EMEA telematics tools.
25. EMEA should engage in the evaluation of EudraPharm and EudraVigilance to identify and implement the right improvements.
26. Clarify and share NCA best practices (with all NCAs) related to involvement in EMEA activity and define according monitoring indicators, both on the EMEA and NCA sides.
27. Transparency of Rapporteurship appointment procedures should be strengthened.
28. EMEA should keep the lead on harmonising pharmacovigilance procedures and tools at the European level.
29. Take into account specific Veterinary challenges.
30. Explore potential impact of recent scientific evolutions on EMEA activities.