EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Ms Emily O'Reilly
European Ombudsman
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26 March 2024
EMA/75085/2024

Sent by email only: [redacted]

Dear Ms O'Reilly,

Subject: Follow-up reply of the European Medicines Agency in response to the European Ombudsman's Decision on how the European Medicines Agency ("EMA") deals with requests for public access to documents (Case 2243/2022/SF)

We refer to the above-referenced Decision of 13 December 2023 on how the European Medicines Agency ("EMA" or the "Agency") deals with requests for public access to document (hereinafter, the "Decision").

In the context of that Decision, you examined two practices which had been developed by EMA in order to manage the backlog of requests for access to documents which had been generated following two extraordinary events, namely, the relocation of the seat of EMA from London to Amsterdam in 2019; and the subsequent emergence of the COVID-19 pandemic in early 2020. More specifically, those two practices pertained to the 5-2-rule[1] and the chronological queue.[2]

In relation to the 5-2-rule, you concluded that the practice constitutes maladministration. EMA acknowledges your findings regarding the limitation of number of requests to access documents per requester. The Agency will make its best efforts to continue to manage excessive requests for access to documents ensuring that all requesters are treated in a fair way, in line with Article 6(3) of Regulation (EC) No 1049/2001 and your Decision in Case 1608/2017/MIG.

1 The so-called 5-2-rule corresponds to the practice of limiting to five the number of requests for access that an applicant may have pending at the same time before EMA; and to two the number of documents that may be linked to each request.

2 The practice of the chronological queue relates to the practice of placing requests for access in a queue in the order in which they have been received, subject to certain exceptions. The requests that are placed in the chronological queue are subsequently handled on a first-come first-served basis.

As regards the use of the chronological queue, you acknowledged the steps that had been taken by EMA in order to minimise and ultimately phase out its recourse to this practice. In that connection, you refrained from issuing a recommendation on the matter; and requested EMA to provide you with an update, by 30 March 2024, on the progress made in order to phase out this practice.

We would like to thank the European Ombudsman (the "Ombudsman") for the opportunity to present the below details of the progress that has been achieved since the submission of our initial reply of 8 May 2023 (the "initial reply of 8 May 2023") in relation to the phasing out of the chronological queue.[3]

1. The expansion of EMA's approach towards the proactive publication of documents

As an initial remark, EMA would like to reiterate that it recognises the important role that the proactive publication of documents can have in facilitating access to documents to members of the public.[4]

Indeed, in our initial reply of 8 May 2023, we had informed you of the steps that had already been instigated in order to ensure that certain documents of major interest are proactively made available by EMA. In that respect, it was explained that EMA had commenced the publication of clinical data and additional safety information for COVID-19 medicinal products,[5] as well as risk management plans ("RMPs") of centrally authorised products that contain new active substances and are considered to be of particular public interest.[6] In addition, we indicated that EMA was examining the feasibility of the proactive publication of periodic safety update reports ("PSURs") and their assessments.

Further to the above, we would like to provide you with the following developments.

First, as of 5 August 2023, EMA has commenced the proactive publication of PSURs and assessment reports issued by EMA's Pharmacovigilance Risk Assessment Committee ("PRAC") for COVID-19 vaccines.[7]

Second, in September 2023, EMA relaunched its policy on the proactive publication of clinical data for medicinal products for human use ("Policy 0070").[8] The relaunch of Policy 0070 has

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3 EMA's initial reply of 8 May 2023 in response to the European Ombudsman's inquiry concerning the handling of requests for access to document (Case 2243/2022/SF) has been published on the following section of the website of the European Ombudsman: https://www.ombudsman.europa.eu/en/doc/correspondence/en/176522.

4 In this respect, EMA is cognisant of the recent findings contained in the European Parliament resolution of 14 March 2024 on the time the European Commission takes to deal with requests for public access to documents (2023/2941(RSP)) and, in particular, points 8 and 10 therein; available at: https://www.europarl.europa.eu/doceo/document/TA-9-2024-0172_EN.pdf.

5 In this respect, see: the first bullet point which is set out under section 1.3 of the initial reply of 8 May 2023 (page 6).

6 In this respect, see: the second bullet point which is set out under section 1.3 of the initial reply of 8 May 2023 page 6).

7 In this respect, reference is made to the section relating to "Transparency: exceptional measures for COVID-19 medicines" of EMA's website; available at: https://www.ema.europa.eu/en/human-regulatory-overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/transparency-exceptional-measures-covid-19-medicines.

8 In this respect, reference is made to EMA's "Clinical Data Publication (CDP) Questions and Answers (Q&As) on the External Guidance on the implementation of the European Medicines Agency policy on the publication of clinical data for medicinal products for human use (Policy 0070)" of 26 July 2023 (EMA/14227/2017, Rev. 3); available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/questions-and-answers-qas-external-guidance-policy-0070-clinical-data-publication-cdp_en.pdf.

entailed, as a first step, the publication of clinical data of medicinal products with new active substances. The next phase (step) of the relaunch of Policy 0070 will extend to regulatory procedures involving extension of indication applications and line extension applications in 2024.[9]

The aforementioned development was welcomed in your Closing Note of 16 November 2023 on the Strategic Initiative on how EMA ensures proactive transparency concerning clinical trial data of centrally authorised medicinal products (SI/3/2023/MIK).[10]

Third, in addition to proactively publishing the RMPs of COVID-19 medicinal products and RMPs requested under Regulation (EC) No 1049/2001, on 20 October 2023, EMA extended the proactive publication of RMPs to all centrally authorised medicinal products.[11] The scope of this initiative includes all initial marketing authorisation evaluations, as well as subsequent updates to RMPs.[12]

The above developments should be understood in the context of a continuous improvement effort by EMA to identify documents, which are of particular public interest and to ensure enhanced transparency, in accordance with Article 80 of Regulation (EC) No 726/2004. In turn, it is envisioned that these steps will effectively reduce the number of requests for access to documents submitted by applicants.

Further, the possibility to proactively publish other documents will continue to remain under the close purview of EMA in the coming months. In this connection, our intention is to initiate a project in Q.3 of 2024 that will identify further possible categories of documents that could be subject to proactive as opposed to reactive disclosure. This assessment would be based on a detailed review of all requests for access to documents that have been received by EMA in the course of the past 5 years. It is linked to the eventual establishment of a public register of a list of documents that have been previously disclosed by EMA.

2. Reinforcing temporarily the capacity of EMA to handle requests for access to documents

In our initial reply of 8 May 2023, we identified the importance of dedicating sufficient personnel to handle requests for access to documents.

Since the submission of our initial reply, we would like to highlight the following steps which have been taken.

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9 For a more comprehensive overview of the relaunch of Policy 0070, reference is made to EMA's reply of 29 September 2023 in response to the letter of the European Ombudsman concerning the proactive transparency of clinical trial data (Case SI/3/2023/MIK); available here: https://www.ombudsman.europa.eu/en/doc/correspondence/en/176095.

10 The European Ombudsman's Closing Note of 16 November 2023 on the Strategic Initiative on how EMA ensures proactive transparency concerning clinical trial data of centrally authorised medicinal products (SI/3/2023/MIK); available at: https://www.ombudsman.europa.eu/en/doc/correspondence/en/177918.

11 As previously explained in our initial reply of 8 May 2023, the publication of RMPs and their summaries (namely, the main body of the document and annexes 4 and 6) may be redacted in order to ensure the protection of commercially confidential information and/or personal data.

12 In this respect, see: the heading titled, "Publication of RMPs and their summaries" of pharmacovigilance section of EMA's website; available at: https://www.ema.europa.eu/en/pharmacovigilance-marketing-authorisation/risk-management/risk-management-plans.

First, EMA has strengthened the Documents Access and Publication Department by allocating additional temporary resources (in the form of four interim contracts) until the end of 2024 for the purpose of assisting with the reduction of the current backlog in the chronological queue.

Second, we would like to note that EMA is currently investigating the possible outsourcing of certain tasks to an external service provider in order to support the capacity of EMA to handle requests for access to documents in a timely manner.

3. Other steps to improve the optimisation of EMA's timely handling of requests for access to documents

In our initial reply of 8 May 2023, we highlighted that EMA was performing a review and evaluation of its access to documents processes with a view to optimising its efficiency with the support of external consultants.

In particular, in the context of that review, we would like to report that we:

- conducted a series of internal workshops in order to review the functioning of the Access to Documents Service;
- finalised a review of access to documents processes and performed a benchmarking exercise supported by external consultants with expertise in process reengineering, to identify possible areas which could be improved in order to enhance the timely handling of requests for access to documents; and
- identified a new workflow-based information technology tool for the purpose of improving the use of existing technology and making the best use of processes to support personnel who are responsible for the handling of requests for access to documents.

We are pleased to report that the implementation of some of the above steps has already resulted in a marked decrease in the number of requests which were pending in the chronological queue between mid-December 2023 and 25 March 2024 from 249 to 180 requests, that is to say, a decrease of almost 28%. We are confident that we will continue to lower these figures significantly in the remaining months of 2024.

We trust you will appreciate the relentless commitment of EMA to reduce the backlog of requests for access to documents further. The progress which has been made over the course of the last ten months in order to reduce this number provides a clear indication that we are on the right track. Further, we are confident that additional organisational measures, both internal and external (through recourse to an external service provider) may have a positive effect in due course.

We remain at your disposal to provide any clarification(s) or any further information that could be needed.

Yours sincerely,

[redacted]

Emer Cooke
Executive Director