



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Annex 2

EU Medicines Agencies Network Strategy to 2020

Summary report of the meeting with Industry Stakeholders Associations for human medicines, 23 June 2015

The meeting was held on 23 June 2015 with the following Industry Associations: AESGP, EFPIA, EFPIA–Vaccines Europe, EBE, EGA EUCOPE, EuropaBio and Europharm SMC. The HMA representatives were Klaus Chicutek (PEI) and Christer Backman (MPA). The meeting was chaired by Noel Wathion (EMA). Other EMA participants were Monica Dias, Melanie Carr, Emer Cooke and Marie-Helene Pinheiro.

The EMA presented the steps taken to develop the joint Network Strategy, the structure of the document, the main focus of each of the four themes and the next steps leading to the adoption of the final document. Each of the industry associations presented their comments on the “EU medicines agencies network strategy to 2020”. All Industry Associations welcomed the new approach of defining one comprehensive strategy for the entire network of medicines agencies. The main issues raised on the Strategy document are listed below.

AESGP

- Highlighted the fact that not all medicinal products developed are innovative and noted that issues other than product shortages are currently being faced by the pharmaceutical industry.
- Appreciates that the appropriateness of classification of medicines is mentioned in the Strategy document but considers more should be done to address the lack of scientific expertise and understanding of the particularities of non-prescription medicines.
- Proposed use of the recently developed methodology (“Brass model”) for quantification of risks and benefits in assessing switches to non-prescription status.
- Considers that the principles of “Better Regulation” should apply to all areas and should be applied by the Network to well-established substances.
- Suggested to further develop the rules for herbal medicines and to increase the cooperation with EFSA so that a good balance between the different categories of products (food and medicinal products) can be achieved.



EFPIA/VE/EBE

- The Strategy to 2020 is aligned with EFPIA priorities for improving medicine R&D. However, the Strategy document does not refer to the development of new trial designs and statistical methods although there has been a great progress in this area in the EU.
- EFPIA/EBE/VE recognise the benefits of providing access to patient level clinical trial information to researchers but believe that EMA is not best placed to provide access to patient level data under a controlled access model.
- Key measures for a vibrant 2020 life science sector are, according to EFPIA, as follows: a balanced and pragmatic regulatory system, reduction in unnecessary bureaucracy, adequate incentives for innovation, successful implementation of the CT Regulation, reduced European Commission decision making timelines, involvement in adaptive pathway pilot and successful transition to a permanent pathway, promoting regulatory and HTA/pricing and reimbursement interactions, active involvement in IMI, embracing big data, international cooperation, a collaborative approach with all regulatory stakeholders, promoting mutual reliance and work-sharing and efficient implementation of the Telematics strategy.
- There is no reference to IMI in the Strategy document even though there is a vast amount of work being carried out in particular in the area of adaptive trials and big data by IMI.
- VE had specific comments on AMR and highlighted that there is an aspect missing in the strategy, i.e. prevention. In addition, VE believes that there needs to be a holistic view on the approach to address AMR. VE also mentioned that only cooperation with HTAs is addressed in the strategy document but there are other bodies of interest to VE.

EGA

- A common EMA/HMA strategy is a very positive step.
- Questioned whether only innovative medicines are in the scope of the Regulators' role. Innovation is extremely important and needs to be supported but should not be the only focus of the Strategy.
- The majority of the population in the EU still needs treatment for common diseases. There is a social responsibility of Regulators to think about the availability of treatment for the majority of the population.
- More support is needed for generics and biosimilars.
- Timely access to medicines should be addressed to all medicines and not only innovative. Reduction of regulatory burden should be addressed for all medicines.

EUCOPE

- Closer cooperation with HTA and pricing and reimbursement bodies should aim at defining common clinical guidelines to ensure alignment on the way patients are treated (standard of care, duration of treatment etc.) and facilitate the selection of common comparators for HTA purposes.
- An enhanced degree of transparency of clinical trial data is welcomed but it is suggested that the Network considers the specific character of data in the field of rare diseases since the data for orphan medicines is particularly difficult to obtain taking into account smaller populations and limited understanding of rare diseases.

- Supporting innovation requires also a concerted approach to off-label use and the EMA and NCAs should develop guidelines on unlicensed use of medicines based on medical need and patient safety as called for by the 2013 European Parliament report on patient safety. The underlying principle of guidelines on off-label use should be that medicinal products are only used within the indications specified in their MA, unless there is a specific medical need.

EuropaBio

- Did not raise any critical comments in relation to the Strategy document but instead highlighted those it believes are positive for its members.
- In general, a single strategy for the Network is supported by EuropaBio and the document addresses key priorities for the life science sector in the coming five years by supporting innovation and increasing collaboration both within the Network and between the Network and its stakeholders. It improves Europe's attractiveness as a location for development of novel medicines.

Additional comments from Industry Associations

- EFPIA – regarding supply chain integrity, there has been already some interactions with EMA, and EFPIA is waiting for direction from Regulators.
- EFPIA – the concept of establishing “centres of excellence” in Europe for various topics, such as the assessment of applications for clinical trials and marketing authorisations, should be considered.
- EuropaBio – questioned whether a gap analysis in terms of expertise in the NCAs had already been undertaken.
- EBE – expertise from patients is considered very valuable and industry is also soliciting their involvement during medicine development.
- AESGP – although the Strategy is a very high level document and detailed description of the activities to be undertaken in order to reduce the administrative burden should not be included, priority should be given to this topic in the various multi-annual work programmes.

Industry Associations were asked to provide further comments on the strategy document in writing using the template available in the EMA website, by 30 June 2015.