Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU

Decision
Case OI/7/2017/KR - **Opened on** 17/07/2017 - **Decision on** 17/07/2019 - **Institution concerned** European Medicines Agency (No further inquiries justified) |

In order to market a new medicine in the EU, 'medicine developers' (mainly pharmaceutical companies) must first submit a 'marketing authorisation application' to the European Medicines Agency (EMA). EMA evaluates the medicine and adopts an opinion on whether it should be authorised. Prior to submitting an application, medicine developers may seek and receive scientific advice from EMA. These 'pre-submission activities' may have some positive consequences for public health. However, it is important to avoid even the perception that the eventual opinions of EMA on medicines were influenced by these earlier interactions.

The Ombudsman carried out an inquiry on her own initiative into these pre-submission activities, as well as the more general transparency of EMA's work concerning the authorisation of medicines.

The Ombudsman found that EMA should carefully manage the contacts its evaluators have with medicine developers during the pre-submission phase. She also found that EMA should provide greater transparency on its pre-submission activities, with the aim of maintaining public trust in its work. The Ombudsman thus made a number of suggestions for improvement to EMA.

1. Background

1. The European Medicines Agency (EMA) plays a key role in ensuring that medicines used in the EU are safe and effective. 'Medicine developers' that wish to market a new medicine (mainly pharmaceutical companies) must obtain a 'centralised marketing authorisation' [1] . To apply for this, they must first submit a marketing authorisation application (MAA) to EMA, which then evaluates the medicine and prepares an opinion on whether or not the European Commission should grant the MAA.

2. EMA's Committee for Medicinal Products for Human Use (CHMP) [2] carries out scientific assessments of MAAs. It evaluates, in particular, the test results of the clinical trials described in an MAA, in order to determine whether the safety, efficacy, and quality of the medicine has been adequately demonstrated.

3. Medicine developers may seek advice from EMA *prior* to submitting MAAs with a view to ensuring that they fully understand the procedures. In particular, they may seek advice on what EMA requires in applications to demonstrate that medicines are safe and effective, including scientific advice. These 'pre-submission activities' entail experts designated by EMA providing advice to pharmaceutical companies on how best to design and carry out clinical trials on medicines.

4. While pre-submission activities EMA's recommendations on whether medicines should be authorised may be influenced - or be perceived to be influenced - by the prior interaction its evaluators have with medicine developers.

5. In this context, the Ombudsman decided to carry out an inquiry on her own initiative to identify what risks are posed by pre-submission activities, and to suggest steps to mitigate and manage those risks.
2. The inquiry
6. For the purpose of this inquiry, the Ombudsman focused **solely** on pre-submission activities [3] in which EMA provides medicine developers with scientific advice [4] . The inquiry also looked more generally at the transparency of EMA's work concerning the authorisation of medicines.

7. In the course of the inquiry, the Ombudsman received EMA's reply [5] to her opening letter [6] , and her inquiry team met twice with EMA representatives [7] .

8. The Ombudsman also carried out a consultation, inviting stakeholders to comment on a number of questions of relevance to the inquiry. [8] The contributions to this consultation were shared with EMA and are made public with this decision [9] .

a. Prior scientific advice and the subsequent evaluation of medicines

b.

Arguments presented by EMA to the Ombudsman

9. EMA provides individual medicine developers with advice on methodology and study design, with the aim of ensuring that the clinical trials on new medicines are fit for purpose. In other words, EMA provides advice to medicine developers on the most appropriate ways to demonstrate that a medicine works and is safe.

10. Scientific advice might concern clinical or non-clinical questions and/or questions relating to product safety. EMA argued that its scientific advice can, for example, help:

· minimise the risks of exposing patients to useless or less useful clinical trials, and maximise the value of the data that clinical trials generate, by ensuring these trials are appropriately designed;

· raise awareness of the data requirements of the approval process, and thereby allow medicine developers to take these into account from the start, preventing delays at a later stage; and

· minimise the administrative burden on both medicine developers and EMA by avoiding misunderstandings in the assessment process.

11. EMA clarified that the scientific advice it provides **is not a pre-evaluation of the data gathered during clinical trials** . In addition, the scientific advice it provides **is not binding on the medicine developer** ; a medicine developer may decide not to follow the advice provided by EMA. Nor is the advice ever binding on EMA.

12. EMA stated, however, that medicine developers that follow EMA's scientific advice stand a better chance of receiving marketing authorisation, as there is a greater likelihood that the trial will have been fit-for-purpose. In this respect, EMA referred to analysis that showed that only 15 percent of medicine developers that complied with scientific advice did not have their MAA approved, compared to 25 percent overall.

13. Formally, scientific advice is adopted, and given to medicine developers, by the CHMP. However, the CHMP delegates the task of preparing scientific advice to the Scientific Advice Working Party (SAWP) [10] , whose members are nominated by the CHMP based on their specific expertise [11] .

Safeguards to ensure the independence of scientific advice

14. EMA stated that, by delegating to the SAWP the preparation of scientific advice, the CHMP distinguishes between its responsibility to provide advice, and its responsibility to assess MAAs. However, there is an overlap in membership between the CHMP and the SAWP: about one-fifth of SAWP members are also members of the CHMP [12] .

15. When a medicine developer asks EMA for scientific advice, two members of the SAWP are appointed as ' **coordinators** ', based on their expertise and the specific nature of the medicine.

16. The coordinators each select their own assessment teams from a pool of experts [13] . The coordinators, with their respective teams, prepare a report that addresses the scientific questions raised by the medicine developer, and details possible issues for discussion within the SAWP. [14]

17. The SAWP, as a whole, then drafts the scientific advice, based on the input from the coordinators. The CHMP then decides on the final report setting out the advice to be given to the medicine developer.

18. EMA contended that its procedures for handling conflicts of interest [15] help to guarantee the independence of the experts involved in providing scientific advice. SAWP members, and any other experts involved, submit a declaration of interests prior to any

involvement in EMA activities. EMA assigns each of these declarations a level of risk based on whether the expert has any direct or indirect interests (financial or other) that could affect their impartiality. Prior to the start of a scientific advice procedure, EMA checks the declarations of interests of the experts involved. If it identifies possible conflicting interests, EMA restricts the rights of the experts concerned, for example by excluding them from participating in discussions, or from voting, on particular topics.

19. EMA explained that its staff members who take part in pre-submission activities are different from those involved in the subsequent evaluation of an MAA [16] , as they belong to different working sections of EMA.

Risk of overlap between those giving scientific advice in the pre-submission stage and those involved in evaluation applications

20. After the pre-submission stage, when a medicine developer actually applies for an authorisation to market a new medicine, the CHMP appoints two **rapporteurs** to follow the MAA. [17] The CHMP appoints these rapporteurs based on what it determines to be the 'best available expertise'. The rapporteurs put together an assessment team from a pool of experts. Each rapporteur and their team summarises the data in the MAA, performs an independent assessment of the data and prepares an assessment report for discussion in the CHMP. All CHMP members can contribute to the discussion and vote on the draft opinion.

21. EMA stated that the fact that a person may be appointed as a coordinator in the pre-submission stage does not mean that the person cannot be subsequently appointed as a rapporteur for evaluating the MAA for the same medicine. In approximately ten percent of MAA evaluations in 2017 and 2018, one of the **rapporteurs** had also acted as a **coordinator** . EMA identified one case in 2017, and one case in 2018, where **both rapporteurs** had also been coordinators for the same medicine.

22. EMA's rules on conflicts of interest also apply to CHMP members, meaning they must submit a declaration of interests prior to any involvement in EMA activities (see paragraph 18 above). EMA stated that the requirements for rapporteurs are stricter than the requirements for other CHMP members [18] .

23. EMA said that it is confident that the current system guarantees impartiality. The fact that there may be overlaps between those involved in providing advice to medicine developers (the coordinators) and those involved in the subsequent evaluation of an MAA for the same medicine (the rapporteurs) is justified because, in certain areas of science and medicine, qualified experts can be scarce. Therefore, EMA argued, it could be detrimental to public health to prevent any of the limited available experts from performing both roles.

c. Views set out in response to the Ombudsman's consultation

24. The Ombudsman received responses to the consultation from: national medicine evaluation authorities, representatives from the pharmaceutical industry, non-governmental organisations, researchers and academics. [19]

25. Nearly all national authorities [20] and industry representatives that responded to the consultation are of the view that the current safeguards applied by EMA are adequate. In particular, they argued that:

· Having the same experts involved in the pre-submission activities and the subsequent evaluation of an MAA ensures consistency in assessing a medicine.

· As qualified experts in some areas may be scarce, it could be detrimental to public health to exclude any of the available experts from, what can be, a highly specialised area of medicine.

· Any potential risks of involving the same people in the pre-submission and evaluation stages of a medicine are sufficiently mitigated. Scientific advice is decided on by the SAWP, which has numerous experts, whereas the evaluation of MAAs is carried out by the CHMP, involving many experts who were not directly involved in the SAWP's advice. Both the SAWP and the CHMP take decisions in a collective and consensual manner.

· The safeguards in place also include, for example, provisions for preventing conflicts of interest when selecting experts for the pre-submission and evaluation phases.

26. By way of contrast, many civil society organisations and academics argued that the current practice concerning pre-submission activities needs be improved to enhance the objectivity of how medicines are evaluated. They argued, for example, that:

· There is a risk of bias if the same individuals are involved in providing scientific advice to medicine developers before they submit MAAs and in subsequently evaluating MAAs for that same medicine. Experts providing scientific advice might subsequently feel bound by that advice when evaluating an MAA and, because of a perceived risk of reputational damage, may be reluctant to change their view, even where the available evidence may have changed. Consequently, EMA should ensure that those involved in giving scientific advice are different from those subsequently involved in evaluating an MAA for the same medicine.

· If EMA cannot separate the roles, it should explain - on a case-by-case basis - why there is an overlap between those giving pre-submission advice on and those subsequently involved in evaluating a medicine, and make this explanation public.

· It could be beneficial to involve a broader group of external experts/stakeholders.

· EMA should ensure that the final evaluation of a medicine is fully independent, and not influenced by prior interactions between the medicine developer and the evaluators, or previous advice that may have been given.

· The scientific advice provided to medicine developers by EMA should be accessible to the

public, for example by publishing details about the topics that were discussed. This would allow for public scrutiny.

d. The Ombudsman's assessment

27. According to EMA, the collective nature of the decisions on scientific advice in the SAWP and opinions on the evaluation of MAAs in the CHMP ensure they are impartial.

28. The Ombudsman notes that coordinators, who take the lead on providing scientific advice, and rapporteurs, who evaluate MAAs, are appointed because their peers on the CHMP and the SAWP deem that they can provide the 'best available expertise'. Because the coordinators and rapporteurs prepare the draft reports that the SAWP and the CHMP discuss, the views of these experts could strongly influence the parameters of the debate. [21] This is not, in itself problematic. However, where there is an overlap between the coordinators and rapporteurs, certain concerns may arise.

29. The Ombudsman recognises that the nature of the advisory role of coordinators, and the nature of the evaluation role of rapporteurs, is different. While coordinators advise medicine developers on how to design and carry out clinical trials, rapporteurs advise the CHMP on whether or not *the results* of such trials prove the safety and efficacy of the medicine. EMA has also pointed out that overlaps between coordinators and rapporteurs are not commonplace (see paragraph 21 above). Nevertheless, it cannot be fully discounted that the evaluation of the results of trials could potentially be influenced by a view previously taken on how best to design and carry out those trials.

30. The Ombudsman acknowledges that the advice given by coordinators is not binding on them, on the CHMP or on EMA. A coordinator who provides scientific advice to a medicine developer on how to design and carry out a clinical trial, and who later acts as a rapporteur for the MAA of the same medicine, may change his or her views on whether the trial was fit-for-purpose. This could happen if knowledge of the therapeutic area has developed, or simply where the rapporteur subsequently considers that the advice he or she had previously provided was not optimal. However, it is natural that a person who has given specific advice may be reluctant to take a different view subsequently. Certainly, there could be a public *perception* that this is the case.

31. There is a public interest in EMA being able to draw on the best available expertise. However, where those involved in providing scientific advice to medicine developers prior to an application are subsequently involved in evaluating the same medicine, there is a risk that this could influence their impartiality, or create the perception of bias.

32. Thus, the Ombudsman is of the view that, to the greatest extent possible, EMA should ensure that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating an MAA for the same medicine. This is already the case for EMA staff members, but should also apply to experts on the SAWP and the CHMP. Ensuring this is so can only help to strengthen public trust in

EMA and the positions it takes on the safety and efficacy of medicines, helping to avoid any risk or perception of bias.

33. To mitigate any such perception, *at the very least* , one of the two rapporteurs for an MAA should not have had any prior contacts with the medicine developer concerning the same medicine.

34. According to EMA, at present, whether or not an expert has been a coordinator is *"not necessarily"* a factor in whether or not to appoint them as rapporteurs for the same medicine. The Ombudsman encourages EMA to change this approach. In appointing rapporteurs, the CHMP should explicitly take into account whether individuals had any prominent role during the pre-submission phase for the same medicine, notably whether they were coordinators for the scientific advice. This should be done with a view to avoiding any overlap or, at least, to ensure that one of the two rapporteurs was not involved in the pre-submission phase.

35. Where EMA finds that it has no choice but to appoint a rapporteur who was a coordinator for the same medicine, it should document the reasons for doing so and make this information public.

36. The Ombudsman will make corresponding suggestions for improvement below.
3. Transparency

a. Arguments presented by EMA

37. According to EMA, its internal rules on transparency are exemplary. Among other things, EMA publishes: clinical data [22] ; scientific information on medicines; information about its internal decision-making process; agendas and minutes of committee meetings, as well as a list of new medicines that are currently being evaluated [23] ; and the declarations of interests of experts with whom EMA works.

38. Since the Ombudsman opened her inquiry, EMA has taken steps to inform the public about its role in the EU process for authorising medicines. An example of this is the recently published EMA brochure ' *From laboratory to patient: the journey of a centrally authorised medicine* ' [24] , which provides information about the procedures in place to authorise medicines. EMA said that is also planning to produce other audio-visual material, explaining its work.

Transparency of scientific advice

39. After its meetings, the CHMP publishes an overview of the scientific advice given to medicine developers. [25] This overview contains: broad details on the substances [26] concerned; information on the intended indications; the type of request; and information regarding the topics discussed.

40. EMA stated that it intends to follow up on a suggestion arising from the Ombudsman's

consultation, namely to explain better certain decisions it makes in selecting experts. For example, it intends to provide explanations as to why experts involved in giving scientific advice in the pre-submission stage are subsequently involved in evaluating MAAs for the same medicine.

41. EMA argued that the content of the scientific advice is considered confidential and should not be made public prior to the submission or during the assessment of an MAA. EMA stated, however, that individuals make requests for access to such advice [27] , in accordance with EU rules on public access to documents [28] . In such circumstances, EMA examines on a case-by-case basis whether or not to grant access.

Transparency of how medicines are evaluated

42. After a medicine has been authorised [29] , EMA publishes a 'European Public Assessment Report' (EPAR), which provides information on the related assessment report adopted by the CHMP. The EPAR describes the data assessed and the reasons for recommending whether the medicine should be authorised or not. The EPAR indicates if a medicine developer requested scientific advice during the pre-submission phase.

43. EMA stated that, since the Ombudsman opened her inquiry, it has increased the transparency of its pre-submission activities. The CHMP report now includes a summary of the type of questions raised and issues discussed in the context of requests for scientific advice (which is included in the EPAR). [30]

44. EMA said that, in principle, it could publish the names of the coordinators responsible for scientific advice. However, it said that it could be necessary to withhold such information, for example when the advice concerns a controversial clinical area, such as relating to the use of animal testing.

45. EMA stated that it could not disclose the names of *EMA staff members* involved in pre-submission meetings, as it has a duty to protect its staff from possible external pressure.

46. EMA sees its engagement with civil society groups, patients and consumer representatives as an important measure for addressing the potential public perception of bias. It has developed strong links with civil society groups, and its work takes into account input from patients, consumers and healthcare professionals at various levels, including in its management board, in scientific committees, working parties and scientific advisory groups. [31]

b. Views set out in response to the Ombudsman's consultation

47. Public authorities and industry representatives who responded to the Ombudsman's consultation were of the view that EMA's current system is sufficiently transparent. They argued that:

• All experts' declarations of interests are in the public domain.

• An appropriate balance has already been struck between transparency and respecting the confidentiality of data, including information that is commercially sensitive.

• Publishing scientific advice opinions before a medicine is authorised could result in commercially confidential information becoming available to competitors. Medicine developers would thus become reticent about seeking such advice.

• The scientific advice is the property of the medicine developer and, therefore, cannot be disclosed. Disclosing scientific advice could lead to issues with the protection of intellectual property.

48. Civil society organisations and academics who responded to the consultation argued that there should be greater transparency concerning pre-submission activities. They argued, for example, that:

• More transparency would enhance EMA's accountability to the public, and potentially increase public trust in EMA's work.

• Only scientific advice concerning commercially sensitive topics should be confidential.

• The content of scientific advice should be published as an annex to the EPAR.

• Publishing such information would enable it to be re-used by relevant stakeholders and researchers.

• To manage conflicts of interest, it is important to name the experts involved. For example, once the scientific advice has been finalised and sent to the medicine developer, publishing the names of those involved in providing the advice could allow public scrutiny as to whether the rules on conflicts of interest were followed.

• Granting public access to the questions posed by medicine developers would enable public scrutiny and reveal potential misuse (for example, when there are requests for waivers from applicable guidelines). It could also foster a general scientific debate about the best approaches to medicine development in individual therapeutic areas.

• Revealing scientific advice would inform the overall medicines development environment, which could improve quality.

c. The Ombudsman's assessment

49. The Ombudsman welcomes the steps taken by EMA to enhance the transparency of its procedures and to improve the information it makes available to the public. This has also

increased the transparency of the advice given to medicine developers prior to them submitting an MAA.

50. The Ombudsman is of the view that keeping a detailed log of each of the pre-submission activities, including the names of the experts involved, could allow the public to understand better the way in which EMA conducts its work. This could diminish the need for individuals to make requests for public access to documents, which can be time consuming, both for applicants and for EMA. Such a log could be provided with the EPAR (the EPAR already contains a summary of the meetings).

51. The Ombudsman welcomes EMA's intention to explain decisions concerning the selection of experts, especially where an expert involved in evaluating an MAA had a prominent role in providing scientific advice on the same medicine. The Ombudsman is of the view that EMA should publish such decisions with the EPAR.

52. The Ombudsman will make suggestions to this end below.

4. Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion:

No further inquiries are justified.

EMA will be informed of this decision **.**

5. Suggestions for improvement

To the greatest extent possible, EMA should ensure that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating an MAA for the same medicine

In appointing rapporteurs to evaluate MAAs, EMA's CHMP should take into account whether individuals were already involved as coordinators in providing advice on the same medicine in the pre-submission stage.

If, in exceptional cases, EMA sees no other option than to appoint as a rapporteur an expert who had a prominent role in providing advice for the same medicine during the pre-submission phase, EMA should document the reasons for its decision. It should publish this information with the EPAR.

EMA should ensure that at least one of the two rapporteurs had no prominent role in the pre-submission activities concerning that medicine.

EMA should attach to the EPAR a detailed log of all relevant pre-submission activities, including the names of the experts involved.

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[1] A centralised marketing authorisation is granted by the European Commission, based on the evaluation and recommendation by EMA's Committee for Medicinal Products for Human Use. An authorisation is valid in all EU Member States and in the European Economic Area. The rules are set down in Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R0726 . For more information on EMA's role, see: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation .

[2] The CHMP consists of one member and an alternate member, nominated by the governments of each of the 28 EU Member States, and from Iceland and Norway. The CHMP also includes up to five "co-opted members", chosen to provide additional expertise in a particular scientific area. The CHMP elects a chair from among its members. More information: https://www.ema.europa.eu/en/committees/committee-medicinal-products-human-use-chmp .

[3] The pre-submission activities that EMA organises to assist medicine developers are varied. They include, amongst other things, providing advice and offering regulatory and scientific support on different aspects of the authorisation process. For a more detailed overview of these activities, see EMA's website http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001768.jsp&r .

[4] This was identified as the most important pre-submission activity in the responses to the Ombudsman's consultation. Through this advice, EMA can influence the information that medicine developers subsequently include in their MAAs. On average around two-thirds of all medicines for which an MAA was submitted received scientific advice during the pre-submission stage.

[5] See: https://www.ombudsman.europa.eu/en/correspondence/en/83875 .

[6] See: https://www.ombudsman.europa.eu/en/correspondence/en/81555 .

[7] See the reports of the meeting of 28 September 2017 (https://www.ombudsman.europa.eu/en/correspondence/en/87563), and the meeting of 15 May 2019 (https://www.ombudsman.europa.eu/en/correspondence/en/116511).

[8] See: https://www.ombudsman.europa.eu/en/public-consultation/en/104905 .

[9] The Ombudsman published a consultation report: https://www.ombudsman.europa.eu/en/correspondence/en/116512 , and all the individual contributions: https://www.ombudsman.europa.eu/en/case/en/49999 .

[10] The SAWP consists of 24 members. They may be CHMP members, or European experts from regulatory authorities or academia. Other EMA committees can propose members of the SAWP. More information: https://www.ema.europa.eu/en/committes/working-parties-other-groups/chmp/scientific-advice-working
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[11] While the main mechanism for giving scientific advice is through the SAWP, EMA identified other specific means by which it gave scientific advice to medicine developers. These include 'protocol assistance' for orphan drug products and scientific advice for paediatric medicine development.

[12] See: https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medic
, p. 5 ('Who's involved in scientific advice').

[13] This pool consists of external experts and/or internal assessors from the national authority or other EU agencies.

[14] The SAWP may ask the medicine developer for additional information. The SAWP may also consult relevant EMA committees, for example, the Committee for Orphan Medicinal Products (COMP), or the Committee for Advanced Therapies (CAT), as well as external experts, widening the pool of experts the SAWP can draw on.

[15] See: https://www.ema.europa.eu/en/about-us/how-we-work/handling-competing-interests .

[16] For example in terms of the benefit/risk assessment and the 'labelling and standards'.

[17] Although referred to as a 'rapporteur' and a 'co-rapporteur' in the applicable legislation, there is no hierarchical distinction between them when they assess an MAA.

[18] EMA did not provide an explanation as regards precisely how these requirements were stricter.

[19] For an overview of contributions to the consultation, see: https://www.ombudsman.europa.eu/en/correspondence/en/116512 .

[20] These contributing authorities consisted of national medicine agencies involved in EMA's provision of scientific advice and evaluation of medicines through the nomination of

experts to EMA's scientific committees.

[21] Nevertheless, EMA has demonstrated that the CHMP can and does take different opinions to those of rapporteurs.

[22] For applications received by EMA after 1 January 2015, the clinical trial results submitted by the medicine developers in support of their MAAs are published. Those seeking to access the data from clinical trials related to MAAs made before 2015 must make a request in line with EU rules on public access to documents.

[23] This list is updated on a monthly basis.

[24] See: https://www.ema.europa.eu/en/documents/other/laboratory-patient-journey-centrally-authorised-medic .

[25] See for example this overview referring to the CHMP meeting of 27 - 29 May 2019: https://www.ema.europa.eu/en/documents/chmp-annex/scientific-advice-protocol-assistance-adopted-c .

[26] For example biological, chemical or other.

[27] See: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32001R1049 .

[28] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents : https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32001R1049 .

[29] A central marketing authorisation is granted by the Commission following a CHMP assessment report that recommends authorisation, see also paragraph 1 above.

[30] In June 2018, EMA took the initiative to provide, in the CHMP assessment report for initial marketing authorisation applications of 'PRIME products', detailed information about the support provided during development, including information on the topics on which medicine developers got scientific advice. Since January 2019, this information is included in the assessment reports for all medicines. The respective EPARs are now being made publicly available.

[31] EMA also has a dedicated Patients and Consumers Working Party that meets four times a year, and is co-chaired by an EMA official and an elected civil society representative. The working party members review written information on medicines prepared by EMA, including precautionary statements and packaging of medicines, EPAR summaries and EMA's public safety communications.