



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Subject: Reply of the European Medicines Agency's in response to the European Ombudsman's inquiry concerning the handling of requests for access to document (Complaint 2243/2022/SF)

Dear Ms Hickey,

We refer to your letter of 14 February 2023 in which you informed the European Medicines Agency (“EMA” or the “Agency”) that the European Ombudsman (“Ombudsman”) has decided to open an inquiry in connection with two practices of EMA for the handling of requests for access to documents pursuant to Regulation (EC) No 1049/2001.

The inquiry comprises **two parts**. The **first part** concerns the practice of deferred processing of requests for access to documents (“deferred processing”). In particular, the first part revolves around the practice of EMA to place requests for access to documents in a **chronological queue**. In connection with the first part of the inquiry, the Ombudsman has asked **two questions** to EMA.¹

The **second part** relates to EMA's practice of limiting the **number of requests for access to documents** that an applicant² might have pending before EMA, as well as the **number of documents that may be linked with each request**. In connection with the second part of the inquiry, the Ombudsman has addressed **four questions** to EMA.³

EMA's Reply is divided in three parts. **First**, EMA would like to present its response on the first part of the inquiry related to the practice of the chronological queue. **Second**, EMA will address

¹ Those two questions correspond to questions 1 and 4 in the letter of the Ombudsman to the Agency of 14 February 2023.

² The term “applicant” is used throughout the present Reply to describe the person that submits a request to EMA under Regulation (EC) No 1049/2001, for access to documents.

³ Those four questions correspond to questions 2, 3, 5 and 6 in the letter of the Ombudsman to the Agency of 14 February 2023.



the second part of the inquiry which concerns the practice of limiting the number of requests that each applicant may have pending before EMA at the same time (as well as the number of documents linked with each request). **Third and finally**, EMA will provide certain clarifications in relation to the underlying complaint which is understood to have prompted the present inquiry.

1. In relation to the first part of the inquiry

1.1 Response to the first question of the Ombudsman asking “What is the basis for EMA’s practice of placing requests for public access into a chronological queue”

At the outset, EMA would like to clarify that the practice of the chronological queue entails that some requests for access to documents will not be handled immediately by EMA, but that they will instead be placed in a queue in the order in which they have been received. The requests that are placed in the chronological queue will be handled on a first-come first-served basis. (There are requests that are eventually not placed in the chronological queue, following a preliminary review of the scope of the request; examples of such requests are presented under section 1.3 of the present Reply.)

It should also be clarified that the practice of placing requests for access to documents in a chronological queue has been in place since October 2019. This temporary practice was introduced to manage the challenges posed by **one event** that was unprecedented in its nature; and was then maintained for the purpose of responding to the challenges of **second event** (that materialised sequentially) and was also unprecedented.

The **first event** relates to the decision of the United Kingdom to withdraw from the European Union (“EU”).

As a direct consequence of this decision, the seat of EMA was relocated from London to Amsterdam.⁴ For the purpose of its relocation, EMA needed to move first, for few months, into a temporary building in Amsterdam; and shortly afterwards EMA moved into its more permanent (and current) premises in Amsterdam. This entails that EMA needed to change sets of premises twice (across two countries). Unfortunately, the relocation prompted the resignation of certain staff members⁵, an increase in long term leave⁶ and the loss of temporary agency workers.⁷

⁴ In this respect, see: Article 1 of Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards the location of the seat of the European Medicines Agency.

⁵ Despite the measures taken to incentivise the relocation of staff members to the new seat in Amsterdam, there were (inevitably) staff members that decided that the relocation was not a viable or preferred personal choice. In this respect, see: section 1.1.4, titled “Impact of relocation on staff members” of the Annual Activity Report of 2019, wherein it was explained that by 31 December 2019, 56 staff members had left the Agency (with 82% of those staff members tendering their resignation). In that regard, the report noted that “[t]hese have been the highest turnover and resignation figures the EMA has experienced since its establishment”; available at: https://www.ema.europa.eu/en/documents/report/annual-activity-report-2019_en.pdf. (**Annex 1** to the present Reply.)

⁶ In this respect, see: sub-section 5.1, titled, “Update on EMA Brexit preparedness” of the Minutes of the 105th meeting of the Management Board of 3 October 2019 (EMA/MB/542228/2019 Adopted); available at: https://www.ema.europa.eu/en/documents/minutes/minutes-105th-meeting-management-board-3-october-2019_en.pdf. (**Annex 2** to the present Reply.)

⁷ The loss of temporary agency workers was linked with the fact that those workers could unfortunately not continue providing their services to EMA on the basis of their existing contracts (which had been concluded with a UK-based recruiter for services to be provided in London). Further, the relocation entailed that some time would need to pass before EMA could launch a new procurement procedure (once in Amsterdam) for the hiring of temporary agency workers in the Netherlands. In total, EMA witnessed a combined loss of almost 200

The (reduced) resources had to also be re-allocated internally in order to cope with the surfeit of disruption that was generated by the relocation of the Agency from London to its temporary and then to its more permanent (and current) premises in Amsterdam. During this exceptional relocation period and due to their scientific background, several members of the Documents Access and Publication Department were temporarily re-allocated to perform other core tasks activities of the Agency, including, but not limited to, tasks related to marketing authorisation applications.

The **second event** relates to the emergence of the COVID-19 pandemic in early 2020. The pandemic entailed that a significant number of resources were urgently shifted to activities related to the authorisation, supervision and pharmacovigilance of medicinal products related to the prevention or treatment of COVID-19.

On balance, the threats that the COVID-19 pandemic posed for public health in the EU (and globally) compelled EMA, in its capacity as the competent scientific authority in the EU for the evaluation, monitoring and pharmacovigilance of medicinal products, to ringfence appropriate resources for the management of the pandemic and the protection of public health.

Further, several members of the Documents Access and Publication Department were re-allocated to perform tasks related to exceptional transparency measures for treatments and vaccines against COVID-19⁸ such as the proactive publication of clinical data for COVID-19 medicines and the management of requests for information (a significant portion of which related to the COVID-19 pandemic).⁹

Both these above-mentioned events **have kept** EMA in a **business continuity status** and have undercut EMA's capacity to start processing all requests for access to documents upon receipt.

The above-outlined considerations are also reflected in question-and-answer 16 of the EMA "Guide on access to unpublished documents",¹⁰ wherein the following is explained:

"Q16. Why are some requests placed in the 'chronological queue' and what is the difference to the queuing system which is explained in Q14? [emphasis in the original]

staff members and temporary workers by the end of 2019. In this respect, see: section 1.1.4, titled "Impact of relocation on staff members" of the Annual Activity Report of 2019 (**Annex 1** to the present Reply).

⁸ Certain transparency activities of EMA in response to the COVID-19 pandemic are set out in the Letter from the European Ombudsman to the European Medicines Agency closing her Strategic Initiative SI/5/2020/DDJ. In her Letter, the Ombudsman acknowledged EMA's commitment to matters of transparency. A more comprehensive list of such transparency activities may be found on EMA's website, at: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines>.

⁹ In 2021 (with the COVID-19 pandemic still ongoing), the number of requests for information **almost doubled** in comparison to the previous four years. In this respect, see: page 134 of the EMA Annual Report for 2021; available at: https://www.ema.europa.eu/en/documents/annual-report/2021-annual-report-european-medicines-agency_en.pdf. The requests for information were 7,055 in 2020 and 12,500 in 2021 (**Annex 3** to the present Reply).

¹⁰ The "Guide on access to unpublished documents" is published on EMA's website and its purpose is to inform prospective applicants about the procedure for the handling of a request to EMA for access to documents. The Guide is available at: https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf. (**Annex 4** to the present Reply.)

In early 2019, the Agency relocated from London to Amsterdam due to the notification by the UK of its withdrawal from the EU. The change of seat of the Agency entailed that resources needed to be reallocated to ensure its smooth relocation. Further, in early 2020, the breakout of the coronavirus disease 2019 (COVID-19) was declared a pandemic. The Agency was operating within a business continuity plan to ensure operational continuity during the COVID-19 pandemic crisis of unprecedented scale which required EMA to dedicate resources specifically to transparency related to COVID-19 and other urgent issues. Whilst every effort is being made to process all requests as soon as possible, due to these exceptional circumstances since October 2019, some requests could not be processed immediately and were dealt with in **chronological order** from the time they were received. These requests were placed in the 'chronological queue' (emphasis in the original)".

In essence, the practice of the chronological queue was launched, hopefully on a **temporary basis**, for the purpose of safeguarding that, notwithstanding the significant disruption of EMA's services as a result of the above-mentioned two events, EMA would still be in the position to continue performing its principal tasks related to the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.

This practice coheres with the general principles articulated under section 4.1.1 of the EMA Policy on access to documents which explains, in particular, that "[i]n dealing with requests for access to documents, EMA will also apply the **principle of proportionality** in order to avoid that performance of core tasks assigned to EMA is jeopardised".¹¹ Further, it enables EMA to handle the numerous and complex requests for access to documents in a manner that takes into account its more urgent principal tasks and its available personnel.¹²

1.2 Response to the fourth question of the Ombudsman asking "How does EMA determine which access requests to place in the queue"

It bears highlighting that requests are placed in the chronological queue only after the review of their content. In the context of this review, it may be established that there are circumstances justifying their immediate processing upon their receipt (and their non-placement in the chronological queue).

In particular, EMA will prioritise a request for access to documents for immediate processing, if the request pertains to:

- confirmatory applications (appeals) in accordance with Article 8 of Regulation (EC) No 1049/2001;

¹¹ In this respect, see: the European Medicines Agency policy on access to document (Policy 0043) of 6 February 2017 (EMA/729522/2016); available at: https://www.ema.europa.eu/en/documents/other/draft-policy/0043-european-medicines-agency-policy-access-documents_en.pdf. (Annex 5 to the present Reply). As noted by Advocate General de la Tour, at point 32, of his recent opinion of 12 January 2023 in *Germany v Pharma Mar and Commission*, Joined Cases C-6/21 P and C-16/21 P, ECLI:EU:C:2023:8, the "EMA policy on transparency and access to documents [...] could be seen as a regulatory measure implementing the right of access to documents, as established in Article 15(3) TFEU and Article 42 of the Charter".

¹² In this respect, see by analogy: the opinion of Advocate General Kokott of 8 September 2009 in *Commission v Technische Glaswerke Ilmenau*, C-139/07 P, EU:C:2009:520, point 67 and the case-law cited therein. In the context of her opinion, Advocate General Kokott noted that "As Regulation No 1049/2001 has to be applied in the light of the principle of proportionality, it is not beyond the bounds of possibility, in exceptional cases and in the interests of the proper performance of other more urgent administrative duties, to refrain from taking a due decision on an application for access".

- safety-related documents regarding ongoing/soon to start regulatory procedures;
- documents claimed to be needed in connection with safety issues (in principle, such documents are requested by patients or healthcare professionals);
- documents requested in connection with litigation; or
- documents not held by the Agency further to a review of the content of the request.¹³

Further, EMA would like to stress that an applicant is informed in writing when their request is placed in the chronological queue.¹⁴ In addition, in the scenario whereby EMA determines subsequently that the request should be handled immediately (either on its own motion or further to clarifications by the applicant), the request will be removed from the chronological queue; and the applicant will be informed accordingly.

As a matter of further transparency, prospective applicants are informed of the operation of the chronological queue at the time of the submission of their request¹⁵; and also by means of publicly available guidance, which is published and revised (as and when required) on its website¹⁶

1.3 The steps taken by EMA to minimise its recourse to the deferred processing of requests for access to documents

Under the present sub-section of the Reply, EMA would like to explain the important steps which it has taken, as of recently, for the purpose of ensuring that applicants can receive timely access to documents under Regulation (EC) No 1049/2001. Similarly, EMA will describe the steps that it is actively exploring for the purpose of reducing the chronological queue.

The aim of such optimisation steps is to reduce reliance on, and ultimately phase out, the mechanism of the chronological queue.

First, EMA is carefully monitoring (and anticipating) areas of its work that may generate public interest from a public access to documents perspective.¹⁷ In this vein, EMA would like to highlight that it has sought to reinforce its commitment towards proactive transparency by means of the following concrete actions:

¹³ Certain circumstances that justify the immediate processing of a request for access to documents are set out in EMA’s “Guide on access to unpublished documents” (op. cit.), question-and-answer 16. EMA acknowledges that not all of the circumstances mentioned in the present Reply are enumerated in the foregoing Guide. To enhance the predictability of the handling of a request for access to documents, EMA undertakes to revise question-and-answer 16 of the foregoing Guide to identify (in a more exhaustive way) the circumstances that may necessitate the immediate processing of a request for access to documents. (**Annex 4** to the present Reply.)

¹⁴ For completeness, EMA has enclosed a sample text which it communicates by email to applicants who are placed in the chronological queue. (**Annex 6** to the present Reply.)

¹⁵ In this respect, see: the information which is published alongside the webform for submitting a request for access to documents to EMA; available at: <https://www.ema.europa.eu/en/about-us/contacts/send-question-european-medicines-agency>.

¹⁶ As a matter of publicity and transparency, members of the public have at their disposal a list of “Policies and guidance documents” which are set out under the “Access to documents” section of the website of EMA; available at: <https://www.ema.europa.eu/en/about-us/how-we-work/access-documents#policies-and-guidance-documents-section>.

¹⁷ In this context, EMA would like to respectfully submit that it is currently implementing the (sixth) suggestion for improvement which is set out the Ombudsman’s Recommendation of 28 March 2023 in Case 01/2/2022/OAM on the time the European Commission takes to deal with requests for public access to documents; available at: <https://www.ombudsman.europa.eu/en/recommendation/en/167661>.

- Since October 2020, EMA has been publishing clinical data for COVID-19 medicines submitted in support of marketing authorisation applications by companies in line with its exceptional transparency measures for treatments and vaccines for COVID-19.¹⁸ Furthermore, additional safety information has been shared on a regular basis with the public in the form of monthly summary safety reports.
- EMA has identified risk management plans (“RMPs”) of approved medicinal products as one of the most frequently requested categories.¹⁹ In light of this finding, since September 2022, EMA has been publishing RMPs for centrally authorised products that contain a new active substance and are considered to be of particular public interest (namely, the RMP relates to a COVID-19 vaccine or treatment; or are considered to be an innovative medicinal product). Further, EMA is systematically publishing RMPs released further to an access to document request.²⁰

The implementation of the above-mentioned steps means that certain documents of major interest for members of the public are proactively made available; thus, potentially reducing the number of requests for those documents under Regulation (EC) No 1049/2001, in accordance with Article 80 of Regulation (EC) No 726/2004.

For completeness, it should be noted that the identification of documents that ought to be published proactively is an ongoing exercise. In this respect, EMA would like to add that it is currently examining the feasibility of a possible proactive publication of periodic safety update reports (PSURs) and their assessment reports.²¹

Second, as regards the matter of personnel, additional interim administrative resources have been allocated to the Access to Documents (“ATD”) team for the purpose of specifically reducing the chronological queue. As these resources are only temporary in nature, also in light of the compelling labour law rules applicable in the Netherlands, the matter of dedicating sufficient personnel to handle requests for access to documents will need to be re-considered in the context of the overall resourcing strategy of EMA, which in turn is subject to the directives and approval of the European Commission, namely DG BUDGET.²²

Third, EMA with the services of external consultants is actively exploring the feasibility of additional measures that could potentially help the ATD team to cut down the chronological queue.

¹⁸ This action is connected to the implementation of EMA’s policy on the proactive publication of clinical trial data, which was suspended in December 2018 (namely, Policy 0070) as part of its business continuity plan following the decision to relocate the seat of EMA from London to Amsterdam.

¹⁹ In this respect, see: Chapter 2, titled “Key figures in 2021” of the EMA Annual Report for 2021 (page 135); available at: https://www.ema.europa.eu/en/documents/annual-report/2021-annual-report-european-medicines-agency_en.pdf. (Annex 3 to the present Reply.)

²⁰ 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. For additional information in relation to this initiative, please consult the website of EMA; available at: <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/pharmacovigilance/risk-management/risk-management-plans>.

²¹ This reflection has been prompted by the observations received by a number of healthcare professionals in the EU who wish to receive expedited access to the PSURs for COVID-19 vaccines and the associated assessment reports.

²² In this respect, EMA would like to respectfully note that it takes into cognisance (by analogy) the (first) suggestion for improvement which is set out the Ombudsman’s Recommendation of 28 March 2023 in Case 01/2/2022/OAM on the time the European Commission takes to deal with requests for public access to documents.

In this framework, EMA is considering the feasibility of introducing a public register. In principle, this tool would enable prospective applicants to establish if the object of their request has already been subject to request for access to documents. Accordingly, this may obviate the need for submitting a request for access to documents (and, in turn, reduce the number of requests received by EMA). One possible complication for the implementation of such public register is the existing huge workload in our Information Management Division, amid several competing projects which are mandated by the pharmaceutical legislation (e.g. the creation of a European Shortages Monitoring Platform according to Article 13 of Regulation (EU) 2022/123; and the functioning at full speed of the Clinical Trials Information System data base foreseen by Regulation (EU) No 536/2014.

In addition, EMA is reviewing its access to documents process in order to optimise efficiency, including with regard to the use of an automation tool that could help reduce the time needed to process a request for access to documents.

EMA would like to confirm that it is cognisant of the fact that **effective access entails timely access**. Exactly for that reason, EMA is actively exploring ways to reduce as much as possible the chronological queue, for the purpose of improving further its implementation of Regulation (EC) No 1049/2001.

2. In relation to the second part of the inquiry

Under the second part of the inquiry, the European Ombudsman has asked four questions focussing on EMA's practice of **limiting the number of requests for access** that an applicant may have pending at the same time before EMA to **five**; as well as the **number of documents** that may be linked to each request to **two**. This practice corresponds to the so-called 5:2 rule.

Prior to the introduction of this rule, there were no limits as to the number of requests one applicant could have pending at the same time before EMA; or the number of documents linked with each request.

Please find our response to the concerned questions.

2.1 Response to the second question of the Ombudsman asking “What is the basis for EMA’s practice of limiting the number of requests per applicant to five in the queue”

The decision to limit the number of requests of each applicant to five was introduced on 1 March 2021.

As explained *supra*, the COVID-19 pandemic and the subsequent public health emergency directly impacted the daily work of EMA, thereby requiring the agency to focus its resources on COVID-19-related assessments.²³ This (coupled with the two-stepped relocation of the EMA) led to the emergence of a chronological queue for the orderly handling of requests for access to documents.

²³ In this respect, see: the “European Medicines Regulatory Network COVID-19 Business Continuity Plan” of 10 September 2020 (EMA/199630/2020, Rev. 1); available at: https://www.ema.europa.eu/en/documents/other/european-medicines-regulatory-network-covid-19-business-continuity-plan_en.pdf.

This limit of 5 pending requests per applicant is explained under question-and-answer 17 of the EMA “Guide on access to unpublished documents”, which highlights that a “*requester/affiliation can have a maximum of 5 access to documents requests in queue*”.²⁴ The Guide further explains that this limit was placed “*in order to ensure a manageable flow of all access-to-documents requests from all requesters in a fair, timely and consistent way*”.

This limit has been applied to ensure an appropriate flow of access to documents requests and fairness between all requesters. The same fair chance is then offered to requesters to start processing their requests as soon as possible and not to remain behind massive requests to access documents. In practice, if a single applicant has five requests in a queue (that is to say, one request that is being processed and the fourth request that is pending), the ATD team will confirm in writing that those requests are held in the queue. In that connection, the applicant will be invited to indicate whether they wish to have their request processed in a different priority order.²⁵

On balance, the basis for this practice rests on the principle of proportionality. It enables EMA to handle the extensive number of requests for documents that are submitted by a single applicant in a manner that: **first**, does not undermine EMA’s principal tasks related to the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products; **second**, is consistent with the capacity of its available personnel; and, **third**, ensures fair treatment between applicants.

2.2 Response to the third question of the Ombudsman asking “What is the basis for EMA’s practice of limiting the number of documents an applicant can request to two documents”

Similarly, the decision to limit the number of documents which an applicant wishes to receive — in the context of a single request for access to documents— to two was introduced on 1 March 2021.

As a matter of publicity and transparency, prospective applicants are informed of this practice under question-and-answer 17 of the EMA “Guide on access to unpublished documents”, which indicates that “[e]ach access to documents request cannot exceed 2 documents”.²⁶

The same fair chance is then offered to requesters to start processing their requests as soon as possible and not to remain behind voluminous requests to access documents.

The rationale for applying this measure corresponds (by analogy) to the decision to limit the number of requests for access to documents (which a single applicant can submit) to a maximum of five, which is described in the preceding sub-section. In a similar vein, the basis for this practice is rooted in the principles of proportionality and fairness.

2.3 Response to the fifth question of the Ombudsman asking “If a request concerns more than two documents, does EMA provide the applicant with a list of

²⁴ In this respect, see: question-and-answer 17, titled “Why since March 2021 does the Agency require each access-to documents request not to exceed 2 documents and a maximum of 5 access to-documents requests to be submitted per requester/affiliation?” of the EMA “Guide on access to unpublished documents” (**Annex 4** to the present Reply.)

²⁵ Ibid.

²⁶ Ibid.

documents falling within the scope of the request, thereby allowing the applicant to choose the documents, in which they are most interested”

As a matter of course, EMA seeks to engage with applicants in a clear and transparent manner at all stages of the processing of a request for access to documents. In this context, EMA endeavours to ensure that the applicants have at their disposal the necessary information in order to enable them to potentially clarify the scope of their request.²⁷

As a matter of good administration, this means that the ATD team will take the initiative to contact the applicant in writing (or, on occasion, by means of a telephone call or teleconference) in order to better understand the scope of a request where the request may concern more than two documents. EMA pursues a similar approach in the scenario whereby a request is formulated in either vague or unclear terms by a requester.

This practice is explained under question-and-answer 17 of the EMA “Guide on access to unpublished documents”, which highlights that “[i]f a request exceeds 2 documents, an ATD coordinator will contact the requester to ask which 2 documents are the subject of this specific request. The requester can then submit another request for the other documents”.²⁸

Without prejudice to the above, and only for completeness, EMA would like to highlight that the “Guide on access to unpublished documents” contains a body of useful information which aims to assist prospective applicants. In this respect, and by way of illustration, the guide explains that the annex(es) and/or appendix(ces) of a document will only be processed upon request. By way of further illustration, the guide also sets out in exacting detail a (non-exhaustive) list of documents which EMA considers to constitute one document.²⁹

2.4 Response to the sixth question of the Ombudsman asking “If the request concerns more than two documents or if more than five requests of an applicant are in queue, does EMA offer the applicant the possibility to narrow down the number of documents/requests, for instance in a phone call”

As explained under the preceding subsections of the present Reply, EMA takes active steps to ensure that applicants are appraised of the possibility to specify the documents and requests which they wish to receive.

As a matter of course, upon receipt of a new request from the same applicant, EMA will contact them in writing to acknowledge the request but also in order to verify whether the applicant wishes to adjust the order of priority in which the requests will be processed. For the purpose of facilitating the applicant’s request, a representative from the ATD team may exceptionally also make themselves available to provide any clarifications that could be needed, by means of a telephone call or teleconference, if so requested.

²⁷ In particular, EMA would like to respectfully submit that it implements (on a continuous basis) the (fourth) suggestion for improvement which is set out the Ombudsman’s Recommendation of 28 March 2023 in Case 01/2/2022/OAM on the time the European Commission takes to deal with requests for public access to documents; available at: <https://www.ombudsman.europa.eu/en/recommendation/en/167661>.

²⁸ In this respect, see: question-and-answer 17, titled “Why since March 2021 does the Agency require each access-to documents request not to exceed 2 documents and a maximum of 5 access to-documents requests to be submitted per requester/affiliation?” of the EMA “Guide on access to unpublished document”, page 11. (**Annex 4** to the present Reply.)

²⁹ In this respect, see: question-and-answer 18, titled “What is considered 1 document” of the EMA “Guide on access to unpublished document”, pages 12-15. (**Annex 4** to the present Reply.)

The foregoing practice is also explained under question-and-answer 17 of the EMA “Guide on access to unpublished documents”, which highlights that “[i]f a requester/affiliation has 5 requests in queue (1 being processed and 4 waiting), an ATD coordinator will contact the requester/affiliation to confirm that 5 requests are already in queue and to ask if a change of priority is needed”.³⁰

3. In relation to the particular request for access to documents that preceded the submission of the present complaint to the European Ombudsman

Under this section of the Reply, EMA would like to provide a number of important clarifications in relation to the request that is understood to have preceded the submission of Complaint 2243/2022/SF.

By way of background, on 5 July 2020, Mr A. Van’t Oever (complainant) submitted an application for access to documents to EMA in relation to the vaccine Bayovac IBR Marker Vivum.³¹ On 10 July 2020, EMA informed the applicant that the request had been registered under ASK-71340. In the context of that acknowledgement of receipt, it was explained that:

“[...] EMA is currently operating within the fourth phase of its business continuity plan to ensure operational continuity during its relocation to Amsterdam. Whilst every effort is being made to process all requests as soon as possible, you should be aware that due to these exceptional circumstances from October 2019 requests cannot be processed immediately and will be dealt in a chronological order from the time they were received”.³²

On 11 May 2021, prior to processing the request, EMA contacted the complainant in order to verify whether he was still interested in receiving the concerned documents. On the same day, the complainant confirmed to EMA that this was indeed the case. The documents that were identified as falling within the scope of the complainant’s request were divided into four batches.³³

³⁰ In this respect, see: question-and-answer 17, titled “Why since March 2021 does the Agency require each access-to documents request not to exceed 2 documents and a maximum of 5 access to-documents requests to be submitted per requester/affiliation?” of the EMA “Guide on access to unpublished document” (**Annex 4** to the present Reply).

³¹ More particularly, the applicant submitted a request for access to documents concerning “*written and oral explanations (provided by the marketing authorization holders on 9 June 1999, 28 September 1999 and 21 December 1999. Oral explanations were given on 13 October 1999) and meeting notes as well as communication to member states, specifically to The Netherlands regarding the outcome of the investigation as well as documents regarding the decision to declare the report (CVMP/768/99) restricted/confidential and the motivation hereof*” (**Annex 8** to the present Reply.)

³² In this respect, see: **Annex 8** to the present Reply.

³³ As the request was received prior to 1 April 2021, the number of requests and documents were not limited in number (that is to say, to five requests and two documents, respectfully). The request was however divided into batches, due to the considerable volume of the identified documents. The decision to release documents in batches is explained under question-and-answer 15 titled, “Will I receive all documents I requested in one transmission?” of the EMA “Guide of unpublished documents”. (**Annex 4** to the present Reply.)

On 1 July 2021, EMA adopted a decision in relation to the first batch of the request.³⁴ On 7 July 2021, the requested document was partially disclosed to the complainant in accordance with Article 4(2), first indent, of Regulation (EC) No 1049/2001.³⁵

On 30 July 2021, the complainant contacted EMA by email. In the context of that email, the complainant informed EMA that he wished to receive several documents, which had been listed under the section titled, “Attachments” of the partially disclosed document under the first batch of ASK-71340.³⁶ Out of the 62 documents that were included under the list of attachments, the complainant sought access to 18 individual documents.³⁷

These documents were not considered as forming part of the initial request for access to documents, by virtue of the fact that they were not included in the main body of the document.³⁸

On 9 August 2021, EMA responded to the complainant and the associated request for the concerned documents. In the context of that email, EMA informed the complainant that the request would have to be processed separately from the initial request for access to documents under ASK-71340. EMA also explained to the complainant that the maximum number of requests that could be processed (at the time) would be five; and that a maximum of two documents could be processed per request.³⁹ More specifically, EMA explained that:

“Please note that the EMA is currently operating under business continuity measures to ensure its operational continuity during the COVID-19 pandemic.

Whilst every effort is being made to process all access to documents requests as soon as possible, due to these exceptional circumstances and in order to ensure a manageable flow of all access-to-documents requests from all requesters in a fair, timely and consistent way, the following approach is applied:

- Each access to documents request cannot exceed **2 documents**
 - A requester/affiliation can have a maximum of 5 access to documents requests in queue.
- You can find more information about this in the ‘Guidance on unpublished documents’ at our website (https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf), specifically Questions 17 and 18.

³⁴ In the context of that decision, it may be clarified that EMA informed the applicant that the (first) part of the request relating to batch 1, namely, possible “*communication to member states, specifically to The Netherlands regarding the outcome of the investigation as well as documents regarding the decision to declare the report (CVMP/768/99) restricted/confidential and the motivation hereof*” had not been identified. As regards the (second) part of the request relating to batch 1, namely, “*Bayer Responses to List of Outstanding Issues (3 November 1999)*”. More precisely, this document concerned the “Second list of answers to Referral Procedure EMEA CVMP 253 99”. It was considered to be disclosable, subject to certain redactions on the basis of Article 4(2), first indent, of Regulation (EC) No 1049/2001. (**Annex 9** to the present Reply.)

³⁵ It may be explained that the reason for the delay between the adoption of the initial decision on 1 July 2021 and the communication of the document on 7 July 2021 was to enable the finalisation of the consultation stage with the marketing authorisation holder. This process is foreseen section 5(7) of the Annex to the Agency’s Policy.

³⁶ A copy of the partially redacted document that was disclosed to applicant is included as **Annex 10** to the present Reply.

³⁷ Ibid, pages 23-24 of the partially disclosed document.

³⁸ Since Q3 of 2021, EMA has introduced guidance on this matter. In that respect, and as explained under section 2.3, *in fine*, of the Reply, question-and-answer 18 of the EMA “Guide on unpublished documents” provides clarification as regards what may be considered as one document for the purpose of EMA’s handling of access to documents. (**Annex 4** to the present Reply.)

³⁹ In this respect, see: **Annex 11** to the present Reply.

You may consider prioritising/indicating the order of your future access to documents request(s).

In case you urgently need your requested document(s), we kindly ask you to indicate the reason of this urgency when you will submit the request(s)”.

As this request did not fall within the scope of the initial request for access to documents that was submitted on 5 July 2020, the practice that is described under subsections 2.1 and 2.2 of the present Reply would be triggered.

EMA would like to highlight at this juncture that no further communication was received from the complainant in connection with this request for access to certain attachments listed in the document which was released under the first batch. In the absence of any subsequent clarification on the matter or any submission of a new access to documents request, EMA was therefore unable to process the request for additional documents.

That being said, **EMA continued to process the remaining three batches relating to ASK-71340.** In that connection, and further to the processing of the remaining three batches, EMA would like to note the following points:

- The decision relating to the second batch was adopted on 23 July 2021;⁴⁰
- The decision relating to the third batch was adopted on 4 October 2021;⁴¹ and
- The decision relating to the fourth batch was adopted on 21 October 2021.⁴²

In light of the above clarifications, EMA would like to respectfully submit that the complainant is not justified in claiming that “*EMA has refused these requests as it (apparently) has a policy to allow only a few documents to be requested at a time, after which it takes months for these documents to be released*”.⁴³

It is clear that EMA communicated with the complainant in a clear and transparent manner. It is also clear that the complainant refrained from cooperating with EMA in specific relation to the processing of certain attachments listed under the document, which had been disclosed in the context of the first batch of ASK-71340.

In conclusion, EMA would like to reassure the Ombudsman that transparency is at the heart of its operations and that it aims to ensure that the objectives of Regulation (EC) No 1049/2001 are fulfilled taking into account the principle of proportionality. In particular, for the reasons that are set out under sub-section 1.3 of the present Reply, EMA is confident that it will continue to find

⁴⁰ The second batch related to “*3rd List of answers to referral procedure 09 Dec 1999 plus Annexes 1-10*”. EMA’s decision is included as **Annex 12** to the present Reply. For completeness, it may be noted that the applicant submitted a confirmatory application against that decision on 9 August 2021. EMA subsequently adopted a confirmatory decision (partially granting the document at issue) on 21 September 2021, which is included as **Annex 13** to the present Reply.

⁴¹ The third batch related to the “*Assessment Report on the answers June 1999*”. EMA’s decision is included as **Annex 14** to the present Reply.

⁴² The fourth batch related to the “*Assessment of the clarifications (including the hearing) on the answers to the (first) CVMP questions (oral explanations 13 October 1999)*”. EMA’s decision is included as **Annex 15** to the present Reply.

⁴³ In this respect, see: page 2 of the complaint dated 7 December 2022 from Mr Stehouwer to the European Ombudsman.

ways to optimise the handling of requests for access to documents submitted by EU citizens; and that the temporary practice of the chronological queue may in good order be phased out.

As always, we remain available to provide any further information that could be useful for the purpose of the Ombudsman's handling of this inquiry. If you believe that a meeting would be necessary to discuss any of the foregoing, we would be happy to organise it at your convenience.

Yours sincerely,



Head of Documents Access and
Publication Department



Head of Legal Department