

# Policies 0070 and 0043: Juggling different requirements

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## Abstract

EMA Policies 0043 and 0070 allow access to a broad range of regulatory documents. This article compares the two policies, highlighting key differences relevant for medical writers and professionals focussing on clinical data transparency. This article then summarises Teva's experience with implementing Policy 0070 and preparing the company's first two Policy 0070 dossiers for publication. Finally, the article reviews major challenges and how to overcome them, for example, how to consider previous Policy 0043 requests for the same drug product. Medical writers need to become familiar with these policies because the increased dissemination of regulatory documents will affect how these are prepared in the future.

Two policies of the EMA grant access to previously undisclosed regulatory clinical documents. In November 2010, the policy on access to documents (Policy 0043) was adopted.<sup>1</sup> This was followed in October 2014 by the policy on publication of clinical data (Policy 0070).<sup>2</sup> Both policies aim to enhance the transparency of the regulatory decision-making process. An additional objective of Policy 0070 is to allow the scientific community to apply the knowledge from past clinical development programmes to future research.

Although the objectives of the two policies are similar, their scope, approach, and procedures

differ (see Table 1 overleaf). According to phase 1 of Policy 0070, after a medicinal product has received a marketing authorisation, its regulatory clinical documents (clinical study reports [CSRs], clinical summaries, and clinical overviews) must be published on an EMA website. In contrast, Policy 0043 allows anyone to request a wide range of clinical and other documents from the EMA without giving a reason. In the vast majority of cases, EMA grants the request, and only the requester receives the documents.<sup>1-5</sup>

According to both policies, protected personal data (PPD) and commercially confidential information (CCI) must not be released in order to protect the privacy of individuals and the commercial interests of drug developers. Personal data is defined as "any information relating to an identified or identifiable natural person" in Regulation 45/2001, to which both policies refer.<sup>6</sup> Clinical documents typically contain personal data of study participants, such as participant identification numbers. Clinical documents may also contain personal data of staff from sponsor, investigational sites, and vendors, such as phone numbers. CCI is defined

in Policy 0070 as "any information ... that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant". Policy 0043 has a similar definition of CCI. The EMA Questions and Answers document for Policy 0070 further confirms that there "will be no difference in the understanding of CCI in the Agency's assessment" between both policies.<sup>1,2,7</sup>

Currently, redacting or masking (rendering information invisible with a coloured bar) is the most widespread method to protect personal data under Policy 0070. Other anonymisation techniques to protect personal data, such as randomisation and generalisation, are encouraged by EMA for Policy 0070.<sup>8</sup> For Policy 0043, redaction is the only accepted method to prevent release of PPD, since it ensures compliance with the legal requirement to grant access to the original documents. For CCI, redaction is the only possibility for preventing release according to either policy.<sup>6,8-11</sup>

Between October 2016, when the clinical data publication website for Policy 0070 went live, and December 2017, EMA published documents for 64 product dossiers. However, by



Table 1. Key differences between Policies 0070 and 0043

Characteristic	Policy 0070 <sup>a</sup>	Policy 0043
Regulatory basis	No direct legal basis <sup>b</sup> ; complementary tool before Clinical Trial Regulation 536/2014 comes into force	Direct legal basis: Regulation 45/2001
Effective date	January 1, 2015	December 1, 2010
Access to documents	Proactive publication on EMA website with options to view and download	Reactive: based on a specific request and released to the requester only
Scope	Clinical CTD Module 2 and 5 documents from concerned dossiers submitted via centralised marketing authorisation procedure (for CSRs: body/synopsis, protocol/amendments, CRF, statistical analysis methods)	In principle, any documents about medicinal products for human and veterinary use held by EMA
Availability of documents	<i>Per Policy:</i> Published within 60 days after EC decision <i>As long as EMA has a backlog:</i> Much later, e.g., more than 1 year after EC decision	After finalisation of regulatory procedure (e.g., after EC decision) <sup>c</sup>
Trigger for MAH to initiate work	<i>Per Policy:</i> MAH can proactively prepare redaction proposal versions <i>As long as EMA has a backlog:</i> MAH may choose to wait for EMA notification letter (not advisable for a large dossier)	EMA receives a specific request for document(s) and consults MAH
Deadline for requesting redactions	<i>Per Policy:</i> Submission of redaction proposal package within 30 days before and 10 days after CHMP opinion <i>As long as EMA has a backlog:</i> Deadline for redaction proposal package per notification letter from EMA, usually several months after letter <sup>d</sup>	MAH usually has five working days to comment on a (batch of) document(s) sent by EMA
Anonymisation report required?	Yes	No
Who provides initial suggestion for PPD anonymisation and how?	MAH (as read-through redaction marks)	EMA (as highlights)
Who decides on PPD anonymisation?	MAH (in consultation with EMA)	EMA (after consultation of MAH)
Amount of PPD anonymised	Usually more than for Policy 0043 <sup>e</sup>	Very limited <sup>e</sup>
Method to protect personal data	Redaction or other anonymisation methods	Redaction only
Who carries out anonymisation/redactions for PPD and CCI?	MAH	EMA
Appearance of redaction marks	PPD: blue box with black overlay text; CCI: black box with red overlay text	Black boxes without overlay text for both PPD and CCI

## Abbreviations:

CCI, commercially confidential information;  
 CHMP, Committee for Medicinal Products for Human Use;  
 CRF, case report form;  
 CSR, clinical study report;  
 CTD, common technical document;  
 EC, European Commission;  
 MAH, marketing authorisation holder;  
 PPD, protected personal data.

<sup>a</sup> Timelines for the redaction proposal package and the publication step apply to initial MAAs, line extension applications, and extensions of indication applications. For Article 58 applications and withdrawals, see External Guidance.<sup>8</sup>

<sup>b</sup> See Questions and Answers document for Policy 0070.<sup>7</sup>

<sup>c</sup> For details and exceptions by document type, see.<sup>3</sup>

<sup>d</sup> For the first dossiers, MAHs were granted only about 2 to 3 months' time from EMA notification to redaction proposal document package.<sup>27</sup> More recently, the timeframe is longer, e.g., up to about 6 months; see<sup>13,14</sup> and Table 2.

<sup>e</sup> Based on Teva experience, the published dossiers on the clinical data publication website,<sup>12</sup> and.<sup>21</sup>

Table 2. Characteristics of the first Teva dossiers subject to Policy 0070

Characteristic	Dossier A	Dossier B
Type of product and application	Initial MAA for a monoclonal antibody	Initial MAA for a combination product: two generic substances plus a device
Clinical studies	Six Phase 3, four Phase 2, and four Phase 1 studies	Four Phase 1 studies
Clinical documents	30 documents	9 documents
Total page count for clinical documents	Approximately 29,000 pages	Approximately 2,500 pages
Special considerations	Includes several old “legacy” documents without text recognition; includes CSRs based on several different templates and thus with different structure	Two duplicate submissions (different tradenames with identical sets of clinical documents) requiring one redaction proposal document package but two final redacted document packages
Date of positive opinion	June 2016	June 2016
Date of EMA notification	May 2017	July 2017
Due date of redaction proposal document package	Early August 2017 Following a request for deferral, a revised due date in early September 2017 was granted by EMA	Early November 2017
Publication date	April 2018	February 2018

Abbreviations: CSR, clinical study report; MAA, marketing authorisation application.

December 2017, a total of 337 product dossiers were subject to publication under the policy. This backlog means that the timelines defined in the policy are not currently applicable. Instead, the EMA notifies marketing authorisation holders long after the Committee for Medicinal Products for Human Use (CHMP) issues an opinion for a product. EMA grants marketing authorisation holders up to about 6 months from notification to the due date of the redaction proposal document package.<sup>12–14</sup>

The following sections of this article describe the implementation of Policy 0070 at Teva (for branded medicinal products) and some of the challenges we had while preparing our first two dossiers subject to Policy 0070. The focus is on Teva-internal processes rather than the procedural steps outlined in the EMA guidance.

## Implementing Policy 0070

To provide direction on practical aspects of Policy 0070, EMA published a guidance document (the so-called External Guidance) in March 2016 and a related Questions and Answers document in March 2017.<sup>8,15</sup> To date, the External Guidance has been revised three times, most recently in September 2017. The revisions were issued while preparation of the

two Teva dossiers was ongoing. It was therefore essential for Teva to continuously follow any changes in EMA’s requirements. Uncertainties in interpretation of the guidance were clarified through interaction with EMA (via industry associations’ webinars and direct interaction, especially for the first dossier with pilot phase) and in discussion with our vendor and other companies (via industry associations).

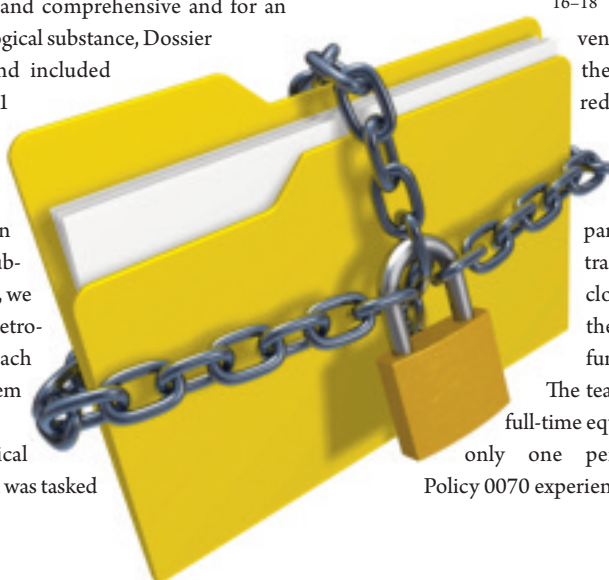
The two dossiers that this article covers were quite different and thus serve well to illustrate various challenges. While Dossier A was relatively large and comprehensive and for an innovative biological substance, Dossier B was small and included only four phase 1 studies (see Table 2). Since all documents had been written without their publication in mind, we had to follow a retrospective approach to preparing them for publication.

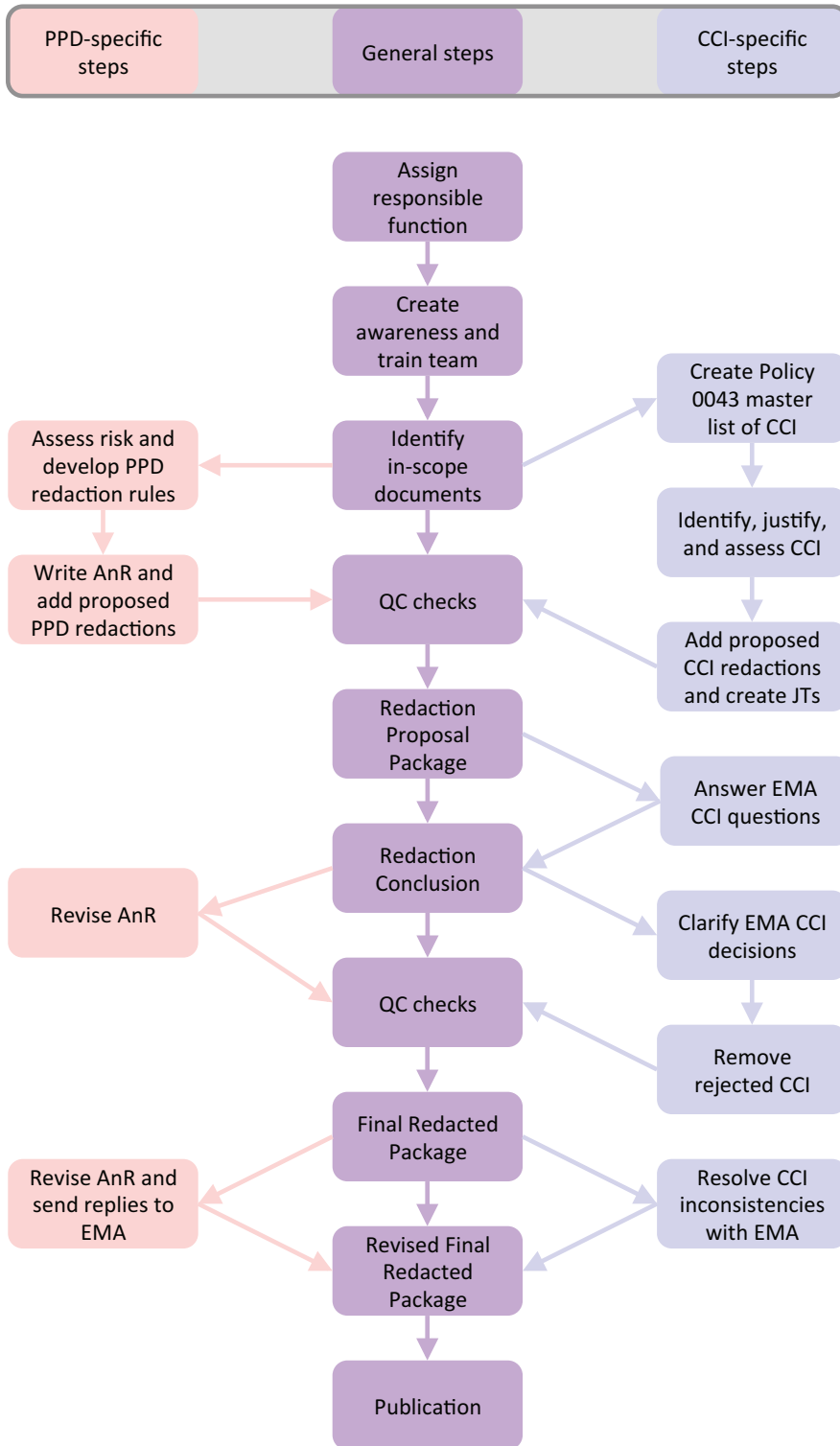
The medical writing function was tasked

to lead Policy 0070 preparations at Teva well before the expected CHMP opinions for the first concerned dossiers. A medical writing vendor with Policy 0070 experience and a software tool to search for PPD was engaged (see Figure 1). Next, a Teva medical writing representative set out together with the vendor to create awareness of Policy 0070 among a broad cross-functional group of Teva stakeholders. Over the following months, the Teva medical writing representative and vendor developed a set of draft PPD redaction rules based on published guidance.<sup>8</sup>

<sup>16–18</sup> Thereafter, the vendor started with the proposed PPD redactions for the Dossier A documents in scope of Policy 0070. In parallel, a dedicated transparency and disclosure team within the medical writing function was formed.

The team comprised four full-time equivalents, of whom only one person had prior Policy 0070 experience.





**Figure 1. Important process steps for preparing a public dossier according to Policy 0070.**

Steps apply to Dossier A, although most steps were also relevant for Dossier B. PPD-specific steps are shown on the left, CCI-specific steps on the right. Common and general steps are presented in the middle column. Abbreviations: AnR, anonymisation report; CCI, commercially confidential information; JT, justification table; PPD, protected personal data; QC, quality control.

By the time we received notification from the EMA for Dossier A, draft PPD redaction proposal versions of the clinical documents and a draft anonymisation report summarising and justifying the PPD redaction approach had almost been completed. However, the identification of potential CCI had not yet begun. Since no internal procedural guidance was available, the transparency and disclosure team prepared ad hoc process plans, guidance documents, and quality control checklists. It took the entire workforce of the transparency and disclosure team to deliver the redaction proposal package for Dossier A on time, while substantially less in-house resources were required for the small Dossier B.

### Protecting personal data

Maintaining data privacy and minimising the risk for an individual to be re-identified are important pre-requisites for clinical documents to be made public. Thus, the marketing authorisation holder must anonymise the clinical documents before publication. At the same time, “a maximum of scientifically useful information” should be retained to ensure data utility for secondary research. However, protecting the privacy of clinical study participants and maintaining data utility are competing objectives because methods that increase data privacy often reduce data utility.<sup>8</sup>

Teva decided to redact PPD in Dossiers A and B based on a qualitative, non-analytical assessment of the risk of re-identification. This is similar to most of the first dossiers published per Policy 0070.<sup>12,13,19,20</sup> A fairly conservative PPD approach was chosen to achieve a very low risk of re-identification. This was justified by the permanent public release of the documents and likely better technological means to re-identify individuals in the future. In addition, more and more personal data may become publicly available over time. This may facilitate linking

data from Policy 0070 documents with other public data to re-identify individuals. For these reasons and because access to documents via Policy 0043 is not public, considerably more PPD was redacted in Teva’s first Policy 0070 dossiers than what EMA usually accepts for Policy 0043 requests.<sup>21</sup>

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PPD-related internal steps including finalisation of the PPD redaction rules, the PPD redaction proposals, and the anonymisation reports were carried out by the transparency and disclosure team in consultation with a legal expert for data protection and a regulatory affairs representative, involving colleagues from clinical development, pharmacovigilance compliance, and statistics as needed.

The anonymisation report is not formally adopted by EMA, and the anonymisation approach is the responsibility of the marketing authorisation holder.<sup>8</sup> Nevertheless, we received a number of detailed EMA comments on the anonymisation reports during the pilot phase for Dossier A and as part of the redaction conclusions for both dossiers. Most importantly, EMA insisted on the anonymisation reports being dossier-specific and listing only those personal identifiers that actually occur in the dossier. The implementation of this comment was a time-consuming challenge because it had not been built into the PPD redaction process and required an additional search of all documents. Furthermore, not all EMA feedback for the anonymisation reports was consistent across both dossiers. Although not an expectation per the current guidance,<sup>8</sup> EMA requested replies to their comments and further modifications of the anonymisation reports after submission of the final redacted document packages (see Figure 1). Thus, our experience substantiates EMA's announcement at the industry associations' webinar in January 2018 to focus more on quality and specificity of anonymisation reports in 2018.<sup>13</sup>

## Identifying commercially confidential information

EMA states in Policy 0070 that in general “clinical data cannot be considered CCI”. What may be accepted as CCI is a matter of considerable debate and remains a case-by-case assessment, particularly given the “lack of a legal definition” of CCI.<sup>1</sup> According to recent decisions of the EU General Court for three Policy 0043 cases, marketing authorisation holders need to provide “concrete evidence of how the release of the contested documents would undermine their commercial interests”.<sup>22</sup> After 1 year of Policy 0070 clinical data publication, proposed CCI was rejected in 76% of the instances. The most frequent reasons for rejections were insufficient justifications followed by information being available in the public domain.<sup>13</sup>

For Dossier A, subject-matter experts from clinical development/pharmacology, intellectual property, bio-assays/immunology, chemistry/manufacturing/control, regulatory affairs, statistics, and non-clinical development were consulted to identify potential CCI. Up front, the transparency and disclosure team educated the subject-matter experts on what might be CCI according to these criteria: 1) information is covered in Annex 3 of Policy 0070, and 2) the item is not listed in Chapter 4 of the External Guidance as information not considered to be CCI, and 3) the item does not meet any of the five EMA rejection codes. In addition, for each CCI item, the subject-matter experts were requested to provide “a specific, pertinent, relevant, not overstated, and appropriate justification” explaining how the release of the information would damage the company's commercial interest.<sup>8</sup>

For Dossier A, subject-matter experts were asked to highlight suggested CCI in the PDF documents and add justifications within the PDF highlights. The transparency

and disclosure team then worked with the subject-matter experts to verify which items were not public, to shorten lengthy CCI suggestions to succinct and specific items such as a word or a number, and to improve the justifications. Quality control checks throughout and across documents aimed to mark CCI items in a consistent manner. As a final and time-consuming step, the transparency and disclosure team together with the vendor created the CCI justification tables and transformed the PDF highlights into correctly formatted CCI redaction proposals (see Figure 1).

For Dossier B, a modified process for identifying CCI was tested. Subject-matter experts were asked to add suggested CCI plus justification to a single justification table for the entire dossier. Checks to verify the suggested CCI items were performed based on this master justification table. Thereafter, the remaining CCI item was marked for redaction in the PDF. This process was much more

manageable than the process for Dossier A. However, since Dossier B was small with few suggested CCI items, the acid test will be Teva's next large dossier with an innovative medicinal product.

A major challenge, in particular for the preparation of Dossier A, were previous and parallel requests for documents for the same product according to Policy 0043. Even if a document in scope of Policy 0070 has previously been released according to Policy 0043, the marketing authorisation holder still has to prepare a new version of the same document for Policy 0070 publication. This is because different methods are required to mark or highlight items for redaction (refer to Table 1); thus, a new version has to be prepared even if the same items were redacted for both policies. In addition, earlier CCI decisions for documents requested according to Policy 0043 but not in scope of Policy 0070 may be relevant for preparing the Policy 0070 dossier, if the respective content is also found in any documents in scope of Policy 0070.

To prevent CCI redactions rejected under

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Policy 0043 from being included within the Policy 0070 redaction proposal package, a master list of items that were accepted or rejected per Policy 0043 was created as a reference source. However, EMA decisions for one relevant Policy 0043 request were obtained too late to allow appropriate consideration for all applicable documents in the Policy 0070 redaction proposal package. This and further aspects (e.g., the large number of scanned pages, and the number and complexity of CCI items suggested by the subject-matter experts) prevented full consistency of proposed CCI across documentation at the time of the Policy 0070 redaction proposal package. Furthermore, EMA decisions on the acceptability of CCI were not consistent between both policies. Hence, additional discussions with EMA and CCI modifications were required after the redaction conclusion and following submission of the final redacted document package (refer to Figure 1).

According to the External Guidance, we expected to have a CCI redaction consultation with a chance to clarify or elaborate on certain CCI justifications. However, apart from a request for further information for two CCI suggestions, EMA proceeded straight to the redaction conclusion.

In general, many proposed CCI redactions were rejected, mainly because justifications were not considered sufficient, the information was in the public domain, or information was considered to be common knowledge. Nevertheless, in the majority of the 30 Dossier A documents, certain CCI items (many occurring more than once) were accepted. Most of the accepted items concerned manufacturing details and immunological bioassay specifications.

## Outlook and role of medical writers

EMA's two transparency policies are the first but not the only initiatives to grant widespread access to regulatory clinical documents. Further initiatives by the EMA,<sup>23</sup> the US FDA,<sup>24,25</sup> and Health Canada,<sup>26</sup> are already effective or are planned to start soon. Although consistency across these initiatives would be highly desirable, new challenges in preparing documents to meet different transparency requirements are expected.

Even if medical writers are not directly involved in preparing documents for release or publication, they need to be aware of the fate of the documents they write. Anticipating the subsequent publication, medical writers can help facilitate the redaction process by adjusting the content and structure of clinical documents. Medical writers can reorganise and streamline company templates for CSRs, clinical study protocols, and statistical analysis plans so that PPD and CCI are minimised upfront, limited to fewer locations within a document, and more easily identified for anonymisation and redaction. Furthermore, medical writers can advise which content is necessary per CSR and Common Technical Document guidelines so as not to compromise the primary purpose of the original documents to support regulatory approval. Medical writers may also help prepare anonymised versions of documents, when a company starts employing PPD anonymisation methods other than redaction. Finally, medical writers are experts in targeting regulatory documents to various audiences, which now also include the general public.

## Acknowledgements

The author would like to thank Joanne Plumb, Janice Carling, and Laura Howard for their critical review of a draft version of the manuscript.

## Disclaimers

The opinions expressed in this article are the author's own and not necessarily shared by her employer or EMWA.

## Conflicts of interest

The author is employed by Teva Pharmaceuticals International GmbH.

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