Writing in plain language for the Summary of Safety and Clinical Performance: Communicating medical device safety and performance data to patients

Katharina Friedrich
Katylistic GmbH, Basel, Switzerland

doi: 10.56012/lozv7387

Correspondence to:
Katharina Friedrich
k.friedrich@katylistic.com

Abstract

Effective communication with patients is paramount in the medical field, particularly in the medical device sector, where the complexity of information can create barriers to understanding. The Summary of Safety and Clinical Performance (SSCP) has been introduced under the European Medical Device Regulation (MDR 2017/745) as a new document to bridge this gap, ensuring transparency and accessibility for patients and healthcare professionals. This article explores the best practices for writing the SSCP in plain language, including strategies to ensure clarity, accuracy, and engagement. It also highlights the current limitations of the SSCP.

The European Medical Device Regulation (MDR 2017/745) sets higher requirements for manufacturers to ensure the safety and performance of medical devices than the previous Medical Devices Directive (MDD). An additional goal of the MDR is to improve transparency to the public, including healthcare professionals (HCPs) and patients. This is reflected in Recital 43 of the regulation:[1]

"(43) **Transparency and adequate access to information**, appropriately presented for the intended user, are essential in the public interest, to protect public health, to empower patients and healthcare professionals and to enable them to **make informed decisions**, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system."

The Summary of Safety and Clinical Performance (SSCP) was introduced under the European Medical Device Regulation (MDR 2017/745) to provide a clear and concise summary of a medical device's safety and performance. It is required for class III and implantable devices. Writing the SSCP in plain language is not just a regulatory requirement but a step toward better access for patients to relevant performance and safety data about medical devices.

The SSCP:

- Can be seen as a summary of the Clinical Evaluation Report.
- Will be made available to the public.
- Always includes a section for HCPs.
- Should include a section for patients for the following devices:
  - Implantable devices with an implant card for patients; and
  - Class III devices directly used by patients.
  - May include a section for patients for any other device where patient information could be relevant. In general, manufacturers are expected to provide a rationale when they don't draft a section for patients.

Challenges when writing the SSCP for patients

The SSCP is often intended for a dual audience: HCPs and patients. While writing for HCPs may come more naturally to medical writers, writing the SSCP section for patients presents some challenges. Since the content of the SSCP should be sourced entirely from the technical documentation, the main difficulty for medical writers lies in balancing a sufficient level of detail with readability (discussed further in next sections). Also, according to MDCG 2019-19,[2] "it should not be assumed that the patient has any formal education in a medical discipline or any prior knowledge of medical terminology or clinical research." This makes it difficult to present results adequately.

> Testing the readability of the SSCP with laypersons is essential to ensure the document meets patient needs.

In Table 1,[3–4] I elaborate on the challenges presented by the different sections of SSCP when written for the patient audience and how to address them.

Principles of plain language writing

Principles of plain language writing are often in line with principles of clear writing in general. Therefore, they are helpful not only for writing the patient section of the SSCP but also for any other document. Using the active voice, writing shorter sentences, and limiting abbreviations can improve every text, independent of the audience.[5] The most relevant and useful principles of plain language writing are summarised in Table 2.

Keeping literacy levels in mind is one of the most challenging parts of writing the SSCP. The Programme for the International Assessment of Adult Competencies (PIAAC) regularly assesses the literacy skills of people aged 16 to 65 among the Organization for Economic Co-operation and Development (OECD) countries on a scale from Level 1 (lowest level) to Level 5 (highest level). According to their latest survey, only 12% of participants rated Level 4 to 5, the highest proficiency level, can comprehend and evaluate long texts or grasp complex or hidden meanings.[6] This also means that most readers of the SSCP likely have a lower proficiency level. As medical writers, we are used to reading and digesting complex information in our daily routine and hence may be unable to fully grasp the needs of general audiences. Therefore, it is essential to test the readability of the SSCP.

Testing the readability of the SSCP

According to MDCG 2019-9 Rev.1, "(…) the readability of the part of the SSCP intended for patients is assessed for example by a test given to lay persons."[2] Other methods, such as software, can also be used to evaluate the readability of the SSCP. Most software solutions, such as Readable or Microsoft Word, use the Flesch Reading Ease and Flesch-Kincaid Grade Level tests. Both tests are briefly described in Table 3.

Considering the limitations of these scores, readability tests with a group of laypersons may

Photo: Freepik

Table 1. SSCP sections for patients

Main sections according to SSCP template MDCG 2019-9 Rev.1	Subsections according to SSCP template MDCG 2019-9 Rev.	Potential challenges and tips to address them
1. Identification of the device and the manufacturer	• Device trade name • Manufacturer; name and address • Basic UDI-DI • Year when the device was first CE-marked	This section is straightforward and can be copied from the section for healthcare professionals.
2. Intended use of the device	• Intended purpose • Indications and intended patient groups • Contraindications	Many manufacturers simply copy this information from the Instructions for Use. However, the intended purpose of the device and related information must also be provided in plain language. This requires an explanation of all medical terms. Consider including a glossary to explain all terms and abbreviations in sufficient detail, especially for complex medical devices and conditions.
3. Device description	• Device description and material/substances in contact with patient tissues • Information about medicinal substances in the device, if any • Description of how the device is achieving its intended mode of action • Description of accessories, if any	Most device descriptions are written with healthcare professionals and Notified Bodies in mind. For the SSCP, think about the most relevant information for the patient and adapt the device description accordingly. For example, it makes sense to precisely describe all relevant accessories to insert a hip implant for the surgeon, whereas such details are likely overwhelming for the patient. However, patients are probably more interested in the general procedure of a hip implant surgery, and it makes sense to clearly describe how the device achieves its mode of action, including pictures when available.
4. Risks and warnings	• How potential risks have been controlled or managed • Remaining risks and undesirable effects • Warnings and precautions • Summary of any field safety corrective action, including field safety notice, if applicable	This section describes the manufacturer's risk management and post-market surveillance system in plain language. Patients should be informed about how the manufacturer identifies, controls, and manages risks. Moreover, all risks provided in the Instructions for Use must be described here in plain language. For many risks, this requires an explanation in one or two sentences rather than replacing a single word. Glossaries for plain language are of great help here, such as the *Plain Language Dictionary* of the Michigan Library[3] or the *Plain Language Thesaurus for Health Communications*[4] provided by the CDC. Warnings and precautions can be restricted to information relevant to the patient. For example, it is not necessary to describe warnings or precautions related to the assembly of a hip implant in plain language. Regarding field safety corrective actions, the patient should be informed about the underlying reason and how the manufacturer addressed the issue.
5. Summary of the clinical evaluation, including post-market clinical follow-up	• Clinical background of the device • The clinical evidence for the CE-marking • Safety	As the heading implies, this section is nothing less than a lay summary of the Clinical Evaluation Report, including performance and safety data from clinical investigations, registries, scientific publications, and any other sources. Similar to the section for healthcare professionals, it makes sense to provide these data in a tabular format. The most relevant performance and safety parameters should be compared with the state-of-the-art. This allows the patient to understand how the device performs when compared to the standard of care.

Main sections according to SSCP template MDCG 2019-9 Rev.1	Subsections according to SSCP template MDCG 2019-9 Rev.	Potential challenges and tips to address them
6. General description of therapeutic alternatives	• General description of therapeutic alternatives	Patients should be informed that they should consult their healthcare professional about alternative diagnostics or treatments. It is important to communicate to the patient that the SSCP is not supposed to provide treatment recommendations. Hence, this section should briefly describe the most relevant alternatives, including their benefits and disadvantages. This can also be done in a tabular format.
7. Suggested training for users	• Suggested training for users	This section is straightforward and can be copied from the section for healthcare professionals.

Abbreviations: CDC, Centers for Disease Control and Prevention; CE, conformité européenne [European conformity]; MDCG, Medical Device Coordination Group; SSCP, Summary of Safety and Clinical Performance; UDI-DI, Unique Device Identification – Device Identifier.

Table 2. Principles of plain language writing

Principles of plain language writing			
1. Clarity and simplicity	Use clear and simple language	✓ Write short sentences. ✓ Avoid jargon, technical, or medical terms. ✓ Use abbreviations consistently.	✓ Use active voice. ✓ Avoid nominalisation. ✓ Use whole numbers, if possible.
2. Structure	Structure in a logic way	✓ Organise information in a clear, logical flow: start with the broader picture and get into detail step by step. ✓ Use headings, subheadings, and bullet points to break down content into manageable sections.	
3. Engagement	Use visuals for more engagement	✓ Incorporate visuals such as diagrams, tables, or flow charts to explain complex data. ✓ Use white space effectively to make the document less intimidating.	
4. Empathy and inclusivity	Write with empathy and be inclusive	✓ Consider the diverse backgrounds and literacy levels of readers. ✓ Avoid language that could inadvertently stigmatise or alienate readers. For example, do not write "the patient" but rather address the reader directly in the SSCP.	

Abbreviation: SSCP, Summary of Safety and Clinical Performance

be the more robust option. However, such tests are expected to be performed with a representative group of people (note: employees of a medical device manufacturer are usually not representative of the standard reader). The tests should be conducted according to a predefined plan and with an appropriate sample size with a statistical rationale. The plan should also describe how updates of the SSCP affect the document's readability and should define criteria when readability tests have to be repeated.

Limitations of the SSCP

The SSCP can potentially improve patient empowerment and transparency but faces significant hurdles in practice. Here are a few thoughts on current limitations:

- Limited awareness: Many patients may not know the document exists. It is also unclear when the European Database on Medical Devices (EUDAMED) will be fully operational and whether the platform will be user friendly.
- Inconsistency in content and detail: The level of detail provided in SSCPs from different manufacturers varies significantly, limiting the ability to make informed decisions.
- Inconsistency in readability: The readability of SSCPs also varies significantly. So far, there seems to be no consistent way of evaluating

Table 3. Overview of standard readability tests

	Flesch Reading Ease Score	Flesch-Kincaid Grade Level Test
Description	This score rates text on a scale of 0 to 100, where higher scores indicate easier readability. It is calculated based on the average sentence length (in words) and the average number of syllables per word.	This score translates the readability of a document into a US school grade level, e.g., a score of 8.0 means the text is understandable by an 8th grader. It uses the same factors as the Flesch Reading Ease Score but provides results in grade levels instead of a numerical scale.
Benefits	• Easy to interpret: A higher score directly correlates to simpler text. • Useful for targeting audiences of different reading abilities.	• More intuitive for educators or writers aiming to match content to a specific grade level. • Useful in educational contexts or for writing age-appropriate materials.
Drawbacks	• May oversimplify readability, as it focuses only on sentence and word length without considering content complexity or context. • Less effective for non-English texts or highly technical content.	• Similar to the Flesch Reading Ease, it doesn't consider deeper semantic and structural complexities. • May not reflect the actual difficulty of content beyond syntax

the readability of SSPCs. Patients may find it difficult to understand critical safety and performance data.

- Limited to specific device types: As described above, the patient section of the SSCP is limited to certain device types. However, many manufacturers create a patient section, even if it is optional.

Conclusion

Writing the SSCP in plain language is critical to improving transparency and trust in the medical device industry. However, the SSCP's impact on patients will become more apparent with the full implementation of EUDAMED. So far, there is no strategy to increase awareness of this document, limiting its reach. Medical writers are crucial in ensuring the document's readability by prioritising clarity, empathy, and inclusivity. When possible, medical writers can also encourage manufacturers to make their SSCPs more visible, for example, by presenting them on their websites or including links in their social media channels.

Acknowledgments

The author would like to thank Sampoorna Rappaz for reviewing this article.

Disclosures and conflicts of interest

The author declares no conflicts of interest.

References

1. EUR-Lex. 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 [cited 2025 Mar 19]. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/ ?uri=CELEX%3A32017R0745
2. European Commission. MDCG 2019-9 Summary of safety and clinical performance. A guide for manufacturers and notified bodies. August 2019 [cited 2025 Mar 19]. Available from: https://ec.europa.eu/docsroom/documents/37323
3. University of Michigan Library. Plain Language Medical Dictionary [cited 2025 Mar 19]. Available from: https://medicaldictionary.lib.umich.edu/
4. Centers for Disease Control and Prevention (CDC). Plain language thesaurus for health communications 2007 [cited 2025 Mar 19]. Available from: https://stacks.cdc.gov/view/cdc/11500
5. Collada Ali L, Friedrich K. First experiences writing summaries of safety and clinical performance for medical devices. Med Writ. 2020;29(4):62–5. https://journal.emwa.org/medical-devices/post-market-clinical-follow-up-insights/article/11817/post-market-clinical-follow-up-insights.pdf
6. Organisation for Economic Co-operation and Development. Adult literacy skills [cited 2025 Mar 19]. Available from: https://www.oecd.org/en/topics/literacy-skills.html

Author information

Katharina Friedrich is a medical writer with experience in MDR regulatory writing and is the founder of Katylistic GmbH in Basel, Switzerland. She prepares Clinical Evaluation Plans and Reports, PMCF Plans and Reports, and SSCPs in compliance with MDR 2017/745 for class I to class III devices.