Medical Devices

SECTION EDITOR

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Editorial

Medical device writers, you, too, can now enhance your skill set by writing for patients. Access to information about medical devices is expanding for patients in Europe with the implementation of the new Medical Device Regulation (MDR). One of the new requirements of the MDR is to provide a summary of safety and clinical performance (SSCP) that includes detailed information on a medical device for both healthcare providers and patients. In this issue, Laura C. Collada Ali and Katharina Friedrich summarise the content of the EMWA webinar they led in September to share their initial experience writing SSCPs. They describe here some of the common pitfalls they encountered and strategies to help you avoid them. If you missed the live webinar or simply want to watch it again, you can access the recording on the EMWA Webinars Archive webpage (https://members.emwa.org/EMWA/Member_Area/Webinars.aspx).

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First experiences writing summaries of safety and clinical performance for medical devices

The Medical Devices Regulation (MDR 2017/745) has been postponed due to the coronavirus pandemic and will now take effect on May 26, 2021.[1] Some manufacturers may regard this as a slight breather, but there are still enough obstacles to overcome. The MDR enforces stricter rules on the clinical evaluation process with a focus on safety and performance of medical devices and introduced several new document requirements. The summary of safety and clinical performance (SSCP) is one such document, completely new to the medical device industry and unique in its structure and purpose. The SSCP will be available to the public, including a section for healthcare professionals and a separate section for patients, if necessary. The patient section is required for implantable devices that include an implant card and for class III devices that are used directly by patients. To prepare this document, medical writers need strong technical writing skills, and in addition, must transfer a lot of technical content into lay language.

In 2019, the Medical Devices Coordination Group published a guidance on the SSCP with writing instructions and recommendations for the minimal required content.[2] The content for the healthcare professional and the patient sections are quite similar; detailed information on the device, pre-clinical and clinical data, alternative treatment methods as well as risk management and post-market surveillance activities have to be disclosed (Table 1).

The SSCP should be completely sourced from the technical documentation. At first glance, preparing such a document does not seem to be a challenge, entailing more copying and pasting of existing text than real writing. However, as a medical writer, you will notice that there are

Table 1. Comparison of SSCP table of contents for healthcare professionals and patients

Healthcare professionals	Patients (lay audiences)
1. Identification of the device and the manufacturer	1. Identification of the device and the manufacturer
2. Intended use of the device	2. Intended use of the device
3. Device description	3. Device description
4. Residual risks, undesirable side effects, warnings and precautions	4. Risks and warnings
5. Summary of the clinical evaluation, including post-market clinical follow-up	5. Summary of the clinical evaluation, including post-market clinical follow-up
6. Diagnostic or therapeutic alternatives	6. General description of therapeutic alternatives
7. Suggested training for users	7. Suggested training for users
8. Reference to harmonised standards	
9. Revision history	

Table 2. Useful resources for writing for lay audiences

Grammar and style online checker	www.grammarly.com
Singh N. Writing lay summaries: What medical writers need to know. Med Writ. 2018;27(2):49–54	http://journal.emwa.org/public-disclosure/writing-lay-summaries-what-medical-writers-need-to-know/article/3806/singh-and-vasudha_writing-lay-summaries.pdf
Readability application online	www.readable.com
EMWA Workshop run by John Dixon at EMWA conferences: 'Using Readability Tools to Help Edit Biomedical Research Articles'.	http://filemaker.emwa.org/workshops/EPDP%20Brochure.php
Good Lay Summary Practice, by the European Federation of Pharmaceutical Industries and Associations	https://efgcp.eu/documents/GoodLaySummaryPractice_PublicConsultation199.pdf
Recommendations for drafting non-promotional lay summaries of clinical trial results, by TransCelerate Biopharma Inc.	http://www.transceleratebiopharmainc.com/wp-content/uploads/2015/04/TransCelerate-Non-Promotional-Language-Guidelines-v10-1.pdf
Summaries of Clinical Trial Results for Laypersons. Recommendations of the expert group on clinical trials for the implementation of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, 5 February 2018	https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf

several potential pitfalls related to the SSCP. Based on our first experience writing SSCPs, here we share some of the challenges we encountered during the writing process and some tips and tricks to overcome these challenges.

Expectations of manufacturers versus competent authorities

The SSCP is intended to be published on Eudamed – the European data base for medical devices. The launch of Eudamed has been postponed to 2022, yet the SSCP continues to be a requirement for MDR submissions. Once this document is available, everybody will be able to access the SSCP: physicians might change their treatment strategies, patients might demand to be treated with a certain device or might even refuse a treatment. For manufacturers, this transparency is a chance to direct attention to their devices and – maybe even more importantly – to gather information on competitor devices as well. While some manufacturers may also consider using this document for marketing purposes, the SSCP should be completely sourced directly from the technical documentation and it is not intended to spread marketing claims. As a medical writer, you will have to focus on the technical information and provide both favourable and unfavourable information on the device.

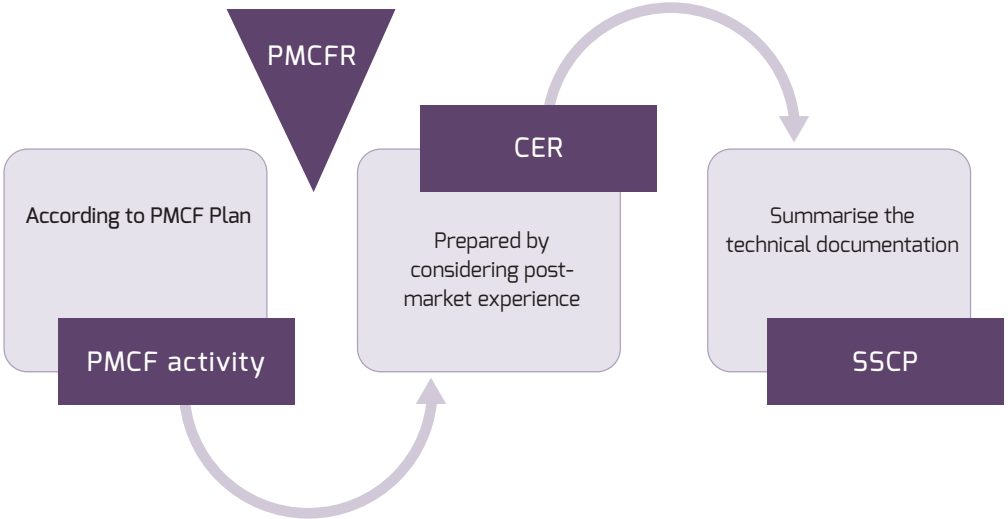

Figure 1. The SSCP in relation to other documents

Abbreviations: PMCF, post-market clinical follow-up; PMCFR, PMCF report; CER, clinical evaluation report.

Table 3. SSCP Q&A session summary

Templates/format/content	
Where can one find templates or example SSCPs?	The Medical Device Coordination Group guideline presents a list of contents and template that can be used. Example SSCPs will be available once Eudamed is published.
How long should the SSCP be?	This is entirely device-dependent; from very simple to extremely complex devices, the document may change in its length to a great extent.
What is the extent of effort needed to prepare an SSCP?	It depends on the complexity of the device and on how well prepared the input technical documentation is.
Applicability of the SSCP	
Do we need to prepare an SSCP for sutures used for aesthetical use? Is a lay summary necessary if the device (e.g., software for testing devices in patients) is just used by healthcare professionals?	The SSCP is a requirement for class III and class IIb implantable devices; still, there is a list of exempt implantable devices which includes the following: sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors. For these devices, the SSCP for patients or lay audiences is not needed. Software is not considered as an implantable device and, as such, it is exempted from the SSCP requirement.
Can the state of the art be the same as the one in the clinical evaluation report (CER) or does it have to be specific for the SSCP?	The SSCP is a summary, and as such, the state of the art needs to be specifically summarised.
Lay audience	
Is the language used in plain language summaries similar to that used in the patients' section of the SSCP?	Yes, as the audience is similar; a lay audience.
Given that the SSCP has two different audiences (technical and lay), do medical writers need to prepare two different documents?	No, it should be one single document, with two differentiated sections; one for healthcare professionals, and one for lay audiences.
Are formal readability tests required for SSCPs as they are for patient leaflets for pharmaceuticals?	SSCP should pass a readability test by lay audiences and the test should be traced within the technical documentation.
Is a lay summary necessary if the device (e.g., software for testing devices in patients) is just used by healthcare professionals?	No. A lay summary is only required for implantable devices that are delivered with an implant card and for class III devices that are directly used by patients.
Compliance	
Even if MDR has been delayed until May 2021, is it already mandatory to provide an SSCP for relevant devices?	The SSCP is an MDR requirement, as such, only devices already complying with the MDR would require an SSCP. If the device in question is still certified under the Medical Device Directive, the SSCP is not needed and will only be prepared when the technical documentation is migrated into the MDR requirements.
Surveillance/risks/complications	
How do you quantify the risks coming from different types of sources (e.g., clinical studies, observational studies, complaint reporting, etc.)? Do you quantify in ranges or categories, or do you report a specific value of incidence?	These should be quantified in the CER from which the SSCP takes the appropriate information and presents it in a summarised manner. Ideally, the different sources should be quantified separately as may not be easily considered as comparable; as an example, it is well known that complaints are under reported, while in clinical studies all complications and complaints are usually traced.
Consistency	
Could you recommend some tools to keep the documents (like CEP, CER, PMCFP and SSCP) consistent?	Microsoft Teams is one of them. There are many others in the market.

Abbreviations: SSCP, summary of safety and clinical performance; CER, clinical evaluation report; MDR, Medical Device Regulation; CEP, clinical evaluation plan; PMCFP, post-market clinical follow-up

Consistency between the SSCP and the technical documentation

Most manufacturers set up MDR project teams to meet the new requirements and their timelines. With the MDR, the documentation from different sections (quality, regulatory, clinical, etc.) have become more interdependent. Sometimes it seems impossible to establish consistency across all MDR documents, especially when the manufacturer plans to prepare the documentation in parallel. Medical writers with experience writing Clinical Evaluation Reports are likely to be familiar with this problem where you have the responsibility to compile all the information from other sections into one file at the last step of the process. And this is the same for the SSCP: no matter how manufacturers plan their timelines, you will not be able to finalise the SSCP before gathering all the information needed from other departments. Figure 1 depicts these dependencies and input documents needed for the SSCP.

Inconsistency between the SSCP and the relevant parts in the technical documentation will cause confusion for the notified body, is likely to raise questions, and will prolong the review period. So, keep your timelines in mind and plan enough time for review cycles and consistency checks. With the SSCP being publicly available, the review is likely to include several people. As if this was not enough, the SSCP also needs to be translated into the same languages as the Instructions for Use! The English version is validated by the notified body, whereas the accuracy of all other translations must be validated by the manufacturer. Annual review cycles are necessary to include new information or changes relevant to the safety and performance of the device.

So how can medical writers handle consistency, timelines, and review cycles? First, make clear that the SSCP can only be completed after all relevant input documents are ready and approved. Second, plan sufficient time for review and approval of the document. Third, think about technical solutions to ensure consistency and streamline review cycles.

The lay audience

After finalising the SSCP section for healthcare professionals, you "only" have to translate the content into lay language for the patient. Okay, the "only" is misleading here. The SSCP compiles information about the state-of-the-art and alternative treatment options to the subject device. It is also expected to provide detailed information on the device, results from clinical trials, methods for risk mitigation, plans for post-market clinical follow-up, and finally, information on residual risks and side effects. Especially for medical writers with a regulatory focus, it is a real challenge to present all this information in a way that is understandable to a general audience. Luckily, lots of online sources and training courses can support you to further develop your lay audience writing skills, including EMWA workshops (Table 2). Here are a few simple tips that you should follow when writing for the public:

- Try to avoid abbreviations or acronyms;
- If abbreviations or acronyms are necessary, use them consistently within the text;
- Explain medical terms in simple language;
- Consider using figures, tables, or graphs for data visualisation;
- Show your text to a non-specialist and proof its readability (readability testing);
- And most importantly: train yourself!

Writing for the public is not easy, especially when you must transfer a lot of technical information into simple language. However, this is another chance for medical writers: lay summaries have gained importance in the last years. They are a strong tool to inform patients and to prevent misinformation. Being a new requirement, the SSCP triggers significant interest within the industry and questions among medical writers, as evidenced by the many questions raised during our EMWA webinar on this topic. To conclude, we have summarised the main topics from the Q&A session held at the end of the webinar (Table 3).

With the SSCP providing so much valuable information to the public, it is likely to become one of the most important documents under the MDR. There are still many uncertainties about what notified bodies expect from the SSCP, but one thing is already clear: it is another great opportunity for medical writers either to test our skills or to gain experience in combining regulatory writing with writing for patients.

Acknowledgements

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References

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. 2017 [cited 2020 Oct 1]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745
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