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Shaping medicinal product information: a before and after study exploring physicians' perspectives on the summary of product characteristics

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ABSTRACT

Objective: To establish, in the context of the revised European Pharmacovigilance Directive and based on physicians' perspectives, how Summaries of Product Characteristics (SmPCs) could be more user friendly and better support physicians' interactions with patients, thereby improving patients' own understanding of their medicines.

Design: Qualitative focus group discussions (step 1), development of an alternative SmPC (step 2) and an online quantitative survey (step 3) comparing the alternative SmPC to the currently approved version.

Setting: Office-based physicians (n=218) from all federal states of Germany.

Participants: 218 German physicians participated, with an equal representation of office-based general practitioners and specialists. For step 1 (n=18), physicians were recruited who frequently consulted SmPCs.

Outcome measures: Planned and performed: Mayring's qualitative content analysis of focus group discussions (step 1), rating on a five-point Likert scale of preference of current versus alternative SmPCs (step 3).

Results: Physicians confirmed the importance of SmPCs as a comprehensive source of medicinal product information, but were moderately satisfied with the current SmPCs, utilised it infrequently and were more likely to engage additional sources of information. The alternative SmPC was consistently preferred. It differed in the way information for particular patient groups was presented, included additional sections (synopsis, checklist for patient information) and used a tabular format. Physicians indicated that SmPCs should be available with search and hyperlink functions, as well as be automatically updated and integrated in available practice software or similar solutions.

Conclusions: This research contributes to the development of an official, reliable medicinal product information system meeting the needs of a modern information society while providing the reliability of an officially authorised source. In the context of health literacy, SmPCs should be established as the primary information source for healthcare professionals to ensure compliant and safe utilisation of medicinal products.

ARTICLE SUMMARY

Article focus

- Explore physicians' perspectives on Summaries of Product Characteristics (SmPCs) in the context of the newly revised (2010) Pharmacovigilance Directive of the European Union.
- Create and test a more user-friendly SmPC to better support physicians' interactions with patients, thereby contributing to a better understanding by patients about their medicines.
- In addition, explore the links to health literacy as patient understanding is a component of the multidimensional concept of health literacy.

Key messages

- Physicians confirmed the importance of SmPCs as a comprehensive source of medicinal product information and were only moderately satisfied with the current SmPC.
- A newly created SmPC version was consistently preferred over the current version. It differed in the way information for particular patient groups was presented, included additional sections (synopsis and checklist for patient information) and was in a tabular format.
- User-friendly SmPCs used in conjunction with equally well-written patient information leaflets can improve the dialogue between healthcare professionals (HCPs) and their patients. Improvement of SmPCs is also expected to contribute indirectly to improving patient understanding. This, in turn, contributes to safer use of medicines and improves decision making by patients about their medicines.

INTRODUCTION

Context of the study

Summaries of Product Characteristics (SmPCs) and patient information leaflets (PILs) are the only officially approved information on prescription-only medicinal products addressing healthcare professionals (HCPs) and patients.[1] While considerable

ARTICLE SUMMARY

Strengths and limitations of this study

- The outcome of this research may add to the development of a medicinal product information system that will meet the needs of a modern information society while providing the reliability of an officially authorised source.
- The representative sample of physicians, as well as the the use of focus groups together with a survey, provides a sufficient degree of reliability, credibility, dependability and confirmability of the research findings to allow a number of general conclusions to be drawn.
- However, future research could investigate whether more complex SmPC documents can also be transferred to the alternative template and whether electronic interactive media can further address different information needs. Further research should also take into account the perspectives and needs of other HCPs, such as pharmacists, and of HCPs from other European countries operating in a different context (eg, using information embedded in electronic decision support systems).

effort has been made to explore the patients' needs in terms of information content and to ensure that the information is clear and understandable for the target audience, few studies exist which focus on information sources for medicinal products and SmPC usage by physicians. Nevertheless, SmPCs are an important primary information source for HCPs and, together with PILs, may also serve as a tool to enhance the HCP–patient communication.

However, the usefulness and comprehensibility of the current SmPCs and PILs remain questionable.[2] The importance of this issue is reflected in the Pharmacovigilance Directive (Directive 2010/84/EC, amending Directive 2001/83/EC),[3] which requires the European Commission to have produced an assessment report on the current shortcomings of SmPCs and PILs by 1 January 2013. Further, the Commission shall, if appropriate, make proposals to improve the readability, layout and content of these documents involving relevant stakeholders (article 59(4) of Directive 2001/83/EC, as amended).[3]

This study enhances the existing knowledge of how physicians assess and employ SmPCs in their current format. On the basis of this information, an alternative format has been developed through focus groups with physicians and evaluated through a web-based survey.

Patient understanding is a component of health literacy, which is defined as the set of competencies a person possesses to access, understand, appraise and apply health information in order to make judgements and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course.[4] A recent European study found that across eight European countries, 47% of the population have limited health literacy.[5] This finding highlights the need for all stakeholders to take action to optimise the health literacy of their patient group. Improving the design and readability of SmPCs for the purpose of enhancing physician–patient dialogue is one such action within this multidimensional concept of health literacy.

Improvements in the readability of information on medicinal products may improve patients' understanding of such products. In turn, this may improve adherence to treatment regimens, health outcomes and patient safety.[6]

Medicinal product information sources used

Research has shown that patients use a wide range of information sources including HCPs, PILs, electronic media (television and internet), other public media (eg, magazines) and non-expert help (such as friends and family).[7 8] The primary source of information for patients is direct consultation of the physician.[7–12] Patients also assign physicians a central role in the management of information when discussing the additional information they have retrieved from other sources with them.[8 13]

In contrast, physicians use specialised internet-based electronic databases, specialised press and websites as research on information needs of physicians and information sources used by physicians as shown.[14] While a wealth of information is available through these means, considerable uncertainty exists over the reliability of such information.[14] Physicians still have some reservations regarding virtual information sources compared with traditional media, such as journals and books.[15] In a recent study investigating physicians' utilisation of information presented in the SmPC email alerts, web pages/portals and medicinal product compendiums were considered as the best sources for receiving medicinal product safety information and the level of knowledge taken from SmPCs was found to be generally lower than expected.[16] In the USA, only 10% of physicians were reported to have actually read the SmPCs or PILs of the medicinal products they prescribed.[17] Another study showed that due to the use of other information sources, physicians had knowledge of drug interactions which were not adequately described in SmPCs. It was found that the interactions were properly included in the SmPCs related to the originator product but were not (yet) considered in the SmPCs related to some generic products.[18] Computerised systems of information on medicinal products integrated in prescribing systems have successfully been introduced in some countries, for example, in the Anglo-American regions, but such systems are not standard practice.[19 20]

The role of information in the health system (health literacy)

Within the literature, health literacy has been viewed as an asset and as a clinical risk.[21] The conceptualisation of health literacy as an asset implies that health literacy is an empowering device, enabling patients to self manage their disease. Health literacy is partly knowledge based

and may be enhanced through patient education and effective health communication. The concept of health literacy as a clinical risk stems from the notion that poor health literacy skills may be a potential risk, which can undermine effective clinical care. There is a need for such a risk to be identified and managed within the context of clinical care. Studies of patients with chronic obstructive pulmonary disease and asthma suggest that adherence to medication regimens may be less than 50%. In this domain, improved patient education addressing complex treatment regimens and demanding inhalation techniques might lead to increased adherence rates.[22]

The existing literature indicates that information for physicians which is used to enhance the physician–patient dialogue is an important means of improving health literacy and patient autonomy.[23] However, studies have demonstrated that physicians overestimate the literacy levels of their patients[24–26] and that patients often do not understand the information provided by their physician.[5] Furthermore, studies have found that patients recall less than 50% of what they are told during consultations[27–29] and that patients and doctors often have conflicting views surrounding the key messages from a consultation.[30–32]

Rosenfeld *et al*[33] highlighted the importance of communication skills (speaking and listening) in the management of chronic illness. Effective communication can be achieved through the use of a variety of techniques: using plain language during physician–patient consultations, using the teachback or talkback method and using images, diagrams and other visual aids to explain health matters. Schillinger *et al*[27] and Weiss *et al*[34] found that such techniques, which can improve physician–patient dialogue, are infrequently employed by physicians.

METHODS

In order to investigate the demands physicians make on SmPCs as the primary source of information on medicinal products, a three-step approach was taken. Office-based physicians were recruited for participation in the study from all federal states of Germany. The groups for steps 1 and 3 comprised general practitioners (GPs) and physicians of medical specialties in order to cover a variety of professional perspectives and to identify expected differences in their needs for information. Step 1 comprised focus groups[35] led by experienced interviewers, in which physicians who frequently consult SmPCs discussed the strengths and weaknesses of SmPCs and provided suggestions on ways to improve the currently authorised SmPC format.[36] Step 2 involved the systematic content analysis[37] of the focus groups and an alternative SmPC template was developed. Step 3 involved the completion of the alternative SmPC template with specific product information. This was evaluated and compared with the current version by physicians via a survey. A process of 'validation' was also undertaken due to the fact that information gathered during the focus groups contained subjective statements and, as such, it was necessary to independently confirm and quantify all results.

Step 1: focus group discussions (qualitative part)

Eighteen physicians participated in four focus groups, with four to five participants in each focus group. Each group discussion lasted approximately 120 min. One interviewer conducted non-directive interviews applying projective and explorative techniques in order to obtain unbiased and genuine statements from the physicians as the experts in handling medicinal product information regarding the following topics (for the detailed interview guide, please refer to online supplementary appendix V):

- General significance, personal relevance of and satisfaction with SmPCs;
- Positive and negative features of the currently approved SmPC examples/suggestions for improvements regarding content, structure and dissemination of SmPCs;
- Relevance of patient information and package inserts;
- Relevance, logical structure, level of detail, density of information and formal aspects of individual SmPC sections;
- Final recommendations regarding the SmPC structure as a basis for a new template.

Two experts analysed the transcripts of each focus group discussion according to Mayring's qualitative content analysis. This method of text analyses gives priority to intersubjective agreement while preserving the richness of meanings.[37]

Step 2: development of an alternative SmPC

On the basis of the data gathered during the focus groups (see section Shortcomings and potential for optimisation of SmPCs), an alternative SmPC template was developed. This template was completed with information related to a simvastatin product. Simvastatin was chosen as a sample medicinal product because it is widely known among physicians and thus ideal for presentation to the group of study participants comprising GPs and specialists. Furthermore, the complexity of SmPCs related to simvastatin was considered average and representative of a wider range of medicinal products.

Step 3: comparison of current and alternative SmPCs (quantitative part)

The alternative and the currently approved versions of SmPCs for a simvastatin product with identical information content in the German language (see English translation in online supplementary appendices I and II) were presented to 200 physicians for evaluation regarding usability, appearance and time saving. This evaluation was performed via a web-based survey. For details about wording and scaling, please see the questionnaire in online supplementary appendix III.

Demographic data and data related to medicinal product information retrieval (sources of medicinal product information used and personal relevance of sources) were explored, as well as the physician's attitude towards the current SmPCs (frequency of usage, general satisfaction, frequency of updating and mode of filing).

The questions related to the SmPC validation included the following activities:

- Structure of SmPCs: intuitive ranking of selected items by personal relevance (before and after evaluations of the alternative SmPC);
- Usability and readability: evaluation of the new sections 'summary' and 'checklist for patient education' (alternative SmPCs for simvastatin film-coated tablets);
- Preference of current versus alternative SmPCs, selected sections (see figure 1);
- Usability: evaluation of the aggregate section 'general and administrative information' (only the idea was presented; no example was given in the alternative SmPC and reference to standard classifications (eg, drug risk classes like cytostatics or vulnerable populations like pregnant women);
- Preference of the current versus the alternative SmPC: evaluation by different perception factors (see figure 1B) and overall preference;
- Specification of the ideal medium and format of SmPCs/impact on usage.

Physicians rated satisfaction, usability, readability and prognosis of usage of the alternative SmPC on a five-point Likert scale.

Physicians also expressed their preferences for the current or the alternative SmPC on a five-point Likert scale. Data were not only evaluated using descriptive statistics, but also recalculated to be displayed as mean differences including 95% CI to a neutral midpoint which indicate no preference for one or the other option.

RESULTS

Characteristics of participants and sources of medicinal product information

The group of physicians participating in this study was balanced in terms of gender and age (see online supplementary appendix VI). An equal representation of office-based GPs and specialists, mainly diabetologists and cardiologists, was chosen. In step 3, physicians reported the sources they used for information retrieval on medicinal products (figure 2). Medical journals were the most frequently reported source of information (69% of responders). However, only 37% found this source to be relevant. Publishing house websites were chosen as the least popular source (23%), and websites of the manufacturers as the least relevant source (3%). While the usage of SmPCs was indicated quite frequently (54%), their relevance ranked at a lower level (24%). Likewise, among the internet portals, SmPCs (http://www.fachinfo.de) constituted only one source of medium usage (49%) among others.

SmPC usage profiles

In the recruitment process, eligibility to participate in the focus group in step 1 required physicians to frequently consult SmPCs. The analysis of the statements in the focus group discussions revealed that physicians generally considered SmPCs to be a highly useful source of medicinal product information because they contain all important information on a medicinal product. Physicians highlighted their need for information on medicinal products particularly when prescribing new active substances. They indicated that the use of SmPCs on a regular basis was currently impractical. Rather than consulting SmPCs repeatedly, they stated a preference for other sources such as the 'Rote Liste' (German drug compendium) or any software in practice.

In the survey (step 3), 54% of the physicians indicated their use of SmPCs as an information source about medicinal products but few attributed relevance (24%)

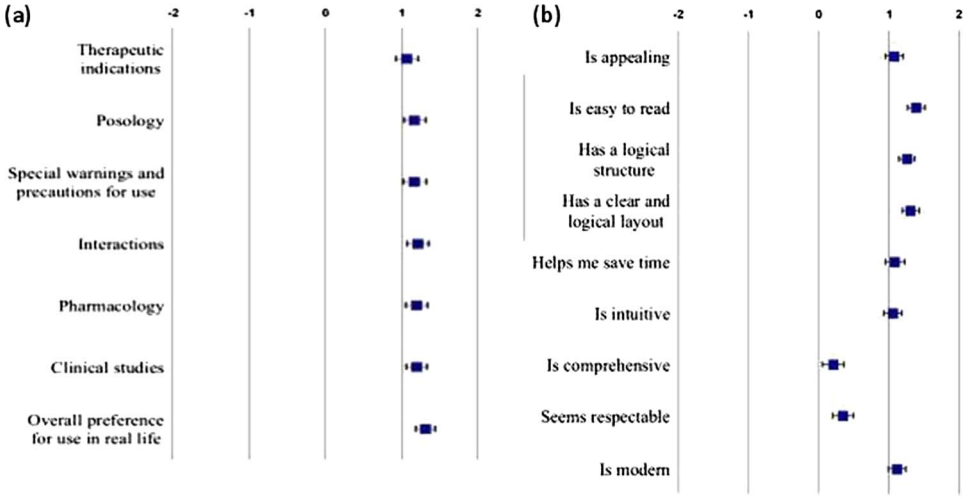

Figure 1 Preference of current versus alternative Summaries of Product Characteristics (SmPCs) by (a) section and (b) perception factors.

Values are mean differences from midpoint, displayed with 95%-confidence intervals. A positive value indicates preference of the alternative SmPC version, a negative value preference of the current version. (N=200)

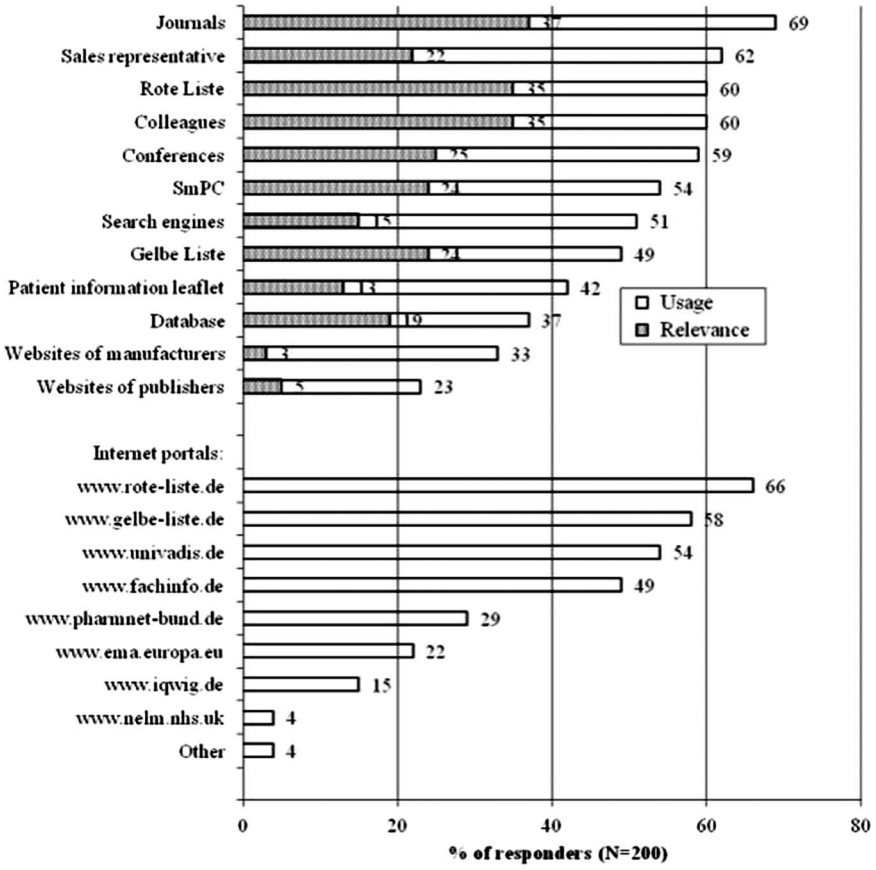

Figure 2 Sources of product information by usage and relevance.

to SmPCs. Approximately 33% stated that they read SmPCs more than once a week, 22% read them once a week, while 46% used them less frequently.

Overall (total N=200), more physicians were satisfied with SmPCs (42% of respondents) than dissatisfied (11%), but only 4% were very satisfied, which might be due to the low relevance reported (table 1). Almost equal proportions of the physicians using SmPCs (N=107) indicated that they systematically filed SmPCs or did not file or dispose of them (31%, 33% and 36%,

Table 1 Evaluation of additional sections to the Summaries of Product Characteristics (SmPCs)/satisfaction with current and usage of ideal SmPCs

Percentage of responders (frequency)						
	Scale					
Legend	1	2	3	4	5	Legend
Brief summary						
Not useful at all	1.0% (2)	4.5% (9)	21% (42)	51.5% (103)	22% (44)	Very useful
Not user friendly at all	0% (0)	4.5% (9)	22.0% (44)	51.0% (102)	22.5% (45)	Very user-friendly
Checklist for patient information						
Not useful at all	2.0% (4)	3.0% (6)	10.0% (20)	49.0% (98)	36.0% (72)	Very useful
Not user friendly at all	1.0% (2)	0.5% (1)	13.5% (27)	54.0% (108)	31.0% (108)	Very user-friendly
General and administrative information						
Not useful at all	0.5% (1)	4.5% (9)	23.0% (46)	55.0% (110)	17.0% (34)	Very useful
Not useful at all	1.5% (3)	5.5% (11)	20.5% (41)	50.0% (100)	22.5% (45)	Very useful
Current SmPCs: general satisfaction						
Not satisfied at all	1.0% (2)	9.5% (19)	48.0% (96)	38.0% (76)	3.5% (7)	Very satisfied
Ideal SmPCs: change in usage intensity						
Using them much less intensively	0.0% (0)	0.0% (0)	31.8% (34)	50.5% (54)	17.8% (19)	Using them much more intensively
Ideal SmPCs: change in usage frequency						
Not using them at all	0.0% (0)	2.2% (2)	26.9% (26)	59.1% (55)	11.8% (11)	Using them very frequently

respectively). Some of the physicians retaining SmPCs (N=68) reported their updating them once every 3 months (25%), 42% once or twice a year, 24% less often than once a year and 10% never updating them.

Shortcomings and potential for optimisation of SmPCs (step 1)

From the transcripts of the focus group sessions, physicians identified the following obstacles in working with SmPCs.

1. The organisation of the content of SmPCs follows a standard structure regulated by the European Commission.[38] Nevertheless, physicians do not recognise the standard structure due to the fact that the sections vary from product to product regarding length and content. Also, the specific information on one topic may be scattered over different sections. Classification standards are experienced as inhomogeneous between SmPC documents.
2. The handling of hardcopy SmPCs is considered time consuming, particularly the physical filing and the search for information without a table of contents or an index.
3. Updates of SmPCs are only sporadically received; therefore, it is often unclear if the copy available is the most up to date (especially in terms of additional indications).
4. There is a general lack of awareness of the online sources of SmPCs with the participants of these focus groups.

Physicians identified the following aspects as crucial for the development of an alternative SmPC template.

1. Structure: SmPCs should start with a new section and a tabular summary covering safety issues such as comedication and overdosing. Further, a new section concentrating on special patient groups and a section on information for doctor–patient consultations should be introduced. The sequence of aspects within the SmPC sections should be arranged on the basis of their relevance as perceived by the physicians. Elements that divert attention, such as legal and administrative information, should be eliminated from the main text.
2. Format: some information in SmPCs is better presented in a tabular format than in a text format.
3. Medium for dissemination: physicians expressed a clear preference for electronic, internet-based versions of SmPCs presented in a Wikipedia-style website layout allowing for the separation of material and the use of hyperlinks to additional detailed information that might not be needed in daily practice, such as clinical pharmacology or PILs for printout. Further assets would be an update service or integration of SmPCs into practice software.

Development of an alternative SmPC (step 2)

The primary objective in redesigning the current SmPCs was to apply a strict focus on the patient and the treatment and not on the medicinal product. This resulted in presentation of information in accordance to specific patient groups, for example, within the 'warnings' and 'dosing instructions' sections. Furthermore, the alternative SmPC template differed from the currently approved structure by the introduction of three additional sections (a synopsis at the beginning, a section comprising information related to and sorted by special patient groups and a checklist for patient information/consultation) and a tabular format for most sections instead of continuous text. The testing of additional interactive elements which could further enhance the user-friendly nature of the template was not within the scope of this study.

Comparison of current and alternative SmPCs (quantitative part and 'validation of alternative SmPC' (step 3)

Ranking items of SmPCs

Physicians had indicated in step 1 of this project that SmPCs would benefit from organising items in the order of relevance to the treating physician. Figure 3 shows how physicians rated selected items of SmPCs (most relevant on top). As compared with the current structure, they attributed higher relevance to 'contraindications' and 'undesired effects', while 'posology and method of administration', 'pharmaceutical form', 'shelf life' and 'special precautions for disposal' were considered less important. Interestingly, there was a very high consistency between the first ranking and the second ranking before and after comparison of the current and the alternative SmPCs (Spearman rank correlation, r=0.99; p>0.001).

Evaluation of new sections

Physicians responded positively to the newly introduced sections 'synopsis' and 'checklist for patient information' in the alternative SmPC (table 1). The majority of physicians who evaluated the synopsis viewed the checklist as useful and were satisfied with the readability of both.

The proposed improvements for presenting general and administrative information and including references to standard classifications were also considered to be useful.

Comparison of the alternative SmPC with the current SmPC by selected sections and perception factors

Direct comparisons between the current and the alternative SmPC revealed that preferences for each of the individual selected sections were all in favour of the alternative SmPC (all $p < 0.001$; figure 1A).

A robust positive evaluation in favour of the alternative SmPC was found for most of the perception factors tested. Only for the factors 'respectability' and 'comprehensiveness' was there no clear advantage of the alternative over the current SmPC. Notably, there was no positive tendency towards the current SmPC in any perception factor (figure 1B).

Overall, that is, considering the structure and the way the information is presented, physicians preferred the alternative SmPC over the current version for use in real life ($p < 0.001$; figure 1A).

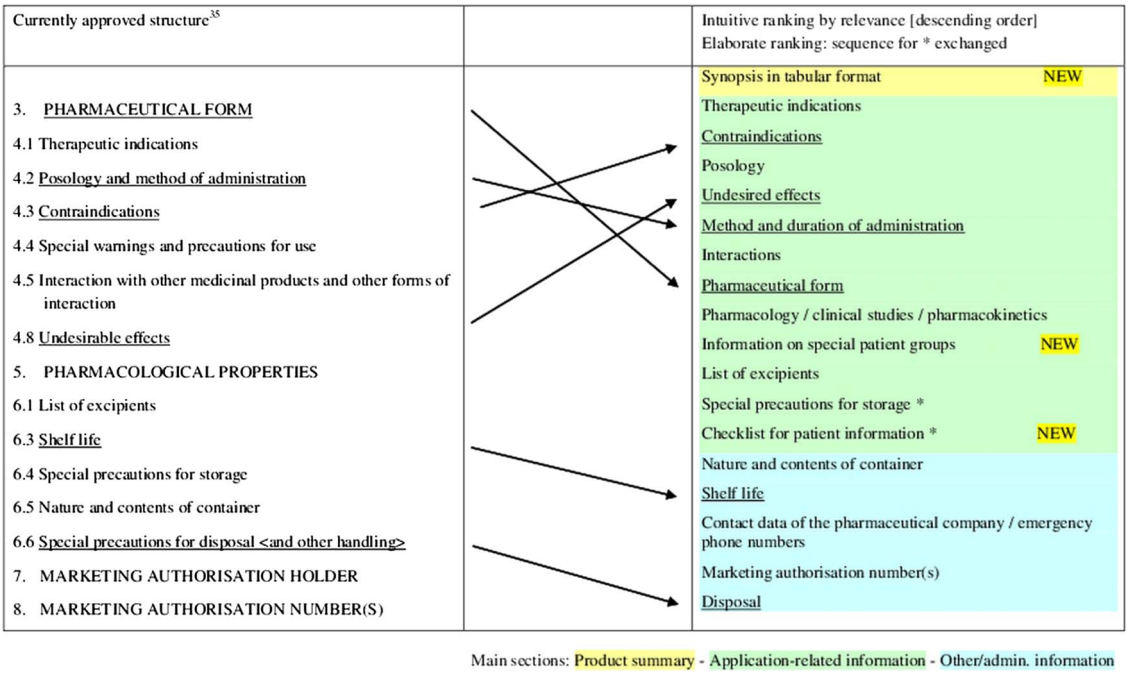

Figure 3 Organisation of Summaries of Product Characteristics (SmPC) items (selected items, N=200).

Ideal medium of SmPCs dissemination and impact of supposed changes on usage

A total of 77% of physicians regarded the internet as the best channel for distribution of SmPCs, followed by manufacturer email newsletters (50%), manufacturer mail services (40%), colleagues (39%) and medical representatives (36%). Physicians favoured the availability of a print copy in addition to an electronic version (72%). Only 4% considered a print copy as sufficient, while 20% of physicians would accept an electronic version only.

A total of 68% of SmPCs users (total N=107) and 71% of SmPCs non-users (total N=93) indicated that they would use an ideal SmPC (SmPCs complying with the respondents' wishes regarding structure and format) more intensely or more frequently (table 1).

SUMMARY AND DISCUSSION

In a three-step approach, this study addressed the demands physicians made on SmPCs to become the primary source of medicinal product information. In the first step, the importance of SmPCs as a comprehensive source for medicinal product information was confirmed while deficits, such as disorganised information, poor layout and unavailability of a modern, searchable format containing hyperlinks, were identified. These hamper readability and usability and render the officially approved information on a medicinal product (SmPCs), a document with only limited relevance in practice. Comparable findings which identified the current structure as a major drawback of SmPCs were illustrated in a study involving Swedish physicians.[20] On the basis of the findings, an alternative SmPC was created. When compared with the current version, the alternative SmPC developed during this study was unambiguously preferred in nearly all of the aspects under investigation, and options for the further development of SmPCs were highlighted.

Innovative SmPC elements to target health literacy of patients

In the focus group discussions and the assessments of the current and proposed alternative SmPC, physicians expressed their wish for a more patient-focused SmPC. Suggestions for improvement had been addressed with the presentation of information in a tabular format (see online supplementary appendix II, sections 'Special warnings and precautions for use', page 5, 'Posology, method and duration of administration', page 2, 'Clinical studies', page 10), with the introduction of new sections for quick orientation (see online supplementary appendix II, section 'synopsis', page 1) and for support of doctor–patient consultations (see online supplementary appendix II, section 'Checklist for patient information/consult, page 11). In addition, the need for a printable PIL was suggested. As shown by the results of the subsequent quantitative assessment, physicians attested to the alternative SmPC for better comprehensibility and usefulness as compared to the current version.

The provision of medical information in an easily understandable format is a key recommendation of health literacy experts.[4 6] Although SmPCs are primarily used by HCPs, they do not only contain all the necessary information about a medicinal product to be communicated to a patient but can also, in alignment with a user-friendly PIL, serve as a tool to facilitate the doctor–

patient dialogue. Since patients still prefer direct conversation with doctors, improving the usability of SmPCs may contribute to better doctor–patient communication and ultimately increase the ability of patients to understand the medicine concerned.

Interestingly, although the current SmPC is written according to a fixed template of headings, physicians do not perceive the documents as standardised because the sections vary from product to product in terms of length and content. This undermines the ability to locate information. Therefore, it is important to develop a standard format and structure that is independent of the amount and complexity of the information to be presented. The tabulated format used in our experiment was favourably accepted. An electronic, Wikipedia-style website layout could further reinforce the benefit of such a format. The new structure should also take into account the need voiced by HCPs to receive more clustered information for special patient groups, while acknowledging at the same time that many patients will belong to more than one group, so the information should not be too compartmentalised.

Limitations of the project: areas of future research

The representative sample of physicians (across Germany, involving specialists and GPs), as well as the use of focus groups together with a survey, provides a sufficient degree of stability, reliability, credibility, dependability and confirmability of the research findings[39] to allow a number of general conclusions to be drawn. It was expected that the information on the needs of GPs and specialists might differ, and therefore evaluations would depend on the professional focus and the different scope for prescribing medicinal products. However, detailed analyses revealed only a few minor differences in the extent of the positive evaluation of the alternative SmPC between GPs, cardiologists and diabetologists that seemed unrelated to professional needs (see online supplementary appendix IV). These, together with the fact that other specialist groups or other HCPs were not engaged in the research, did not enable further conclusions to be made. In addition, the SmPC structure will be valid for all medicinal products. Different information needs may be addressed by electronic interactive media.

In our study, the alternative version of SmPC preserved the content as required by current regulations while optimising readability, which was confirmed through a web-based survey. Superiority over the current SmPC regarding usability in an applied context of medical decision-making needs to be explored. In further tests, it should also be investigated whether more complex SmPC documents can be transferred to the alternative template and whether they are evaluated as positively as the alternative SmPC developed in this study. In addition to personal preferences, alternative SmPC versions might also be tested for comprehensibility.

Beyond the perspectives and needs of German physicians, the ideas of other HCPs, such as pharmacists, and of HCPs from other European countries also need to be studied. They may provide additional and differing perspectives on the use of information on medicinal products embedded in electronic decision support systems, which are not yet generally established in Germany. The existing applications are not harmonised as yet and have not been a focus of this study. Further research is needed to address these topics as well as systems for web-based access and update handling. Version control and the rapid provision of newly updated information to stakeholders have been flagged as a particular challenge to be addressed.[18] The extent to which a web-based approach can solve this problem needs to be further investigated. Integration of categorisation classes (eg, for pregnancy, lactation or overdosing) will require standardisation activities at the European Union (EU) level.

Conclusions

This project was undertaken to engage with physicians and to explore their perspectives as one stakeholder contributing to the public debate of redesigning SmPCs in the context of Directive 2010/84/EU. Physicians consider SmPCs as one important source of medicinal product information, but the actual usage ranks on a lower level. In the context of health literacy, it is important to not only support physicians' knowledge of medicinal products, since they are a primary source of information for patients, but also to consider SmPCs as a tool to improve the doctor–patient conversation (to be used in conjunction with a well-written PIL). Also, other HCPs rely on SmPCs as a source of information and knowledge base for patient consultations and their needs regarding SmPCs should also be considered. Ultimately, fulfilling these requirements should ensure the compliant and safe utilisation of medicinal products.

The outcome of this research provides a validated example of SmPCs with an innovative structure and layout, as well as suggestions to access modalities in order to comply with modern users' requirements.

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Contributors The study was designed by ESt and LV with the special research assistance of MR. The data were interpreted by the researchers and in addition by AR, SPO and GD. GD contributed especially by linking the health literacy concept to the study. The study manuscript was prepared by ESc and edited as well as reviewed by all contributors. All the authors approved the final version of the manuscript for submission. LV had final responsibility for the decision to submit for publication. LV and ESt act as guarantors for the study.

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Competing interests LV, AR, ESt, SPO and MR are employees of MSD. ESc received a fee for the writing of the manuscript and for the statistical analysis. GD did consultancy work for MSD, Ireland and received a research grant from MSD.

Ethics approval Step 3 of the project was performed as a web-based survey observing the applicable legal obligations and market research guidelines.[40–42]

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Raw data has been deposited in the dryad data respository (http://datadryad.org/) with the DOI 10.5061/dryad.jh667.

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