EMA's response to Prescrire's analysis of EMA's transparency policy over the last 10 years

Prescrire sent a copy of its article "European Medicines Agency: transparency policy marred by too many failings" (*Prescrire Int* 2022; 31 (237): 130-138) to Emer Cooke, Executive Director of the European Medicine Agency. In this article, Prescrire calls for an official inquiry in order to analyse the causes of EMA's failings, and to enable Members of the European Parliament to take appropriate steps. Here is Emer Cooke's reply (20 May 2022), with comments added by Prescrire.

Thank you for writing to me to share your article on the European Medicines Agency's (EMA) transparency policy over the last 10 years (1).

In your letter dated 5 May 2022, you acknowledge that EMA has made strides towards greater transparency, in close cooperation with its stakeholders, including your organisation, and the European Ombudsman.

We agree that transparency and the timely release of information about medicines, including clinical data, is a crucial element of medicines regulation. We hope you will also agree that, despite some concerns you raise, the policy changes instituted over the past decades have put EMA at the forefront of transparency on regulatory issues. In addition, EMA goes far beyond what is required by EU legislation so that it can provide as much information as possible to the public (2).

We believe that transparency is key to reinforcing public trust in regulatory decisions and the medicines placed onto the EU market. However, we also acknowledge that, despite these advances, we need to continue finding ways to adapt our transparency policy and our processes as the needs of our stakeholders evolve.

In your article, you raise a number of concerns which we believe misrepresent the spirit and the true impact of an initiative which has ushered in unprecedented levels of transparency both in Europe and globally. We would like to take this opportunity to respond to your points below, and you are welcome to publish the full reply.

Prescrire: Thank you for your detailed response on this important issue pertaining to EMA practices and the applicable legislation. It is useful to carry on our dialogue as to the interpretation and application of the rules. As you requested, your reply has been published on our website with comments from Prescrire listed below.
In practice, what matters to us is our ability to obtain the information we need from the Agency in order to best serve the subscribers to our journals, and their patients, within a time frame compatible with the timely provision of information that contributes to the quality of care. That is why we are asking more generally for an official audit, and are calling upon Members of the European Parliament and the European Commission to face up to their responsibilities.

EMA's redaction of documents

Redacting documents before releasing them is an essential part of managing requests for documents. EMA is bound by EU legislation requiring the Agency to redact commercially confidential information (CCI), and we have a duty to anonymise protected personal data (PPD) that could lead to the identification of individuals, including patients.

We would like to caution against judging the appropriateness of redactions by how large they may appear in isolated cases. As an illustration of the extent of our redactions, please note that for documents published in the first year of our implementation of policy 0070, around 1 in 10,000 pages had redactions due to CCI (3). Depending on the nature of the document, anonymisation of PPD may account for a larger proportion of redactions, as it is paramount that individuals such as patients cannot be identified. EMA methodically assesses PPD in all documents released under Regulation 1049/2001 or published under policy 0070.

Prescrire: We approve of course of the anonymisation of personal data. We wholeheartedly support the goal of protecting the identity of participants in clinical trials.
Our issue is with the redaction of documents, blacking out of clinical data that are essential for informing healthcare professionals and patients about a drug's benefits and risks, such as the precise nature of its adverse effects, the frequency with which they occur, the size of the population exposed to the drug, and so on.

Queuing system to manage processing of requests

The queuing mechanism may apply to situations where a requester submits one or more requests while the Agency is processing an earlier request from the same requester. This means that only one request per requester will be processed at any given time.

In 2019, the European Ombudsman concluded that "*EMA's queuing mechanism constitutes a fair and appropriate solution for cases in which EMA would otherwise have to refuse public access due to an excessive administrative burden.*" Furthermore, the Ombudsman noted that, "*EMA applies this mechanism in a reasonable and proportionate manner.*" (4)

This system is in place to ensure that EMA can meet its obligation to as many requesters as possible.

Due to constraints brought about by EMA's relocation to Amsterdam and the COVID-19 pandemic, some requests cannot be processed immediately and are therefore placed in a 'chronological queue'

and dealt with as soon as possible. When communicating with requesters, we evaluate the urgency of their requests; unless there is a particular urgency, they are processed in chronological order (5).

Prescrire: The queuing mechanism used to manage multiple requests for access to documents submitted by the same requester, and the fact that the EMA does not take into account the time these requests are held in the queue, pose a real problem and force us into self-censorship. The current situation is quite different from the 2017 complaint, on which the European Ombudsman concluded that there had been no maladministration on the Agency's part. Today, our requests are sometimes queued for many months, a situation that appears contrary to the objective stated in Regulation 1049/2001, which stipulates that applications should be handled promptly. It would be useful for the European Ombudsman to reassess the situation, to determine how many requests are inactivated, how much time they spend in the queue, and whether this is compatible with the spirit of Regulation 1049/2001. It is worth emphasising that the Agency's procedure effectively prevents us from filing a complaint with the Ombudsman, since there has been no actual refusal of access to the document, nor failure to meet the processing deadlines, given that the EMA does not in fact take into account the time that requests spend in the queue.

Giving 10 days' notice prior to releasing documents

When EMA disagrees with redactions proposed by a third party (often a marketing authorisation holder or clinical trial sponsor), we give the third party a notice period of 10 working days prior to releasing the concerned document.

While EMA seeks to release documents as soon as possible, it is important that the third party has an opportunity to decide to seek judicial review before the Court of Justice of the European Union. If the Agency were to release the documents immediately, the third party would not be able to exercise its legal right to challenge the legality of EMA's decisions, decisions which the Agency will defend robustly in court.

We do not agree that the 10-day period is 'excessively generous' or that our policy in general is overcautious.

We note that your article does not highlight the fact that the 10-day notice period applies only where EMA and the third party disagree on the release of a document or the redaction proposed.

Prescrire: It is true that our article does not mention that the 10-day notice period applies only to cases where the EMA and the third party disagree on the release of a document or the proposed redaction. However, a letter the EMA sent to Prescrire in February 2021 about some specific cases gave the impression that this was routine practice.

Disclosure of the identity of requesters

For access to document requests, EMA discloses the name of the organisation requesting documents to the concerned third parties. This practice has been in place since 2015 and follows a European Ombudsman's recommendation (6).

Please note that although we may release the name of the organisation that has made a request, we do not disclose the personal name, personal email address or any other details of the individual who sent the request. Before deciding to release the name of the organisation, the Agency will consider any objections the organisation may have.

While it is understandable that a requester may seek anonymity, in the spirit of transparency, the original source of the data in question may also wish to have information on who is in possession of their unpublished data.

Prescrire: We have duly noted the EMA's explanations. We feel it is important to point out the possibility that pharmaceutical companies could use intimidation strategies against requesters, and that the means at the disposal of these companies far outweigh those of small non-profit organisations such as Prescrire. The danger of intimidation was amongst the factors that led to the introduction of European legislation to protect whistleblowers.

Release of documents in batches

Article 6(3) of Regulation (EC) No 1049/2001 states that "*In the event of an application relating to a very long document or to a very large number of documents, the institution concerned may confer with the applicant informally, with a view to finding a fair solution.*"

On the basis of this article, EMA's approach to requests for multiple or voluminous documents is to process the requests in batches (7).

As per our normal practice, the Agency processes each batch within the Regulation deadline of 15 working days. The processing time for a batch can also be extended in exceptional situations for an additional 15 working days. In such cases, the Agency provides the requester with the reason for the extension.

Prescrire: Regulation 1049/2001 does indeed allow for the release of long documents as a series of batches. The examples we provided highlighted the consequences for requesters: a request for one long document blocks all other requests for several months because of the current queuing mechanism. The Regulation is vague, and this particular case illustrates its limitations.

Ongoing legal proceedings or scientific assessments

EMA may temporarily refuse to release certain documents when they relate to legal proceedings that are ongoing. EMA robustly defends its decisions to release documents when challenged in court by companies, and we would like to avoid any actions that could affect ongoing proceedings and ultimately undermine the release of documents to the public.

In the same vein, EMA may temporarily refuse the release of a document concerning scientific assessments while they are ongoing. This practice is an implementation of Article 4.3 of Regulation 1049/2001, which states that:

"Access to a document … which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

In all cases, EMA provides justification for the refusal, and requester retains the right to appeal. Once the legal proceedings or assessments have concluded, the requester can ask for access to the documents concerned.

Prescrire: Our analysis stated the reasons given to justify refusing certain requests for access to documents when legal proceedings were ongoing, based on the exception to disclosure set out in Article 4.3 of Regulation 1049/2001. Our intention in citing these examples, where access to safety data on a drug was refused, was to show the consequences for healthcare professionals. In order to honour their Hippocratic Oath and to "First do no harm", healthcare professionals need up-to-date information about the efficacy and safety of drugs without delay, including data on safety signals indicating a potential new danger. On this point, as in our previous point, we wish to underscore the problems posed by the vagueness of certain articles in Regulation 1049/2001. In our view, in the case of access to clinical data relating to patient safety, there is an overriding public interest in disclosure.

Fair consideration for requesters with no ties to industry

The Agency ensures that it processes each request fairly and equally, irrespective of the requester's affiliation.

We value the work that Prescrire does as a not-for-profit organisation, however the preferential treatment requested will go against our principle of fairness towards each requester. Please note that EMA does not judge the intentions of requesters when processing their requests.

We note that one of the Prescrire headlines reads, "*The EMA gets tough with Prescrire.*" Perhaps this was written to focus the attention of the reader. We would like to point out that the implication that EMA has been treating your organisation unfairly cannot be further from the truth. We endeavour to treat all requesters fairly and equally and this aim is reflected in our processes.

Prescrire: Prescrire is certainly not asking for special, preferential treatment. Our experience is that the queuing mechanism unfairly penalises organisations that submit multiple requests which, on the whole, are easily satisfied. There was no implication in the subheading "*The EMA gets tough with Prescrire*" that Prescrire has been singled out for unfair treatment. It simply reflected the content of the article, which described the history of our requests and exchanges with the EMA, which have deteriorated over time.

Resources for managing requests

Decisions on the allocation of resources for the Agency fall within the purview of the European Commission and the European Parliament. EMA, like all EU bodies, has to manage available resources as efficiently as possible to meet ever growing demands.

Over the past years, the number of requests for access to documents has increased dramatically, with a consequent impact on our processing times for requests. The pandemic has also resulted in considerable pressure on resources in many areas. As highlighted in our recent discussions with you, we are taking stock of the current situation, including staffing, and considering ways to best serve the public.

I would like to thank you for writing to me on behalf of Prescrire and for the work of your organisation as an advocate for transparency over the years. As always, we value your feedback and also the meeting that was held between EMA and Prescrire on 6 September 2021. We look forward to continuing our close work in the interests of European patients and the public.

Emer Cooke
Executive Director
European Medicines Agency

Prescrire: The EMA ought to be equipped with the financial and human resources needed to carry out its multiple missions, and also to implement its transparency policy. Otherwise, it is merely window dressing. We sincerely hope that the European Commission, the European Parliament and Member States will soon take the necessary measures to promptly provide the EMA with the public funding required to carry out tasks that are in the public interest, which include ensuring transparency over clinical data, and prompt handling of requests for access to documents. Timely access to the information health professionals expect and need, including information published in our journals, in order to ensure quality care for patients, is a very important issue and is in the public interest. We certainly recognise that you do not hold all the cards required to improve the situation: this is why we are also calling on the European Ombudsman, Members of the European Parliament and the European Commission to take action.
Thank you again for your letter.

References **1-** Prescrire Editorial Staff "European Medicines Agency: transparency policy marred by too many failings" *Prescrire Int* 2022; 31 (237): 130-138 **2-** https://www.ema.europa.eu/en/medicines/what-we-publish-medicines-when-0 **3-** https://www.ema.europa.eu/en/documents/report/clinical-data-publication-policy-0070-report-oct-2016-oct-2017_en.pdf **4-** https://www.ombudsman.europa.eu/en/decision/en/111254 **5-** See Question 16 in EMA's Guide to unpublished documents: https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf **6-** https://www.ombudsman.europa.eu/nl/decision/en/91452 **7-** See Question 15 of EMA's Guide to unpublished documents: https://www.ema.europa.eu/en/documents/other/guide-access-unpublished-documents_en.pdf