



# Overview

- European Medicines Agency (EMA) policy on publication of clinical data for medicinal products for human use
- EMA's experience in Access to Documents
  - Statistics and pending litigation



## European Medicines Agency Policy on publication of clinical data for medicinal products for human use (Policy 0070)

- Main objectives of Policy 0070:
  - By making clinical data available proactively, to enable:
    - public scrutiny; and
    - application of new knowledge in future research;
  - all this in the interest of public health.
- Adoption and next steps:
  - Policy adopted by the Management Board on 2 October 2014;
  - Policy to be implemented on a step-wise approach starting from 1 January 2015.



## The Policy (I)

- The Policy has been shaped in the absence of any specific legal provision mandating the EMA to publish documents submitted by third parties
- Mutually agreed approach was needed taking into account different stakeholders' competing interests
- Introduction of a publication process through Terms of Use (ToU), as part of the Policy:
  - Govern the access to and use of clinical data, and a user-friendly technical tool allowing such access.
- Management of commercially confidential information (CCI) in clinical reports through redaction principles and a process for consultation and publication of clinical reports



## The Policy (II)

- The EMA has defined a process for publication of clinical reports with two different modalities to see the data:
  - Clinical reports available on-screen for any user, with a simple registration process:
    - The intended use is for general information.
  - Downloadable clinical reports available to registered identified users:
    - The intended use is academic and non-commercial research purposes;
    - Individuals will need to provide the EMA with elements concerning the identity of the user.
- Both situations will be governed by dedicated ToU



## Concept of Commercially Confidential Information (I)

- The concept of CCI is defined neither in the EU legislation nor in the case law of the Court of Justice of the European Union
- CCI is defined, for the purpose of the Policy, as:
  - *“any information contained in the clinical reports submitted to the Agency by the applicant/marketing authorisation holder (MAH) that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH”.*
- Annex 3 to the Policy provides principles for the redaction of CCI that may be contained in clinical reports:
  - Aim: to ensure a clear and transparent understanding on the part of applicants/MAH.
- Applicants/MAHs will be asked to submit redacted clinical reports for publication



## Concept of Commercially Confidential Information (II)

- The starting point of the redaction principles is that clinical reports do not, in general, contain CCI
- However, in a limited number of instances there might be pieces of information that could be considered CCI:
  - In such cases the EMA is prepared to consider and assess MAH's justifications for redactions, as clarified in the policy;
  - It is for the EMA to take the final decision on what is and is not to be redacted. The extent of what the EMA will redact will always be visible in the final documents that the EMA makes available.

## Policy 0070 and Clinical Trial Regulation

	Policy 0070	Clinical Trial Regulation (Regulation (EU) No 536/2014)
<b>Medicinal products covered</b>	Centrally authorised products only	Investigational medicinal products regardless of whether they have a marketing authorisation
<b>Clinical studies covered</b>	Clinical studies submitted to the Agency in the context of a MAA, Article 58 procedure, line extension or new indication, regardless of where the study was conducted	Clinical trials conducted in the EU and paediatric trials conducted outside the EU that are part of paediatric investigation plans
<b>Documents published</b>	Clinical data (clinical overview, clinical summaries and clinical study reports) and the anonymisation report	All clinical trial-related information generated during the life cycle of a clinical trial (e.g. protocol, assessment and decision on trial conduct, summary of trial results including a lay summary, study reports, inspections, etc.)
<b>Publication channel</b>	<a href="#">EMA clinical data publication website</a>	Future EU portal and database
<b>Date it applies</b>	1 January 2015 (MAA or Article 58 procedure) or 1 July 2015 (line extension or new indication)	<a href="#">Expected October 2018</a>
<b>Publication from</b>	October 2016	Expected in 2019



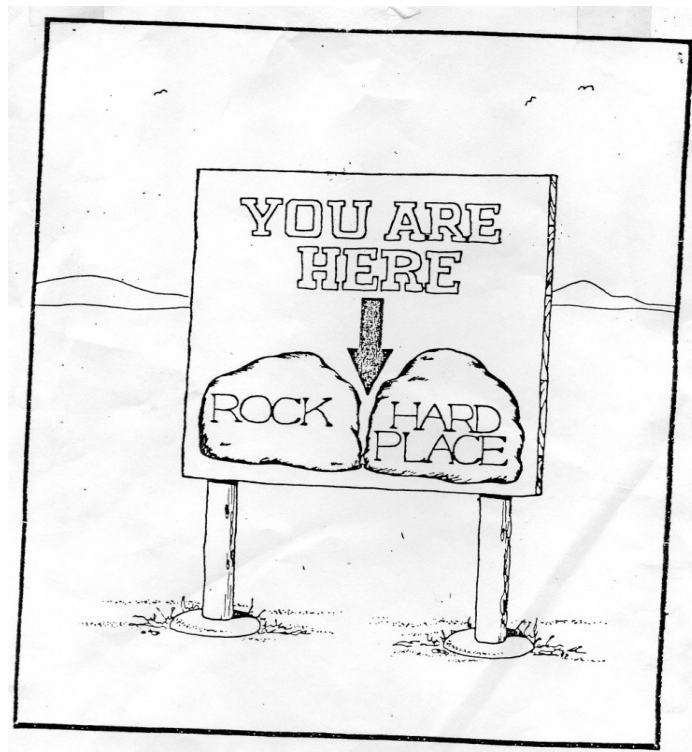
## Policy 0070: The final deliverable

- **Common elements to both sets of ToU:**
  - Trial subjects may not be re-identified;
  - Clinical reports may not be used to support a MAA/post-authorisation procedure, and no unfair commercial use may be made;
  - Watermark is applied to the published information;
  - EMA accepts no responsibility for compliance with the ToU.





## Access to Documents in the EMA...



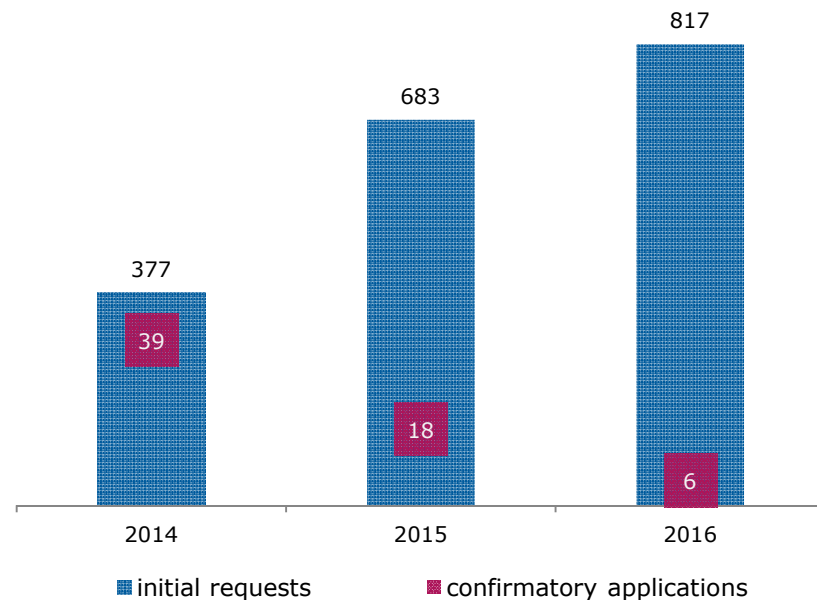
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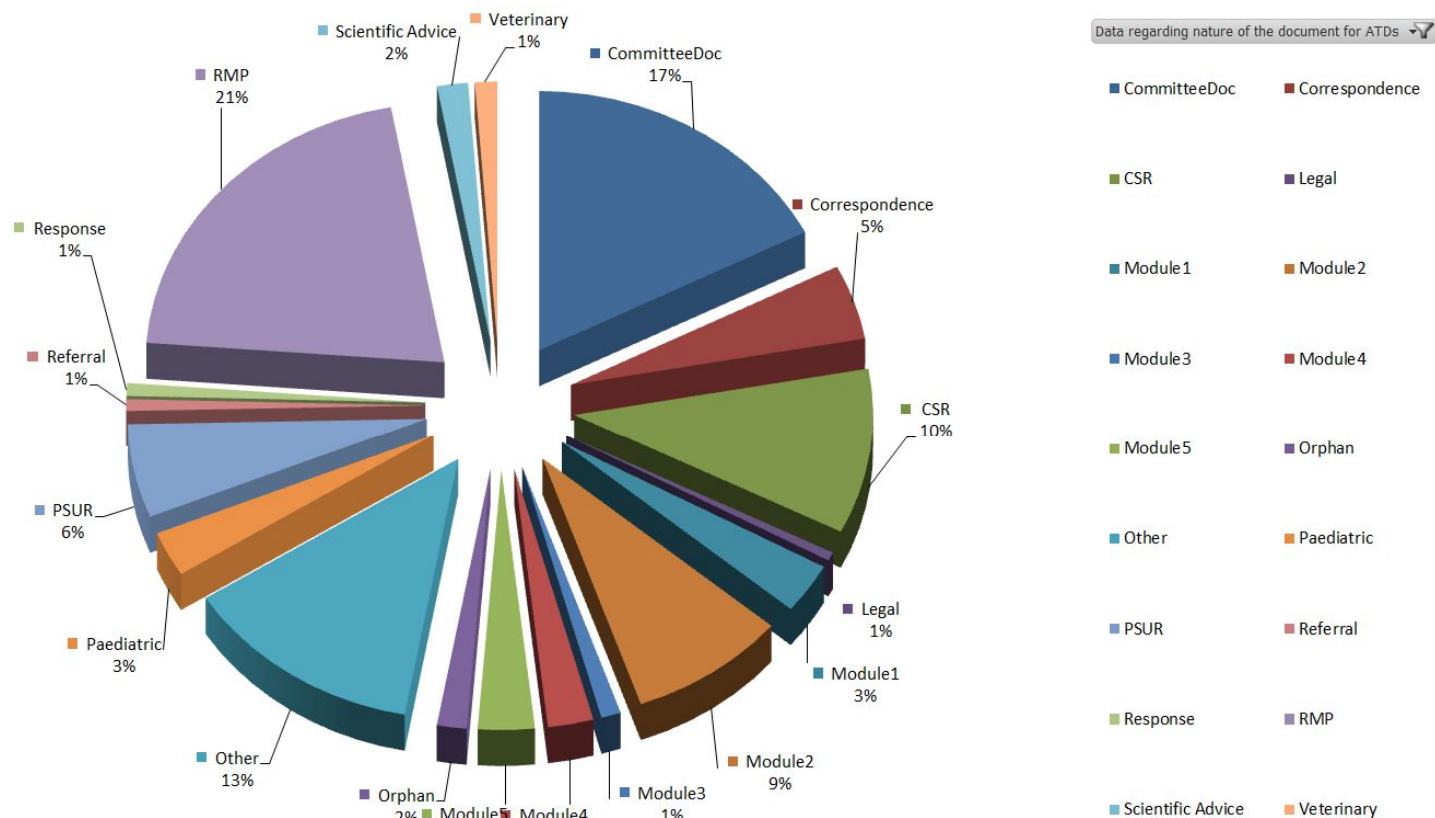
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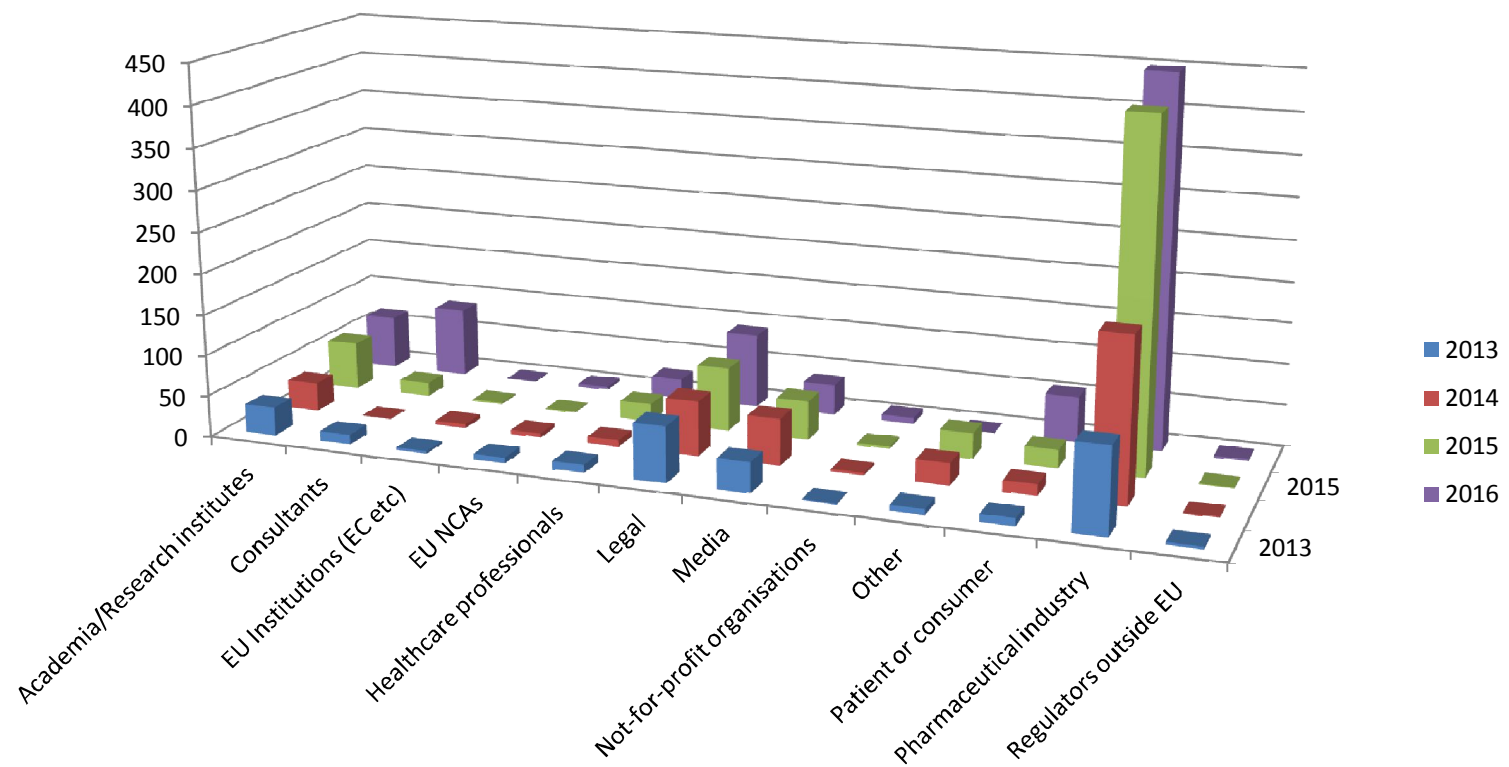
## Access to documents activities in the EMA

Period	No. of ATD requests received	No. of pages released	No. of documents released
<b>2011</b>	191	1,019,187	Not available*
<b>2012</b>	281	685,489	Not available*
<b>2013</b>	290	316,760	Not available*
<b>2014</b>	416	167,309	1,771
<b>2015</b>	701	333,999	2,972
<b>2016</b>	<b>823</b>	<b>380,911</b>	<b>2,876</b>
<b>Total</b>	<b>2718</b>	<b>2,910,745</b>	<b>7,619</b>

Requests for access to documents received (2014-2016)









## Access to documents activities in the EMA – 2016 and 2017

... approximately **300 initial requests** since 1 January 2017

<b>AtD requests</b>	Q1 2016	<b>Q1 2017</b>
Received	205	<b>~240</b>

...AND COUNTING...



## Pending litigation for EMA decisions to release documents (I)

### **Case T-235/15 *Pari Pharma v EMA***

**Main action:** Action for annulment of EMA decision to release the CHMP reports concerning the similarity and superiority of Vantobra over TOBI Podhaler

- MAH opposed the release of the two documents as a whole but also proposed some redactions
- Oral hearing took place in mid-February
- Ruling expected later this year
  - It is expected to be a first ruling on the merits of an access to documents case involving EMA.

#### **Interim measures:**

- Interim Orders of the President of the General Court preventing the release were annulled by the Vice-President of the Court of Justice and the documents were already released

## Pending litigation for EMA decisions to release documents (II)

### **Case T-718/15 *PTC Therapeutics International v EMA***

**Main action:** Action for annulment of EMA decision to release two Clinical Study Reports for Translarna

- MAH opposed the release of the two documents as a whole and did not propose any redactions
- Oral hearing may take place later this year
- Ruling expected later this year or early next year

**Interim measures:**

- Interim Orders of the President of the General Court preventing the release were upheld on appeal by the Vice-President of the Court of Justice and the documents will not be released before the ruling of the General Court



## Pending litigation for EMA decisions to release documents (III)

### ***Case T-729/15 MSD Animal Health Innovation and Intervet International v EMA***

**Main action:** Action for annulment of EMA decision to release two toxicology studies for Bravecto

- MAH opposed the release of the two documents as a whole
- Oral hearing took place on 16 May 2017
- Ruling expected later this year or early next year

#### **Interim measures:**

- Interim Orders of the President of the General Court preventing the release were upheld on appeal by the Vice-President of the Court of Justice and the documents will not be released before the ruling of the General Court





## Pending litigation for EMA decisions to release documents (IV)

### **Case T-33/17 *Amicus Therapeutics UK and Amicus Therapeutics v EMA***

**Main action:** Action for annulment of EMA decision to release a Clinical Study Report for Galafold

- MAH opposed the release of the document as a whole
- The processing of further requests for this and similar documents (e.g. another CSR) was suspended by EMA
- It also affects the publication of the CSR in accordance with Policy 0070



## Conclusion

- The Agency strives for ever increasing transparency through both reactive and proactive publication despite:
  - constantly increasing workload;
  - very high complexity of the documents and information subject to publication;
  - additional need of resources in this area but constraints stemming from the need to curb the number of posts in the EU institutions;
  - need to constantly consider and balance competing public interests;
  - ever-present risk of legal challenge from various stakeholders and continuous scrutiny by the European Ombudsman.



# Thank you for your attention

## Further information

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### **European Medicines Agency**

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

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