PRESFORM

The identification and development of a minimum data set for cross-border prescription form items

Jolanda de Bie
Marcel Bouvy
Sanne Snoeijs
Liset van Dijk

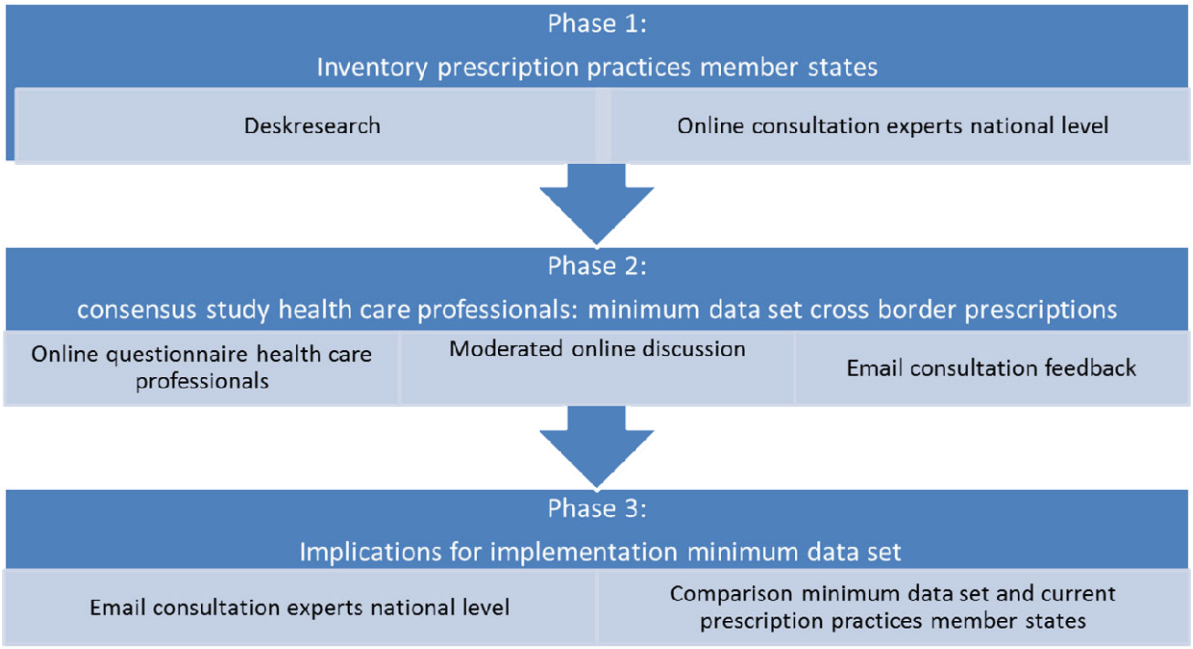
NIVEL – Netherlands institute for health services research &
Utrecht University / SIR Institute for Pharmacy Practice and Policy
Utrecht, September 30th 2011

Content

Executive Summary

On 24 April of 2011 the new Directive on the Application of Patients' rights in Cross-Border Healthcare[1] came into force. Within 30 months this Directive should be implemented in national legislation of individual Member States. In this Directive the European Commission is called upon to adopt measures to facilitate the recognition of prescriptions issued in another Member State. These cross border prescriptions relate to medicinal products and medical devices prescribed in one Member State and dispensed in another.

Citizens in the European Union (EU) have the right to carry along or to receive a reasonable amount of medicines and medical devices in foreign Member States, obtained lawfully for personal use. Member States currently vary when it comes to recognition and reimbursement of medical treatment provided in other countries. Recognition of prescriptions from other Member States is not obvious and standards with this regard vary between countries (Mäkinen 2007). DG SANCO initiated a policy support study to develop a proposal for a non-exhaustive list of elements (or minimum data set) to be included in cross-border prescription forms for medicinal products and medical devices issued in EU Member States. This is in order to facilitate effective recognition of prescriptions among EU Member States (MS) in respect of patient safety. On request of the European Commission (DG SANCO) the PRESFORM study has studied the information that is minimally required for a safe use of cross border prescriptions for medicinal products and medical devices in outpatient settings in Europe. The results of this PRESFORM project are described in this report.



The PRESFORM study has taken an extensive look at the information that is minimally required for a safe use of cross border prescriptions in outpatient settings in Europe. The steps taken are summarised in the figure above

As a result of this study we present the PRESFROM proposal minimum data set for cross border prescriptions for medicinal products (23 items) and medical devices (20 items), as displayed below. For this proposal different group of experts were consulted in three phases, including experts at national level of most Member States and practice based experts (also) working in daily practice in European outpatient settings in different European Member States. The objective of the first phase

[1] Directive 2011/24/EU of the European parliament and of the Council

of the PRESFORM project was to construct an overview of current prescription form practices in European Member States. For this purpose, both desk research as well as a consultation of experts designated by Member States via an online questionnaire was conducted. In total experts from 21 of the 27 Member States responded in round 1 (78%).

The objective of the second phase of the PRESFORM project was to develop a proposal for a core set of items for cross border prescription forms, using a consensus study approach. In the second phase of the study, a three-round online Delphi approach among healthcare professionals working in practice in Europe was conducted. In total 90 respondents (physicians, pharmacists and clinical pharmacologists) were included. In the first consensus round participants were asked to rate a long list of items originating form phase 1, using an online questionnaire. In the second round a moderated online focus group discussion was held, followed by a short consultation via email. Additionally, an online consultation of patients 'organizations was conducted.

The aim of last phase of the PRESFORM project was to provide an overview per Member State as to how Member States' current prescription forms deviate from the proposed minimum set of medical prescription form items and what potential barriers there may be for implementing the minimum set. Per country an overview was constructed in which the preliminary advice for a minimum set of prescription form items (following phase 2) was compared to the items required on the country's prescription form. In addition, deviations from the advice for the set of minimal items were stated. This overview was sent to the respondents of phase 1 with a request to check whether the overview was accurate and how they viewed issues surrounding implementation of the proposed set.

On the basis of this study we propose a minimum data set of 23 items for medicinal products and a minimum data set of 20 items for medical devices for cross border prescriptions. For a large part of the proposal we expect little problems with implementation for most Member States, especially those where in most countries items are already part of current prescription forms or are commonly added in practice. Items referring to the identification of the prescriber in both proposed minimum data set are for instance mostly in line with current practice in most Member States. Most deviations between the proposed minimum data set and current practice are found for the category *other information for medicinal products*, for instance for items such as *Indication for prescribing* and *Substitution allowed*. In addition, current prescription forms for medical devices deviate more from the proposed minimum data set that those for medicinal products. In some Member States separate prescription forms for medical devices do not even exist at the moment. Although for some countries the current proposal could be implemented with no or little changes to current practice, for some countries substantial changes will have to be made for implementation of this set, mainly because at the moment little information is included on the prescriptions. However, we feel that given the results of this study implementing this proposed minimum data set will aid the safe use of cross-border prescriptions for patients in Europe. Monitoring the impact of changes in prescription practices in Europe is essential however, to ensure this assumption is justified or whether adjustments are needed.

PRESFORM proposal minimum data set cross border prescriptions - Medicinal products
Identification of the prescriber
Surname
First name (s) or initials
Profession
Work address
Contact details for direct contact (telephone, fax or e-mail)
Signature (written or digital)
Identification of the patient
Surname
First name(s) or initials
Gender
Date of birth
Home address
Identification of the medicinal product
International non-proprietary name (INN)
Brand name
Route of administration
Quantity
Strength
Dosage regimen or directions for use
Intended duration of use
Composition (in case of extemporaneous compounding)
Other information
Indication for prescribing
Date of prescription
Period that prescription is valid
Substitution possible (yes/no)

PRESFORM proposal content minimum data set cross border prescriptions –Medical devices
Identification of the prescriber
Surname
First name (s) or initials
Profession
Work address
Contact details for direct contact (telephone, fax or e-mail)
Signature (written or digital)
Identification of the patient
Surname
First name(s) or initials
Gender
Date of birth
Home address
Identification of the medical device
General product description
Brand name
Product type
Directions for use
Quantity
Compatibility with device
Other information
Indication for prescribing
Date of prescription
Period that prescription is valid

1. Introduction

On 24 April of 2011 the new Directive on the Application of Patients' rights in Cross-Border Healthcare[2] came into force . Within thirty months this Directive should be implemented in national legislation of individual Member States. In this Directive the European Commission is called upon to adopt measures to facilitate the recognition of prescriptions issued in another Member State. These cross border prescriptions relate to medicinal products and medical devices prescribed in one Member State and dispensed in another. On request of the European commission (DG SANCO) The PRESFORM study has studied the information that is minimally required for a safe use of cross border prescriptions for medicinal products and medical devices in outpatient settings in Europe. The results of this PRESFORM project are described in this report.

1.1 Background

Citizens in the European Union (EU) have the right to carry along or to receive a reasonable amount of medicines and medical devices in foreign Member States, obtained lawfully for personal use. Member States currently vary when it comes to their recognition and reimbursement of medical treatment provided in other countries. A study in 2007 showed that recognition of prescriptions from other Member States was not obvious and standards with this regard vary between countries (Mäkinen 2007).

1.1.1 Cross border care

EU citizens have a right to access to healthcare, not only in their home countries but also in other EU Member States. Cross-border healthcare has become a more prominent phenomenon in the EU (EU) (Wismar 2011). In a 2007 survey over half of the population (53%) in the European Member States expressed their willingness to use healthcare in other Member States. Currently patients indeed increasingly call upon healthcare services in other countries albeit there are considerable differences among Member States as well as within social groups (European Commission, 2007). Dissatisfaction with healthcare provision in the home country and experiences involving deficiencies in the health system at home are considered important reasons for patient mobility. In addition, "patients increasingly act as informed consumers who claim the right to choose their own provider, including beyond their national borders" (Wismar et al, 2001, p.1). While the willingness to use cross-border healthcare seems to increase, potential barriers to access exist. These barriers include for example population coverage, content of benefits baskets, cost-sharing arrangements, geographical factors, choice among available providers, medical criteria for a health intervention, and organizational barriers (Mäkinen 2007; Roscam Abbing 2010). Countries vary with respect to barriers to access to healthcare (Busse 2011). Countries such as Luxembourg, Italy, Belgium and The Netherlands (Hermans 2000) have been more willing to give their citizens permission for medical treatment in another country than other EU-countries. Next to access to care, both the quality and safety of care may be reasons for patient to look at cross-border options. Albeit common values and principles in healthcare exist across Member States, implementation of standards in quality and safety are widely divergent. While some countries already have formal structures and systems in place to address patient safety issues, patient safety is only becoming just established in many European countries (Legido-Quigley, 2011a). As such, uncertainties regarding quality and safety are key issues also for patients. While patients may want to look for high quality care abroad, they may be deterred from exerting their rights for reasons of not knowing what to expect in another Member State.

European Directive on cross-border care

[2] Directive 2011/24/EU of the European parliament and of the Council

On the 2nd of July 2008 the European Commission adopted a proposal for a new Directive on the application of patients' rights in cross-border healthcare. After the second reading vote by the European Parliament (19th of January 2010) this Directive was formally adopted by the Council (28 February 2011) and came into force the 24th of April 2011. Member States have until 25th October 2013 to transpose this Directive into national law. The Directive aims to provide more legal certainty regarding rights and entitlements to care in another Member State, facilitating access to safe and high-quality cross-border care and to promote cooperation in healthcare issues between Member States (Palmer 2011). The Directive applies to individuals who decide to seek healthcare in a Member State other than their own Member State.[3] [4] Member States must ensure that the healthcare providers apply the same scale of fees for healthcare for patients from other Member States, as for domestic patients in a comparable medical situation. The Directive includes medicinal products as well as medical devices. Article 11 of aims to improve the recognition of prescriptions issued in another Member State for medicinal products as well as medical devices. (See Box 1.1 for a full text of this article).

Cross-border care: Medicines and medical devices

Medicines and medical devices are an important part of medical care and citizens have the right to carry along or receive a reasonable amount of medicines in foreign Member States. This right is based on the internal Market of the EU and the fundamental right of free movement of goods as laid down in Article 28 of the Treaty on the Functioning of the EU (TFEU). Citizens may have several reasons to purchase medicines in foreign EU states varying from lower prices to running out of their medication while staying abroad. Issues that come up when purchasing medicines in or from another European Member State (MS) include acceptance of foreign prescriptions, availability of the required drug, cross-border import of drugs and reimbursement by health insurance companies (Mäkinen 2007). The EURO-Med-STAT project, for example, showed large differences in the availability of drugs between European Member States[5] and as such it may not be assumed that a drug prescribed in one country will be available in another country as well.

The range of medical devices in the EU is large and also varies across countries. Over the last decades the market for medical devices benefited from technological progress and innovation. While citizens can greatly benefit from such devices, there are challenges with regard to safety issues. Safety or hazard notices sometimes recommend stopping using a particular device. [6] There are three main Medical Devices Directives regulating the EU market for devices. Moreover, the Commission runs the European Databank on Medical Devices – EUDAMED[7] . This databank aims "to strengthen market surveillance and transparency in the field of medical devices by providing Member State competent authorities with fast access to information on manufacturers and authorized representatives, on devices and certificates and on vigilance and clinical investigation data, as well as to contribute to a uniform application of the Directives, in particular in relation to registration requirements".

---

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF, accessed September 2011

[4] The Directive does not apply to:

-services in the field of long-term care;

- allocation of and access to organs for the purpose of organ transplants;

- public vaccination programmes against infectious diseases.

[5] http://www.euromedstat.cnr.it, accessed September 2011

[6] The EU-funded EUDAMED project aims to ensure patients safety for example by developing a structure for announcing incidents with medical devices.

[7] http://ec.europa.eu/consumers/sectors/medical-devices/marketsurveillance-vigilance/eudamed/index_en.htm, accessed September 2011

Box 1.1: Directive 2011/24/EU of the European Parliament and of the council on the application of patients' rights in cross-border healthcare

Article 11 : Recognition of prescriptions issued in another Member State

1. If a medicinal product is authorised to be marketed on their territory, in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004, Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force, and that any restrictions on recognition of individual prescriptions are prohibited unless such restrictions are:
(a) limited to what is necessary and proportionate to safeguard human health, and non-discriminatory; or
(b) based on legitimate and justified doubts about the authenticity, content or comprehensibility of an individual prescription.
The recognition of such prescriptions shall not affect national rules governing prescribing and dispensing, if those rules are compatible with Union law, including generic or other substitution. The recognition of prescriptions shall not affect the rules on reimbursement of medicinal products. Reimbursement of costs of medicinal products is covered by Chapter III of this Directive. In particular, the recognition of prescriptions shall not affect a pharmacist's right, by virtue of national rules, to refuse, for ethical reasons, to dispense a product that was prescribed in another Member State, where the pharmacist would have the right to refuse to dispense, had the prescription been issued in the Member State of affiliation.
The Member State of affiliation shall take all necessary measures, in addition to the recognition of the prescription, in order to ensure continuity of treatment in cases where a prescription is issued in the Member State of treatment for medicinal products or medical devices available in the Member State of affiliation and where dispensing is sought in the Member State of affiliation. This paragraph shall also apply to medical devices that are legally placed on the market in the respective Member State.

2. In order to facilitate implementation of paragraph 1, the Commission shall adopt:
(a) measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so through developing a non-exhaustive list of elements to be included in the prescriptions and which must be clearly identifiable in all prescription formats, including elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection;
(b) guidelines supporting the Member States in developing the interoperability of e-prescriptions;
(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;
(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage.
Measures referred in point (a) shall be adopted by the Commission no later than 25 December 2012 and measures in points (c) and (d) shall be adopted by the Commission no later than 25 October 2012.

3. The measures and guidelines referred to in points (a) to (d) of paragraph 2 shall be adopted in accordance with the regulatory procedure referred to in Article 16(2).

4. In adopting measures or guidelines under paragraph 2, the Commission shall have regard to the proportionality of any costs of compliance with, as well as the likely benefits of, the measures or guidelines.

5. For the purpose of paragraph 1, the Commission shall also adopt, by means of delegated acts in accordance with Article 17 and subject to the conditions of Articles 18 and 19 and no later than 25 October 2012 measures to exclude specific categories of medicinal products or medical devices from the recognition of prescriptions provided for under this Article, where necessary in order to safeguard public health.

6. Paragraph 1 shall not apply to medicinal products subject to special medical prescription provided for in Article 71(2) of Directive 2001/83/EC.

Recognition of cross border prescriptions

While the principle of mutual recognition of cross-border prescriptions is already in place within the EU, the effective acceptance of cross border prescriptions within the EU is not obvious. This may be hampered by the fact that in some Member States up to now prescriptions are only recognised if issued in a restricted number of other Member States (as is the case in some Nordic countries). Another reason that prescriptions from foreign countries are not always accepted is the fact that verification or a form of authentication of the prescriber is required before the medicine is dispensed. Restrictions on dispensing of foreign prescriptions can be related to the type of prescribed product, the authenticity of the prescription, and the medium of the prescription ("paper, fax, electronic"). E-prescriptions, for example, are not common in all countries and this may have an impact on the acceptance in other countries. A recent consultation of pharmacists' organisations study concluded that in only 5 of the 27 EU countries e-prescriptions are part of daily practice, and only in Sweden and Denmark is nationwide use of e-prescriptions reported. (Mäkinen, 2011) One of the aims of the EU-funded epSOS project is to explore possibilities to come to an agreement on a common structure of E-prescriptions, and, as such, about common data sets to be shared between Member States.[8]

The Mäkinen report (2007) showed that (therapeutic) substitution is commonly applied to overcome problems with local non-availability of prescribed products. Without verification with the prescriber especially therapeutic substitution is undesirable from the perspective of patient safety. Reasons for prescribing this particular drug are unknown and it can be questioned whether the alternative product is a good choice for this particular patient. From the perspective of patient safety, it is important to know more about the context of the patient before dispensing a medicine , for example about the patient's co-morbidity and co-medication.

Wish for policy action

Up to date there is no harmonization in the EU when it comes to prescription forms for both medicines and medical devices. The reasoning above shows that there is a need for more uniformity between Member States on what information is requested for dispensing of medicinal products or medical devices based on prescriptions from other Member States, and as such the information that is included in cross border prescriptions in the country of origin.

1.2 Objective

The objective of the PRESFORM project is to develop a proposal for a non-exhaustive list of elements to be included in cross border prescription forms for medicines and medical devices issued in EU Member States in order to facilitate effective acceptance of prescriptions among EU Member States (MS) in respect of patient safety. The study will focus solely on the content of the information on cross border prescriptions. The PRESFORM project will further focus on prescriptions for medicinal products and medical devices dispensed in outpatient settings in European healthcare.

1.3 Aims

Three steps will be taken with the following aims:

1. Making an inventory of prescription form practices in all Member States for both medicinal products and medical devices:
   What are the current prescription form practices in the Member States of the EU? What are the similarities and differences between MS in these practices? (Phase 1)

[8] http://www.epsos.eu/test/work-package-31.html; accessed September 2011

2. Composing a consensus-based core set of medical prescription form items for cross-border prescriptions:
   Which elements should be included in the core set of medical prescription forms according to experts to fulfil the requirements described above? (Phase 2)

3. Assessing the potential implications of implementing the core set in each Member State:
   What are the differences between the proposed core set and the current prescription from practices in the Member States? (Phase 3)

Figure 1.1 illustrates the main steps in the phases of the study. In Phase 2 an additional consultation of patients'organizations was conducted.

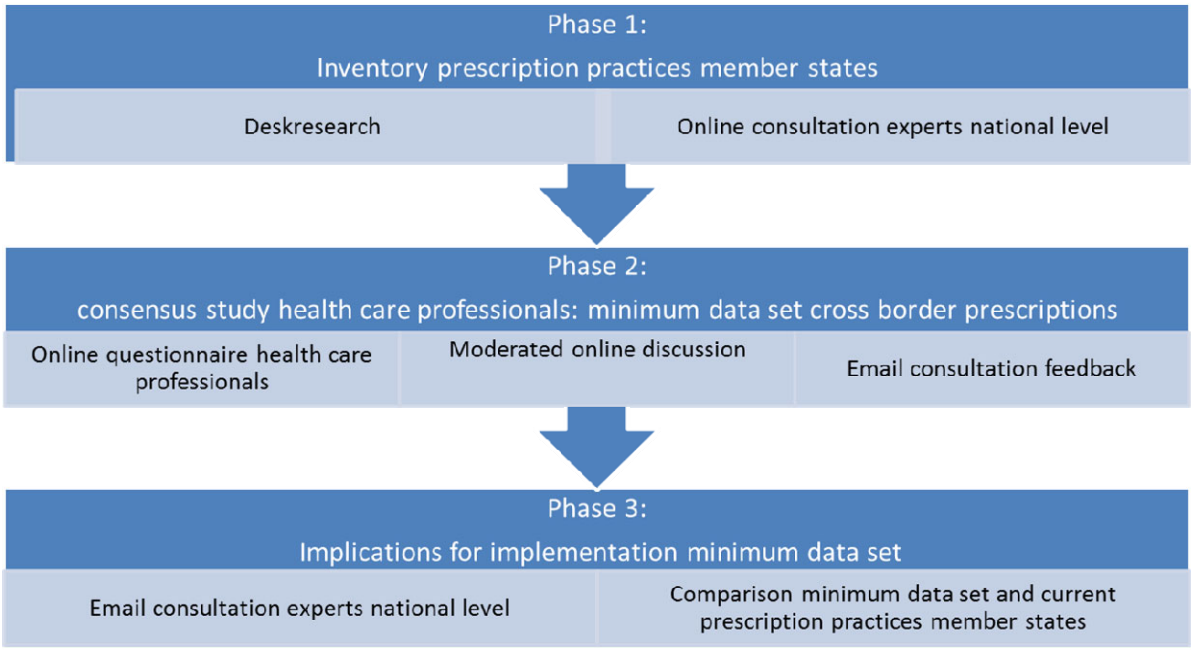


Figure 1.1

In this report the PRESFORM study will be described following the three phases as illustrated above. Chapter 2 will describe phase 1 the inventory of prescription practices in the different Member States. In chapter 3 the consensus study among health care professionals of phase 2 will be described, as well as the consultation of patients 'organizations. Chapter 4 will describe the third phase of the project assessing the implications of the advice following phase 2 for the different Member States. Finally in chapter 5 the results of the different phases will be discussed

2. Phase 1: Inventory of prescription form practices in Europe

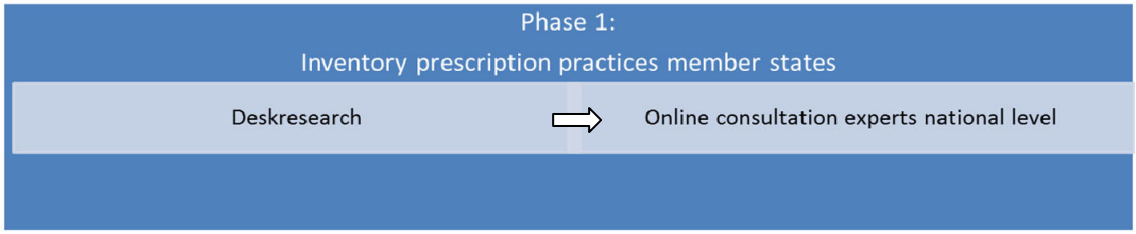


Figure 2.1

The objective of the first phase of the PRESFORM project was to construct an overview of current prescription form practices in European Member States. For this purpose, both desk research as well as a consultation of experts designated by Member States were conducted. (see Figure 2)

The following issues were central in this inventory:

- What are mandatory prescription form items (*based on legal requirements*) for medicinal products and medical devices in each Member State?
- What information items are explicitly banned from appearing on prescription forms *(based on legal requirements*)?
- What Information items are not mandatory, but are commonly added to prescription forms in practice?

Several additional issues were addressed in the inventory in order to get a better overview of prescription form practices in the different Member States, including: what modalities of prescriptions are allowed, which groups of healthcare professionals have authorisation to prescribe and possibilities for authentication of the prescriber.

2.1 Desk research

An initial search of the literature in Pubmed revealed few published empirical studies on cross-border prescriptions in outpatient[9] settings in the EU. A literature review on this specific subject in the EU15 by Mäkinen (2007) also showed a dearth of empirical studies on this subject (in regard to publications prior to 2007). Subsequently an additional ad hoc search was performed in order to include so-called grey literature on cross-border prescribing, e-prescriptions and prescribing authorisation via an online search and consultation of relevant websites, supplemented by references provided via the research group and DG SANCO. In addition for medical devices a medical devices nomenclature in database format was consulted, for which access was granted for this project.[10]

For clarification of some of the issues emerging from the desk research, such as differences between Member States in healthcare professionals that are authorised to prescribe, heterogeneity of characteristics describing medical devices and lack of information on frequency of cross border prescriptions, we conducted several informal, telephone, e-mail and live meetings. We consulted,

[9] For practical reasons the scope of the literature search was limited to prescriptions for products in outpatient settings.

[10] For medical devices different systematic approaches to nomenclature coexist, such as the Global Medical Devices Nomenclature (GMDN) and the Universal Medical Device Nomenclature System (UMDNS). As part of the desk research access was granted to the database of the GMDN. We choose to consult this database, because of the adoption of the GMDN by the EUDAMED project (see chapter 1).

among others a researcher on nurse prescribing [11], the research team of the Matrix- State-of-Play project[12] and the CEO and a senior consultant of the GMDN Agency.

The information obtained from the desk research and consultations was used for the construction of an initial long list of potential items to be included in cross-border prescription forms for medicinal products and medical devices (Long list I, see Box 2.1), as well as for the construction of the questionnaire for the expert consultation round. (a.o. DG enterprise EC 2001, DG information society EC 2007, EpSOS 2011, EDQM 2009, EPF 2011, Expert group on safe medication practices 2006, HPRO card 2009, Mäkinen 2007, Mäkinen et al 2011, PGEU 2009, PGEU 2010, WHO 2003, WHO 2011) The relevant items from the literature were included after a preliminary validation by the researcher and two project leaders.

Box 2 contains all items included in long list I. The items of this list were divided in six categories: A) identification of the prescriber, B) identification of the patient, C) identification of the medicinal product, D) identification of the medical device, E) additional clinical information and F) other information. These categories were the result of a discussion within the project team, based on the results from the desk research.

From the desk research, it became obvious that information for the purpose of identification of medical devices was more heterogeneous than for the identification of medicinal products. Therefore, in addition to general information, information for devices used in the care for four specific conditions were added as an example for the kind of information needed: Diabetes, Asthma/Chronic obstructive pulmonary disease (COPD), Ostomy care and incontinence care.[13]

[11] M. Kroezen, NIVEL , Utrecht

[12] EAHC/2010/Health/01/Lot1: Health Reports for the Mutual Recognition of Medical Prescriptions: State of Play.

[13] Reasoning behind choosing these conditions as examples was that these were common in primary care, thus fitting with the scope of the study in outpatient settings.

Box 2.1: Long list I: *(Initial long list after desk research)*	
A. Identification of the prescriber	B. Identification of the patient
- Initials - First name(s) - Surname - Profession - Specialty - Prescriber identification number - Contract nr health insurance - Work address - Private address - Identification number institution - Written signature - Digital signature - Telephone - Fax - E-mail - Identifying Stamp	- Initials - First name(s) - Surname - Gender - Date of Birth - Patient is baby/infant - Patient is child - Weight for baby - Weight for child - Address - Telephone - Fax - E-mail - Social security number - Name of insurance company - Type of insurance
C. Identification of the medicinal product	D. Identification of the medical device
- International Non-proprietary Name (INN) - Brand name - ATC code - Holder of the marketing authorisation - Form of administration - Strength - Dosage regimen - Length of use - Quantity - Composition - Detailed formula - Article number	General - Product generic name - Product brand name - Product type - Directions for use Asthma/COPD care - Type of device - Compatibility of or with device Diabetes care - Size (e.g. of needles) - Compatibility of or with device Ostomy care - Diameter - Material - Length - Compatibility of or with device Incontinence care - Material - Size - Type incontinence product
E. Additional clinical information	F. Other information
- Indication for prescribing - Co-medication - Co-morbidity - Contraindications - Renal function - Allergies of the patient	- Date of prescription - Serial number prescription - Number of country for non-residents - Information generic substitution - Information repeat prescription

2.2 Consultation of experts – questionnaire inventory prescription form practices

2.2.1 Participants

A list of experts on prescription form practices in the different Member States was composed. Part of the list (28 experts from 17 Member States) was delivered by DG SANCO, after requesting this information from the national Health attaché's of the Permanent Representation to the EU of all Member States. After further consultation of the network of the PRESFORM project team, the list was completed to include 51 experts. The experts consisted of representatives of Ministries of health, Healthcare inspectorates, Health insurance funds, Medicines agencies, Pharmacists' associations and academic experts. Their background was medical, pharmaceutical or in law. All experts were first contacted by e-mail with an invitation for participation, followed up by an e-mail invitation with a direct link to an online questionnaire (see 2.2.2). Two reminders were sent within a 3 week period to those experts that had not yet started or had not finished filling in the questionnaire. On request, a reference copy of the questionnaire was provided to the experts in PDF format for the purpose of consultation with other experts.

2.2.2 Questionnaire

Based upon the long list of prescription form items an online questionnaire was constructed. The questionnaire consisted of questions on:

- Background of the expert (e.g. discipline, organisation)
- Different formats for prescription forms used in the Member State[14]
- Data items included on prescription forms for the defined categories (see Box 1).
- For each item respondents could indicate whether this was a mandatory item (legal requirement), a banned item (legal requirement), included for reimbursement purposes[15] or commonly added on prescription forms in practice. In addition, additional or missed items could be listed and per category comments on the items could be made.

In addition to the questions on the prescription form items, other topics were addressed in the questionnaire. These topics either were needed to interpret the list of prescription form items or were related to medication safety of patients when using cross-border care. The topics included:

- Allowance for substitution, repeat prescription and validity period of prescription forms
- Types of prescription that are allowed
- Groups of healthcare professionals with authorisation to prescribe
- The scope and possible limits of the authorisation to prescribe for these groups
- Registration and accessibility of information on the registration of healthcare providers
- Known problems with dispensing of cross border prescriptions
- Exemptions for regular prescription forms (special medical prescriptions and possible other medicinal products that should, in respect of patient safety, be exempt from acceptance of cross border prescriptions for dispensing).

Appendix III contains the complete questionnaire. Respondents could start the questionnaire and return at any given time and could go back and forward in the questionnaire for reference purposes.

[14] If more than one prescription form was used in a Member State, questions referred to the most common form and at the end of the questionnaire deviations from this standard in other formats were asked for.

[15] Although in this project we are not primarily focussed on which items are added for reimbursement purposes, this answer category was added, because the researchers felt not being able to indicate this answer for an item on the gross list may give unnecessary rise to confusion for the respondents.

2.2.3 Analysis

Descriptive statistics were computed using STATA 11®. Information for non-responding countries was collected for the benefit of phase 3 if available from reports from the PGEU (2011) and EDQM (2009). A 'long list' was constructed of all mandatory items mentioned in at least one Member State and commonly added items mentioned in five or more countries. Commonly added items mentioned in less than five countries were discussed within the project team and added in case of agreement of relevance. A list with items that are banned in at least one MS was also constructed. If an item was mandatory or usually added to the prescription form in one or more MS and banned in one or more other MS, this aspect received extra attention in the following round.

2.2.4. Results

2.2.4a Response

Table 2.1 displays the Member States from which a response was received before the deadline. In total experts designated by 21 of the 27 Member States responded in round 1 (78%). There was a range of responses originating from 1-3 email invitations sent to experts per Member State. In addition it became clear from direct correspondence with participants, as well as through comments in the questionnaire, that in several Member States experts opted to give a joint answer. This concerned experts that were already invited to join that gave a joint answer, as well as experts that were not originally invited that were additionally approached by the invited experts, based on their expertise. In several cases a PDF file containing the questionnaire was distributed (for reference and consultation purposes only). Because we could not differentiate between individual responses given, because of the reasons stated above, it was decided to analyse response at a national level only. For three Member States more than one online questionnaire was completed. The answers of these respondents were compiled at Member State level. In case of differences between answers this data was cross checked using relevant reports on EU prescriptions as a reference (PGEU (2011), EDQM (2009)). All comments made by the different respondents for these three Member States were taken into account.

Table 2.1 Response to the Inventory of prescription practices at Member State level.

Responding Member States		Non-responding Member States
Austria	Latvia	Cyprus
Belgium	Lithuania	Greece*
Bulgaria	Malta	Luxembourg
Czech republic	The Netherlands	Romania
Denmark	Poland	Slovakia*
Estonia	Portugal	United Kingdom*
Finland	Slovenia	
Germany	Spain	
Hungary	Sweden	
Ireland	France	
Italy		

**more extensive information was provided for these countries at a later stage (see Phase 3)*

2.2.4b Items on prescription forms in participating countries

This section describes mandatory and banned items, grouped per category, for the 21 participating Member States. In addition, it will be described whether an item is commonly added to a prescription form (in case it is not mandatory) and whether reimbursement purposes contribute to the fact that an item is mandatory. On average Member States required 26 mandatory items to be included on the prescription form.

A. Identification of the prescriber

The first group of prescription form items refers to the identification of the prescriber: what information is needed to know who the healthcare professional is, who prescribed the medicinal product or medical device. Table 2.2 shows that in all 21 Member States both the surname and the written signature are mandatory items on prescription forms as is the first name of the prescriber in all but one states. In 18 Member States the name of the prescriber is not sufficient and a prescriber identification number is required. A respondent from one Member State further remarked that prescriber identification number is mandatory for medicinal products, but not for medical devices. Prescribers' initials are required in only five Member States and are otherwise not usually added. Fifteen Member States have the work address as a mandatory item (and in three it is commonly added), including telephone number in 11 Member States (in 6 usually added). Both profession and specialty of the prescriber are not required in all Member States: 12 and 9 respectively (and commonly added in respectively 2 and 4 Member States). Three items are not required in any Member State: private address of the prescriber, identification number of the institute and the e-mail address. Only one Member State requires a fax number. Almost all items on prescriber's identification are not banned in any of the Member States. The only exception is the digital signature that is banned in two Member States.[16] Surname, first name and identification number are the items that are mentioned most often to be mentioned for reimbursement purposes (8 Member States), followed by the written signature, identifying stamp and specialty (7 Member States). Respondents from three Member States commented on the existence of national databases where identification as well as current prescribing rights of the healthcare professionals could be verified or looked up in case of missing information in this category on the prescription form. A respondent form one Member States additionally mentioned the use of the number of the personal identification number (ID) of the prescriber.

Table 2.2 : Frequency of listed prescription form items for Identification of the prescriber that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are usually added in practice (Member State level, n=21)

Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
Surname	21	0	8	0
Written signature	21	0	7	0
First name(s)	20	0	8	0
Prescriber identification number	18	0	8	1
Work address	15	0	6	3
Profession	12	0	4	2
Telephone	11	0	2	6
Identifying Stamp	11	0	7	3
Speciality	9	0	7	4
Digital signature	8	2	1	0
Initials	5	0	1	2
Contract nr health insurance	3	0	4	1
Fax	1	0	1	3
Private address	0	0	0	2
Identification number institution	0	0	6	3
E-mail	0	0	0	4

[16] This was the case for Belgium and Slovenia.

B. Identification of the patient

The next topic in the questionnaire referred to the identification of the patient. As was the case with the professionals, surname is mandatory on prescription forms in all Member States (Table 2.3). The patient's first name is required in 20 countries. Other items that are mandatory in over half of the Member States are patient's date of birth (n=14) and address (n=13). Those four items are also most often mentioned for reimbursement purposes. All other items are required in less than a quarter of the Member States. For this category no items were banned for the responding Member States. None of the Member States require patient's telephone number, fax and/or email. Moreover, most items are not commonly added in Member States. Weight for baby/infant and weight for child are mentioned most often, but these items each only concern two Member States. Additionally respondents from two Member States report that age of the patient is mandatory if the patient is a child under 12.

Table 2.3: Frequency of listed prescription form items for Identification of the patient that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are commonly added in practice (Member State level, n=21)

Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
Surname	21	0	6	0
First name	20	0	6	0
Date of birth	14	0	6	0
Address	13	0	6	1
Social security number	5	0	5	0
Gender	4	0	3	0
Patient is baby or infant	4	0	1	2
Patient is child	4	0	3	2
Initials	3	0	0	1
Insurance number	3	0	5	0
Weight for baby or infant	2	0	1	2
Weight for child	2	0	1	2
Name of insurance company	2	0	6	1
Type of insurance	2	0	5	0
Telephone number	0	0	0	1
Fax number	0	0	0	0
E-mail address	0	0	0	0

C. Identification of the prescribed medicinal product

Characteristics of the prescribed medicinal product were also asked for (see table 2.4). Here quantity, strength and dosage regime are the items that are most often mandatory (in 21, 20, and 19 Member States respectively). Brand name and form of administration are required in most countries as well (n=17). These items are also most often mentioned for reimbursement purposes (n = 5 to 7 Member States). All other items are required in less than half of the Member States. Items on the medicinal product are hardly ever banned, in one Member State brand name, article number, holder of the marketing authorisation and ATC code are banned.[17] The item that is most often commonly added is length of use: in six countries. This means that in fourteen Member States the length of use is mandatory or commonly added to the prescription form.

[17] This was the case for Lithuania.

Table 2.4: Frequency of listed prescription form items for Identification of the prescribed medicinal product that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are commonly added in practice (Member State level, n=21)				
Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
Quantity	21	0	6	0
Strength	20	0	7	0
Dosage regimen	19	0	7	0
Brand name	17	1	5	2
Form of administration	17	0	7	1
Composition	9	0	3	0
International non-proprietary Name	8	0	3	3
Length of use	8	0	4	6
Detailed formula	7	0	3	0
Article number	2	1	1	2
Holder of the marketing authorisation(producer)	2	1	1	1
ATC code	1	1	0	0

D. Identification of the prescribed medical device

Regarding prescriptions for medical devices some general items were formulated as well as some diseases-specific items. Table 2.5 shows a different picture compared to the medicinal products were five items were mandatory in more than half of the countries. For medical devices this only holds for product brand name (n=13) and product type (n=11). In case items are required, this often seems to be for reimbursement purposes. Some items are relatively often mentioned as “commonly added”: diameter for medical devices for ostomy care (n=7), length of material for ostomy care (n=5) and type of devices for asthma/COPD care (n=5). None of the items are banned in participating Member States.

Two items were mentioned that were not listed: code of medical device and quantity (e.g. number of pieces). Four Member States specifically stated that no legal requirements exist and prescriptions are not mandatory for medical devices, although these may be required for reimbursement purposes. Several respondents commented on the differences between prescriptions for medicinal products and medical devices, and the complexity of defining elements that appropriately identify specific products due to the heterogeneity of this group of products.

Table 2.5: Frequency of listed prescription form items for Identification of the prescribed medical device that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are usually added in practice (Member State level, n=21)				
Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
General				
Product brand name	13	0	8	3
Product type	11	0	9	3
Directions for use	7	0	7	3
Product generic name	6	0	5	2
Asthma / COPD care				
Type of device	7	0	6	5
Compatibility of or with device	2	0	3	2
Diabetes care				
Size (e.g. needles)	6	0	6	5
Compatibility of or with device	2	0	3	3
Ostomy care				
Diameter	6	0	7	7
Material	6	0	6	4
Length of material	5	0	6	5
Compatibility with other medical aids	2	0	3	2
Incontinence care				
Material	6	0	6	4
Size	6	0	6	5
Type incontinence product	4	0	5	4

E. Additional clinical information

Table 2.6 shows that additional clinical information is hardly required or commonly added on prescription forms across Europe, with the exception of indication for prescribing which is mandatory in seven Member States and commonly added in another Member State. Items referring to clinical information are also not banned across Europe, with the exception of indication for prescribing in one Member State.[18] In another Member State where the indication is mandatory it is noted that this requirement is limited to 44 critical indications and for off label use. However, in practice this information is almost never included on the prescription form but is included in the patient record. Items mentioned in this category – next to the ones mentioned in our list - were: Pregnancy, Suckling mother and ICD or ICPC code for diagnosis.

[18] This was the case for Poland

Table 2.6: Frequency of listed prescription form items for additional clinical information that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are commonly added in practice (Member State level, n=21)				
Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
Indication for prescribing	7	1	4	1
Co-medication	0	0	0	3
Co-morbidity	0	0	1	2
Contraindications	0	0	1	2
Renal function	0	0	0	2
Allergies of the patient	0	0	1	3

F. Other information

Finally, we asked for items that were not included in the sections before. Date of prescription is mandatory in all Member States (Table 2.7). The period that a prescription is valid an can be filled by the patient (validity period) is mentioned in more than half of the Member States as is the fact whether or not it is a repeat prescription (14 and 11 respectively). The serial number has to be mentioned in 10 Member States, often for reimbursement purposes. Information on repeat prescriptions or generic substitution are both banned in one Member State.[19] The frequency of filling the prescription was mentioned as an additional item in this category.

Several respondents noted that validity period is not mandatory to add on a prescription form because this validity period is already defined in legislation. In some Member States it is only mandatory to include the validity period on the prescription when this is shorter than the general validity period defined in legislation. The range of validity periods mentioned in this respect differed considerably (ranging from one week to two years) .

Table 2.7: Frequency of listed prescription form items for other information that are mandatory (legal requirement), Banned(legal requirement), added for reimbursement purposes and items that are commonly added in practice. (Member State level, n=21)				
Prescription form item	Mandatory	Banned	Reimbursement purposes	Commonly added
Date of prescription	21	0	5	0
Validity period	14	0	6	1
Information repeat prescription	11	1	4	2
Serial number prescription	10	0	7	2
Information generic substitution	5	1	4	3
Number of country for non-residents	3	0	3	1

[19] This is the case for Poland and Belgium respectively.

2.2.4c Types of prescriptions and prescription-related issues

Table 2.8 shows which types of prescription are allowed in the different Member States. All countries allow printed paper prescriptions and nineteen countries allow handwritten paper prescriptions. All other types of prescriptions are less frequently allowed, with E-prescriptions more often accepted than faxed or telephone prescriptions. In Member States where e-prescriptions via electronic patient records (EPR) are allowed the median percentage that this type of prescriptions make-up of the total percentage is 50%.

Table 2.8: Allowed types of prescriptions: number of Member States where type of prescription is allowed and estimated percentage of prescriptions that is processed of this type in the Member States (median and range)

Type of prescription	Number of Member States where type is allowed	Estimated percentage processed prescriptions Median (Range)
Paper prescription (printed)	21	50 (4-100)
Paper prescription (handwritten)	19	20 (0-90)
Faxed Prescription (printed)	4	2 (1-5)
Faxed Prescription (handwritten)	3	0 (0-1)
Telephone prescription without written confirmation	3	<1 (1-3)
Telephone prescription with written confirmation	2	0 (0)
E-prescription via email	5	1 (1)
E-prescription via internet	5	1 (0-60)
E-prescription via shared electronic patient records	7	50 (0-90)

Member States can differ in their policy towards generic substitution. Generic substitution implies that pharmacists may deliver a generic version (a version of the drug with the same active ingredient) in case the prescriber prescribed a specific brand. In 15 Member States generic substitution is allowed, unless otherwise stated on the prescription form (Table 2.9). One respondent added that generic substitution is not only allowed, but that is it obliged. In one other Member State generic prescription is allowed but only if it is specifically stated on the prescription form. In two Member States, generic substitution is not allowed. Table 2.9 also shows whether or not repeat prescriptions are allowed. In 15 Member States this is the case, albeit in 14 of them exceptions are made. These exceptions usually hold for narcotics, hypnotics, sedatives and other psychotropic medication.

Table 2.9: Generic substitution and repeat prescriptions	
	Number of Member States
Generic substitution allowed?	
- yes, unless it is specifically excluded on the prescription form	15
- yes, but only in case it is specifically indicated on the form	1
- no, this is not allowed without further permission from prescriber	2
- other	2
Use of repeat prescriptions allowed?	
- yes, in general, but exceptions are made	14
- yes, for all medicinal products and medical devices	1
- no	6

In about half of the Member States limits are set for the number of medicinal products or medical devices that may be prescribed on a single prescription form (n=12; Table 2.10). In four countries the maximum of medicinal products is one, in another five countries it is two and in the rest it is between 3-5 products. Four Member States have also a maximum amount of defined doses (table 2.10). With regard to medical devices, six Member States allow a maximum of one device, the other countries allow between 2-4 devices. In one country medical devices do not require a prescription.

Table 2.10: Maximum sets on prescription forms	
Is there a maximum set on the prescription form for:	Number of Member States that has a maximum set on this issue
number of medicinal products	12
number of medical devices	12
amount of defined doses	4

Designated experts from twenty Member States answered the question that referred to what medicinal products require special medical prescriptions. In almost all countries narcotics need special prescriptions and in several Member States some other psycho tropics do need this as well. As such, prescriptions related to the central nervous system are most often subject to limitations and special prescription forms.

2.2.4d Prescribing authorisation

Member States differ with regard to which healthcare professionals are authorised to prescribe. Next to physicians (who are – naturally – authorised to prescribe everywhere), dentists have prescribing authorisation in a large majority of Member States (n=19). Midwives and nurses have authorisation to prescribe in a minority of Member States and pharmacists in none of the states that participated in the survey.(see Table 2.11)[20]

In case a professional group has the authorisation to prescribe, this does not automatically imply that all professionals within this group have this authorisation. For physicians, six Member States have limitations as to who is allowed to prescribe. For example, one Member State requires physicians to be registered in a national register. In nine Member States not all physicians are authorised to prescribe all medicinal products, for example because they do not have the required specialist knowledge. In the 19 countries where dentists have authorisation to prescribe, no limits were mentioned as to the type of dentists that are authorised to prescribe. Remarkably only 8 respondents (compared to 9 for physicians) state that dentist are not authorised to prescribe all medications but that this is limited to medications that are related to their profession. The seven Member States where midwives have authorisation to prescribe all put limits on the type of products that they are allowed to prescribe. In addition, two Member States also put restrictions on which midwives have the right to prescribe. These two Member States require midwives to have additional training before being authorised to prescribe. The four Member States where nurses have an authorisation to prescribe all put restrictions on which nurses are allowed to prescribe and which products they are allowed to prescribe. In all these countries nurses are only authorised to prescribe after following special additional training and they are only allowed to prescribe certain medication, for example as described in a special list.

[20] Although not represented in this survey, it is know that pharmacist do have an authorisation to prescribe in the United Kingdom.

Table 2.11: Prescribing authorisation to types of healthcare professionals		
Type of healthcare professional	Prescribing authorisation (nr of Member States)	Limitations on prescribing for
Physicians	21	Specific prescribers: 6 Specific type of products: 9 Other limitations: 3
Dentists	19	Specific prescribers: 0 Specific type of products: 8 Other limitations: 0
Midwives	7	Specific prescribers: 2 Specific type of products: 7 Other limitations: 0
Nurses	4	Specific prescribers: 0 Specific type of products: 8 Other limitations: 0
Pharmacists	0	

Nineteen Member States have a registration or up to date list of qualified healthcare professionals with authorisation to prescribe. Seven Member States do not provide this information to dispensing healthcare professionals in other countries. In the other 12 Member States websites are the most common form to verify whether or not a professional is registered (n=9), followed by telephone (n=5). (Table 2.12)

Table 2.12: Availability of information on prescribing authorisation for dispensing healthcare professionals in other countries in the 19 countries that have a register/list with authorised prescribers	
Information is available	*Number of Member States*
- via telephone	5
- via email	1
- via a website	9
- in a different manner	3
- not available	7

2.2.4e Problems with patient safety

Respondents were asked whether there where known problems in their country, in respect of patient safety, with the dispensing of cross border prescriptions. Respondents from five Member States reported known problems, seven stated that such problems did not exist and nine Member States indicated that they did not know whether or not this was the case .

The following problems were reported:

- *Authentication of a physician from another country (3x)*
- *Product prescribed in other country is not available in own country (2x)*
- *Information needed to verify the prescription is lacking (1x)*
- *Lack of harmonization in classification of medicine in EU (1x)*
- *No patient information available and communication with patient in other language (1x)*

- An European technical/legal standard for e-prescribing is lacking (1x)
- Problems of fraud (1x)

2.2.4f Inclusion, exclusion and adapted items after round 2

Box 2.2 provides an overview of all items that were in the long list that was judged in the expert consultation round. For each item inclusions, exclusion or adaptation is indicated. In addition items that were added following comments made on missed items were added per category. The resulting Long list II is displayed in Box 2.3.

Box 2.2 Changes to long list I: Inclusion, exclusion and adaptation following phase 1	
A. Identification of the prescriber	○= inclusion, ×= exclusion Δ = adaptation for long list II
- Initials	○
- First name(s)	○
- Surname	○
- Profession	○
- Speciality	○
- Prescriber identification number	*Δ Identification number*
- Contract nr health insurance	○
- Work address	○
- Private address	x
- Identification number institution	Δ Identification number institution/practice
- Written signature	○
- Digital signature	○
- Telephone	○
- Fax	○
- E-mail	x
- Identifying Stamp	○
B. Identification of the patient	
- Initials	○
- First name(s)	○
- Surname	○
- Gender	○
- Date of Birth	○
- Patient is baby/infant	○
- Patient is child	○
- Weight for baby	Δ Moved to category other information
- Weight for child	Δ Moved to category other information
- Address	○
- Telephone	x
- Fax	x
- E-mail	x
- Social security number	Δ Personal identification (e.g. social security number)
- Name of insurance company	○
- Type of insurance	○

Box 2.2 – continued Changes to long list I: Inclusion, exclusion and adaptation following phase 1	
C. Identification of the prescribed medicinal product	
- International Non-proprietary Name	o
- Brand name	o
- ATC code	o
- Holder of the marketing authorisation	o
- Form of administration	o
- Strength	o
- Dosage regimen	o
- Length of use	o
- Quantity	o
- Composition	o
- Detailed formula	o
- Article number	o
D. Identification of the prescribed medical device	
General	
- Product generic name	o
- Product brand name	o
- Product type	o
- Directions for use	o
Asthma/COPD care	
- Type of device	x
- Compatibility of or with device	Δ→[21]general
Diabetes care	
- Size (e.g. of needles)	Δ→ general
- Compatibility of or with device	x
Ostomy care	
- Diameter	x
- Material	Δ→ general
- Length	x
- Compatibility with other medical aids	x
Incontinence care	
- Material	x
- Size	x
- Type incontinence product	x
+ Number of pieces	Added item
+ Code of medical device	Added item

[21] After discussion in the project team, and based on the results and the comments made for medical devices, it was decided to abandon the structure with examples, adopted earlier and to revert back to one general category medical devices.

Box 2.2 – continued Changes to long list I: Inclusion, exclusion and adaptation following phase 1	
E. Additional clinical information	
- Indication for prescribing	Δ→ moved to category other information
- Co-medication	X
- Co-morbidity	X
- Contraindications	X
- Renal function	X
- Allergies of the patient	X
F. Other information	
- Date of prescription	o
- Serial number prescription	o
- Number of country for non-residents	o
- Information generic substitution	Δ generic substitution possible (yes/no)
- Information repeat prescription	Δ repeat prescription possible (yes/no)
+ Suckling mother	Added item
+ ICD or ICPC diagnosis	Added item
+pregnancy	Added item
+ frequency repeat prescription	Added item

Box 2.3 Long list II (following phase 1)	
A. Identification of the prescriber	B. Identification of the patient
- Initials	- Initials
- First name(s)	- First name(s)
- Surname	- Surname
- Profession	- Gender
- Speciality	- Date of Birth
- Identification number	- Patient is baby/infant
- Contract nr health insurance	- Patient is child
- Work address	- Address
- Identification number institution/practice	- Personal identification (e.g. social security number)
- Written signature	- Name of insurance company
- Digital signature	- Type of insurance
- Telephone	
- Fax	
- Identifying Stamp	
C. Identification of the prescribed medicinal product	D. Identification of the prescribed medical device
- International Non-proprietary Name	- Product generic name
- Brand name	- Product brand name
- ATC code	- Product type
- Holder of the marketing authorisation	- Directions for use
- Form of administration	- Compatibility of or with device
- Strength	- Size
- Dosage regimen	- Material
- Length of use	- Number of pieces
- Quantity	- Code of medical device
- Composition	
- Detailed formula	
- Article number	
E. Other information	
- Indication for prescribing	
- Date of prescription	
- Serial number prescription	
- Number of country for non-residents	
- Generic substitution possible (yes/no)	
- Repeat prescription possible (yes/no)	
- Suckling mother	
- ICD or ICPC diagnosis	
- Pregnancy	
- Frequency repeat prescription	

3. Phase 2: consensus on a core set of medical prescription forms

The objective of the second phase of the PRESFORM project was to develop a proposal for a core set of items for cross border prescription forms, using a consensus study approach. In the second phase of the study, a three-round online Delphi approach was conducted, as illustrated in Figure 3.1 Different groups of healthcare professionals across Europe were approached for participation in the study. In the first round participants were asked to rate a long list of items (Long list II, see Box 4), using an online questionnaire. In the second round a moderated online focus group (or discussion) was held, followed by a short second online questionnaire. Additionally an online consultation of patients 'organizations was conducted.

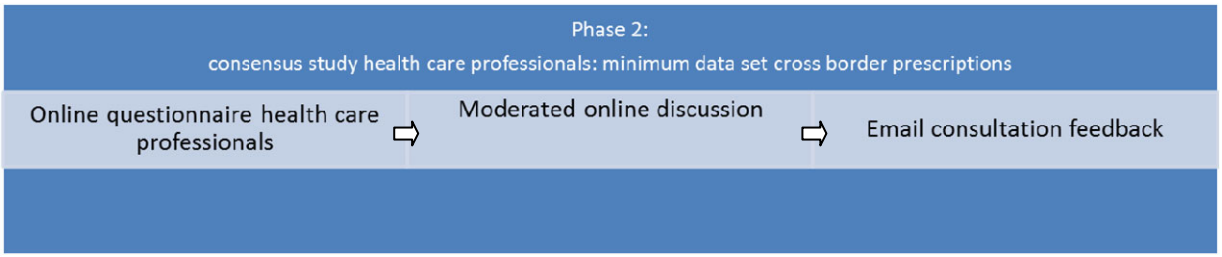


Figure 3.1

3.1 Participants

For the consensus study three groups of healthcare professionals were approached: 1) prescribers (mainly physicians), 2) Pharmacists and 3) clinical pharmacologist. These three groups were chosen based upon their professional background with prescribing or dispensing of medication and medical devices and/or their expertise on pharmacology and patient safety. The approached prescribers and community pharmacists were currently or until recently working in practice as healthcare professionals. Overall we strived for a representation of Member States in at least one of these groups. We also strived to include professionals who have experience with cross-border prescriptions.

Several different recruitment strategies were used to strive for sufficient participants for the consensus study, as described in Appendix IV. We strived for 50 prescribers, 50 community pharmacists and 10 pharmacologist, divided over a medicinal product group and a medical devices group. However, despite these numerous efforts, the number of participants was low in the beginning. Because of this lagging number of participants and – additionally – the likelihood of low response rates during summer it was decided, in consultation with and after approval by DG SANCO in June, to adjust the approach and to include participants in two partly overlapping periods. Group 1 (also referred to as this in the following text) was included in June, the group 2 started in July. Both groups were asked to rate and discuss both items concerning medicinal products as well as medical devices.

3.2 Round 1: Rating of the items

3.2.1 Questionnaire

For each form item listed on the long list, participants were asked both to indicate the need for inclusion in a core set of items for cross border prescriptions and the relevance of the item for patient safety and/or identification (per category). The RAND/UCLA Appropriateness Method (RAM) was used. This method uses a rating scale from 1 to 9 (RAND 2001) and median scores as a measure of consensus for the subject under investigation.

For this study all participants were asked to rate the items on the long list for:

- The need for inclusion in a core set of elements for cross border prescriptions; 1(almost) no need for inclusion to 9 very high need for inclusion
- The relevance of the item for patient safety ; 1(almost) no relevance -9 very high relevance
- The relevance of the item for identification; per category, not included for all categories 1(almost) no relevance -9 very high relevance

Participants could also indicate that they were not able to rate a specific item. Patient safety was defined as: the prevention of errors and adverse effects to patients associated with healthcare

An online questionnaire was constructed, which participants could access using a personal link in an email invitation. The questionnaire could be filled in one go or in several sessions. Two reminders were sent to each potential participant that did not yet fill in the (entire) questionnaire.

3.2.2 Analysis

Quantitative data were analysed using STATA 11®, all qualitative data were analysed using MS EXCEL®. Distribution of scores per item and median scores were calculated for overall inclusion, relevance to patient safety and relevance to identification. Criteria and implications of the different possible median scores for the advice that will be given for in or exclusion in the core set are summarised in Box 3.1.

Box 3.1 Overview of criteria used in rating method and implications for advice given	
Criteria	Implication advice
No agreement: > 25% at both ends of scale (1-3 and 7-9)	*Exclusion from core set*
Median score inclusion 7-9	*Inclusion in core set*
Median score relevance to patient safety 7-9	*High relevance patient safety*
Median score relevance to identification 7-9	*High relevance identification*
Median score inclusion 4-6	*In-/exclusion inconclusive*
Median score relevance to patient safety 4-6	*Relevance patient safety inconclusive*
Median score relevance to identification 4-6	*Relevance identification inconclusive*
Median score inclusion 1-3	*Exclusion from core set*
Median score relevance to patient safety 1-3	*Low relevance patient safety*
Median score relevance to identification 1-3	*Low relevance identification*

3.2.3 Results

3.2.3a Response

For group 1, 144 European healthcare professionals (prescribers, pharmacists and clinical pharmacologists) were approached by email. Of these potential participants, 25 filled in the online questionnaire (17,4%). After analysis four respondents were further excluded, because they rated less than 1 category of prescription form items. The remaining 21 respondents of group 1 filled in the entire online questionnaire. This group consisted of 10 prescribers, 8 pharmacists and 3 clinical pharmacologists. For group 2, 114 individual emails were sent. Additionally, members of the European Forum for Primary Care and the European Society for Clinical Pharmacy were approached via email with a request for participation with a direct link to the online questionnaire. In total, 69 respondents completed the questionnaire. Because of the diverse approaches to recruit participants calculation of a response rate is not possible for this group.
In total, 90 respondents completed the questionnaire.

3.2.3b Results prescription form items per category

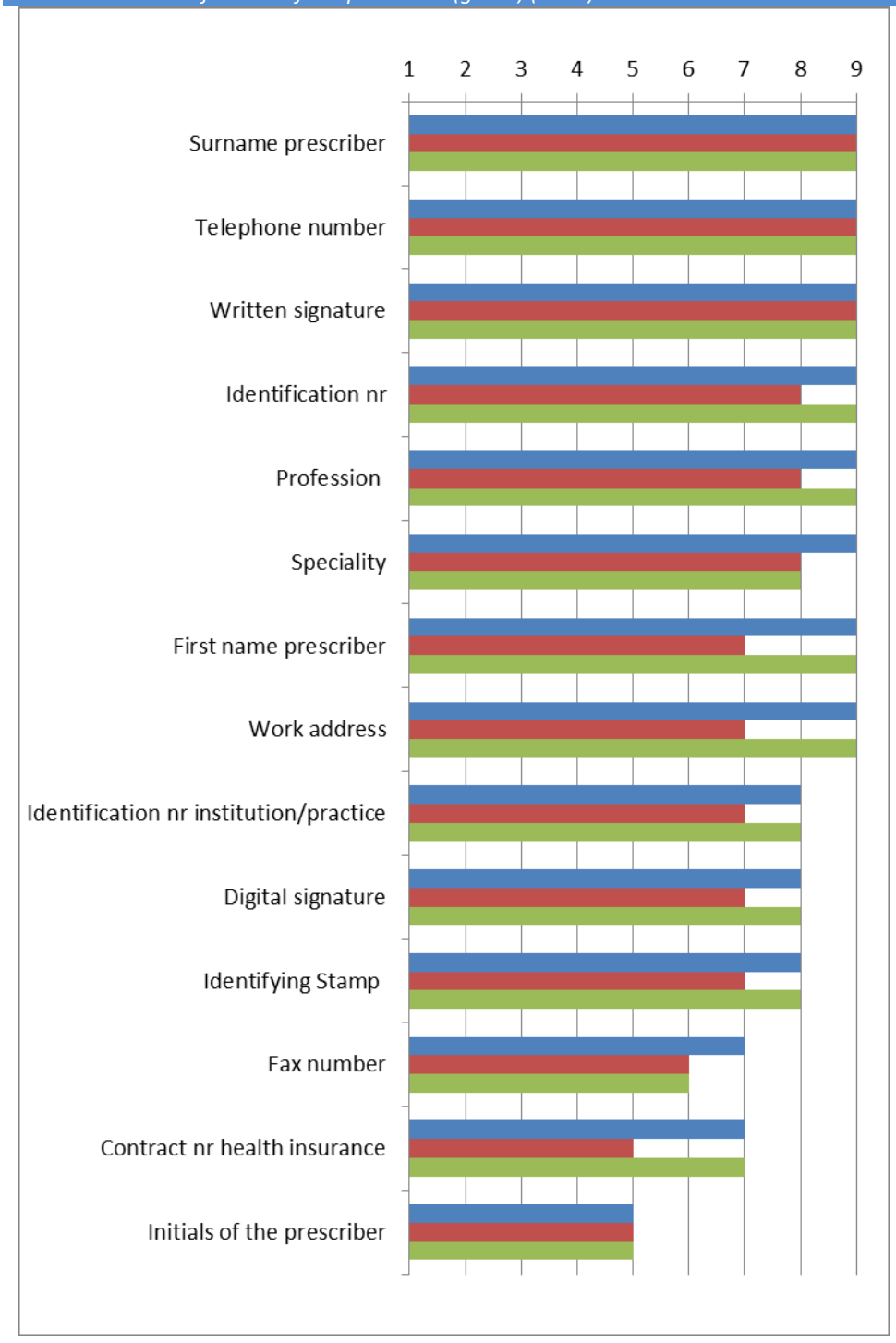
A. Identification of the prescriber

Identification of the prescriber consisted of 14 potential prescription form items. Figure 3.2 shows median scores for need for inclusion in the prescription form, relevance of inclusion to patient safety and relevance of inclusion for identification of the prescriber. Two items *contract number health insurance* and *initials* failed to reach the criterion for agreement. Of the remaining 12 items describing the identification of the prescriber, more than half (8 items) obtained the maximum inclusion score of 9 and three items obtained a high inclusion score (7, 8). Although differences can be seen between the inclusion scores and the scores for relevance with regard to patient safety and identification, most of them were also rated as highly relevant. Fax number obtained an inclusion score of 7, while relevance for both patient safety as well as identification scored inconclusive (6). Additionally for the items *digital signature* the relevance scores for patient safety were inconclusive. This may have been caused by some ambiguity concerning this item. Respondents made several additional remarks regarding written versus digital signature indicating that written signature can only apply in the case of paper based prescriptions, while digital signature only has relevance in relation to e-prescriptions.

Several respondents commented on the items. One respondent stressed the importance of legibility, either by using an identifying stamp, a pre-printed prescription pad or a computer generated printed text. Another respondent noted that nationally different identification numbers could be in use and a uniform European identification number may be of importance. Missed items that respondents mentioned included the email address of the prescriber and the prescriber's website address.

Figure 3.2

Identification of the prescriber: Median scores for need for inclusion (blue); relevance to patient safety (red) and relevance to identification of the prescriber (green) (n=90)



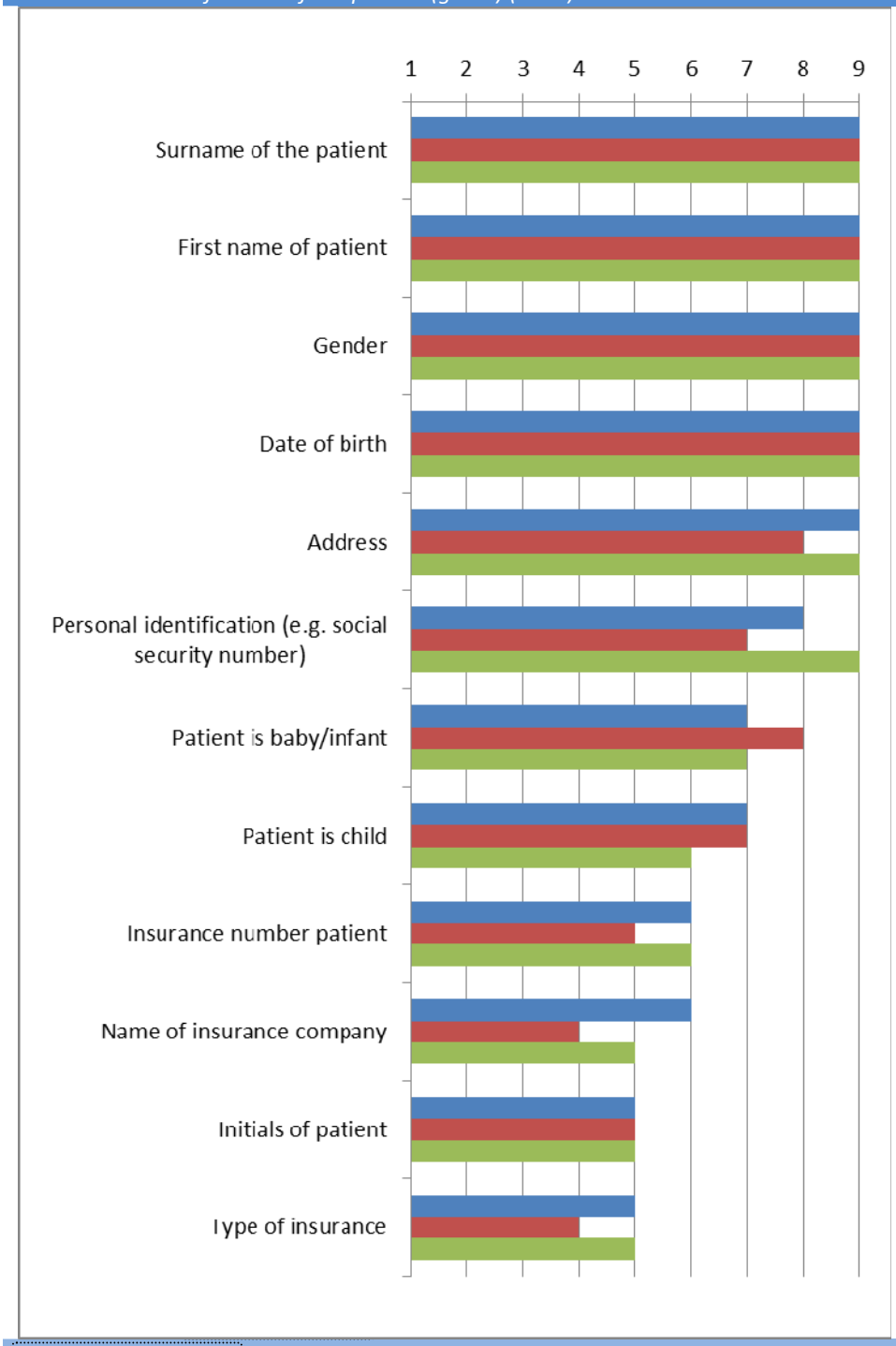
No agreement for items: Contract nr health insurance and Initials of the prescriber

B. Identification of the patient

Figure 3.3 shows median scores for need for inclusion in the prescription form, relevance of inclusion to patient safety and relevance of inclusion for identification of the patient. Identification of the patient consisted of 12 potential prescription form items. Three items failed to meet the criterion for agreement: *Insurance number patients; initials patient,* and *type of insurance.* Five items scored the maximum inclusion score (9) and the maximum or high relevance scores for patient safety (8-9) and identification (9). Although *Name of insurance company* obtained an inclusion score of 7, it was rated as inconclusive for relevance to patient safety and identification of the patient. The items *patient is child* and *patient baby/infant* obtained inclusion scores of (7). One respondent noted that when the year of birth is indicated it has no use to separately have an indication "baby/infant". Other comments noted that including social security number, name of insurance company and number of contract would result in too much information on the prescription form. Another respondent, however missed an identification or passport number for identification of patients without insurance.

Figure 3.3

Identification of the patient: Median scores for need for inclusion (blue); relevance to patient safety (red) and relevance to identification of the patient (green) (n=90)



No agreement for items: Insurance number patient, initials patient, type of insurance

C. Identification of the medicinal product

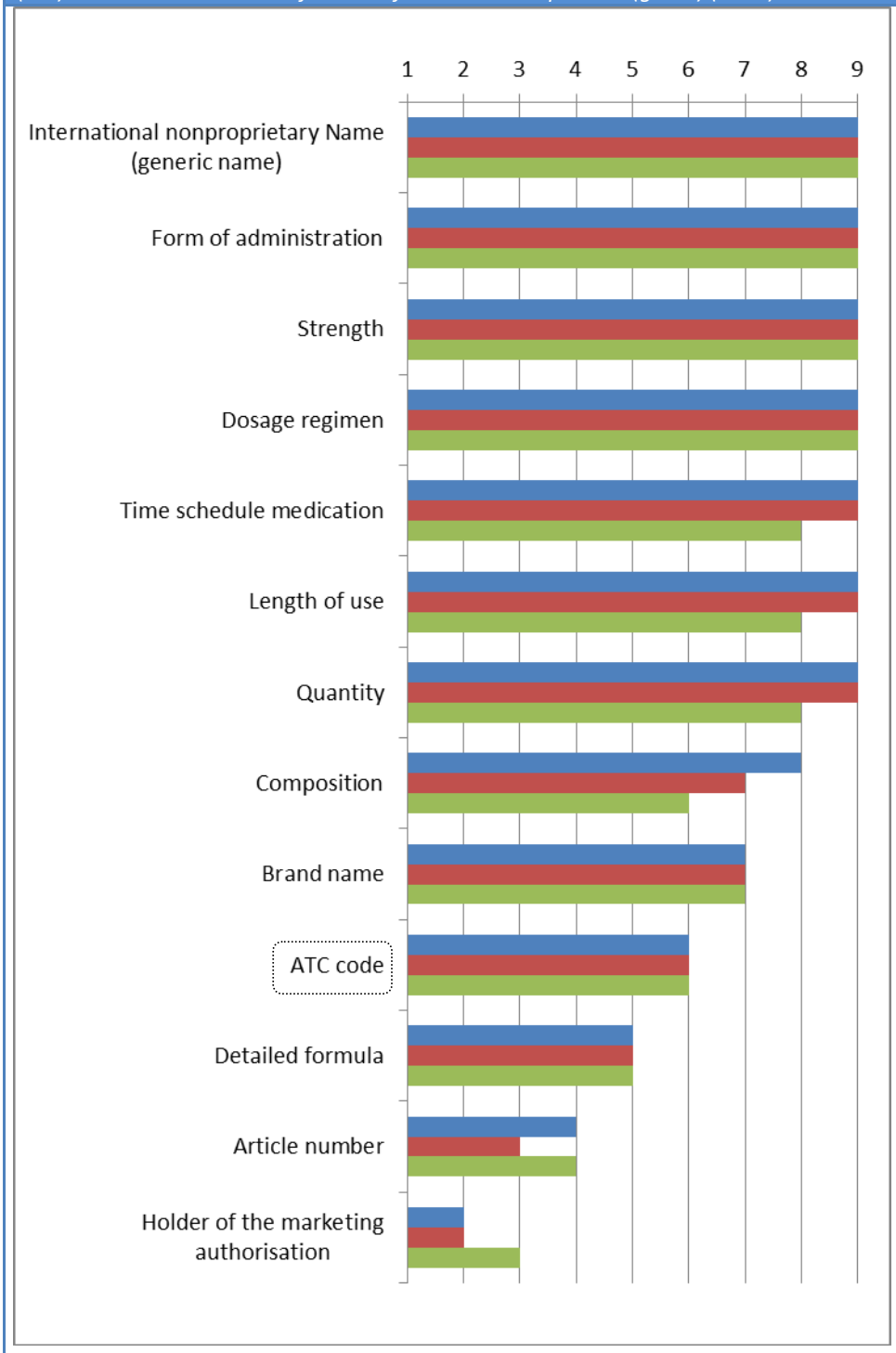
Identification of the medicinal product consisted of 13 potential prescription form items. Figure 3.4 shows median scores for need for inclusion in the prescription form, relevance of inclusion to patient safety and relevance of inclusion for identification of the medicinal product. One item failed to reach the criterion for agreement: *ATC code.*

Four items were rated the maximum score (9) for inclusion, relevance to patient safety and relevance to identification of the medicinal product, namely *international non-proprietary name (INN)*, s*trength, Form of administration* and *dosage regime*. *Time schedule medication*, *length of use* and *quantity* all scored 9 for inclusion and relevance to patient safety, and 8 for identification. Brand name obtained an inclusion score and relevance scores of 7. '*Composition*' was rated 8 for inclusion, 7 for relevance to patient safety, but scored inconclusive for relevance to identification (6). *Detailed formula* scored inconclusive for all aspects, while *holder of the marketing authorisation* and *article number* scored low inclusion and relevance scores. Several comments were made with regard to the items *article number*, to the effect that this item was not clear and that article number is not used uniformly internationally and may therefore not serve as unique identifier for a product.

One respondent noted that there were more details listed than required in relation to medicinal products and that generic name (INN) and ATC should describe what product is needed. Another respondent noted that original packs are safer than special compositions due to different traditions in different countries which may give rise to mistakes. One respondent suggested adding active ingredient to the list of elements, although this is also included in the INN.

Figure 3.4

Identification of the medicinal product: Median scores for need for inclusion (blue); relevance to patient safety (red) and relevance to identification of the medicinal product (green) (n=90)



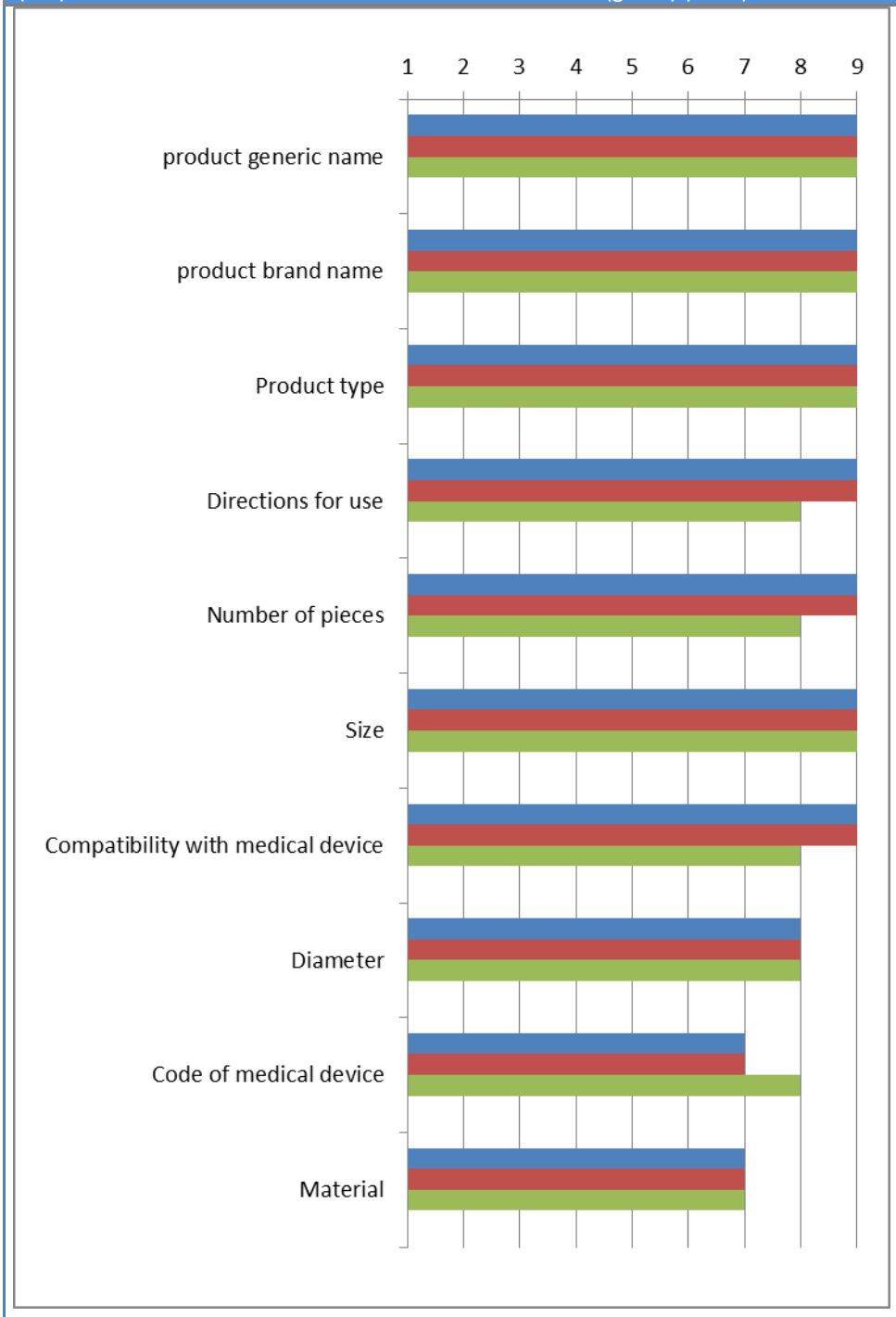
No agreement for item: ATC code

D. Identification of the medical device

Identification of the medical device consisted of 10 items (see Figure 3.5). The items *product generic nam, product type* and *product brand name* obtained maximum inclusion and relevance scores for both patient safety as well as identification. *Number of pieces* and *size* also obtained high inclusion scores (8-9) and were rated highly relevant for patient safety and identification (7-8). *Directions for use* and c*ompatibility of or with* device also obtained high scores for inclusion and patient safety, but were rated inconclusive for identification. The item *code of medical device* obtained an inclusion score and relevance score for patient safety of 7, while a relevance score of 8 for identification was obtained. However several respondents commented that it was not sufficiently clear what was meant by this code, or who assigned such a code.

From the comments made it became clear that not all items were comprehensible for the healthcare professionals responding, because these items were either unclear or because the professional had limited experience with medical devices. This last issue also arose from the inventory in Phase one where it was noted that not all countries use prescriptions for medical devices.

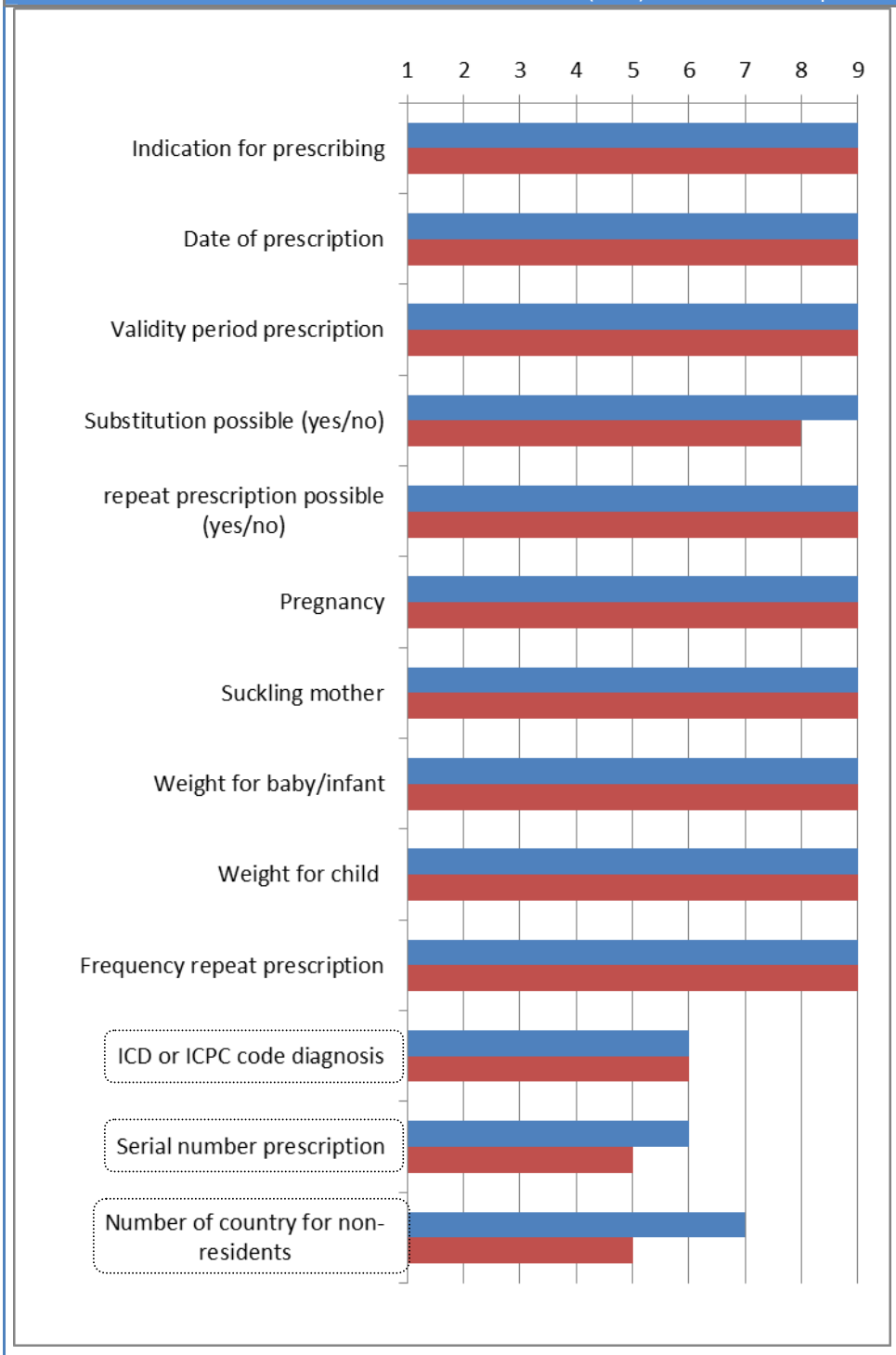
Figure 3.5
Identification of the medical device : Median scores for need for inclusion (blue); relevance to patient safety (red) and relevance to identification of the medical device (green).(n=90)



E. *Other information*

There were 13 items covering other information. Figure 3.6 shows median scores for need for inclusion in the prescription form and relevance of inclusion to patient safety and relevance. Three items did not reach the set criterion for agreement (*ICD or ICPC code diagnosis, serial number prescription, number of country for non-residents). Nine* items were rated the maximum score of 9 for both inclusion as well as relevance to patient safety. Substitution possible was also rated 9 for need for inclusion and was rated an 8 for relevance to patient safety.
Several respondents made comments with regard to items in this category. Suggestions included adding a comment section to prescription forms to allow the mention of relevant allergies, contra-indications and monitoring instructions. Another suggestion was to give new medicines and regular repeat medicines a separate location on the prescription. One respondent noted that although a lot of the items suggested in this category are desirable in respect of patient safety, they are currently uncommon in national prescriptions and mandating such information would be likely to meet resistance.

Figure 3.6
Other information: Median scores for need for inclusion (blue)and relevance to patient safety (red).(n=90)



No agreement for items: ICD or ICPC code diagnosis, Serial number prescription, Number of country for non-residents

3.3 Round 2: Moderated Online Discussions (MODs): preliminary results

After rating of prescription form items on long list II by group 1 (see Box 2.3), results for some items were not conclusive. Therefore, these items were discussed using a mediated online discussion. The participants were all provided with a summary document in which the results of the ratings for the first group (June 2011) were presented (Appendix V). Discussion statements were formulated for those items for which no consensus for in- or exclusion existed. In addition we posed statement on items that we did not include in the rating questionnaire but that were indicated as "missed items" by respondents.(see Appendix VI for an overview of all discussion statements).

Next to discussion on prescription form items we also posed questions on the following topics:

- Current experiences with cross-border prescriptions;
- Acceptance of cross-border prescriptions as included in the new EU-Directive;
- Introduction of e-prescriptions in cross-border care;
- Wish for a public and searchable register for prescribing healthcare professionals.

Below we first describe the main results of the discussion on the rated items followed by the results for the three extra topics.

3.3.1 Discussions on rated items

3.3.1a Items on prescriber identification

There were two items where respondents did not agree on whether or not to include them in a cross-border prescription form: *prescriber's initials* and p*rescriber's fax number*. Also in the MOD there was no clear consensus on including initials, albeit most respondents did not think initials are needed. One prescriber stated that initials would be helpful in case medical questions arise, but another respondent stated that – although initials might be useful - in that case the prescriber's full name would be required. Yet another respondent argued that initials are not needed in case there is a prescriber identification number (which is required in many Member States). For the fax number opinions were mixed as well. Arguments mentioned in favour of including the fax number are that it is a reliable way of communication, that is broadly available and often used. However, one respondent stated the opposite: *"The use of fax devices is limited. Other means of communication are more common*" (prescriber07).

Items that were suggested to be added to the prescription form but were not rated in the rating round were *prescriber's email address/website.* All participants agreed on the importance of an email address. Reasons they mentioned in favour of including an email address on the prescription form include that it is a fast way of communication and it allows easy access to prescribers in other countries. One prescriber stated that complementary contact details are still needed since not all prescribers systematically use email. All participants stressed the importance of being able to contact prescribers in other countries regardless of the method to do so. All arguments mentioned in favour of this refer to patient safety (for example being able to check interactions or allergies, to discuss a wrong dosage or other mistakes).

3.3.1b Items on patient identification

For four items in this cluster no agreement was reached in the rating round: *a) Initials of the patient; b) Type of insurance; c) Patients is baby/infant; d) Patient is child*. Like with the prescriber's initials the MOD-participants' reactions were mixed on including the patient's initials. Albeit the items were considered to be useful (for example for quick clarification), there is other information (e.g. a patient identification number) that could be used as well. Inclusion of type health insurance is considered to be useful by all MOD-participants. Reasons that were mentioned in favour of including this information included that not all medication is accepted by (all) health insurance companies and it is helpful in case there are multiple insurance agencies in the healthcare system. Reactions on indicating whether the patient is a baby/infant/child were mixed as well. Some participants thought it is useful because some medication or dosages should not be given to youngsters. However, another participant stated that such identification is not needed in case the patient's date of birth is on the prescription.

The passport number of the patients was suggested as an additional item that could be added to the prescription form in the rating round. MOD-participants agreed on the fact that a patient should be able to identify her/himself in the pharmacy but that other documents are acceptable as well. Therefore, this information does not necessarily have to be added to the prescription form.

3.3.1c Items on identification of the medicinal product

Four items referring to the medicinal product were discussed in the MOD: 1) *Article number*, 2) *ATC-code*, 3) *Composition of the product* and 4) *Detailed formula*. MOD-participant agreed on these items. The article number and ATC-code were considered helpful to be included for example in case of products that are not known by the pharmacist. The composition of the product and a detailed formula can be omitted according to the prescription form according to the MOD-participants. One prescriber suggested an online public register of all medicinal products which is common for all European prescribers.

During the rating round the active ingredient was added as an extra item that might be helpful to add to the prescription form. Reactions in the MOD were mixed. Some think it should indeed be included, while other participants argued that generic name and ATC-code provide similar information.

Some additional information was asked about how to present certain information on a medicinal product on the prescription form: 1) *Dosage regimen*; 2) *Quantity* and 3)*Time schedule for taking the medication*. In general, the participants preferred defined daily dosages as the way to indicate the dosage. For quantity the participants prefer the number of units along the number of packages or as a participant stated: *"number of packages with a clear definition of the size of one package".* With regard to the time schedule for taking the medication MOD-participants think that in general it is enough that pharmacists explain the intake schedule, but for some medications (such as corticosteroïds, antibiotics and antidiabetics) the prescriber should specify the time schedule.

3.3.1d Items on identification of medical devices

Three items were discussed in the MOD since no agreement was reached in the rating round for group 1: 1) *Code of medical device*; 2) *Diameter*; 3) *Material*. Generally the participants find these information not very important for clinical practice. However, with regard to the material one respondent pointed to the possibility of allergy to the substances in the device and raised the question whether these should be on the prescription.

Several missed items were mentioned in the rating round. However, the participants only reflected on adding the contact information of the producer or manufacturer: they find this important information to add.

When asked for the information needed for professionals to exchange with other providers (for example between prescriber and pharmacist) the following items were mentioned: name of the device, size and serial number or other possibility for safe identification, quantity, name of producing company.

3.3.1e Items related to other information

For three items in the section *other information* there was no agreement in the rating round: 1) *ICD or ICPC-code;* 2) *serial number of the prescription and* 3) *number of country*. The MOD-participants agreed that serial number and number of country could be omitted. With regard to the ICD/ICPC code they stated that in principal this is useful information but that not all prescribers are familiar with this information. Therefore, they advised to add a free text diagnosis next to these codes.

3.3.2 Current experience with cross-border prescriptions

Most professionals who participated in the MOD stated that their experience with cross-border prescriptions is rather limited. An exception is a participant from Malta who said that cross-border prescriptions are a common phenomenon there because of the tourist industry. Problems mentioned by the professionals include the fact that a certain medicine prescribed in another country is not available in their own country or that a specific brand is not available. Also, different names are sometimes used in different countries for the same medicine. One professional suggested to set up a European database with both brand names and generic names. Another problem refers to blurred instructions on the prescription form (for example on how long the medicine has to be taken). Pharmacists then need to verify this information from either the patient or the prescriber, which is not always easy.

3.3.3 Acceptance of EU-Directive

Only few participants responded to the statement on how they think about the acceptance of prescriptions in the new EU-Directive. They agree that it might increase the safety of the patient: *"it will increase the safety of the patient as the prescription is an important source of information about a patient who is completely unknown to me"(prescriber03)*. However, another prescriber argued that some requirements have to be fulfilled in order to increase patient safety: "*If the patient can get the prescribed medicine in any country in Europe the pharmacist and the doctor has to know more about which medicines the patient take to avoid interactions with other drugs and to avoid over dosage and abuse. One way is that all patients have an online electronic personal medical record with a list of medicines taken which can be shown to the doctor or pharmacist. That would make prescription safer. Otherwise I am afraid the cross border prescription will become unsafe"(prescriber 22).*

3.3.4 E-prescriptions

E-prescriptions are prescriptions that are exchanged between health providers through electronic communication such as e-mail or e-health information systems. Opinions on e-prescriptions were mixed among the MOD-participants. In Sweden e-prescriptions form the majority of all prescriptions and experiences are positive: *"it is safe and convenient … the prescription cannot be lost*" (prescriber22) This participant strongly supported the idea of e-prescriptions: "*To get the possibility of e-prescriptions in cross border care should be top priority when EHR is introduced in the country´s healthcare*"*.* However, other participants did not agree and mentioned that some countries do not have any history in e-prescribing: *´Advanced technology is still not common in some countries. Neither prescribers nor patients will be prepared to conform with such initiative'* (prescriber07).

Opponents also referred to safety issues: *"e-prescriptions are not secure, open to public, and target of the industry" (prescriber01).*

3.3.5 Public register for prescribers

We asked the MOD-participants whether there should be a public and searchable register for prescribing healthcare professionals in all EU Member States? And if so, whether it should be on European or national level. Most participants stated that there is no need for such register in case the prescriber can be clearly identified and it is able to contact the prescriber by phone, fax or email. However, in case these criteria are not fulfilled, a register at the EU-level is wished for by those participants. One participant states that such register should wished for anyway for reasons of patient safety because sometimes prescribers continue prescribing after they have lost their right to do so due to malpractice.

3.4 Round 3: email consultation

After the online mediated discussion a last consultation of the healthcare professionals was conducted, focussing on the clarity of the wording of the items and items that were still under discussion. Participants with known email addresses (n=63) were contacted with an email and attached document containing a preliminary proposal for a minimum set for cross border prescriptions for medicinal products and medical devices. Participants were asked to indicate 1) whether the wording of the items was sufficiently clear; 2) whether items essential for patient safety were currently not included and 3) what there view was on the final items still under discussion.

3.4.1 Preliminary proposal: long list III for medicinal products and medical devices

The preliminary proposal (long list III, see Box 3.2 and 3.3) for the minimum set of prescription form items was based on the inclusion scores, taking into account the discussion points generated via the questionnaire and MOD. An initial list was generated based on the rating of the need for inclusion (inclusion = 9; under discussion = 7 or 8; exclusion: ratings without agreement and/or inclusions scores 1-6). In order to further minimise the amount of items and to avoid unnecessary overlap and items with only national relevance, three additional criteria were applied before inclusion in the preliminary proposal:

1) Item has relevance at EU level (item is not only relevant at national level)
2) Redundancy of items, because of overlap between multiple items or because item is already defined in national legislation
3) No implicit burdens are placed on healthcare professionals by including this item in the minimum data set

In Box 3.2 the changes made to Long list II after phase 2 and after application of the three criteria above is displayed. In Boxes 3.4 and 3.5 the resulting preliminary proposal for medicinal products and medical devices as sent to the participants via email, is displayed.

Box 3.2 Changes to Long list II (following Phase 2 and additional criteria) (o= include item in core set, x= exclude item)(→reason exclusion), ? = under discussion; Δ = adapt item)	
Identification of the prescriber	
Surname of the prescriber	o
First name of the prescriber	Δ → Combined item: first name (s) or initials
Profession	o
Speciality	X → Redundancy after inclusion Profession
Identification number institution/practice	X → only national relevance of number
Work address	o
Telephone number	Δ → combined item : details for direct contact with prescriber (telephone, fax number or email)
Written signature	Δ → combined item: Signature (written or digital)
Digital signature	Δ → combined item: Signature (written or digital)
Identifying Stamp	X → Only relevant at national level
Identification number prescribing professional	X → Number only relevant at national level
Initials of the prescriber	Δ → No agreement; Combined item: first name (s) or initials
Contract number prescriber at health insurance	X →No agreement
Fax number	Δ → combined item : contact details
Identification of the patient	
Surname of the patient	o
First name of patient	Δ → Combined item: first name (s) or initials
Gender	o
Date of birth	o
Address	Δ → Home address
Personal identification (e.g. social security number)	X→ Only relevant at national level
Name of insurance company	X → Only relevant at national level
Insurance number patient	X →Only relevant at national level
Patient is baby/infant	X → Redundancy (because of inclusion Date of birth)
Patient is child	X → Redundancy (because of inclusion Date of birth)
Initials of patient	Δ → Combined item: first name (s) or initials
Type of insurance	X → No agreement; Only relevant at national level
Identification of the prescribed medicinal product	
International nonproprietary Name (generic name)	Δ → International Non-proprietary Name (INN)
Route of administration	o
Strength	o
Dosage regimen	Δ → Dosage regimen or directions for use
Time schedule medication	X → redundancy with item : Dosage regimen or directions for use
Length of use	Δ → Intended duration of use
Quantity	o
Brand name	? → inclusion score = 7
ATC code	X → Inclusions score < 7; No agreement
Composition	Δ → Composition (in case of extemporaneous compounding)
Article number	X → inclusion score < 7; No agreement

Detailed formula	X → Inclusions score < 7; No agreement
Holder of the marketing authorisation	X → Inclusion score < 7; No agreement

Box 3.2-continued Changes to Long list II (following Phase 2 and additional criteria) (○= include item in core set, ×= exclude item, ? = under discussion; Δ = adapt item)	
Identification of the prescribed medical device	
Product generic name	Δ → General product description
Product type	○
Directions for use	○
Number of pieces	Δ → Quantity
Product brand name	Δ → Brand name
Size	X → Redundancy with product type and General product description
Compatibility with device/medical aids	Δ → compatibility with device
Code of medical device	X → Not relevant at EU level
Diameter	X → Redundancy with product type and General product description
Material	X→ Redundancy with product type and General product description
Other information	
Indication for prescribing	○
Date of prescription	○
Validity period prescription	Δ → period that prescription is valid
Substitution possible (yes/no)	○
Repeat prescription possible (yes/no)	X → Redundancy, subject to national legislation
Pregnancy	○ → Inclusion score = 9
Suckling mother	Δ → Breastfeeding mother
Weight for baby/infant	Δ → Combined in Weight for baby/child
Weight for child	Δ → Combined in Weight for baby/child
Frequency repeat prescription	X → Redundancy, subject to national legislation
ICD or ICPC code diagnosis	X → No agreement
Serial number prescription	X→ No agreement
Number of country for non-residents	X → No agreement

Box 3.3: PRELIMINARY PRESFORM proposal content minimum data set cross border prescriptions -Medicinal products (input for email consultation)
Identification of the prescriber
Surname First name (s) or initials Profession Work address Contact details Signature (written or digital)
Identification of the patient
Surname First name(s) or initials Gender Date of birth Home address
Identification of the medicinal product
International non-proprietary name (INN) Brand name Route of administration Quantity Strength Dosage regimen or directions for use Intended duration of use Composition (in case of extemporaneous compounding)
Other information
Indication for prescribing Date of prescription Period that prescription is valid Substitution possible (yes/no) Breastfeeding mother Weight for baby/child Pregnancy

Box 3.4: PRELIMINARY PRESFORM proposal content minimum data set cross border prescriptions –Medical devices (input for email consultation)
Identification of the prescriber
Surname First name (s) or initials Profession Work address Contact details Signature (written or digital)
Identification of the patient
Surname First name(s) or initials Gender Date of birth Home address
Identification of the medical device
General product description Brand name Product type Directions for use Quantity Compatibility with device
Other information
Indication for prescribing Date of prescription Period that prescription is valid

3.4.2 Results email consultation healthcare professionals

Of the 63 participants who were consulted by email on the preliminary proposal (see Box 3.3 and 3.4 in the previous section) 21 responded (response rate 33%) to the online questions regarding the preliminary proposal.

3.4.2a Clarity of the wording of the items, missed items and items under discussion

Almost all respondents (95%) felt that the wording of the items was sufficiently clear. One respondent felt that most items were clear, with two exceptions. Instead of *Form of administration* it was suggested to use *pharmaceutical dosage form*. With regard to the *period that prescription is valid*, this respondent suggested date of expiry. Additionally it was remarked that date should be displayed in a uniform manner (day, month year etc.). A majority of 81% of the respondents did not feel any essential items for patient safety were missing. Four respondents did miss items, namely: allergies of the patient (2x), known reasons for not prescribing or substitution a medication, and referral or specialist needed after dispensing the prescription. With regard to items still under discussion, a majority of respondents felt these should be included *Brand name* (52%), *Composition* (67%).

3.5 Patient Organizations Consultation

The objective of the additional consultation of patients' organizations was to gain insight in the experiences and viewpoints of European MS patient organizations with cross border prescriptions. Patient organizations are seen as representatives of those who ask for prescribed medication and who might experience problems with recognition of foreign prescriptions: the patients.

3.5.1 Method

Patient organizations were chosen based on their representative function within the EU or based on their representative function on national level. Emphasis was put on representation of patients from all Member States within the selected organizations. The Burson Marsteller European patient group directory (third edition 2009-2010) [22], was used as the primary source for the selection of European patient organizations to be included in this study. A pre-selection of 50 patient organizations was formulated that together represented patients from all European MS and included a wide range of diseases and disorders. From this initial selection the final selection of 34 patient organizations was made (See Appendix VI). Additionally 10 national patient organizations were selected. All 44 organisations received an e-mail invitation with a link to an online questionnaire. Organizations that filled in the were subsequently invited to join an online mediated online discussion group. The information provided in the structured questionnaires, as well as a results document of inclusion scores (group 1) was used as a basis for the mediated online discussion.

3.5.2 Patient organization questionnaire and online discussion

A short online questionnaire was developed, the content of which included the origin, scope and structure of the patient organization (See Appendix VIII). All 44 patient organisations were formally invited by email, the email contained a personal link to an online questionnaire. After two weeks as well as two days before the deadline reminders were sent to those patient organizations from which no response had been received. Due to low response, a third reminder was sent to all organizations and the deadline was extended with two weeks.

[22] http://burson-marsteller.eu/2010/01/european-patient-group-directory-third-edition-2009-2010/

It was intended to use the information provided in the online questionnaire in the online mediated discussion. Based on the general focus of the PRESFORM project main subjects were selected:

- discussion of cross-border prescription form use and the problems that might occur
- comprehensibility of prescription forms for patients (also as control mechanism and tool in patient safety)
- occurring problems with cross border prescription forms (also discussion of those problems mentioned in the structured questionnaires)
- proposed solutions for the possible problems with cross-border prescription forms

Based on these subjects specific topics were developed (See Appendix IX). The patient organizations participating in the structured questionnaire were invited via email invitation to join the online forum discussion. Each organization received a personal username and password. After two weeks a first reminder was sent as well as two days before the deadline. In order to improve response, the deadline was extended an additional three weeks. The reminder following this extension included the login data and additionally the discussion topics were included, providing the patient organizations the opportunity to respond directly the project team.

3.5.3 Results

Despite the extensive efforts to improve the response, only six organizations completed the online questionnaire. Subsequent to this low response, the response to the online discussion was low as well. The results section will jointly discuss the results from both the questionnaire and the online discussion.

3.5.3.a Response

Six organizations completed the online questionnaire of which three national and three international patient organizations. This reflects a response of merely 14%. All representatives who responded to the questionnaire were female, with an average age of 50 (range 35-68). Respondents provided information on their professional background which ranged from medical, pharmaceutical, political sciences to public health. The participants were asked to provide information on the patient organization they represented. Despite the low response, all MS were included in the patient organizations that participated, merely because two patients organization represented (almost) all MS. Table 3.1 provides an overview of the characteristics of the participating patient organizations.

Table 3.1
Characteristics of participating patient organizations

Organization	national / international	number of MS represented	number of national organizations represented	number of individual patients represented
a.	national	1	-	1150
b.	national	1	-	5500
c.	national	1	-	250
d.	international	all (27)	199	-
e.	international	25	385	-
f.	international	15	32	-

In order to provide reasons for the overall low response, the responses provided by patient organizations via email, through the questionnaire and on the online discussion forum were

reviewed. Most mentioned reasons for (partial) non-response were no lack of time or resources (12x), insufficient expertise on this subject (7) and organization has no position or focus on these issues (2x).

The following sections describe the answers of the six participating representatives of patient organizations.

3.5.3.b Use of cross-border care

When asked about the represented patients need for cross-border care one organization described that their patient group often needs or encounters cross-border healthcare, three organizations described an occasional need and two organizations described that their patients rarely need or encounter cross-border healthcare. When asked what subjects related to cross-border care are or might be relevant for the patients represented by the patient organization most participants described consultations with a doctor/specialist, followed by emergency treatment, follow-up dispensing of medication or dispensing of generic substitutes of medication/medical devices and/or medical aids. None of the respondents mentioned consultation with a general practitioner or first dispensing of medical devices and/or medical aids. When asked about reasons for the use of cross-border care in general, most organizations mentioned the cost of medication and the accessibility of healthcare. Followed by the quality of healthcare and living in a border region. Travelling related or accident/emergency need for cross-border care was only mentioned by one participant. Additionally, two organizations mentioned a lack of expertise and provision of treatment and the unavailability of surgical procedures in the country of affiliation.

3.5.3.c Use of cross-border prescriptions

When asked specifically about the use of cross-border prescriptions, one of the patient organizations described a moderate need and two organizations described the patients represented by their patient organizations rarely made-use of cross-border prescriptions. Potential risks or problems related to cross-border prescriptions were mentioned by four participants and included:

- problems concerning payment for the medication provided,
- drug related follow-up in the home country
- difficulties in the ability to read/dispense the prescription (also concerning brand name/INN)
- the possible inequity in access due to inherent costs of travel

Some additional comments were provided by three organizations and included a recommendation about the use of international brand names. Additionally it was mentioned that patients with a so called ‘rare disease’ have a disproportionally high need cross border healthcare as it is not realistic to have the highest level of expertise and quality of care for such diseases in each country of the EU, making cross-border healthcare life-saving for rare diseases patients. Lastly one of the participants described that a public and searchable register for prescribing healthcare professionals in all EU Member States would be a good initiative as healthcare professional and users can gain important information on the reliability of these healthcare providers.

Final comments on the patient organization consultation provide additional information on the reasons behind the low response as the participation organizations mentioned the difficulty of the subjects discussed and additionally explained the lack of specific expertise on cross-border prescriptions.

4. Phase 3: Possible implications of implementing of the minimum data set for each Member State

4.1 Objective

The aim of last phase of the PRESFORM project was to provide an overview per Member State as to how Member States' current practices deviate from the proposed minimum set of medical prescription form items and what potential barriers there may be for implementing the minimum set.

4.2 Methods

Per country an overview was constructed in which the preliminary advice for a minimum set of prescription form items was compared to the items required on the country's prescription form. In addition, deviations from the advice for the set of minimal items were stated. (see Appendix X for an example). The sent format contained two prescription forms: one for medicinal products and one for medical devices. The overview was sent to the expert(s) who responded in round one. For the six countries that did not reply to the questionnaire in the first round, the comparison between the proposed minimum set of items and the country's own prescription form was either based on the PGEU-report (PGEU, 2011) or left open in order to enable non-responding Member States to complement the format for their own country.

The experts were asked to answer the following questions:

1. Do you feel this overview with regard to {*Member State*} is correct? If no, please clarify.
2. Please let us know whether the following items are mandatory, banned or commonly added in {*Member State*} :
    - Breastfeeding mother (Medicinal products; other information)
    - Pregnancy (Medicinal products; other information)
    - Quantity (Medical devices; Identification of the medical device)
3. Do you expect or foresee any problems with embedding of the set as listed here in this preliminary advice in {*Member State's*} cross border prescription forms? If yes: Please clarify your answer
4. With regard to timing what period do you feel is realistic for embedding the set as listed here for {*Member State's* } cross border prescription forms?
    - By September 2013
    - By September 2014
    - By September 2016
    - Other, namely:

Given the tight planning of the project, respondents had 7 days to reply and received one reminder after this deadline.

4.3 Results

Experts from 20 Member States participated in this final round of the PRESFORM project. A number of them changed the status of some of the prescription form items. Usually the change was from "mandatory" to "commonly added" or vice versa of from "mandatory" to "not mandatory" (and not commonly added).

4.3.1 Medicinal products

Table 4.1 shows for how many countries (of the responding 20 Member States) their current prescription form for medicinal products is in line with the proposed minimum set for cross-border prescriptions. Three items that refer to the identification of the prescriber are mandatory in all 20 Member States: surname, first name/initials and signature. With regard to initials, one country (Poland) noted that initials are banned (while the first name is mandatory). The Belgian expert stated that digital signatures are banned in their country. Work address of the prescriber is required in 14 countries and profession in 13 countries. Details for direct contact are required in only nine Member States, but in seven others this information is commonly added. Overall, looking at both mandatory items and items that are commonly added, it can be stated that the items referring to the identification of the prescriber in the proposed minimum set are in line with current practice in most Member States.

For the identification of the patient, the surname and first name are mandatory or commonly added in all Member States (albeit initials are banned in Poland). The patient's home address is mandatory in the majority of Member States (12) and commonly added in another two countries. Date of birth of the patient is required on the prescription form in nine countries, while in another four countries it is commonly added. Gender of the patient is only mandatory in two Member States and commonly added in another. For this item, current practice clearly deviates from the proposed minimum set for cross-border prescriptions.

Four items in the proposed minimum set referring to identification of the medicinal product are mandatory in 15 to 17 Member States: the form of administration, quantity, strength, and dosage regime. Moreover, they are usually commonly added in other Member States. Looking at the name of the product, it can be seen that the brand name is mandatory in 13 countries and the INN in eight countries. While the brand name is commonly added in five countries, two countries mention that it is either banned (Lithuania) or contrary to the national policy on generic prescribing (United Kingdom). In case of extemporaneous compounding 11 Member States require the composition to be mentioned on the prescription form, while the intended duration of use is mandatory in seven Member States.

Most deviations between the proposed minimum set and current practice are found for the category other information. The only item that is mandatory in virtually all Member States is the date of prescription. The period that the prescription is valid is mandatory in 11 countries. Three country experts from countries where this is not mandatory or even banned note that this period is regulated by law. The indication for prescribing is mandatory in eight countries, but banned in two others (Austria and Poland). Prescribers are required to add whether substitution of the product is allowed in four countries, but they are prohibited to do so in three other countries. Whether the patient is a breastfeeding mother or a pregnant woman is information that is not required in any of the Member States as is the weight for a baby/child. This information is also not commonly added.

In sum, items of the proposed minimum set that are currently mandatory in half or less than the (20) Member States include: contact details of the prescriber, gender of the patient, patient's date of birth, INN, intended duration of use, indication for prescribing, breastfeeding mother, pregnant woman, and weight baby/child. Some of these items (f.e. contact details and patient's date of birth, INN) are commonly added in quite a few other countries.

Table 4.1:
Similarity between current practices of Member States and the proposed minimum set of prescription form items (n=20 countries)

	Number of countries	
	In line proposal	Differences with proposal
Identification of the Prescriber		
Surname	20	
First name(s) or initials	20	Initials banned: 1 (first name mandatory)
Profession	13	Not mandatory: 2 Commonly added: 4 Unknown: 1
Work address	14	Not mandatory: 3 Commonly added: 3
Details for direct contact with prescriber (either telephone, fax or email)	9	Not mandatory: 4 Commonly added: 7
Signature (written or digital)	20	Written signature mandatory, digital signature banned: 1
Identification of the patient		
Surname	19	Mandatory if patient < 12 yrs: 1 Commonly added: 1
First name(s) or initials	18	Mandatory if patient < 12 yrs: 2 Commonly added: 1 Initials banned: 1 (first name mandatory)
Gender	2	Not mandatory: 16 Commonly added: 1 Unknown: 1
Date of Birth	9	Age is mandatory: 1 Not mandatory: 3 Mandatory if patient < 12 yrs: 2 Commonly added: 4 Unknown: 1
Home address	12	Not mandatory: 5 Mandatory if patient < 12 yrs: 1 Commonly added: 2 Unknown: 1

Table 4.1-continued :Similarity between current practices of Member States and the proposed minimum set of prescription form items (n=20 countries)		
	Number of countries	
Identification of the medicinal product	In line proposal	Differences with proposal
International Non-proprietary Name (INN)	8	Not mandatory: 5 Commonly added: 6[23] Unknown: 1
Brand name	13	Commonly added: 5 Contrary to the policy on generic prescribing: 1 Banned: 1
Route of administration	16	Commonly added: 3 Unknown: 1
Quantity	16	Not mandatory: 1 Commonly added: 2 Unknown: 1
Strength	17	Not mandatory: 1 Commonly added: 2
Dosage regimen or directions for use	15	Not mandatory: 2 Commonly added: 3
Intended duration of use	7	Not mandatory: 6 Commonly added: 5 Unknown: 1
Composition (in case of extemporaneous compounding)	11	Not mandatory: 5 Commonly added: 4 Unknown: 1
Other information		
Date of prescription	19	Not mandatory: 1
Indication for prescribing	8	Not mandatory: 6 Commonly added: 1 Banned: 2
Period that prescription is valid	11	Not mandatory: 8 Commonly added: 1 Banned: 1
Substitution possible (yes/no)	4	Not mandatory: 9 Commonly added: 3[24] Banned: 3 Unknown: 1
Breastfeeding Mother	0	Not mandatory: 14 Unknown: 5 Banned: 1
Pregnancy	0	Not mandatory: 14 Unknown:4 Banned: 1

[23] Either INN or brand name is commonly added in Ireland, this is encouraged in Latvia

[24] 1x Added in case prescriber does not want the pharmacist to substitute

Weight for baby/child	0	Not mandatory: 16 Commonly added:1; unknown: 3

Because they were not mandatory in any Member State three items of the category other information were excluded after analysis of the similarities between current prescription practices and the preliminary proposal (Pregnancy, breastfeeding mother and weight for baby/child).

We also looked for each Member State how many of the items in the proposed core set are already mandatory or commonly added in current practice (Table 4.2). The current prescription forms of the Estonia, Latvia, and Sweden are largely in line with the proposed core set for cross-border prescriptions. In Estonia, for example all 23 items are either mandatory or commonly added. Other countries with relatively many items that match with the proposed core set for cross-border prescriptions include Denmark, Poland, Slovenia, and Spain, and in case commonly added items are considered as well, Austria, Cyprus and Slovakia. Countries where current practice fits worst with the proposed set are Ireland, Italy, and the UK. While the UK has least mandatory items (n=5), Italy deviates most if both mandatory and commonly added items are considered. The current form of Italy overlaps matches with the proposed core set for cross-border prescription for only 11 items.

Table 4.2 Number of items in line with the proposed minimum set of prescription form items for medicinal products per country (n=20 countries, proposed minimum set exists of 23 items)

	Mandatory	Commonly added
Austria	14	5
Belgium	12	5
Bulgaria	15	0
Cyprus	17	4
Denmark	18	1
Estonia	21	2
Germany	16	0
Hungary	15	0
Greece	12	0
Ireland	9	10
Italy	9	2
Latvia	20	2
Lithuania	16	1
Poland	17	1
Portugal	12	5
Slovakia	15	3
Slovenia	18	2
Spain	18	0
Sweden	20	0
United Kingdom	5*	13

** two items extra for children under age 12.*

In Table 4.3 an overview is given of items and current status in the different Member States (M = mandatory, CA = commonly added, B = banned).

Table 4.3 Medicinal products

	Austria	Belgium	Bulgaria	Cyprus	Czech Rep.	Denmark	Estonia	Finland	France	Germany	Greece	Hungary	Ireland	Italy
Identification prescriber														
Surname	M	M	M	M	M	M	M	M	M	M	M	M	M	M
First name(s)/initials	M	M	M	M	M	M	M	M	M	M	M	M	M	M
Profession	M	CA		M		M	CA	M	M	M	?	M	M	M
Work address	M	CA	M	CA	M	M	M	CA	M		M	M	M	
Details for direct contact	CA	CA	M	CA	M	M	M				M	M	CA	
Signature (written/digital)	M	M	M	M	M	M	M	M	M	M	M	M	M	M
Identification patient									M					
Surname	M	M	M	M	M	M	M	M	M	M	M	M	M	M
First name(s)/initials	M	M	M	M	M	M	M	M	M	M	M	M	M	M
Gender							M	M	M		?			
Date of birth	CA			CA	M	M	M	M	M	M	?	M	*	
Home address	CA		M	M	M	M	M		M	M	?		M	M
Identification medicinal product														
INN	CA	CA		M			M	M	M	M	?			
Brand name	M	M	M	M	M	M	CA	M	M	M	M	M	CA	M
Form of administration	M	M	M	M	M	M	M	CA	M	M	?	M	CA	
Quantity	M	M	M	M	M	M	M	M	M	M	?	M	CA	M
Strenght	M	M	M	M	M	M	M		M	M	M	M	CA	
Dosage regimen/directions	M	M	M	M	M	M	M	M	M		M	M	CA	
Intended duration of use	CA	CA	M	M		CA	M	CA	M	M	?		CA	
Composition	M			M	M		M	M	M		?		CA	
Other information														
Date of prescription	M	CA	M	M	M	M	M	M	M	M	M	M	M	M
Indication for prescribing	B	M			M	M	M	M			M	CA		
Period that prescription is valid	B*			M			M	M	M	M	M	M		M
Substitution possible	B	B				CA	M	M	M		?			

Table 4.3 Medicinal products –continued

Identification prescriber	Latvia	Lithuania	Luxembourg	Malta	Netherlands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	UK
Surname	M	M	M	M	M	M	M	?	M	M	M	M	M
First name(s)/initials	M	M	M	M	M	M	M	?	M	M	M	M	M
Profession	M	CA	M		M	M	M	?	M	M	M	M	M
Work address	M	M	M		M	M	CA	?	M	M	M	M	M
Details for direct contact	M	M	M	M	M	M	CA	?				M	CA
Signature (written/digital)	M	M	M	M	M	M	M	?	M	M	M	M	M
Identification patient													
Surname	M	M	M	M	M	M	M	?	M	M	M	M	M/CA
First name(s)/initials	M	M	M	M	M	M	M	?	M	M	M	M	M/CA
Gender			?		M			?		M			CA
Date of birth	M	M	?		M	M		?		M	M	M	CA
Home address	M	M	?			M		?	M	M			CA
Identification medicinal product													
INN		M	M		M	M	CA	?	M	CA	M		M
Brand name			M	M	M	M	CA	?	M	M	M	M	(B)
Form of administration	M	M	?		M	M	M	?	CA	M	M	M	CA
Quantity	M	M	M	M	M	M	M	?	M	M	M	M	CA
Strength	M	M	?	M	M	M	M	?	M	M	M	M	CA
Dosage regimen/directions	M	M	M	M	M	M	M	?	M	M	M	M	CA
Intended duration of use	M		M		M	CA		?	CA		M	M	CA
Composition	M	M	?					?	M	M	M	M	CA
Other information													
Date of prescription	M	M	M	M	M	M	M	?	M	M	M	M	M
Indication for prescribing	M		?			B		?	M			M	
Period that prescription is valid	M	M					M	?		CA	M	M	
Substitution possible	M						CA	?	M	CA		M	B

4.3.2 Medical devices

Table 4.4 shows for how many countries (out of 20 Member States) their current prescription form for medical devices is in line with the proposed minimum set for cross-border prescriptions.[25] The results for identification of the prescriber and identification of the patient are comparable to those of the prescription form for medicinal products, albeit some items are less often mandatory (such as surname and first name) but commonly added. All characteristic referring to the identification of the medical device are mandatory in ten or less Member States. The items most often required include brand name (10), product type (10), and quantity (9). With regard to the three items in the category other information date of prescription is the item that is required in most countries (n=14). The period that the prescription is valid is mandatory in nine countries and the indication for prescribing in five. In sum, current prescription forms for medical devices deviate more from the proposed minimum set of prescription form items than those for medicinal products.

Table 4.4: Similarity between current practices of Member States and the proposed minimum set of prescription form items (n=18 countries[26])

	Number of countries	
	In line proposal	Differences with proposal
Identification of the Prescriber		
Surname	16	Commonly added: 2
First name(s) or initials	16	Commonly added: 2 Initials banned: 1 (first name mandatory)
Profession	9	Not mandatory: 2 Commonly added: 5
Work address	11	Not mandatory: 1 Commonly added: 3
Details for direct contact with prescriber (either telephone, fax or email)	6	Not mandatory: 3 Commonly added: 4 Unknown: 1
Signature (written or digital)	16	Digital signature banned:1 Commonly added: 2
Identification of the patient		
Surname	15	Commonly added: 2
First name(s) or initials	15	Commonly added: 2 Initials banned: 1 (first name mandatory)
Gender	2	Not mandatory: 12 Added if needed: 1 Commonly added: 1
Date of Birth	9	Not mandatory: 6 Commonly added: 2 Added if needed: 1
Home address	9	Not mandatory: 5

[25] Cyprus and Denmark are excluded because their experts stated that prescription forms are not used for medical devices. For Denmark: in case the medical device is used to contain a medicinal product, the requirements for prescription forms for medicinal products hold.

[26] This table not filled out for Denmark and Cyprus since no prescription forms are required there

		Commonly added: 2
Identification of the medical device		
General product description	6	Not mandatory: 8 Commonly added: 2
Brand name	10	Not mandatory: 6 Commonly added: 2
Product type	10	Not mandatory: 5 Commonly added: 2
Directions for use	5	Not mandatory: 8 Commonly added: 2
Quantity	9	Unknown: 4 Not mandatory: 1 Commonly added: 2
Compatibility with device	1	Not mandatory: 10 Commonly added: 1 Unknown: 2
Other information		
Indication for prescribing	5	Not mandatory: 9 Commonly added: 1 Banned: 2
Date of prescription	14	Commonly added: 2 Not mandatory: 1
Period that prescription is valid	9	Not mandatory: 7 Commonly added: 1

We also looked for each Member State how many of the items in the proposed minimum set are mandatory or commonly added in current practice (Table 4.5). The currents prescription forms of Estonia and Slovenia are largely in line with the proposed minimum set for cross-border prescriptions. Other countries with relatively many items that match with the proposed minimum set for cross-border prescriptions include Latvia, Lithuania and, Poland, and Spain, and in case commonly added items are considered as well, the Ireland, Sweden, and United Kingdom. Countries where current practice fits worst with the proposed set Austria, Belgium, Germany, Greece, and Hungary.

Table 4.5: Number of items in line with the proposed minimum set of prescription form items per country for medical devices (n=18 countries, proposed minimum set exists of 20 items)

	Mandatory	Commonly added
Austria	6	4
Belgium	6	4
Bulgaria	11	0
Estonia	19	1
Germany	9	0
Greece	9	0
Hungary	8	0
Ireland	1	13
Italy	9	4
Latvia	16	0
Lithuania	15	0
Poland	15	2
Portugal	10	3
Slovakia	13	0
Slovenia	18	0
Spain	11	0
Sweden	14	2
United Kingdom	0	15

In Table 4.6 an overview is given of items and current status in the different Member States.

Table 4.6 Medical devices

	Austria	Belgium	Bulgaria	Cyprus	Czech Rep	Den-mark	Estonia	Finland	France	Ger-many	Greece	Hungary	Ireland	Italy
Identification prescriber														
Surname	M	M	M		M		M	M	M	M	M	M	CA	M
First name(s)/initials	M	M	M		M		M	M	M	M	M	M	CA	M
Profession	M	CA					CA	M	M	M	?	M	CA	M
Work address	M	CA	M		M		M	CA	M		M	M	CA	
Details for direct contact	CA	CA	M		M		M			M	?	M	CA	CA
Signature (written/digital)	M	M	M		M		M	M	M		M	M	CA	M
Identification patient														
Surname	M	M	M		M		M	M	M	M	M	M	CA	M
First name(s)/initials	M	M	M		M		M	M	M	M	M	M	CA	M
Gender							M	M	M		?			
Date of birth	CA				M		M	M	M	CA	?	M		M
Home address	CA		M		M		M		M		?		CA	
Identification medical device														
General product description	CA						M	CA	M	CA	?		CA	
Brand name	M		M		M		M	CA	M		M		CA	M
Product type	M		M		M		M	CA	M		?		CA	M
Directions for use	M				M		M	CA	M		?		CA	M
Quantity	?	?	M		?		?	?	?	M	?		CA	?
Compatibility with device					M		M	CA	M		?			
Other information														
Date of prescription	CA	M	M		M		M	M		M	M		CA	M
Indication for prescribing	M	CA			M		M	M	M		?	M		
Period that prescription is valid	CA	CA					M	M	M		M	M	CA	M

Table 5.6 Medical Devices – continued	Latvia	Lithuania	Luxem-bourg	Malta	Nether-lands	Poland	Portugal	Romania	Slovakia	Slovenia	Spain	Sweden	UK
Identification prescriber													
Surname	M	M	M	M	M	M	M	?	M	M	M	M	M
First name(s)/initials	M	M	M	M	M	M	M	?	M	M	M	M	M
Profession	M	CA	M		M	M	M	?	M	M	M	M	M
Work address	M	M	M		M	M	CA	?	M	M	M	M	M
Details for direct contact	M	M	M	M	M	M	CA	?				M	CA
Signature (written/digital)	M	M	M	M	M	M	M	?	M	M	M	M	M
Identification patient													
Surname	M	M	M	M	M	M	M	?	M	M	M	M	CA
First name(s)/initials	M	M	M	M	M	M	M	?	M	M	M	M	CA
Gender			?		M			?		M			CA
Date of birth	M	M	?		M	M		?		M	M	M	CA
Home address	M	M	?			M		?	M	M			CA
Identification medical device													
General product description		M	?			M	CA	?	M	M	M		CA
Brand name		M	M	M	CA	M	M	?	M	M	M	M	CA
Product type	M	M	?		CA	M	M	?	M	M	M	M	CA
Directions for use	M	M	?	M		CA		?	M	M			CA
Quantity	?	M	M	?	?		M	?	M	M	?	M	CA
Compatibility with device			?			CA		?	?				
Other information													
Date of prescription	M	M	M	M	M	M	M	?	M	M			CA
Indication for prescribing	M		?			B		?	M	M	M	M	
Period that prescription is valid	M	M					M	?		M	M	M	

4.3.3 Problems foreseen by experts in embedding the proposed minimum set

All experts were asked to give their opinion on whether problems would arise for their country in case the proposed minimum set of items would be introduced for cross-border prescriptions. It is important to stress experts were designated by Member States, but did not formally represent Member States. However, for ease of reading we will refer to "countries" instead of "experts designated by countries".

Two countries did not reply to this question. Three countries expect no problems: Austria, Estonia, and Greece. For Estonia this can be explained by the fact that its current prescription form is very similar to the proposed minimum set of items. The two other countries differ more from the proposed minimum set. Two countries expect no problems for medicinal products but do so for medical devices: Denmark and Italy. Denmark has no requirement for such prescriptions and in Italy there is currently not a specific data flow for medical devices. Other countries do expect problems but do not specify which problems they expect; two of these countries (Poland and Lithuania) state that it depends on the final dataset. Community-privately owned pharmacies cannot provide such care for free. The Spanish expert expects problems because, if the proposed minimum dataset for cross-border prescriptions would become effective, Spanish national law should be adapted. Also Sweden refers to conflicts with current national law. First, the information included in the proposed minimum set of items may conflict with legislation on personal integrity or use of personal information in Sweden. This argument is also posed by the German expert. Secondly, in case the INN should be required instead of the brand name this would demand generic prescribing which is not used in Sweden today. While the Swedish expert expects problems when the INN would be required, the Latvian experts foresees problems in case of the brand name would be included as a mandatory item, due to differences in local markets and the concrete brand name availability, as well as because it arises the treatment expenses for patients and state budget. Also the Portuguese expert states that substitution may cause problems in case brand names differ across countries. In the UK problem with substitution are foreseen. UK medicines legislation is based on the principle that the pharmacist dispenses in accordance with the prescription. The UK expert believes that there would be potential risks to patient safety if a medicine prescribed in one EU country could be substituted by a pharmacist in another. In addition, the proposed data set includes items that are addressed by British legislation and as such the UK expert is not convinced they need to form part of the prescription as well. The Irish expert argues that a reasonable lead in time is need before the EU minimum set is introduced since unexpected hurdles will inevitably present along the way. Adaptations take time: existing prescription forms will have to be used up and new revised forms generated and supplied as necessary to prescribers. In addition, legislation to incorporate new prescription writing rules may have to be drafted/ revised. The Irish expert also refers to costs related to the current economic climate: any additional costs for Member States may cause delays. Following the same line of arguing Germany says that any new item will increase bureaucratic burden of doctors that has to be justified in detail by a concrete benefit precisely quantified. Germany argues that the development of separate "cross border prescription forms" does not seem to be reasonable as it might not be foreseeable at the time of prescription neither for the doctor nor for the patient whether the prescription will be used in the home country or another country. Therefore the question should be, whether it might be possible to include additional information in the national standard prescription forms rather than introducing a general prescription form. Some items cannot be complied with, according to the German expert, Items such as "Dosage regimen or directions for use" or "Intended duration of use" for example, cannot be followed in case of more complex therapies. Finally, Germany foresees problems because of the fact that albeit some of the included items might be desirable they should not supposed to be mandatory as the potential benefit is uncertain. Therefore, they argue in favour of a reduction of the proposed data set.

4.3.4 Timing

The last question we posed the experts was what, according to their opinion is a realistic time period for embedding the proposed minimum set in national prescription forms. Five countries feel September 2013 is a realistic time to strive for: Austria, Lithuania, Portugal, UK, and Slovenia. Slovenia adds that this holds for the majority of medicinal products, except restricted medicinal products, antimicrobial medicinal products for acute treatment and medicinal product which are allowed to be prescribed by certain specialists. Three countries feel that September 2014 is realistic (Bulgaria, Estonia, Ireland), while another four countries agree on September 2016 (Denmark, Greece, Latvia, Poland). Some of the countries that mention a date add that it depends on the time the final minimum data set for cross border prescriptions will be set and that it depends on the content of the final set. Four countries refer to the fact that the moment of embedding depends on the political decision-making process (Belgium, Cyprus, Italy, Spain). Germany states that there is no need for having two prescription forms. In Sweden the proposed set would entail an investigation on how generic prescribing could be introduced in Sweden. In addition, other changes in legislation and changes in codes of statues could be needed.

5. Discussion and conclusion

5.1 General Overview

On request of the European commission (DG SANCO) The PRESFORM study has studied the information that is minimally required for a safe use of cross border prescriptions for medicinal products and medical devices in outpatient settings in Europe. The result is the PRESFORM proposal for a minimum data set for cross border prescriptions for medicinal products (23 items) and medical devices (20 items), as displayed in Boxes5.1 and 5.2.

Box 5.1: PRESFORM proposal minimum data set cross border prescriptions - Medicinal products
Identification of the prescriber
Surname
First name (s) or initials
Profession
Work address
Contact details for direct contact
(telephone, fax or e-mail)
Signature (written or digital)
Identification of the patient
Surname
First name(s) or initials
Gender
Date of birth
Home address
Identification of the medicinal product
International non-proprietary name (INN)
Brand name
Route of administration
Quantity
Strength
Dosage regimen or directions for use
Intended duration of use
Composition
(in case of extemporaneous compounding)
Other information
Indication for prescribing
Date of prescription
Period that prescription is valid
Substitution possible (yes/no)

Box 5.2: PRESFORM proposal content minimum data set cross border prescriptions –Medical devices
Identification of the prescriber
Surname
First name (s) or initials
Profession
Work address
Contact details for direct contact
(telephone, fax or e-mail)
Signature (written or digital)
Identification of the patient
Surname
First name(s) or initials
Gender
Date of birth
Home address
Identification of the medical device
General product description
Brand name
Product type
Directions for use
Quantity
Compatibility with device
Other information
Indication for prescribing
Date of prescription
Period that prescription is valid

To come to this proposal different group of experts were consulted in three phases of the study. This group included:

- experts at the national level of most European Member States for the inventory of current prescription practices (phase 1) as well as for the validation and inventory of implication for implementation (phase 3)

- practice based experts in European outpatient settings to reach consensus on a core set of elements (minimum data set) (phase 2)

We feel this combination of steps and different groups of consulted experts provides a unique perspective on current prescription practice and experienced need for information items on cross border prescriptions.

Although we present the result of the PRESFORM study in this report, the set ultimately adopted by the European Commission for implementation will be the result of a discussion with and consultation of stakeholders in the different Member States and at European level, following this study. This proposal can thus be seen a starting point for further debate on the issues surrounding the recognition of cross border prescriptions for medicinal products and medical devices between Member States.
Some issues related directly to the items that were in- or excluded and related issues became apparent, which may be helpful for further discussion of the minimal data set. We will discuss these in the next section.

In this study we also touched on subjects that were outside of the scope of this project, which was constructing the minimum dataset. Our scope was limited because parallel studies are currently underway, such as on factors and possible problems associated with acceptance of cross border prescriptions and e-prescriptions in cross border context. Additionally, this study focuses solely on the *content* of the information needed, while other factors, such as modality, lay-out and design as well as language may also be important in the safe use of cross border prescriptions. Where such issues were mentioned by participating experts however, we have mentioned them in the results sections since these issues will be part of the discussions following this project.
In the following we will first discuss the different categories of the proposal, for this purpose we will jointly discuss medicinal products and medical devices, except where this is specifically mentioned. Next we will discuss implications for implementation, the consultation of patients' organizations, implication for implementation and some limitations of this study.

5.2 Identification of the prescriber

Identification of the prescriber is primarily important for two purposes: firstly for authentication of the prescriber and the prescription and secondly for enabling communication between prescriber and dispenser in case of questions or problems arising. Article 11 of the patient's right in cross border Directive[27] calls upon the Commission to adopt measures enabling a health professional to verify the authenticity of the prescription and whether the prescription was issued in another Member State by a member of a regulated health profession who is legally entitled to do so. In the proposal the following items will help to facilitate such authentication: *first name (s) or initials, surname, profession, work address and signature (written or digital)*.

With regard to signature, we both included "written" or "digital" to facilitate for both written as well as e-prescriptions. However, digital signatures are currently banned in two Member States. Spread of e-prescriptions within the EU currently is still slow and limited to some countries (Mäkinen, 2011). Different types of e-prescriptions were allowed in 5-7 Member States participating in Phase 1. Practicalities of interoperability for e-prescriptions in cross border context are still very much under development and only experimentally piloted locally[28]. However, limiting this item to written signature would not facilitate possible future developments in this area. In the online discussion the

[27] Directive 2011/24/EU/article11/2(a)

[28] E.g. in the Epsos project, see introduction

opinions of participating healthcare professionals on e-prescriptions in the context of cross border care ranged from very positive with mention of benefits for patients safety, to strong apprehension about e-prescriptions because of concerns of patient safety issues. The experience or lack of experience in the originating Member State with e-prescriptions nationally or regionally may play a role in this.

The item *Profession* in the proposed set was combined with the item specialisation where this is relevant for the authorisation to prescribe. This is for instance the case in Member States where not all, but certain groups of physicians, midwives as well as nurses, are authorised to prescribe, either depending on specific specialisation or additional training requirements. For nurses for instance, the number of countries where nurses are allowed to prescribe has risen in the last few years but often not all nurses are allowed to prescribe (Kroezen, 2011) An example is the Netherlands where a change in legislation giving specific groups of specialised nurses authorisation to prescribe certain medication was very recently approved. For authentication purposes information on specialisation where this is related to prescribing authorisation will have to be added to the information on profession. Additional measures may be needed to enable a check of authorisation status for prescribing professionals in case of doubt. Where most of the Member States represented in our consultation in Phase 1 indicated an up-to-date list of professionals with an authorisation to prescribe was available, only just over half confirmed to have this information available for healthcare professionals in other countries. For effective authentication in the context of cross border care introduction of either an European database or central information point for reference to Member States' national databases would be an improvement to current possibilities in this respect.

For the purpose of enabling direct communication between prescribing and dispensing healthcare professionals the item *Details for direct contact* was included, which is a combined item for fax number, email address and telephone. In the different consultations it was stressed by healthcare professionals that means for direct contact in case of questions or problems with the prescription is very important for safe dispensing of prescriptions. The Directive itself also mentioned that a prescription should include: *'*elements to facilitate, if needed, contact between the prescribing party and the dispensing party in order to contribute to a complete understanding of the treatment, in due respect of data protection'[29]. A database or reference point for national databases as discussed above may additionally be of help in case such information is not added to the prescription in practice. However, in the online discussion the participating professionals preferred adding information for direct contact with the prescriber on the prescription form for this purpose. Of course, the practicality of contacting prescribers in a cross border context is also dependent on issues of language as well as familiarity with the health service system in the Member State where the prescription originated. For instance, in cross border regions it can be expected less barriers will be perceived for contacting prescribing professionals, than in cases where countries are further apart and where differences in healthcare systems are greater. Differences of perceived professional roles of dispensing and prescribing professionals may also play a role in willingness to contact a prescriber or be contacted by a dispensing professional.

Overall implementation of the items with regard to identification of the prescriber are not expected to give serious problems in the different Member States. Most items are already mandatory or commonly added in most Member States. For details for direct contact, this item (consisting of minimally either email, telephone of fax nr) is not currently mandatory or commonly added in 5 Member States.

[29] Directive 2011/24/EU, Article 11, para. 2 (a)

5.3 Identification of the patient

For Identification of the patient the following items are included in the PRESFORM proposal: *First name or initials, Surname, Gender, Date of birth* and H*ome address*. Identification of the patient is important to verify the right medicine is dispensed to the right person. Additionally, some identification data can also enable extra safety checks performed by dispensing professionals. For example date of birth could also be used for extra checks by dispensing healthcare professionals of age related issues, such as extra checks on dosage, warnings for specific age groups, anticipated age specific drug related problems or expected practical problems with the use of the medicinal product (for instance for the elderly or for children). In respect of patient safety this item was also rated as highly relevant in the consensus study.

Home address is currently included in this proposal. Further suggestions were made by respondents on adding details for direct contact with the patient. However, this item was not included in the consensus study because the inventory of Phase 1 showed that this was neither mandatory nor commonly added in any Member State. Including details for direct contact, however, would enable dispensing professionals to contact the patient in case of errors noticed after dispensing with the medicinal product or medical device, or in case of call-back procedures. This information may be essential in the prevention or mitigation of seriousness of incidents with dispensed medicinal product or medical devices. Alternatively dispensing professionals can also be encouraged to verify this information at the time of dispensing and subsequently document this in (electronic) patient records. A study on documentation of patients in electronic patient records in Dutch community pharmacies showed for instance that patients' telephone number was only recorded in 38 percent of electronic patients records (Floor-Schreudering et al, 2009). For cross-border patients documenting contact details may be of extra importance, because contacting the patient through the prescriber may also be more complicated than in a national context. (*see above*). In the cross-border context documenting mobile telephone numbers or email address which are regularly checked by patients when abroad and at home may be preferable to home telephone numbers.

The item *Gende*r is mandatory or commonly added in only 6 Member States, which means that for implementation this item would be newly introduced in at least 20 Member States. However, the item scored a maximum score in the consensus study for need for inclusion as well as for relevance for both patient safety and identification of the patient.

Overall implementation of the items with regard to identification of the patient are not expected to give serious problems in the different Member States, with the exception of gender of the patient.

5.4 Identification of the medicinal product

Central to the recognition of cross border prescriptions is the identification of the correct medicinal product that has been prescribed. Article 11[30] refers to correct identification of medicinal products (or medical devices) prescribed in one Member State and dispensed in another. In the Directive[31] it is also specifically stated that:

- the Commission shall adopt measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution ;
- the Commission shall consider – inter alia- using the International Non-proprietary Name and the dosage of the medicinal products;

[30] Para. 2 (c)

[31] Article 11, para (c)

- measures should be include to facilitate comprehensibility of information for patients, including an indication of active substance (included in INN) and dosage (article 11 (para 2 (d)).

Items included in this category in the PRESFORM proposal are : *International non-proprietary name, Brand name, strength, quantity* and *form of administration*. In addition the manner in which and for how long a period the medicine should be used are identified by *Dosage regimen/directions for use* and *intended duration for use*). In case of extemporaneous compounding the item composition was added to the proposal.
The *international non-proprietary name* (WHO) is a universal name for a medicine, including the active ingredient of the medicine, while not referring to specific manufacturers or holders of marketing authorisation for a particular product. In the context of prescriptions the *brand names* are the names given to a medicine by its manufacturer and are only related to the medicine specifically produced by this manufacturer. Although in some cases there is only one manufacturer, for many products this is not the case. The same manufacturer can also use different brand names per market, resulting in differences in brand names between Member States. Prescribing by either INN or Brand name or both differs across European Member States. Brand name is mandatory in 20 Member States, commonly added in three Member States, but banned in one Member State (United Kingdom). INN is mandatory in 12 Member States, and commonly added in four. In nine Member States both INN and Brand name are mandatory. In the consensus study INN obtained maximum scores for inclusion, relevance to patient safety, and identification of the medicinal product. Although brand name scored lower than INN, it also scored high in need for inclusion as well as relevance to patient safety and identification of the medicinal product, which is why both were added in this proposal. The discussion related to Brand name and INN is directly related to the system in place in the different Member States for generic substitution, as legislation on this issue differs for the Member States.

Finally for extemporaneous compounding a specific item was included. Although frequency of compounding following a prescription within the cross-border context is expected to be low, impact of errors made with compounding can potentially be quite severe. When a prescription is dispensed, national legislation and guidelines will apply.

Overall implementation of the items with regard to identification of the medicinal product may cause problems, especially with regard to the choice for INN and/or brand name. While some countries only include brand names, other countries do not and in the United Kingdom brand name is even banned.

5.5 Other information

Other information added to the proposal of minimum data set for medicinal products were: *Indication for prescribing, Date of prescription, Period that prescription is valid and Substitution possible yes/no.* Most deviations between the current prescription forms and the proposed set were found for this category of items, specifically for indication to prescribe, period that prescription is valid and substitution possible (yes/no). These three items were banned in at least one Member State and were not often mandatory. *Indication for prescribing* sometimes give rise to discussion about privacy of the patient, however this item is also considered as highly important for inclusion and highly relevant for patient safety. For *period that prescription is valid* it was noted several times that the validity period is not included because this is already laid down in national legislation. However, because of a broad range of different validity periods allowed in the different Member States, this may give rise to confusion in the cross-border context and it may be preferable to mention this period on the prescription.

5.6 Medical Devices

For the proposal for the minimum data set for medical devices the same items for identification of the prescriber and patient are included in the set. For identification of the medical device the following items are included: *General product description*, *Brand name*, *Product type*, *Directions for use*, *quantity, compatibility with device*.

In all phases of the PRESFORM study it became obvious that for medical devices harmonisation is complicated by differences both in current prescription forms used in practice or regulations pertaining to medical devices, as well as in the description of this heterogenic group of products. Compared to medicinal products more deviations were found for current prescription forms for medical devices and the proposed set. Moreover for two Member States no prescriptions were used for medical devices at all. Harmonisation on these issues may be needed before more detailed information can be added to a cross-border prescription. With regard to universal coding or a universal nomenclature systems, although these are in development (such as that of the Global Medical Device Nomenclature) they are currently not in use in practice in healthcare for prescription or dispensing purposes. In the future the use of one universal system for identifying medical devices or aids would be important for minimising errors and incorrect identification of medical devices or aids in a cross-border context.
For the category Other information, only *Indication for prescribing*, *Date of prescription* and *Period that the prescription is valid* are included. (for a discussion of these items see 5.5).

5.7 Overall implications for implementation in Member States according to experts

Main areas mentioned by the experts from the Member States for problems with implementation are problems associated with current national legislation, in particular regarding substitution and indication for prescribing on prescription forms (privacy regulations). In addition, some experts from the national level indicate that they expect problems in implementation of cross-border prescriptions, especially in case many adaptations are needed. In view of danger of more bureaucratic burden for professionals they argue for a reduction of items in the minimum data set. Costs associated with potential adaptations are also mentioned. The added value of developing a separate cross-border prescription form is questioned by one national expert, because physicians will not always know whether or not the prescription will ultimately be used for cross-border care. Finally, some items were considered not viable for more complex therapies (such as dosage regimen and intended duration of use). With regard to timing several of the national experts were not willing or able to comment on a reasonable timeline for adaptation of national legislation because this would have to be the result of political processes in their respective Member State. Of the responding experts five felt 2013 would be realistic, three felt 2014 would be realistic and a further four felt 2016 was realistic.

5.8 Limitations of the study

In Phases 1 and 3 experts designated by all 27 Member States were given the opportunity to respond. Not all have chosen to do this. Some only responded in either the first phase (Inventory) or the third phase (validation of data) and three did not respond at all. We were able to cross-check (but not validate) most data for non-responding Member States using available reports, with the exception of Romania and (partly) Luxembourg. Language problems could have played a part in the non-response of five Member States in the Phase 1 and seven Member States in Phase 3, as questionnaires were only provided in English. Some remarks were made on the fact that no translated questionnaire was

available, in all three phases. Possibly some terms and definitions used were also less clear for some respondents as a result of this.

Response was lagging for the consensus study (Phase 2) as well. Using two waves of data collection we were able to lift the response from 21 in the first wave to 90 healthcare professionals, where we aimed for 100. The choice for two waves caused that the results document, which was a starting point for the online discussion was based solely on the summaries of the result of the first group. The results for all 90 respondents resulted in higher scores for several items than displayed in this "results document", resulting in higher inclusion scores for several items that were categorized "under discussion" based upon the results of the first wave only. This may have had an impact on the activity level of the online discussion, which may have been higher if less discussion points had been added. However, with three consultations and the opportunity for participants to add comments and remarks in all steps we feel we have gotten a sufficient clear result to base our proposal on.

The complexity of the issues involved in needed information on cross-border prescriptions and perhaps little practical experience in practice may have also impacted a lag in response. With a few exceptions (for instance in Malta), respondents noted that they saw few cross border prescriptions in daily practice. The active involvement later on of two organisations with a specific interest in primary care and clinical pharmacy in Europe (and as such perhaps a better grasp of these complex issues) was very successful in increasing the response. The complexity of the issues and lack of expertise was also named as a primary source of non- or part response of the consultation of patients' organizations.

5.9 Concluding remarks

On the basis of this study we propose a minimum data set of 23 items for medicinal products and a minimum data set of 20 items for medical devices for cross border prescriptions. For a large part of the proposal we expect little problems with implementation for most Member States, especially those where in most countries items are already part of current prescription forms or are commonly added in practice. Items referring to the identification of the prescriber in both proposed minimum data set are for instance mostly in line with current practice in most Member States. Most deviations between the proposed minimum data set and current practice are found for the category *other information for medicinal products*, for instance for items such as *Indication for prescribing* and *Substitution allowed*. In addition current prescription forms for medical devices deviate more from the proposed minimum data set that those for medicinal products. In some Member States separate prescription forms for medical devices do not even exist at the moment. Although for some countries the current proposal could be implemented with no or little changes to current practice, for some countries substantial changes will have to be made for implementation of this set, mainly because at the moment little information is included on the prescriptions. However, we feel that given the results of this study implementing this proposed minimum data set will aid the safe use of cross-border prescriptions for patients in Europe. Monitoring the impact of changes in prescription practices in Europe is essential however, to ensure this assumption is justified or whether adjustments are needed.

Literature

Busse R, Van Ginneken E, Wörz M. Access to healthcare services within and between countries of the EU. In: Wismar M, Palm W, Figueras J, Ernst K, Van Ginneken E (eds). Cross-border Healthcare in he EU. Mapping and analysing practices and policies. WHO, on behalf of European Observatory on Health Systems and Policies, 2011, p 23-46.

European Commission. Cross-border health services in the EU. Analytical report (Flash Eurobarometer Series No. 210). Brussels, European Commission Directorate General Communication, 2007.

Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR. The RAND/UCLA Appropriateness Method User's Manual. RAND CORP Santa Monica CA, 2001

Hämäläinen R-M, Koivusalo M, Ollila E. EU Policies and Health. Themes from Finland 1/2004. National Research and Development Centre for Welfare and Health. Helsinki, 2004.

Hermans H. Cross-border healthcare in the EU: recent legal implications of “Decker and Kohll”. J Eval Clin Pract 2000;6(4):431-9.

Legido-Quigley H, Glinos IA, Walshe K, Van Beek B, Cucic C, McKee M. Quality and safety. In: Wismar M, Palm W, Figueras J, Ernst K, Van Ginneken E (eds). Cross-border Healthcare in he EU. Mapping and analysing practices and policies. WHO, on behalf of European Observatory on Health Systems and Policies, 2011, p 121-159.

Mäkinen M. Delivery of European cross-border healthcare and the relevance and effects of EU regulations and judicial processes with reference to delivery of drugs and blood donor information material. University of Turku, Turku, 2007.

Mäkinen M, Rautava P, Forsström J, Aärimaa M. Electronic prescriptions are slowly spreading in the EU. Telemed Journal of E Health. 2011; 17(3): 217-22.

Sakslin M. Palveluiden ja tavaroiden vapaa liikkuvuus ja sairaanhoitoon liittyvä sosiaaliturva [Free movement of services and goods and social security related to healthcare]. In: Euroopan unionin syventyminen ja sosiaaliturva [Integration of the EU and social security]. Sosiaali-ja Terveysministeriö. Julkaisuja 1999:2, pp. 68-81. Helsinki: Oy Edita Ab, 1999.

Wismar M, Palm W, Figueras J, Ernst K, Van Ginneken E (eds). Cross-border Healthcare in he EU. Mapping and analysing practices and policies. WHO, on behalf of European Observatory on Health Systems and Policies, 2011.

List of Appendixes

I. PRESFORM project team
II. Consulted reports and websites phase 1
III. Questionnaire Inventory Phase 1
IV. Recruitment strategy for phase 2
V. Questionnaire Phase 2 round 1 (in separate PDF)
VI. Results document online discussion phase 2 round 2 (in separate PDF)
VII. Selection of patient organizations
VIII. Questionnaire patient organizations
IX. Discussion document patient organizations

Appendix I: PRESFORM project team

Projectleader:	Liset van Dijk, MSc, PhD(NIVEL/UU)
Co-projectleader:	Prof. Marcel Bouvy, PhD, PharmD (UU/SIR)
Researcher:	Jolanda de Bie, MA, PhD (NIVEL/SIR)
Assistant researcher:	Sanne Snoeijs, MSc (NIVEL)
Advisors:	Prof. François Schellevis, PhD, MD (NIVEL)
	Prof. Cordula Wagner, PhD (NIVEL)
	Remco Coppen, LLM, PhD (NIVEL)
	Chantal Leemrijse, MSc, PhD (NIVEL)

Appendix II: Consulted reports and websites Phase 1

Authors/organisation	Title	Relevance to study
Council of Europe		
Committee of Ministers	Resolution ResAp (2001)2. Concerning the pharmacist's role in the framework of health security. 2001	*Resolution on the role of pharmacists*
Committee of Ministers	Resolution ResAp (2007)1 on the classification of medicines as regards their supply. 2007	*Resolution on the classification of medicines as regards their supply*
EDQM	Survey requirements prescription forms. 2009	*Survey on requirements for prescription forms*
Expert group on safe medication practices	Creation of a better medication safety culture in Europe: Building up safe medication practices. 2006	*Report on medication safety culture in Europe*
European Parliament		
	Directive of the European parliament and of the council on the application of patients' rights in cross-border healthcare. 2011	*Text Directive*
European commission		
Directorate General Enterprise	Medical Devices: Guidance document. 2001	*Guidance document*
Directorate General Information Society	Study on the legal framework for interoperable eHealth in Europe. 2007.	*Study on legal framework for e-prescriptions*
EU funded studies		
EpSOS – European patients Smart open services	Smart open services for European patients. D3.1.2 Final definition of functional service requirements – EPrescription. http://www.epsos.eu/	*Study on functional requirements for e-prescriptions*
HPRO Card	List of the competent authorities for healthcare professional in each EU Member State. 2009.	*list of competent authorities*
HPRO Card	Report on interoperability of different health professionals' authentication systems based on statutory, organizational, semantic and technical criteria. 2009.	*Analysis of interoperability of authentication systems for healthcare professionals*
EUREGIO (LIGA), 2007	Evaluation of Border Regions in the EU (EUREGIO). Final report.	*Evaluation study of cross-border cooperation in Health in EU 25*
Östereichisches Bundesinstitut für Gesundheitswesen	Rational use of Medicines in Europe	*Generic substitution in different Member States*

Other European organisations		
Pharmaceutical group of the EU (PGEU)	PGEU Factsheet E-prescribing and electronic Health records. 2009.	*Factsheet on e-prescribing*
Pharmaceutical group of the EU (PGEU	PGEU Statement. eHealth solutions in the EU community pharmacies: helping to realise professional potential. 2010.	*Policy/viewpoint pharmacists on eHealth and e-prescription*
Pharmaceutical group of the EU (PGEU)	PGEU Policy Statement. Recognition of Cross-Border Prescriptions. 2011.	*Policy/viewpoints pharmacists on cross-borders prescriptions*
Pharmaceutical group of the EU (PGEU)	PGEU Report. Prescriptions in EU. 2011.	*Study reportprescription practices memberstates*
CPME (Comite Permanent des Médecins Européens)	CPME welcomes adoption of cross-border healthcare Directive. 2011	*Reaction to the adoption of the cross-border Directive by physician organisation*
European Patients' forum	EPF's verdict: Cross-border Healthcare. 2011	*Reaction to the apotion of the cross-border Directive by European patients'forum*
World Health Organisation		
	Medical Device Regulations. Global overview and guiding principles. 2003	*Overviewreport on issues related to medical devices*
	Cross-border Healthcare in the EU. Mapping and analysing practices and policies. 2011.	*Study on practices and policies cross-border healthcare*
Relevant other studies		
Groene et al	Quality requirements for cross-border care in Europe: a qualitative study of patients', professionals'and healthcare financiers'views. Quality and Safety, 2009.	*Study on (hospital) cross-border care*
Sunol R et al	Cross-bordercare and healthcare quality improvement in Europe: the MARQuIS research project. Quality and Safety in Healthcare, 2009.	*Study on (hospital) cross-border care*
Mäkinen	Delivery of European cross-border healthcare and the relevance and effects of EU regulations and judicial processes. Thesis Turku University, 2007.	*Study on cross-border healthcare*
Mäkinen et al	Electronic prescriptions are slowly spreading in the EU. Telemed J E Health. 2011 Apr;17(3):217-22.	*Follow up on previous study on spread of electronic prescriptions*
Kroezen et. al	Legal nurse prescribing of medicines in Western European and Anglo-Saxon countries: a systematic review of the literature. Submitted	*Study on Nurse prescribing*

Websites		
Global Medical Devices Nomenclature Agency	www.gmdnagency.org, accessed September 2011	*Database for nomenclature of medical devices, adopted for use in Eudamed*
Eudamed	http://ec.europa.eu/consumers/sectors/medical-devices/marketsurveillance-vigilance/eudamed/index_en.htm	*Database for postmarketsurveilance of medical devices in EU*
Euromedstat	http://www.euromedstat.cnr.it	Database on statistics on Medicines in Europe
EudraPharm	http://www.eudrapharm.eu	
Search strategies in Pub med	Cross border care AND Euro*; Cross border care AND prescription; Cross border AND medic* AND Euro*; Identification AND prescriber; identification AND medic* AND cross border; Prescription AND travel AND Euro*	

Appendix III: Questionnaire 1: inventory prescription practices

This questionnaire was administered as an online questionnaire.
This paper copy contains all the questions asked in this questionnaire, however differences in layout and navigation may influence the interpretation of questions.

Introduction

The identification and development of a core set of medical prescription form items: PRESFORM

Inventory of current prescription practices and experiences in the Member States

Citizens have the right to import or receive a reasonable amount of medicines and medical devices in foreign Member States, obtained lawfully for personal use. Member States vary when it comes to their acceptance of medicinal products and medical devices provided to their citizens in other countries. Harmonisation and standardization of prescription forms for medicinal products and medical devices
within the EU is a necessary first step to guarantee the quality and safety of medical treatment in all EU Member States.

The objective of this PRESFORM project is to contribute to the development of a non-exhaustive list of elements to be included in prescription forms for medicinal products and medical devices issued in EU Member States in order to facilitate effective mutual recognition of prescriptions among EU Member States in respect of patient safety.

The PRESFORM project will focus on prescriptions for medicinal products and medical aids or devices as dispensed in outpatient settings. Prescriptions for medicinal products subject to special medical prescription* are excluded from this study. Unless specifically stated, all questions concern prescriptions for medicinal products or medical aids or devices NOT subject tot special medical prescription.

We estimate that filling in the questionnaire may take from 40 minutes to an hour.

We appreciate the time and effort taken to fill in this questionnaire. Please proceed or move forward in the questionnaire by using the next and previous buttons. Please keep in mind that data will only be recorded after the next button is used. If you so choose you can leave the questionnaire and fill it in at a later time.

** As defined in article 71 (2) of Directive 2001/83/EC: narcotic or psychotropic substance, or the product is likely, if incorrectly used to present an substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes or the medicinal product contains a substance which because of its novelty or properties could be considered as needing precautionary measures for possible misuse for illegal purposes.*

Background
Please specify requested background information

Name:

Educational/professional background:
More than one answer can be given

Medical
Pharmaceutical
Legal
Other:

Organisation:

Department:

Current position in your organisation:

Country :

Formats for prescription forms

In the following section you will be asked to indicate the different prescription forms that are used in your country.

How many different types of prescription forms are in use in your country?

One format (skip to Data items on prescription forms)
More than one format: (number)

What is the basis of the difference between the different formats?
More than one answer can be given

Difference in
Type of medicine
Type of medical device
Type of indication
Patient group
Prescribing professional
Insurance type

Other difference:

Please give a short description of the different formats for prescription forms.
Name format and short description

1.
2.
3.
4.
5.
6.

Data items on prescription forms

In this section you will be shown a number of different data items that could be part of a prescription form for medicinal products or medical devices.

We have differentiated in data items which refer to:

A. Identification of the prescriber
B. Identification of the patient
C. Identification of the prescribed medicinal product
D. Identification of the prescribed medical device
E. Additional clinical information
F. Other items

For this study we are interested to find out which items are:
- Mandatory because of legal requirements
- Banned because of legal requirements
- Needed for reimbursement purposes
- Usually included on prescription forms in practice

In case of differences between the items for different types of formats for prescriptions, please answer with reference to the most generic prescription form.

A Data items for identification of the prescriber

For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*
It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
Initials				
First name(s)				
Surname				
Profession				
Specialty				
Prescriber Identification number				
Contract nr health insurance				
Work address				
Private address				
Identification number institution				
Written signature				
Digital signature				
Telephone				
Fax				
E-mail				
Identifying stamp				

Other (category):

Commentary:

B Identification of the patient

For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*

It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
Initials				
First name(s)				
Surname				
Gender				
Date of birth				
Patient is baby or infant				
Patient is child				
Weight for baby				
Weight for child				
Address patient				
Telephone patient				
Fax patient				
E-mail				
patient Social security number				
Name of insurance company				
Insurance number				
Type of insurance				

Other (category):

Commentary:

C Identification of the prescribed medicinal product
For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*
It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
International Nonproprietary Name				
Brand name				
ATC code				
Holder of the marketing authorisation				
Form of administration				
Strength				
Dosage regimen				
Length of use				
Quantity				
Composition				
Detailed formula				
Article number				

Other (category):

Commentary:

D Identification of the prescribed medical device

For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*
It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
General Product generic name Product brandname Product type Directions for use				
Diabetes care Size (e.g.of needles) Compatibility of or with device				
Astma/ COPD care Type of device Compatibility of or with device				
Stoma care Diameter Material Length of material Compatibility with other medical aids				
Incontinence care Material Size Type incontinence product				

Other (category):

Commentary:

E Additional clinical information

For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*

It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
Indication for prescribing				
Co-medication				
Co-morbidity				
Contraindications				
Renal function				
Allergies of the patient				

Other (category):

Commentary:

F Other information

For each named item please indicate whether this item is mandatory (due to legal requirements), banned (due to legal requirements), added for reimbursement purposes, or usually included (non-mandatory). *More than one answer can be given.*

It is possible to give a short commentary and to list additional data items.

	Mandatory (legal requirement)	Banned (legal requirement)	For reimbursement	Usually included (non-mandatory)
Date of prescription				
Serial number prescription				
Number of country for non residents				
Information generic substitution				
Information repeat prescription				
Validity period				

Other (category):

Commentary:

Is substitution from speciality to generic products by the dispensing professional allowed in your country?

Yes, but only if this is specifically stated on the prescription form

Yes, unless this is specifically excluded on the prescription form

No, this is not allowed without further permission from the prescriber

What is the validity period of a prescription in your country

Number of days:

Is the use of repeat prescriptions allowed in your country?

Yes, for all medicinal products and medical devices

Yes, in general, but exceptions are made for:

No

Short clarification:

Is there a maximum set for:

	Yes	No, Limited to:
The number of medicinal products on one prescription form		
The number of medical devices on one prescription form		
The amount of defined daily doses (DDD) on one prescription form		

Which of the following types of prescriptions are allowed in your country?
More than one answer can be given

Paper prescription (printed)
Paper prescription (handwritten)
Faxed Prescription (printed)
Faxed Prescription (handwritten)
Telephone prescription without written confirmation
Telephone prescription with written confirmation
E-prescription via email
E-prescription via internet
E-prescription via shared electronic patient records
Other:

Can you give an estimate of the percentage of prescriptions that is currently processed using the following types of prescription forms?
%
1 Paper prescription (printed)
2 Paper prescription (handwritten)
3 Faxed Prescription (printed)
4 Faxed Prescription (handwritten)
5 Telephone prescription without written confirmation
6 Telephone prescription with written confirmation
7 E-prescription via email
8 E-prescription via internet
9 E-prescription via shared electronic patient records
10 Other:

Healthcare providers with prescribing authorisation

Which of the following groups of healthcare providers have authorisation to prescribe in your country?

	Yes	No, extending authorisation in preparation	No, no known plans for extending authorisation	Unknown
Physicians	→ answers physician section beneath			
Dentists	→ answers Dentists section beneath			
Midwives	→ answers Midwives section beneath			
Nurses	→ answers Nurses section beneath			
Pharmacists	→ answers Pharmacists section beneath			
Other:	→ answers other section beneath			

Please specify the scope of the authorisation to prescribe for this group of healthcare providers.

Physicians
Is authorisation limited to specific groups of physicians?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?
Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Dentists

Is authorisation limited to specific groups of dentists?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?

Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Midwives

Is authorisation limited to specific groups of midwives?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?

Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Nurses

Is authorisation limited to specific groups of nurses?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?

Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Pharmacists

Is authorisation limited to specific groups of pharmacists?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?

Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Other

Is authorisation limited to a specific group of providers?

Yes, limited to:

No, authorisation for entire group of providers

Is authorisation limited to specific types of medicinal products and/or medical devices?

Yes, limited to:

No, authorisation for prescription of all medicinal products and medical devices

Other limitation of prescription authorisation applicable? (please specify)

Is there a registration or up to date list of qualified providers with prescribing authority?

Yes
No

Please specify

Yes, via telephone
Yes, via e-mail
Yes, via the following website:

Yes, in a different manner:

No, this information is not available

Is information on authorisation status of this group of providers available for dispensing professionals internationally?
Yes
No

Are there known problems in your country, in respect of patient safety, with the dispensing of cross border prescriptions?
Yes
No
Unknown

Please give an short clarification:

The following questions refer to exemptions from regular prescription forms

As defined in article 71 (2) of Directive 2001/83/EC: prescriptions for special medical prescription are used for : narcotic or psychotropic substance, or the product is likely, if incorrectly used to present an substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes or the medicinal product contains a substance which because of its novelty or properties could be considered as needing precautionary measures for possible misuse for illegal purposes.

For what medicinal products is a special medical prescription needed in your country?

Are there other types of medicinal products that should, in respect of patient safety, be exempt from acceptance of cross border prescriptions for dispensing?
Yes
No

Please clarify your opinion

Are there areas that were covered in this questionnaire where you feel additional expert opinion is needed?
No additional expert opinion is needed
Types of prescription forms (if more than one type is used)
Mandatory, banned and additional items on prescription forms for medicinal products
Mandatory, banned and additional items on prescription forms for medical devices
Legal status of different types of prescriptions
Prescribing authorisation for healthcare professionals
Registration of prescribing healthcare professionals and accessibility of information on authorisation status

Please specify and give a suggestion of an additional expert.
(Name affiliation and contact details)

Appendix IV: Recruitment strategy for phase 2

Different strategies were adopted for recruitment of healthcare professionals:

- PRESFORM team members approached their expert contacts working in practice in healthcare, in academia in the field of health services research, primary care, pharmaceutical care or clinical pharmacology, in professional associations or working in academia, with a request for participation or suggestions of names of possible participants.

- Experts in primary care and pharmaceutical care that currently collaborate of have collaborated in the past on research project with NIVEL and-or SIR were approached with a request for participation or suggestion of names of possible participants

- The Institutional members of the European Forum on Primary Care were approached with a request for participation or suggestion of names of possible participants

- Members of the European forum on Primary Care were approached in a number of ways for participation
- All members received a digital newsletter with a short announcement of the study and a direct link to more information and an application questionnaire to participate in the study
- On the Online Linkedin group for European forum for Primary care the same announcement and link was placed under discussions
- Institutional members were approached by email with a request for participation or suggestion of names of possible participants
- Publicly listed individual members were approached by email with a direct link to the online questionnaire

- Members of the World organisation for family doctors WONCA in European Member States that are publicly listed were approached by email with a direct link to the online questionnaire

- Authors of relevant articles on prescribing, dispensing or cross border care in Europe, also working in practice were approached by email with a direct link to the online questionnaire.

Appendix V: Questionnaire phase 2 round 1 : (attached as PDF document)

Appendix VI Results document MOD phase 2 , round 2 (attached as separate PDF)

Appendix VI Selection of patient organizations

Source documents:

- the European patient group directory (http://burson-marsteller.eu/2010/01/european-patient-group-directory-third-edition-2009-2010/).
- The membership list of the EU Health Policy Forum (http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm)

Selection criteria:

The following selection criteria were used:
1. Organisation size; derived from the number of EU Member States represented within the organisation, a cut-of point of 14 EU Member States was used (half if all MS).
2. Disease/disorder type; both organisations aimed at patients in general as well as organizations aimed at patients suffering form specific types of disease/disorders were included. The major diseases indicated as 'the big six' (namely diabetes, asthma/COPD, cardiovascular diseases, psychiatric diseases/disorders, rheumatism and malignant cancer) were included. Additionally an organization aimed at patients suffering from rare diseases was included.
3. Medication/medical devices relatedness; organizations specifically aimed at patient safety were included, as well as organizations aimed at patients with a higher need for medical devices were selected (for example ostomy patients or hard hearing people).

In case of low response, national patients' organizations from the different Member States will be approached additionally.

Appendix VII Structured Questionnaire Patient Organization Consultation

Welcome to the PRESFORM questionnaire

Thank you for participating in the PRESFORM projects. This questionnaire contains questions on the following subjects:

- Background information
- The patient organization you represent
- Cross-border healthcare

At the end of this questionnaire you are also able to add any additional comments.

Filling in this questionnaire will take approximately five to ten minutes.

Getting started

You will enter the questionnaire when you click on the next button on this screen. Your answers are saved each time you click on the next button. In the questionnaire you can move forwards and backwards by clicking on the next or previous button. You can choose to stop and return to the questionnaire at any given time using the link in your email invitation. You will then return to this screen and after clicking next you will return to the questionnaire where the last data was saved. Please fill in the entire questionnaire before the 22nd of July.

Please do not hesitate to contact the researcher via j.debie@stevenshof.nl in case of any questions.

PRESFORM Patient Organization Questionnaire

1. Gender
   - ❑ Male
   - ❑ Female

2. Birth year
   . . . .

3. Highest level of education completed
   - ❑ Elementary School
   - ❑ High School
   - ❑ College
   - ❑ University

4. Professional background
   - ❑ Legal
   - ❑ Medical
   - ❑ Pharmaceutical
   - ❑ Other;

     ……

5. What is your country of residence?

……

6. Please specify which patient organization you represent:
……
……

7. What is your current position within the patient organization?
……
……

8. Please specify the EU Member States from which patients are represented in the/your patient organization;
(*check all that apply*)

- ❑ All 27 Member States

❑ Austria	❑ Germany	❑ Netherlands
❑ Belgium	❑ Greece	❑ Poland
❑ Bulgaria	❑ Hungary	❑ Portugal
❑ Cyprus	❑ Ireland	❑ Romania
❑ Czech Republic	❑ Italy	❑ Slovakia
❑ Denmark	❑ Latvia	❑ Slovenia
❑ Estonia	❑ Lithuania	❑ Spain
❑ Finland	❑ Luxemburg	❑ Sweden
❑ France	❑ Malta	❑ UK

9. Are there national patients organizations represented in the patient organization?
- ❑ This is a national patient organization
- ❑ Yes (please specify the number of organizations)
  ……
- ❑ No

10. Are there individual patients represented in the patient organization?
- ❑ Yes (please specify approximate number of patients)
  ……
- ❑ No

11. Does the patient organization focus on patients with a specific type of disease or disorder?
- ❑ No, we are a general patient organisation
- ❑ Yes, we represent the following patient group(s):

……
……

12. How often do the patients represented by your patient organization have a need for, or encounter, cross-border healthcare in EU Member States?
- ❑ Often
- ❑ Moderately
- ❑ Occasionally
- ❑ Rarely
- ❑ Never
- ❑ Unknown

13. Please specify the subjects related to cross border healthcare that are/might be relevant for patients represented in your patient organization;

(*check all that apply*)

- ❑ Emergency treatment
- ❑ Consultation with general practitioner
- ❑ Consultation with medical doctor/specialist
- ❑ Long-term hospital care
- ❑ Dispensing generic substitutes of medication/medical devices and/or medical aids
- ❑ First dispensing of medication
- ❑ Follow-up dispensing of medication
- ❑ First dispensing of medical devices and/or medical aids
- ❑ Dispensing of repeat prescriptions
- ❑ Unknown
- ❑ Other, namely;

  ……
  ……

14. How often do the patients represented by your patient organization make use of cross-border prescription forms for medication, medical devices or associated medical products?

- ❑ Often
- ❑ Moderately
- ❑ Occasionally
- ❑ Rarely
- ❑ Never
- ❑ Unknown

15. What do you consider main reasons for the use of cross-border care:

- ❑ The cost of medication
- ❑ The accessibility of healthcare
- ❑ The quality of healthcare
- ❑ Travelling due to holiday
- ❑ Travelling due to employment
- ❑ Living in a border region
- ❑ Accident/emergency when abroad
- ❑ Unknown
- ❑ Other, namely;

  ……
  ……

17. Please specify below, what you consider risks or problems that could/might occur with cross-border prescriptions:

……
……

18. If you have any additional remarks, please specify below:

……
……

Appendix VIII Mediated Online Discussion Patient Organization Consultation

1. Cross border prescriptions: when and why do patients use them?
In the questionnaire most patient organizations indicated that the represented patients occasionally or rarely make use of cross border healthcare. One patient organization indicated that their patient group often make use of cross border healthcare.

- In your impression, when and why do patient have a need for cross border healthcare and subsequently need cross border prescriptions?

2. Cross border prescriptions: are there problems?
In the questionnaire some patient organizations indicated that the identification of the medication prescribed could be a problem. Not only because of nomenclature but because of differences in expertise as well. Additionally financing was considered a potential problem.

- Are there currently any problems that your patient group encounters? What do you consider important problems that might occur with cross border prescriptions and what could be a solution for these problems?

3. Safety of cross border prescriptions: to what extend do patients have personal responsibility?

- What personal responsibility do you feel that patients themselves have for the safety of cross border prescriptions? (e.g. contacting their own healthcare provider, providing information on their condition or medication)

4. Comprehensibility of prescriptions: an important issue?

- How important is the comprehensibility of a prescription form for patients? (e.g. readability, lay-out)

5. Information required on cross border prescriptions.
We have asked experts to rate for items whether or not these should be included in a cross border prescription. The following subjects were discussed by a representative in each Member State:
A. Identification of the prescriber
B. Identification of the patient
C. Identification of the prescribed medicinal product
D. Identification of the prescribed medical device
E. Additional clinical information
F. Other information
A score of 9 means that these items should definitely be included, and a score of 1 means that they should definitely not be included. You can find the results document in the background at the top of the discussion points page.

- What is your general opinion? Do you agree with the items that are likely to be included on a prescription form or are there items missing? Are there items specifically important for the patient group you represent?

6. E-prescriptions: what are the possibilities in cross border care?

- What do you think of the possibility of the introduction of e-prescriptions in cross border care?

7. The newly adopted Directive: is it an improvement?
In April 2011 a new Directive on cross border healthcare has been adopted by the European Member States. The new Directive provides clarity about the rights of patients who seek healthcare in another Member State and supplements the rights that patients already have at EU level through the legislation on the coordination of social security schemes. ("DIRECTIVE 2011/24/EU of the European parliament and of the council of 9 March 2011 on the application of patients' rights in cross-border healthcare").

- Do you know this Directive? What is your opinion on this Directive? Is sufficient information on the implications of this Directive available? What do you think about the acceptance of cross border prescriptions as included in this new Directive?

8. Register for prescribing healthcare professionals: a good idea?

- Should there be a public and searchable register for prescribing healthcare professionals in all EU Member States? What would be the benefits and drawbacks?

9.What other comments would you like to make or what discussion points do you miss?