[redacted]

From: [redacted]
Sent: 31 January 2019 13:08
To: EO-PresubmissionConsultation
Cc: [redacted]
Subject: VS: Comments Ombudsman Inquiry on EMA pre-submission activities
Attachments: Response to the EU ombudsman Fimea.docx

Follow Up Flag: ema9
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Good afternoon,
The version I send was unfortunately not the final one, enclosed you have the final one where "Finland " has been replaced with "Fimea".
Kind regards,
Esa Heinonen

Esa Heinonen, MD PhD, Adjunct Professor of Drug Development
Director
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Lähettäjä: Heinonen Esa
Lähetetty: 31. tammikuuta 2019 12:36
Vastaanottaja: [redacted]
Kopio: [redacted]
Aihe: Comments Ombudsman Inquiry on EMA pre-submission activities
Good morning,
Fimea (Finnish Medicines Agency) wants to comment the Ombudsman Inquiry on EMA pre-submission activities, our response is enclosed.
Kind regards,
Esa Heinonen

Esa Heinonen, MD PhD, Adjunct Professor of Drug Development
Director
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Summary response from the Finnish Medicines Agency to the EU Ombudsman - Public Consultation on EMA pre-submission activities

The European Ombudsman has invited all relevant parties to put forward their views on European Medicines Agency (EMA) presubmission activities, i.e. arrangements EMA has in place for engaging with individual medicine developers before they submit applications for authorisations to market their medicines in the EU. The detailed questions posed by the Ombudsman relate to participation of the same EMA staff members and experts in both preauthorisation activities and marketing authorisation processes of the same medicinal product, concerns that legal non-bindingness of preauthorisation activities may not be fully maintained, transparency issues and possible improvements and restrictions in EMA preauthorisation activities. Role of EMA scientific advice is emphasised in the inquiry.

The legal background of preauthorisation activities is in the Article 57-1 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, in which it is stated that one of the tasks of the Agency is advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products.

Finland has been an active member state in all EMA preauthorisation activities, in particular in EMA scientific advice with 60-70 scientific advice and protocol assistance procedures annually. Overall, the Finnish Medicines Agency (FIMEA) fully agrees with the comprehensive response to the inquiry provided by the Heads of Medicines Agencies (HMA), and is of the opinion that EMA preauthorisation activities play a key role in protecting European patients by avoiding unethical, unnecessary clinical trials, and in ensuring high quality drug development in Europe resulting in faster access to innovative medicines. In addition, FIMEA sees preauthorisation activities as an essential element of the regulatory framework that ultimately ensures consistency and high scientific standards of drug safety.

As a national competent authority FIMEA would particularly emphasize the following aspects in response to the individual questions posed by the Ombudsman:

Questions 1-2: FIMEA does not consider participation of the same individuals in the preauthorisation activities and subsequent marketing authorisation evaluation a concern. Rather a concern would be a lack of consistency in scientific views between these activities, and limitations in the participation of individual experts in different regulatory activities. The limited availability of high-level scientific expertise in the regulatory framework of many therapeutic areas is a well-known fact, and is particularly prominent in small member states such as Finland. FIMEA would further highlight the fact that EMA preauthorisation advice is never an opinion of an individual member state or assessor, but a consensus view based on an extensive scientific discussion and evaluation by the entire working party and adopted by the respective Committee. Thus, it *de facto* provides a broader and more institutional and transparent scientific view than individual national agencies could provide.

Question 3: Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 clearly defines the legal framework of preauthorisation activities. FIMEA is convinced that the non-binding nature of preauthorisation activities is evident for the Applicants, and being clearly defined in the instructions to the Applicants, evident also for a broader audience. The Finnish experts involved in the scientific advice have also nationally confirmed that i) the legal non-bindingness of advice is verbally expressed in all scientific advice meetings with the Applicants ii) issues/questions raised by the Applicants but not considered to be within the scope of scientific advice are not answered, and this is clearly outlined in the advice letters.

Questions 4-5: As stated in the HMAs response, all EMA experts and Scientific Advice Members are listed in the public domain, as are their Declarations of Conflicts of Interest. As the experts are mostly nominated from or in collaboration with national medicine agencies, their conflicts of interests are also nationally reviewed, further ensuring the transparency.

Question 6: Scientific advice process is open to all developers, including academic institutions and other non-profit organisations. Given the fact that advice is open to all stakeholders, scientific nature of advice and that high-level scientific consistency is maintained throughout individual advice procedures, FIMEA would see little value in making individual advice letters available to all developers.

Questions 7-8: Considering the rapid evolution of drug development, particularly in some therapeutic areas such as anti-cancer products or advanced therapies, FIMEA sees apparent risks in restricting advice questions; in rapidly evolving fields of medicine it is not possible to foresee the therapeutic landscape so that scientific advice could be replaced by guidelines. It is rather the opposite: regulatory guidelines are a result of scientific interaction, and previous scientific advices may not only be a trigger for guideline development but also an essential scientific source for it.