SECTION: PIL

IN THE HON'BLE SUPREME COURT OF INDIA
(CIVIL ORGINAL WRIT JURISDICTION)

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF

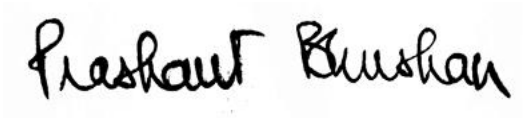
DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

FILING INDEX

S. NO.	PARTICULARS	COPIES	C. FEES
1.	REJOINDER NOTE OF ADVOCATE PRASHANT BHUSHAN TO THE ORAL SUBMISSIONS OF THE SOLICITOR GENERAL ON BEHALF OF THE UOI	1	**NIL**



(PRASHANT BHUSHAN)
COUNSEL FOR THE PETITIONER
301, NEW LAWYERS CHAMBER
SUPREME COURT OF INDIA
NEW DELHI-110 001
CODE NO. 515

NEW DELHI
DATED: 21.03.2022

IN THE HON'BLE SUPREME COURT OF INDIA
(CIVIL ORGINAL WRIT JURISDICTION)

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF

DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

PAPER BOOK

INDEX

COUNDEL FOR THE PETITIONER: **PRASHANT BHUSHAN**

IN THE HON'BLE SUPREME COURT OF INDIA
(CIVIL ORGINAL WRIT JURISDICTION)

WRIT PETITION (CIVIL) NO. 607 OF 2021

IN THE MATTER OF

DR. JACOB PULIYEL .....PETITIONER

VERSUS

THE UNION OF INDIA & ORS. .....RESPONDENTS

REJOINDER NOTE OF ADVOCATE PRASHANT BHUSHAN TO THE ORAL SUBMISSIONS OF THE SOLICITOR GENERAL ON BEHALF OF THE UOI

1. At the outset it is submitted that the Solicitor General, Mr. Tushar Mehta's arguments seem to proceed on the basis that the petitioner is seeking a mandamus against vaccination. The petitioner has throughout reiterated that the present petition is only challenging vaccine mandates which lead to the denial of fundamental rights to the unvaccinated and for transparency of vaccination trial data as well as data regarding adverse events following immunization.

2. The burden of Mr. Mehta's submissions is broadly to show that the rules and systems in place for the approval of vaccines, vaccine trials and adverse events evaluation are excellent and many layered and that therefore there is no need for the court to go into the issues raised by the petitioner as that would only promote vaccine hesitancy. He further contends that disclosure of trial data could promote vaccine

hesitancy by people drawing their own independent conclusions at variance with the view of the expert bodies. He also contends that there is an excellent portal called 'COWIN' for reporting adverse events due to the vaccine and a national AEFI committee for evaluating adverse events and that nothing further therefore needs to be done regarding adverse events. He contends that disclosure of data would also violate the confidentiality and privacy of the subjects in the vaccine trials and is forbidden by the rules and the undertakings given to the trial subjects. He further points out that more than 90% of the country's population has already received the vaccine (at least one dose) and therefore this petition is infructuous as vaccines are already a fait accompli.

Re rules and systems in place for vaccine approval

3. Mr. Mehta submitted that there is a Subject Expert Committee (SEC) which approves vaccines and an apex body called the National Technical Advisory Group on Immunisation (NTAGI) for approving vaccines (of which the petitioner was a member) and that all vaccine trial data is shared with these bodies. The fact that this is not true is clear from the fact that the recently granted approval for vaccinating 12-14 year of children has been done without the approval of the NTAGI (https://science.thewire.in/health/centre-approved-corbevax-12-14-age-group-without-ntagi-clearance/) several of whose members have publicly opposed this decision.

> "NTAGI has not recommended it. I don't know which other body has done it," Jayaprakash Muliyil, a member of

NTAGI, told The Wire Science on March 14 evening. Muliyil is also a former professor of community medicine at the Christian Medical College, Vellore."

(A copy of the report in The Wire Science is annexed as **Annexure RN 1 at (Page 13 to 14).**

4. Moreover, the fact also is that even the top expert advisory bodies like the NTAGI and the SEC are often not provided with the trial data or sometimes proceed to take decisions without even looking at the trial data. This is clear from the petitioners own case. When the petitioner was a member of NTAGI, the manufacturers of Covaxin, Bharat Biotech had sought NTAGI approval for Rotavac vaccine against rotavirus diarrhea. This was the first vaccine that Bharat Biotech had ever manufactured. NTAGI asked for data on adverse events at the Vellore Centre where a number of children developed a complication that has the potential of causing gangrene of the intestine of infants. This information was denied despite the NTAGI requesting for it.

5. This is therefore completely contrary to Mr. Mehta's contention that the data has been seen by the SEC and the NTAGI in accordance with the Rules. Further, there is nothing in the "recommendations" of the SEC available on the website (these are not the minutes) that suggests what data was presented to the SEC and what were the SECs deliberations based on that data. The recommendations of the SEC on the website do not inspire any confidence that the data has indeed been presented to the SEC, has been scrutinized and evaluated by it before granting approval for the vaccines.

6. In the rotavac case, when the data was denied to the NTAGI, the petitioner was forced to file a PIL seeking that data. In that case, even the SEC was not provided that data, despite intervention of the PMO. The Supreme Court in that case said that the petitioner being a member of the NTAGI could not file this as a PIL, as a result of which it was withdrawn with liberty to another member of the public to file this petition, which was thereafter filed by Mr. Chinu Srinivasan , managing trustee of Low Cost Standard Therapeutics, at Vadodra Gujarat, an expert active for over 35 years in the field of health care, low cost medicine manufacture, etc. Ironically, the government now argues that the court must trust the domain experts, however as shown in the case of the Rotavac gangrene, the government would clearly not trust the domain experts.

7. In the present case itself, the manner of emergency approval of Covaxin by the SEC shows that the SEC did not look at the trial data before granting emergency use approval. A perusal of the recommendations of the SEC meetings available on the website show that the SEC changed its mind about Bharat Biotech's Covaxin within a span of two days. On the 30th December 2020, the recommendations of SEC state:

> "After detailed deliberation, the committee recommended that the firm should update and present immunogenicity, Safety & efficacy data for further consideration."

On the 1st of January 2021 the recommendations state:

> "Efficacy is yet to be demonstrated. After detailed deliberation, the committee recommended that the firm should try to expedite the recruitment and may perform interim efficacy analysis for further consideration of restricted emergency use approval"

However on the 2nd of January 2021 the SEC suddenly changes its mind without reasons and EUA was granted obviously without the SEC examining even what it had sought 2 days prior, much less, the raw trial data:

> "after detailed deliberation, the committee recommended for grant of permission for restricted use in emergency situation…"

(See Annexure 45 at Page 279-283 of the Written Submissions)

8. The pathetic state of affairs regarding the functioning of these regulatory expert bodies in the matter of granting approval to drugs has been detailed in the Parliamentary Standing Committee Report of 2012 on the need for transparency in drug regulation. (Written Submission compilation page number 295-299, Writ Petition: Report at Page 139-190) Though that report is of the year 2012-2013, the egregious violations of rules, ethical principles, fabrications and conflicts of interest narrated in the case of multiple drugs on multiple occasions shows that it would be totally hazardous to assume that merely because an elaborate system of regulatory approval has been put in place on paper, that everyone should assume that the regulatory approvals are robust and unquestionable. Accepting the argument of Mr. Mehta would mean that the courts should give a go-

by to the Right to Information Act and deny people the right to even examine what various public authorities have done, merely because an elaborate regulatory approval process is in place on paper. The lapses pointed out in the report make it even more urgent for data with regard to mass vaccination to be disclosed to the public.

9. Regarding Mr. Mehta's claim that disclosure of trial data would allow different people to draw their own conclusions and may create vaccine hesitancy, it may be pointed out that this is against all principles of scientific disclosure as well as a citizen's right to information especially with respect to matters that concern public health and safety. A District Court in the US has recently ordered the Food and Drug Administration to make public the data it relied on to license Pfizer's COVID-19 vaccine, imposing a dramatically accelerated schedule that should result in the release of all information. In Public Health and Medical Professionals for Transparency v. Food and Drug Administration, the Plaintiff's Freedom of Information Act (FOIA) requested "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System" from the Food and Drug Administration ("FDA"). The Court hereinafter made the following order for disclosure of information:

> "…And, particularly appropriate in this case, John Mc Cain (correctly) noted that "excessive administrative secrecy…feeds conspiracy theories and reduces the public's confidence in the government."

Echoing these sentiments, "[t]he basic purpose of FOIA is to ensure an informed citizenry, [which is] vital to the functioning of a democratic society." NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214, 242 (1977). "FOIA was [therefore] enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" Batton v. Evers, 598 F.3d 169, 175 (5th Cir. 2010) (quoting Dep't of the Air Force v. Rose, 425 U.S. 352, 361 (1976)). And "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" Open Soc'y Just. Initiative v. CIA, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H.R. REP. NO. 93-876, at 6271 (1974)). When needed, a court "may use its equitable powers to require an agency to process documents according to a court-imposed timeline." Clemente v. FBI, 71 F. Supp. 3d 262, 269 (D.D.C. 2014).

Here, the Court recognizes the "unduly burdensome" challenges that this FOIA request may present to the FDA. See generally ECF Nos. 23, 30, 34. But, as expressed at the scheduling conference, there may not be a "more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting every American vaccinated, [and] making sure that the American public is assured that this was not [] rush[ed] on behalf of

> the United States . . . ." ECF No. 34 at 46. Accordingly, the Court concludes that this FOIA request is of paramount public importance."

(A copy of the District Court order in Public Health and Medical Professionals for Transparency v Food and Drug Administration, is annexed as **Annexure RN2 at (Page 15 to 18)**

10. Mr. Mehta is also not correct is saying that no where in the world is such data not disclosed. In fact an examination of the law as it stands in the European Union is reflective of how global jurisdictions encourage disclosure of data. The European Medicines Agency's document titled "European Medicines Agency policy on publication of clinical data for medicinal products for human use" states that the Agencys aim is to protect and foster public health and that Transparency is a key consideration for the Agency in delivering its services to patients and society. The Scope of the policy relates to clinical data, composed of clinical reports and individual patient data (IPD) submitted under the centralized marketing authorization procedure after the effective date, either using the common technical document format or another format. The policy statement states that the main objectives of the policy by making clinical data available proactively, are to enable public scrutiny and application of new knowledge of public health. It further states that <u>"a high degree of transparency will take regulatory decision-making one step closer to the EU citizens, and promote better-informed use of medicines. In addition, the agency takes the view that access to clinical data will benefit public health in future…furthermore it will enable the wider scientific community to make use of detailed clinical data to</u>

develop new knowledge in the interest of public health. Access to clinical data will allow third parties to verify the original analysis and conclusions, to conduct further analyses, and to examine the regulatory authority's positions and challenge them where appropriate."

The European law seems to encourage further independent analyses of clinical trial data and to examine the regulatory authorities. Contrary

https://www.ema.europa.eu/en/documents/other/european-medicines-agency-policy-publication-clinical-data-medicinal-products-human-use_en.pdf

(A copy of The European Medicines Agency's document titled "European Medicines Agency policy on publication of clinical data for medicinal products for human use" is annexed as **Annexure RN3** at **(Page 19 to 40).**

11. Under the Right to Information Act in India, all the information with the government including regulators (and if Mr. Mehta is correct, should be with the government), must be disclosed to the public, except for subject confidentiality information and information involving commercial confidence. Even these exemptions are subject to public interest override. In this case the Petitioner has made it amply clear that he is not seeking subject names, which can clearly be redacted. There is no violation of privacy so far as names redacted trial data is concerned and clearly this information has to be provided. In fact, on the COWIN website, where adverse events are recorded, they are recorded by the government along with persons name and other details.

12. The claim of Mr. Mehta that the COWIN platform and a national adverse events evaluating committee is adequate for transparency and robustness of adverse events reporting and evaluation is incorrect for the following reasons:

a. The COWIN reporting system only allows the vaccinator to report the adverse event and not the vaccinees. Thus if a vaccinator refuses to report an adverse event or comes to his subjective conclusion that the adverse event is not related to vaccination, the vacinee has no recourse. The petitioner has asked for a system like the VAERS in the US where individuals can report their adverse events and have them registered with a registration number. This must be widely advertised repeatedly and the online forms must be easy to fill, given low literacy in the country. It must be the responsibility of the government to contact these people to obtain more details needed for causality assessment.

b. That the rules currently being followed provide that unless an adverse event is a known adverse reaction to the vaccine, it will not be reported as a vaccine reaction. (See Annexure 51 Page 317-340 of the Written Submissions for changed policy). That is why not a single death has been recognized as a vaccine death in India because deaths are not regarded as known adverse events of the vaccine. A quick calculation of this data presented by the government in its paper compilation at page 366-388 is revealing.

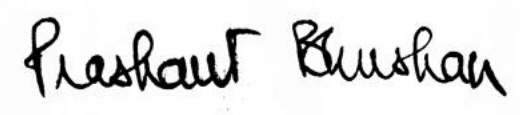
Number of vaccine doses administered in India: 176 crores (approx). Number of adverse events reported: 76,814 (page 366). This comes to approximately 1 adverse event per 23,000 doses. The same vaccine Astrazeneca in Europe has caused 244,603 adverse events in 69 million doses (page-49), which translates to approximately 1 adverse event per 282 doses. This level of discrepancy (about a factor of 80 lesser compared to Europe) is absurd, and points to the utter callousness in AEFI collection by GoI.

c. The fact that the sytem is not working is clear from the detailed complaint about the working of the AEFI system by a group of several medical experts and physicians, appealing for a time bound and transparent investigation following deaths and serious adverse effects after COVID-19 vaccination. (Written submissions annexure 52 page no. 341-342)

13. Mr. Mehta contend that the ethics committee prohibits disclosure of trial data. The ethics committee stipulates that trial participant's personal data is kept confidential. The Solicitor is being disingenuous when he tries to confuse the trial subject's personal identity and his past medical history (which is integral to his right to privacy) with trial data, when he says that trial data must not be disclosed because it is 'medical data' of the trial participant! He goes on to make an outrageous claim that people will not volunteer for trials if trial data (even with all person identification redacted) is

disclosed. Altruistic persons who participate in trials at risk to themselves do it so that society may benefit from their sacrifices. Non disclosure of trial data would go against the very interest of these trial subjects since non disclosure would mean their participation in trials was only to further commercial interests of the drug manufacturers.

THROUGH:



(PRASHANT BHUS HAN)
COUNSEL FOR THE PETITIONER

NEW DELHI
DATED: 21.03.2022

ANNEXURE: RN1

THE WIRE SCIENCE

Centre Approved Corbevax for 12-14 Year Olds Without NTAGI Clearance

15/03/2022

BANJOT KAUR

Healthcare workers administer COVID-19 vaccines to recipients aged 15-18 years, Mumbai, January 31, 2022. Photo: PTI

The Centre has announced that children aged 12-14 years will become eligible for COVID-19 vaccination from March 16.A health ministry press release on March 14 said the government had taken the call after "due deliberations with scientific bodies" – but didn't specify which bodies.The Wire Science has learnt that the National Technical Advisory Group on Immunisation wasn't one of these bodies.The NTAGI has a three-level approval process that includes the inputs of topical experts, and its approval is required before the NEGVAC's clearance.The Centre's decision to skip the NTAGI's approval for Corbevax deprives the vetting process of three levels of checks, including by subject experts.

New Delhi: The Centre announced on March 14 that children aged 12-14 years will become eligible for COVID-19 vaccination from March 16. A press release issued by the Union health ministry on March 14 said the government had taken the call after "due deliberations with scientific bodies".

However, the government did not specify which were those "bodies", and the reason for the ambiguity in the health ministry release wasn't clear.

But The Wire Science has since learnt that the National Technical Advisory Group on Immunisation (NTAGI) wasn't one of these bodies. The NTAGI is one of the bodies whose clearance is required before a vaccine, approved by the drug regulator, can become part of the national COVID-19 vaccination drive.

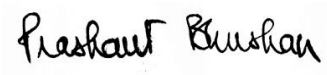
The Centre's approval for Corbevax is the first to defy this step of the vaccine clearance process, at least according to the public record.

The NTAGI is one of the most important groups in the chain of granting approval to vaccines. After a recommendation from the Drugs Controller General of India (DCGI), the NTAGI, constituted by the Centre itself, deliberates on the vaccine's ability to participate in the national vaccination drive.

The body comprises government officials as well as independent subject experts. After the NTAGI's approval, the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has to make a decision. The Union health ministry finally approves a COVID-19 vaccine only after the NEGVAC's decision.

"NTAGI has not recommended it. I don't know which other body has done it," Jayaprakash Muliyil, a member of NTAGI, told The Wire Science on March 14 evening. Muliyil is also a former professor of community medicine at the Christian Medical College, Vellore.

Link: https://science.thewire.in/health/centre-approved-corbevax-12-14-age-group-without-ntagi-clearance/



(TRUE COPY)

ANNEXURE: RN

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

v. **No. 4:21-cv-1058-P**

FOOD AND DRUG ADMINISTRATION,

Defendant.

ORDER

This case involves the Freedom of Information Act ("FOIA"). Specifically, at issue is Plaintiff's FOIA request seeking "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System" from the Food and Drug Administration ("FDA"). *See* ECF No. 1. As has become standard, the Parties failed to agree to a mutually acceptable production schedule; instead, they submitted dueling production schedules for this Court's consideration. Accordingly, the Court held a conference with the Parties to determine an appropriate production schedule.[1] *See* ECF Nos. 21, 34.

"Open government is fundamentally an American issue"—it is neither a Republican nor a Democrat issue.[2] As James Madison wrote, "[a] popular Government, without popular information, or the means of acquiring it, is but a Prologue to a Farce or a Tragedy; or, perhaps, both. Knowledge will forever govern ignorance: And a people who mean to be their own Governors, must arm themselves with the power which

[1]Surprisingly, the FDA did not send an agency representative to the scheduling conference.

[2]151 CONG. REC. S1521 (daily ed. Feb. 16, 2005) (statement of Sen. John Cornyn).

knowledge gives."[3] John F. Kennedy likewise recognized that "a nation that is afraid to let its people judge the truth and falsehood in an open market is a nation that is afraid of its people."[4] And, particularly appropriate in this case, John McCain (correctly) noted that "[e]xcessive administrative secrecy . . . feeds conspiracy theories and reduces the public's confidence in the government."[5]

Echoing these sentiments, "[t]he basic purpose of FOIA is to ensure an informed citizenry, [which is] vital to the functioning of a democratic society." *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1977). "FOIA was [therefore] enacted to 'pierce the veil of administrative secrecy and to open agency action to the light of public scrutiny.'" *Batton v. Evers*, 598 F.3d 169, 175 (5th Cir. 2010) (quoting *Dep't of the Air Force v. Rose*, 425 U.S. 352, 361 (1976)). And "Congress has long recognized that 'information is often useful only if it is timely' and that, therefore 'excessive delay by the agency in its response is often tantamount to denial.'" *Open Soc'y Just. Initiative v. CIA*, 399 F. Supp. 3d 161, 165 (S.D.N.Y. 2019) (quoting H.R. REP. NO. 93-876, at 6271 (1974)). When needed, a court "may use its equitable powers to require an agency to process documents according to a court-imposed timeline." *Clemente v. FBI*, 71 F. Supp. 3d 262, 269 (D.D.C. 2014).

Here, the Court recognizes the "unduly burdensome" challenges that this FOIA request may present to the FDA. *See generally* ECF Nos. 23, 30, 34. But, as expressed at the scheduling conference, there may not be a "more important issue at the Food and Drug Administration . . . than the pandemic, the Pfizer vaccine, getting every American vaccinated, [and] making sure that the American public is assured that this was not [] rush[ed] on behalf of the United States . . . ." ECF No. 34 at 46.

---

[3]Letter from James Madison to W.T. Barry (August 4, 1822), *in* 9 WRITINGS OF JAMES MADISON 103 (S. Hunt ed., 1910).

[4]John F. Kennedy, Remarks on the 20th Anniversary of the Voice of America (Feb. 26, 1962).

[5]*America After 9/11: Freedom Preserved or Freedom Lost?: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 302 (2003).

Accordingly, the Court concludes that this FOIA request is of paramount public importance.

"[S]tale information is of little value." *Payne Enters., Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988). The Court, agreeing with this truism, therefore concludes that the expeditious completion of Plaintiff's request is not only practicable, but necessary. *See Bloomberg, L.P. v. FDA*, 500 F. Supp. 2d 371, 378 (S.D.N.Y. Aug. 15, 2007) ("[I]t is the compelling need for such public understanding that drives the urgency of the request."). To that end, the Court further concludes that the production rate, as detailed below, appropriately balances the need for unprecedented urgency in processing this request with the FDA's concerns regarding the burdens of production. *See Halpern v. FBI*, 181 F.3d 279, 284–85 (2nd Cir. 1991) ("[FOIA] emphasizes a preference for the fullest possible agency disclosure of such information consistent with a responsible balancing of competing concerns . . . .").

Accordingly, having considered the Parties' arguments, filings in support, and the applicable law, the Court **ORDERS** that:

1. The FDA shall produce the "more than 12,000 pages" articulated in its own proposal, *see* ECF No. 29 at 24, **on or before January 31, 2022.**
2. The FDA shall produce the remaining documents at a rate of **55,000** pages every **30 days**, with the first production being due **on or before March 1, 2022**, until production is complete.
3. To the extent the FDA asserts any privilege, exemption, or exclusion as to any responsive record or portion thereof, FDA shall, concurrent with each production required by this Order, produce a redacted version of the record, redacting only those portions as to which privilege, exemption, or exclusion is asserted.

4. The Parties shall submit a Joint Status Report detailing the progress of the rolling production by **April 1, 2022**, and every **90 days** thereafter.[6]

SO ORDERED on this **6th day** of **January, 2022.**

Mark T. Pittman
UNITED STATES DISTRICT JUDGE

(TRUE COPY)

[6]Although the Court does not decide whether the FDA correctly denied Plaintiff's request for expedited processing, the issue is *not* moot. Should the Parties seek to file motions for summary judgment, the Court will take up the issue then.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2019
EMA/144064/2019

European Medicines Agency policy on publication of clinical data for medicinal products for human use

POLICY/0070
Status: Adopted
Effective date: 21 March 2019
Review date: No later than March 2021
Supersedes: Policy/0070, dated 2 October 2014 (EMA/240810/2013)

1. Introduction and purpose

The aim of the European Medicines Agency ('the Agency') is to protect and foster public health. Transparency is a key consideration for the Agency in delivering its service to patients and society.

Although the Agency since its creation has launched several initiatives to increase transparency of information on medicinal products, there is growing demand from stakeholders for additional transparency, not only about the Agency's deliberations and actions, but also about the clinical data on which regulatory decisions are based. The Agency is committed to continuously extend its approach to transparency and has, therefore, taken the initiative to develop a policy on publication of clinical data, in accordance with article 80 of Regulation (EC) No 726/2004[1]. Consultations with a broad range of stakeholders and European Union (EU) bodies have taken place in drafting this policy. It should be noted that this policy is without prejudice to Regulation (EC) No 1049/2001[2], and, therefore, it does not replace the existing 'Policy on access to documents (related to medicinal products for human and veterinary use)' (POLICY/0043) (EMA/110196/2006), which came into effect in December 2010. Moreover, the provisions of this policy are not intended in any manner to limit the application or the rights given by Regulation (EC) No. 1049/2001. Any natural or legal person may continue to submit a request for access to documents to the Agency independently of the proactive publication mechanisms established by this policy.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
[2] 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

This policy is also without prejudice to Regulation (EU) No 536/2014[3].

2. Scope

The scope of the policy relates to clinical data, composed of clinical reports and individual patient data (IPD), submitted under the centralised marketing authorisation procedure after the effective date (see chapter 4.3. for further information), either using the common technical document (CTD) format or another format:

- as part of a marketing authorisation application (MAA);
- or as part of a post-authorisation procedure for an existing centrally authorised medicinal product;
- or as part of a procedure under Article 58 of Regulation (EC) No 726/2004;
- or submitted by a third party in the context of a MAA or a post-authorisation procedure for an existing centrally authorised medicinal product;
- or requested by the Agency/ submitted by the applicant/marketing authorisation holder (MAH) as additional clinical data in the context of the scientific assessment process for the aforementioned situations.

The following clinical data are not covered by the scope of the policy:

- Clinical data held by the Agency for applications submitted under the centralised procedure before 1 January 2015, and for extension of indication applications and line extension applications submitted before 1 July 2015.
- Clinical data (either data provided to the Agency before 1 January 2015 or data not yet held by the Agency) submitted to the Agency for non-centrally authorised products.

These clinical data continue to be made available to external requesters on a reactive basis in accordance with the aforementioned Agency's policy on access to documents.

In addition, the following clinical data are not covered by the scope of the policy:

- Clinical data that are not held by the Agency, even if they concern a medicinal product that has been authorised by the Agency (e.g. clinical trials on an authorised product conducted by independent investigators and not submitted to the Agency).
- Pharmacovigilance data based on individual case safety reports (ICSRs). Access by third parties to ICSR data is addressed in the Agency's 'EudraVigilance access policy for medicines for human use' (EMA/759287/2009 corr.).

3. Definitions

For the purpose of this policy the following definitions apply:

- **Applicant/MAH:**

Applicant/MAH shall mean the natural or legal person(s) or organisation(s) that submitted the clinical reports to the Agency in the context of applications in support of centralised marketing authorisations (MAs)/post-authorisation submissions for existing centrally authorised medicinal products, as well as

[3] Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the clinical reports.

- **Clinical data:**

Clinical data shall mean the clinical reports and IPD.

- **Clinical reports:**

Clinical reports shall mean the clinical overviews (generally submitted in module 2.5) and clinical summaries (generally submitted in module 2.7) and the clinical study reports (generally submitted in module 5, "CSR"), together with appendices to the CSRs no. 16.1.1 (protocol and protocol amendments), 16.1.2 (sample case report form) and 16.1.9 (documentation of statistical methods).

- **Clinical study:**

Clinical study shall mean any investigation in relation to humans intended to:

- discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
- identify any adverse reactions to one or more medicinal products; or
- study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining the safety or efficacy of those medicinal products.

- **Commercially confidential information (CCI):**

CCI shall mean any information contained in the clinical reports submitted to the Agency by the applicant/MAH that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH.

- **Individual patient data (IPD):**

IPD shall mean the individual data separately recorded for each participant in a clinical study.

- **Personal data:**

Personal data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to their physical, physiological, mental, economic, cultural or social identity (Article 2(a) of Regulation (EC) No 45/2001).

4. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy.
- Characteristics of the policy.
- Date of coming into effect of the policy.

4.1. Objectives of the policy

The main objectives of the policy by making clinical data available proactively, are to enable

- public scrutiny,

- and application of new knowledge in future research,

all this in the interest of public health.

A high degree of transparency will take regulatory decision-making one step closer to EU citizens, and promote better-informed use of medicines. In addition, the Agency takes the view that access to clinical data will benefit public health in future. The policy has the potential to make medicine development more efficient by establishing a level playing field that allows all medicine developers to learn from past successes and failures. Furthermore, it will enable the wider scientific community to make use of detailed clinical data to develop new knowledge in the interest of public health. Access to clinical data will allow third parties to verify the original analysis and conclusions, to conduct further analyses, and to examine the regulatory authority's positions and challenge them where appropriate.

The Agency also takes the view that transparency should be mutually respected. Those who perform secondary analysis of clinical data, published in accordance with this policy, must be held to the same standard of transparency as those who generate clinical data in the first place. Hence, all secondary analyses are expected to also be in the public domain and accessible for further scrutiny by the scientific community. In addition, those who perform secondary analysis of clinical data published in accordance with this policy, are encouraged to provide the Agency with a copy of any article resulting from such secondary analysis before publication, in particular in those circumstances where the secondary analysis might result in the need for regulatory action to protect public health. This is a critical consideration in view of the Agency's role and responsibilities for a timely review of all available information which might have an impact on the benefit/risk ratio of centrally authorised products.

The Agency cannot guarantee that all secondary data analyses that are enabled by the policy will be conducted and reported to the highest possible scientific standard; this is not possible with a truly open approach.

Allowing external parties access to clinical data held by the Agency will directly or indirectly affect different stakeholders' rights, interests and values. In developing this policy the Agency had to consider a number of competing principles which needed to be carefully balanced in order to best ensure the overarching, long-term goal of protecting and fostering public health. These principles, as well as the Agency's positions and views, are described below:

- **Protecting personal data:**

The protection of personal data is enshrined in EU legislation; it is a fundamental right of EU citizens. The policy has to ensure adequate personal data protection; it must be fully compliant with applicable regulations in the EU, in particular Regulation (EC) No 45/2001 and Directive 95/46/EC. There are ways and means to anonymise data and protect patients from retroactive identification. Yet, the Agency is primarily concerned that emerging technologies for data mining and database linkage will increase the potential for unlawful retroactive patient identification. The Agency, therefore, takes a guarded approach to the sharing of patient-level data, which is done to enable legitimate learning from sharing patient-level data while preventing rare but potentially damaging instances of patient identification. Furthermore, patients' informed consent should be respected. The secondary analysis of personal data will have to be fully compatible with the individual privacy of clinical trial participants and data protection.

- **Protecting commercially confidential information (CCI):**

The Agency respects and will not divulge CCI. In general, however, clinical data cannot be considered CCI. The Agency acknowledges that there are limited circumstances where information could constitute CCI.

- **Protecting the Agency's and the European Commission's deliberations and decision-making process:**

Regulators have a legal mandate to evaluate medicines. In doing so, they should only focus on the science and the best interests of patients. The decision-making process should be protected against external pressures from whatever direction. Once a decision has been reached, this consideration no longer applies.

- **Ensuring future investment in pharmaceutical research and development (R&D):**

Sustained and extensive pharmaceutical research activity is a precondition for future improvements in public health. The policy has no intention to negatively impact on the incentives to invest in future pharmaceutical R&D. It is designed to guard against unintended consequences, e.g. breaches of intellectual property rights that might disincentivise future investment in R&D.

4.2. Characteristics of the policy

The main characteristics of the policy are:

- Introduction of a publication process for clinical reports.
- Management of CCI in clinical reports.
- Methods for balancing the protection of patients' privacy whilst retaining scientific value of the data.
- Stepwise implementation of the policy.

4.2.1. Introduction of a publication process for clinical reports

The introduction of a publication process for clinical reports is based on 2 pillars:

- Terms of use (ToU) which govern the access to and use of clinical reports.
- A user-friendly technical tool allowing access to such clinical reports.

The ToU provide more information in relation to the access to the information contained in the clinical reports and the intended use of such information. Two sets of ToU are available, depending on the intended use of the information contained in the clinical reports, as described below:

- **Clinical reports available on-screen for any user, with a simple and limited registration process:**

The main characteristics are:

Registration process:

- Obtaining a user ID/password.
- Accepting the ToU.

ToU for general information purposes (see annex 1):

- Intended use is for general information and non-commercial purposes, including non-commercial research purposes.
- Clinical reports are made available in a "view-on-screen-only" mode.
- Clinical reports will be made available in a searchable format and will be permanently available.

- **Downloadable clinical reports available to identified users:**

The main characteristics are:

Registration process:

- Obtaining a user ID/password.
- Accepting the ToU.
- Providing the Agency with elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for juridical persons, the affiliation and position within the organisation of the user should also be provided).

ToU for academic and other non-commercial research purposes (see annex 2):

- Intended use is for academic and non-commercial research purposes.
- Clinical reports can be downloaded, saved and printed.
- Clinical reports will be made available in a searchable format and will be permanently available.

Common to the two sets of ToU are the following elements:

- No attempt shall be made to re-identify the trial subjects or other individuals from the information.
- The clinical reports may not be used to support a MAA/ extensions or variations to a MA nor to make any unfair commercial use of the clinical reports.
- A watermark is applied to the published information to emphasise the prohibition of its use for commercial purposes.
- The Agency accepts no responsibility for the user's compliance with the ToU.

4.2.2. Management of CCI in clinical reports

Although generally the information contained in clinical reports should not be considered CCI, the Agency acknowledges that in limited circumstances the clinical reports could contain CCI, and could, therefore, be subject to redaction prior to publication. Where redaction of CCI is proposed by the applicant/MAH, a consultation with the applicant/MAH will be undertaken, following scrutiny by the Agency of the proposed redaction, including the justification provided by the applicant/MAH, as to whether the definition of CCI applies (see annexes 3 and 4).

4.2.2.1. Redaction principles

The clinical reports that will be published in accordance with this policy shall only be subject to redactions when needed to protect those specific elements which qualify as CCI that should not be released. This complements the aforementioned use controls that will need to be accepted by recipients of the documents in order to protect the originator against misuse of the data as a whole. This covers information that is not in the public domain or publicly available and where disclosure may undermine the economic or competitive position of the applicant/MAH. In this regard, the assessment of this information will take into account the justification provided by the applicant/MAH with regard to various factors, including the nature of the product concerned, the competitive situation of the

therapeutic market in question, the approval status in other jurisdictions, the novelty of the clinical development, and new developments by the same company.

In general, as already mentioned, most of the information in clinical reports would not be considered CCI. There, are, however, limited circumstances where the clinical reports could contain CCI.

The information referred to in annex 3, which is contained in the sections of the clinical reports, may be considered CCI and, therefore, may have to be redacted as per the aforementioned redaction principles, after assessment by the Agency of the justification provided by the applicant/MAH. The same rules regarding CCI and the redaction principles will apply to the same information presented in other formats or other sections in the documents submitted by the applicant/MAH to the Agency.

If justification for additional redaction going beyond the list in annex 3 has been provided by the applicant/MAH, and agreed upon by the Agency, the Agency will then proceed with the publication of the so redacted clinical reports. The Agency will, once further experience with the implementation of the policy has been obtained, undertake first a consultation with all relevant stakeholders in order to explore if the outcome of the individual case(s) should exceptionally lead to a revision of the redaction principles.

4.2.2.2. Process for publication of clinical reports

The process for publication of clinical reports is described in annex 4. This process foresees in consultation with the applicant/MAH in case the Agency disagrees with the redaction proposed by the applicant/MAH.

4.2.3. Methods for balancing the protection of patient's privacy whilst retaining scientific value of the data

Protection of patients' identity is of crucial importance. In order to achieve this objective both identification and re-identification of patients need to be avoided. Particular challenges in this respect are continuous developments in the field of technologies relating to data mining and database linkage, as well as specific scenarios to be considered in the area of medicine regulation, for instance the situation of rare diseases. In deciding on the most optimal approach (anonymisation versus pseudonymisation) the Agency will take due account of recent developments, e.g. the work undertaken by the network of EU Data Protection Authorities on anonymisation techniques[4], and subsequently discuss with stakeholders (e.g. patients' organisations, academia, pharmaceutical industry) to agree on the best way forward.

4.2.4. Stepwise implementation of the policy

The implementation of the policy will be undertaken in a stepwise manner:

- In a first phase, the publication of clinical data will relate to clinical reports only.
- In a second phase, the Agency will review various aspects in relation to IPD, including finding the most appropriate way to make IPD available, the latter in compliance with privacy and data protection laws[5].

[4] Opinion 05/2014 on anonymisation techniques, adopted on 10 April 2014 by the Article 29 Data Protection Working Party.
[5] The Agency will notify the European Data Protection Supervisor (EDPS) accordingly.

4.2.4.1. First phase: publication of clinical reports

The publication of clinical reports will be in accordance with the arrangements described in chapters 4.2.1., 4.2.2. and 4.2.3. of the policy.

In addition, the following principles will apply as regards the timing of publication:

The timing of publication takes into account the need to protect the Agency's and the European Commission's deliberations and decision-making process. In order not to undermine such decision-making process the Agency will only publish clinical data once the concerned procedure has been finalised. In practical terms this means:

- following the European Commission Decision granting or refusing the MA/post-authorisation submission outcome; or
- following the scientific committee Opinion if there is no subsequent European Commission Decision; or
- following the scientific committee conclusion if there is no Opinion; or
- following receipt of the applicant's/MAH's letter notifying the withdrawal of the MAA/post-authorisation submission.

The process described in chapter 4.2.2.2. for publication of clinical reports, including where necessary interaction with the applicant/MAH, will start following the adoption of the scientific committee Opinion/conclusion or the receipt of the withdrawal letter, as referred to above.

4.2.4.2. Second phase: reviewing various aspects in relation to IPD

Before IPD can be made available, there is a need to first clarify:

- the submission of IPD for subsequent scientific review by the Agency, and
- how to best provide access to such IPD, including the conditions to be fulfilled.

It is important to emphasise in this regard that the Agency will not request applicants/MAHs to submit IPD for the sole purpose of publication of IPD.

The Agency will first undertake a targeted public consultation with all concerned stakeholders on the various aspects in relation to IPD to provide clarification. Subsequently, in consultation with the Agency's Management Board, the policy will be amended to reflect the outcome of this targeted public consultation.

4.3. Date of coming into effect of the policy

For the coming into effect of the policy a stepwise approach will be applied.

The effective date will be 1 January 2015 for any new MAAs, and Article 58 applications submitted as from the effective date onwards.

The effective date will be 1 July 2015 for extension of indication applications and line extension applications relating to existing centrally authorised medicinal products submitted as from the effective date onwards. For all other post-authorisation procedures relating to existing centrally authorised medicinal products where supporting clinical reports have been submitted, the effective date will be determined in 2015.

5. Related documents

Further information on the development and implementation of the policy is provided in a Q&A document[6].

6. Changes since last revision

The following changes have been made:

Further to the decision by the United Kingdom to leave the European Union in accordance with the provisions of Article 50 TEU, the governing law of the Terms of Use is changed from England and Wales' to the Netherlands' and the Amsterdam District Court replaces London as a non-exclusive jurisdictional venue. Annex I and Annex II hereto have been updated accordingly.

London, 21 March 2019

Signature on file

Guido Rasi
Executive Director

[6] Q&A on the European Medicines Agency policy on publication of clinical data for medicinal products for human use (EMA/357536/2014).

Annex 1

Terms of Use for general information purposes

These Terms of Use ("***Terms***") govern the access and use of clinical data, as defined in chapter 3. of the EMA policy on publication of clinical data, Policy 0070 ("***Policy***"), that are made available to *Users* via such *Policy*. By accepting these *Terms* and upon being granted access to the *Clinical Reports*, you agree to be bound by these *Terms*. Please read them carefully.

1. Definitions

In these *Terms* the terms below have the following meaning:

"**EMA**" means the European Medicines Agency.

"**Clinical Reports**" means the clinical overviews (module 2.5), the clinical summaries (module 2.7) and the clinical study reports (module 5, "CSR"), together with appendixes to the CSRs no. 16.1.1, 16.1.2 and 16.1.9 which are accessible via the *EMA* website as a result of the implementation of the *Policy*.

"Applicant/MAH" means the natural or legal person(s) or organisation(s) that submitted the *Clinical Reports* to the *EMA* in the context of applications in support of centralised marketing authorisations/post-authorisation submissions under Regulation (EC) No 726/2004, as well as any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the *Clinical Reports*.

"**User**" means the natural or legal person or organisation who, having registered with the *EMA* website in connection with the implementation of the *Policy*, receives access to the *Clinical Reports*.

2. Access to the *Clinical Reports* under the *Policy*

The *User* acknowledges that the *Clinical Reports* are protected by copyright or other intellectual property rights of the *Applicant/MAH* and can be considered commercially valuable when used for commercial and regulatory purposes.

The *User* acknowledges that the *Clinical Reports* will be made available to the *User* on the *EMA* website in a "view-on-screen-only" mode, after completing the registration process. The *User* agrees that the *User* is not permitted to download, save, edit, photograph, print, distribute or transfer the *Clinical Reports*. The *User* agrees not to access the *Clinical Reports* using a method other than the interface provided by the *EMA*, or remove, bypass, circumvent, neutralise or modify any technological protection measures which apply to the *Clinical Reports*.

3. Use of the *Clinical Reports*

The *User* agrees to use the *Clinical Reports* according to these *Terms* and, in particular, that:

a) The *User* may use the *Clinical Reports* for general information and non-commercial purposes, including non-commercial research purposes, subject to these *Terms*.

b) The *User* is not granted any intellectual property or other commercial rights in relation to the *Clinical Reports* other than as expressly set out in these *Terms*.

When using the *Clinical Reports*, the *User* shall:

a) acknowledge that its source is the *Applicant/MAH*;

b) not use it in a way that suggests that the *Applicant/MAH* endorses the *User's* use of the *Clinical Reports* for any other purpose than general information and non-commercial purposes, including non-commercial research purposes;

c) ensure that the use of the *Clinical Reports* comply at all times with applicable law;

d) not misrepresent the source of the *Clinical Reports*;

e) not seek to re-identify the trial subjects or other individuals from the *Clinical Reports* in breach of applicable privacy laws.

The *User* may not:

- use the *Clinical Reports* to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
- share the *User's* username, password or other account details with a third party or otherwise provide a third party with access to the *User's* account;
- make any unfair commercial use of the *Clinical Reports*.

If the *User* fails to accurately complete the registration process, comply with these conditions, or uses the *Clinical Reports* in breach of these *Terms*, the rights to access and use the *Clinical Reports* will be revoked.

4. Warranties and liability

Without prejudice to any obligation of the *Applicants/MAHs* in accordance with the Union legislation:

- The *EMA* and the *Applicant/MAH* exclude all representations, warranties, obligations and liabilities in relation to the *Clinical Reports* as accessible via the *EMA* website to the maximum extent permitted by law;
- Neither the *EMA* nor the *Applicant/MAH* are liable for any errors or omissions in the *Clinical Reports* as provided via the *EMA* website and shall not be liable for any loss, injury or damage of any kind caused by its use.
- The Agency accepts no responsibility for the *User's* compliance with the *Terms*.

5. Third party rights

The restrictions and conditions and the warranty and liability provisions of these *Terms* are also made for the benefit of any and all *Applicants/MAHs* and, accordingly, each such *Applicant/MAH* may in its own right enforce these *Terms* in accordance with the provisions of the Dutch Civil Code ("Burgerlijk Wetboek").

6. Governing law

These *Terms* and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of the Netherlands.

7. Jurisdiction

The Amsterdam District Court shall have non-exclusive jurisdiction to settle any dispute or claim arising out of or in connection with these *Terms* or their subject matter or formation (including non-contractual disputes or claims).

Annex 2

Terms of Use for academic and other non-commercial research purposes

These Terms of Use ("***Terms***") govern the access and use for academic and non-commercial research purposes of clinical data, as defined in chapter 3. of the EMA policy on publication of clinical data, Policy 0070 ("***Policy***"), that are made available to *Users* via such *Policy*. By accepting these *Terms* and upon being granted access to the *Clinical Reports*, you agree to be bound by these *Terms*. Please read them carefully.

1. Definitions

In these *Terms* the terms below have the following meaning:

"**EMA**" means the European Medicines Agency.

"**Clinical Reports**" means the clinical overviews (module 2.5), the clinical summaries (module 2.7) and the clinical study reports (module 5, "CSR"), together with appendixes to the CSRs no. 16.1.1, 16.1.2 and 16.1.9 which are accessible via the *EMA* website as a result of the implementation of the *Policy*.

"Applicant/MAH" means the natural or legal person(s) or organisation(s) that submitted the *Clinical Reports* to the *EMA* in the context of applications in support of centralised marketing authorisations/post-authorisation submissions under Regulation (EC) No 726/2004, as well as any person(s) or organisation(s) who own(s) copyright or other intellectual property rights in the *Clinical Reports*.

"**User**" means the natural or legal person or organisation who, having registered with the *EMA's* website in connection with the implementation of the Policy, receives in electronic format a copy of the *Clinical Reports*.

2. Access to the *Clinical Reports* under the *Policy*

The *User* acknowledges that the *Clinical Reports* are protected by copyright or other intellectual property rights of the *Applicant/MAH* and can be considered commercially valuable when used for commercial and regulatory purposes.

The *User* acknowledges that the *Clinical Reports* will be made available to the *User* in electronic format for academic and non-commercial research purposes. Before being granted access to the *Clinical Reports* in electronic format, the *User* shall provide the EMA with:

- An e-mail address,
- A place of address in the European Union; in the event that the *User* does not have a place of address in the European Union and wishes to avail itself of the services of a third party resident or domiciled in the European Union, such third party shall be considered *User* for the purposes of these *Terms* and shall comply with all the terms hereof,

- Elements concerning the identity of the user (i.e. name, date of birth, passport or ID card number, expiry date of the document; for juridical persons, the affiliation and position within the organisation of the user should also be provided).

3. Use of the *Clinical Reports*

The *User* agrees to use the *Clinical Reports* according to these *Terms* and, in particular, that:

a) The *User* may use the *Clinical Reports* solely for academic and non-commercial research purposes, subject to these *Terms*.

b) The *User* is not granted any intellectual property or other commercial rights in relation to the *Clinical Reports* other than as expressly set out in these *Terms*.

The *User* may not:

- use the *Clinical Reports* to support an application to obtain a marketing authorisation and any extensions or variations thereof for a product anywhere in the world;
- share the *User's* username, password or other account details with a third party or otherwise provide a third party with access to the *User's* account;
- make any unfair commercial use of the *Clinical Reports*;
- seek to re-identify the trial subjects or other individuals from the *Clinical Reports* in breach of applicable privacy laws.

For the avoidance of doubt, the *User* is permitted to download, save and print the *Clinical Reports*, subject to these *Terms*.

If the *User* fails to accurately complete the registration process, comply with these conditions, or uses the *Clinical Reports* in breach of these *Terms*, the rights to access and use the *Clinical Reports* will be revoked.

4. Warranties and liability

Without prejudice to any obligation of the *Applicants/MAHs* in accordance with the Union legislation:

- The *EMA* and the *Applicant/MAH* exclude all representations, warranties, obligations and liabilities in relation to the *Clinical Reports* as made accessible to the *Users* to the maximum extent permitted by law;
- Neither the *EMA* nor the *Applicant/MAH* are liable for any errors or omissions in the *Clinical Reports* as made accessible to the *Users* and shall not be liable for any loss, injury or damage of any kind caused by its use.
- The Agency accepts no responsibility for the *User's* compliance with the *Terms*.

5. Third party rights

The restrictions and conditions and the warranty and liability provisions of these *Terms* are also made for the benefit of any and all *Applicants/MAHs* and, accordingly, each such *Applicant/MAH* may in its own right enforce these *Terms* in accordance with the provisions of the Dutch Civil Code ("Burgerlijk Wetboek").

6. Governing law

These *Terms* and any dispute or claim arising out of or in connection with them or their subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of the Netherlands.

7. Jurisdiction

The Amsterdam District Court shall have non-exclusive jurisdiction to settle any dispute or claim arising out of or in connection with these *Terms* or their subject matter or formation (including non-contractual disputes or claims).

Annex 3

Information contained in the sections of the clinical reports that may be considered CCI

The information contained in the clinical reports that may be considered CCI and the reference to the relevant sections is provided in the table below. Guidance described in column 2 advises what should be discussed in case of information that may be considered CCI.

Title	Information that may be considered CCI	Justification for redaction
Elements relating to clinical trials and contained in "The common technical document for the registration of pharmaceuticals for human use" (from ICH harmonised tripartite guideline, Module 2 and 5)		
Product Development Rationale *Information expected to be found in section 2.5.1 of the clinical overview as per ICH M4(R3) guideline*	• "Describe the clinical development programme of the medicinal product, including ongoing and planned clinical studies and the basis for the decision to submit the application at this point in the programme…." • "Regulatory guidance and advice from outside the EU should be identified, with discussion of how that advice was implemented." • "Formal advice documents (e.g., official meeting minutes, official guidance, letters from non EU regulatory authorities) should be referenced…."	• Information for planned clinical studies may include "exploratory endpoints" that are not intended to yield data in support of the then-current approval of a use or indication, but could provide clues to potential uses and indications for competitors. • Regulatory advice from outside the EU is typically non-public and includes agreements with regulators on study design, strategies for organisation and presentation of findings, and other aspects of the regulatory process that competitors could copy. • Same justification as above.
Overview of Biopharmaceutics *Information expected to be found in section 2.5.2 of the clinical overview as per ICH M4(R3) guideline*	• Detailed assay information/quantitative composition/lot numbers	• As the Biopharmaceutical Summary Documents (2.7.1) are considered CCI, this section may contain some overlapping information.
Overview of Clinical Pharmacology *Information expected to be found in section 2.5.3 of the clinical overview as per ICH*	• Stereochemistry issues.	• Competitors could gain a detailed understanding of the stereoisomers and three-dimensionality of the molecule.

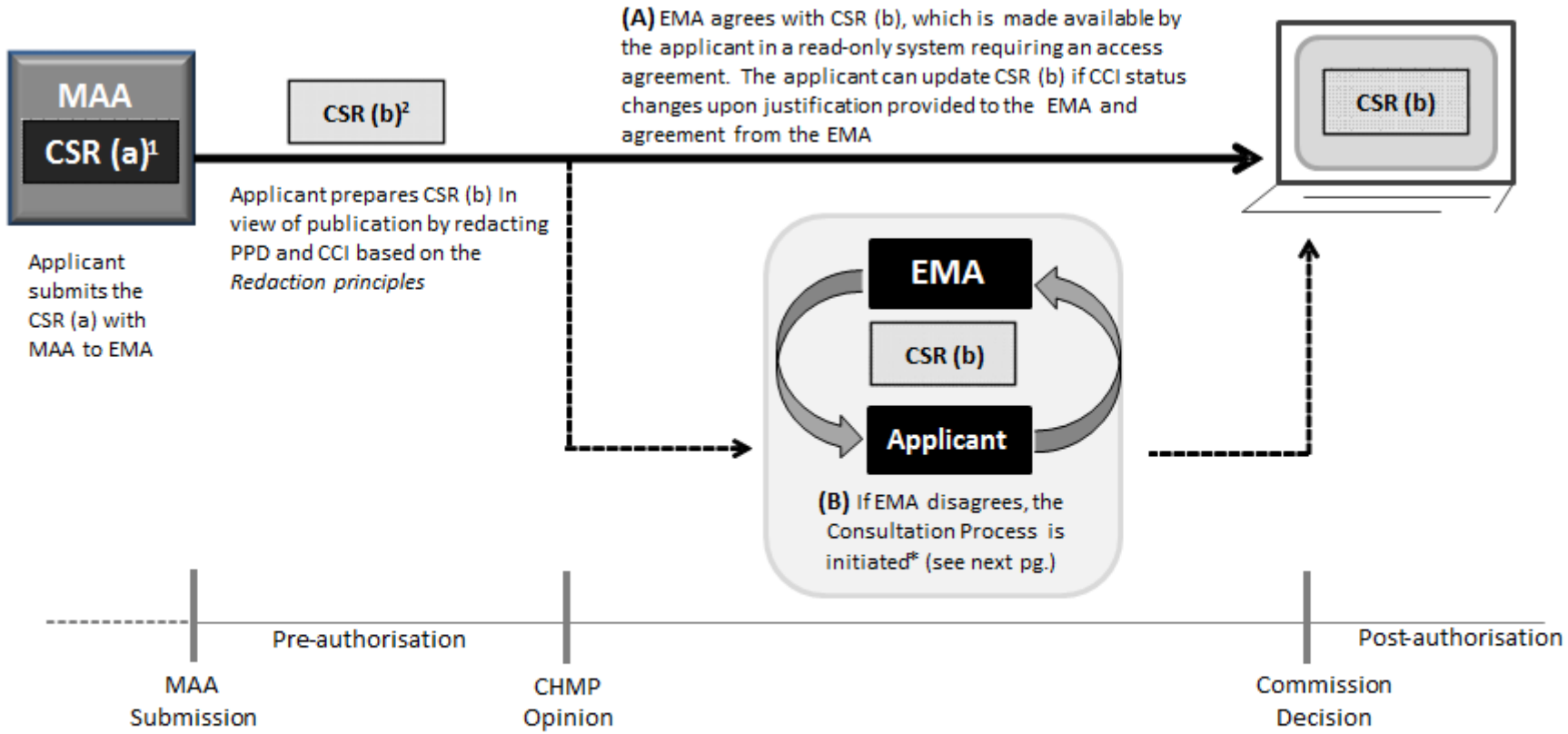
Title	Information that may be considered CCI	Justification for redaction
M4(R3) guideline		
Benefits and Risks Conclusions *Information expected to be found in section 2.5.6 of the clinical overview as per ICH M4(R3) guideline*	• Implications of any deviations from non EU regulatory advice or guidelines.	• The company may include justifications for any deviation from regulatory advice or guidance outside of the EU jurisdiction, a competitor may have an unwarranted new perception of the regulatory risk associated with a certain regulatory strategy.
Summary of Biopharmaceutic Studies and Associated Analytical Methods *Information expected to be found in section 2.7.1 of the clinical summary as per ICH M4(R3) guideline*	• Information about specifications on company assays.	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.
Summary of Clinical Pharmacology Studies *Information expected to be found in section 2.7.2 of the clinical summary as per ICH M4(R3) guideline*	• Information about specifications on company assays and immunogenicity assays.	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.
Reports of Biopharmaceutic Studies *Information expected to be found in section 5.3of module 5 "Clinical study reports" as per ICH M4(R3) guideline*	• Information about specifications on company assays by which the results of the studies (e.g. Bioavailability, In Vitro – In Vivo Correlation) are obtained. • Information about company innovative bioassays/analytical methods.	• This section may contain CCI in the form of details and specifications on assays developed by the company. The information may bring significant advantages to competitors if published.

Title	Information that may be considered CCI	Justification for redaction
Structure and content of clinical study reports (CSRs) (from ICH harmonised tripartite guideline, E3)		
Introduction *Information expected to be found in section 7 of the clinical study reports as per ICH E3 guideline*	• Development of the protocol or any other agreements/meetings between the sponsor/company and non EU regulatory authorities that are relevant to the particular study, should be identified or described.	• May contain non-public information that the sponsor agreed in another jurisdiction outside of the EU.
Study Objectives (including Exploratory Endpoints and Efficacy and Safety Variables) *Information expected to be found in sections 8 and 9.5 of the clinical study reports as per ICH E3 guideline*	• Statements/descriptions relating to objectives that are not supportive of a label claim and they were not taken into consideration in the overall benefit/risk evaluation. This includes the definition of efficacy and safety variables collected and analysed in support of exploratory objectives.	• The exploratory study objectives could be used by a competitor to gain insights into additional future study plans and/or indications for the product. For example, in some trials for a new anti-inflammatory medicinal product, an exploratory lipid profile was included, investigating the lipid metabolism in patients treated with the product, to inform future studies rather than to support the MAA. The results of these analyses were included in the CSRs submitted to the EMA in the course of the MAA procedure. • Alternatively the exploratory objectives may include biomarkers that could be used as 'hypothesis generating' for future studies. At that stage there would not be enough information to file patent applications on these objectives until some data are available from clinical and non-clinical studies. Disclosing these exploratory objectives may preclude obtaining patents that would cover biomarkers/diagnostics themselves, as well as method of use patents directed to

Title	Information that may be considered CCI	Justification for redaction
		patient subpopulations.
Determination of Sample Size *Information expected to be found in section 9.7.2 of the clinical study reports and appendix 16.1.9 as per ICH E3 guideline*	• Analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates).	• The sample size per se is not considered CCI. However there may be occasions when the intellectual consideration that goes into the analysis of the information that drives the sample size calculation (e.g. estimates of endpoint variability, measurement precision, screening and retention rates) is considered CCI.
Method of PK/PD determination *Information expected to be found in section 9.5.4 of the clinical study reports as per ICH E3 guideline*	• CCI on analytical methods.	• This section may have proprietary information on how analyses are performed.

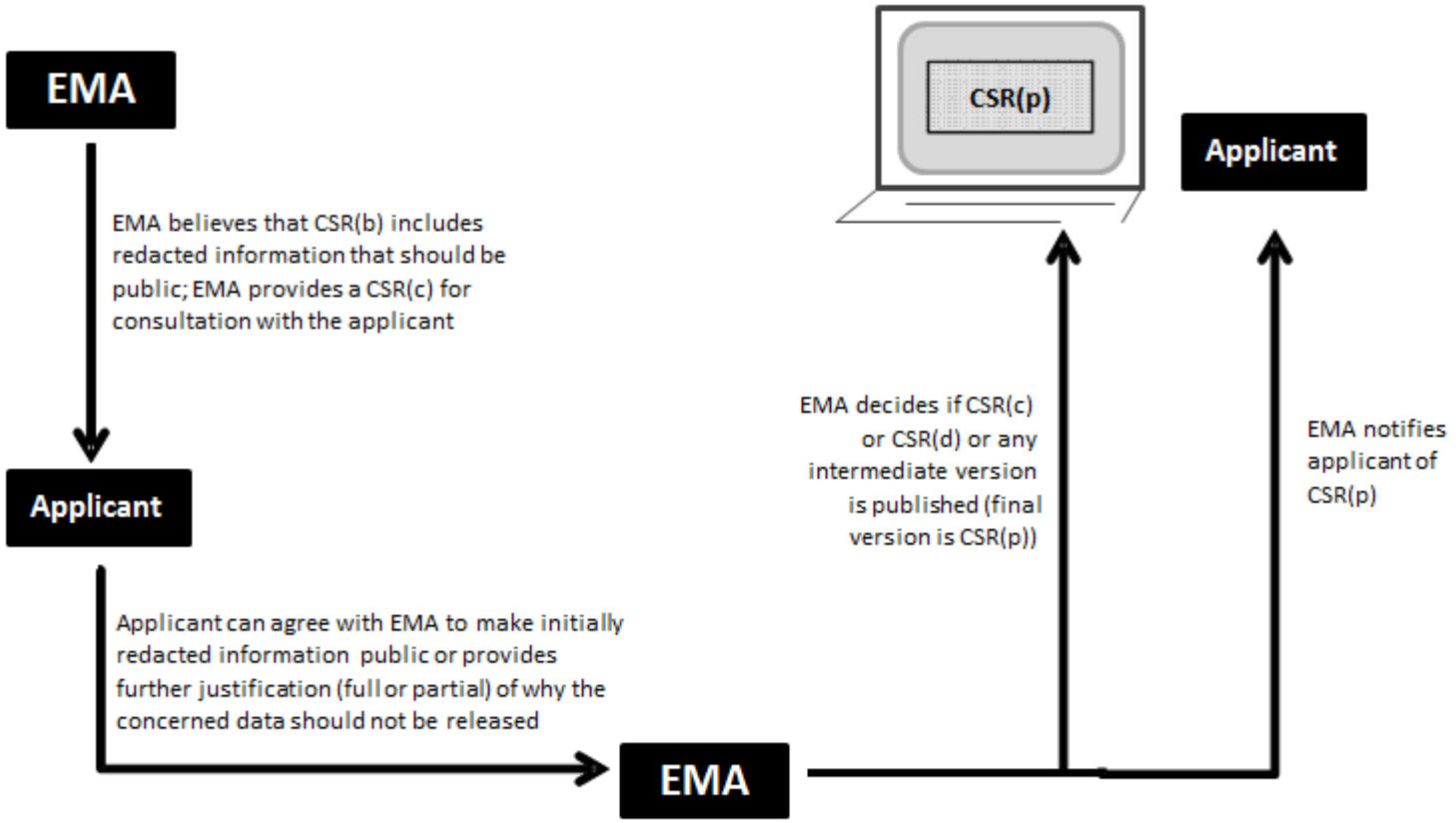
Annex 4

Process for publication of clinical reports (scenario: MAA)



1. CSR (a) = CSR in accordance with EMA guidance (1995 and 2004)
2. CSR (b) = CSR available under the EMA policy

*Consultation process



* Consultation process to be concluded within Decision making process timelines – exact timing still to be determined.

(TRUE COPY)