European Ombudsman

Strategic inquiry into **Pre-submission activities** organised by the European Medicines Agency

Report on consultation

May 2019

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1. Introduction

In July 2017 the Ombudsman opened an inquiry into the arrangements that the European Medicines Agency (EMA) has in place for engaging with individual medicine developers before they submit applications for marketing authorisations ("pre-submission activities").

In October 2018, the Ombudsman invited comments from the public on how best the EMA can engage with medicine developers before they apply for authorisations to market their medicines in the EU. The deadline for submitting comments was 31 January 2019.

The consultation sought to inform the Ombudsman of the different viewpoints that exist among concerned parties in the public, private and voluntary sectors, and others. The consultation also aimed to promote discussion on the matter.

2. Issues

The consultation invited comments on eight questions (see annex 1), covering four main issues, namely:

- A separation between those partaking in pre-submission activities and the subsequent evaluation;
- Precautionary measures to prevent the pre-evaluation of data during the pre-submission phase;
- The transparency of pre-submission activities;
- The availability of scientific advice.

3. Contributions

The Ombudsman received **38 responses**.

Eleven contributions were submitted by national authorities, seventeen by non-governmental organisations, including independent research institutes, seven by interest representatives from industry, and three responses from individuals who either have an academic or a professional interest in the subject.

Ten out of eleven national authorities that contributed are either a member of EMA's Management Board (9) or an alternate member (1). The other national authority that contributed collaborates with EMA and European Health Technology Assessment (HTA) organisations, which are independent institutes for scientific decision-making support in the health sector.

Of the non-governmental organisations, two are members of EMA's Management Board, three are part of the Health Technology Assessment (HTA) network, with which EMA has cooperated to bring regulators and HTA organisations closer, and one is involved in the operation of the European medicines regulatory network (see annex 2 for further details).

From the contributions received, it appears that many stakeholders attach great importance to the effective functioning and the independence of EMA, as well as to an appropriate level of transparency in EMA's operations. The main issues set out in the responses will feed into the Ombudsman's analysis concluding this inquiry that she expects to publish in June 2019.

Annex 1 - Questions

The consultation contained the following eight questions:

1. It may happen that EMA staff members and experts who participate in pre-submission activities will be involved in the subsequent *scientific evaluation and/or marketing authorisation* procedure for the same medicine. To what extent is this a matter of concern, if at all? Are there specific pre-submission activities of particular concern in this regard? How should EMA manage such situations?

2. Should EMA allow experts from national authorities, who have previously provided scientific **advice** at national level on a particular medicine, to be involved in EMA's scientific **evaluation** of the same medicine?

3. What precautionary measures should EMA take to ensure that information and views provided by its staff members and experts in the context of pre-submission activities are not, in practice, considered as a "binding" pre-evaluation of data used to support a subsequent application for authorisation?

4. Is the way in which EMA engages with medicine developers in pre-submission activities sufficiently transparent?
   If you believe that greater transparency in pre-submission activities is necessary, how might greater transparency affect: i. EMA's operations (for example the efficiency of its procedures, or its ability to engage with medicine developers) and ii. medicine developers?

5. Is there a need, in particular, to enhance the transparency of scientific advice EMA provides to medicine developers? Would it, in your opinion, be useful or harmful, for example, if EMA:
   - disclosed the names of the officials and experts involved in the procedures;
   - disclosed the questions posed in scientific advice procedures; and/or
   - made public comprehensive information on the advice given.
   If you have other suggestions, for example regarding the timing of the publishing of information on scientific advice, please give details and the reasons for your suggestions.

6. What would the advantages and disadvantages be of making scientific advice, given to one medicine developer, available to all medicine developers?

7. Should EMA be limited to providing scientific advice only on questions not already addressed in its clinical efficacy and safety guidelines[4]?

8. Any other suggestions on how EMA can improve its pre-submission activities? If so, please be as specific as possible.

Annex 2 - List of contributions

National authorities:

1. Federal Agency for Medicinal Products and Health Products - Belgium
2. Danish Medicines Agency - Denmark
3. Federal Institute for Drugs and Medical Devices (BfArM) - Germany
4. Agency for Veterinary Medicinal Products - France
5. Medicines Evaluation Board - The Netherlands
6. Medicines and Medical Devices Agency - Austria
7. Fimea Medicines Agency - Finland
8. Swedish Medical Products Agency - Sweden
9. Medicines & Healthcare products Regulatory Agency - UK
10. National Institute for Health and Care Excellence (NICE) - UK
11. Norwegian Medicines Agency - Norway

Non-governmental organisations

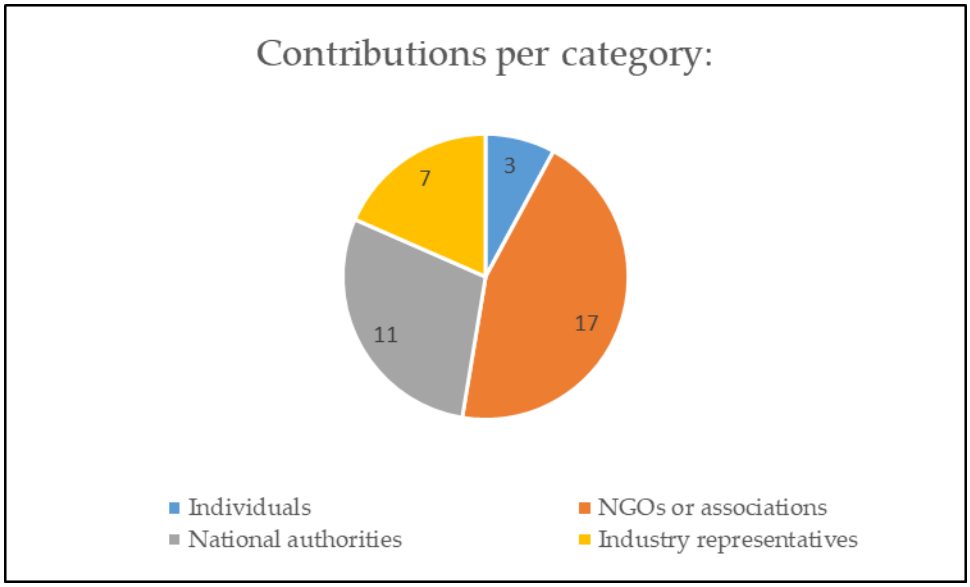
1. Association of European Cancer Leagues (ECL)
2. BEUC, European Consumer Organization
3. European Forum for Primary Care
4. European Organisation for Rare Diseases (Eurordis)
5. European Patients' Forum
6. European Public Health Alliance (EPHA)
7. European Social Insurance Platform
8. Federation of Veterinarians of Europe
9. Fondazione Telethon / Istituto San Raffaele Telethon per la Terapia Genica (SR-TIGET)"
10. German Association of Statutory Health Insurance Funds
11. Heads of Medicines Agencies (HMA)
12. Health Action International
13. Institute for Quality and Efficiency in Health Care (IQWiG)
14. International Society of Drug Bulletins
15. Ludwig Boltzmann Institute for Health Technology Assessment
16. Main Association of Austrian Social Security Institutions
17. Standing Committee of European Doctors

Industry representatives:

1. AnimalhealthEurope
2. Bayer
3. Biotest AG
4. Ceva Santé Animale
5. European Association for Bioindustries, EuropaBio
6. European Federation of Pharmaceutical Industries and Associations (EFPIA)
7. German Pharmaceutical Industry Association

Individuals:

1. Leeza Osipenko - Senior Lecturer in Practice, London School of Economics
2. Dr. Dario Veretnik - Tox and Human DNA ID Evaluations, Toxen2020
3. Dr. Markus Zeitlinger - Medicial University of Vienna



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