EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Healthcare systems

Report

Public consultation on measures for improving the recognition of prescriptions issued in another Member State

(Article 11 of Directive 2011/24/EU)

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1. INTRODUCTION

Article 11 of the 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 addresses the recognition of prescriptions issued in another Member State.

In Article 11 of the Directive is stated that the Commission shall adopt the following measures:

- "Article 11 para. 2 (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;

- Article 11 para. 2 (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;

- Article 11 para. 2 (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."

In Article 11 para 4 of the Directive it is stated that the Commission shall have regard to the proportionality of compliance costs as well a likely benefits from the above measures which the Commission plans to adopt by 25 October 2012. In keeping with this, an impact assessment is drafted to evaluate various policy options under consideration.

In order to inform the impact assessment, DG Health & Consumers launched a stakeholder consultation: "Measures for Improving the recognition of prescriptions issued in another Member State". This web-based consultation ran between 28 October 2011 until 08 January 2012.

Target groups included were patients, health professionals prescribing medicinal products and/or medical devices, health professionals dispensing prescriptions for medicinal products and/or medical devices, and the medical industry involved in manufacturing and wholesale dealing of medicinal products and/or medical devices are welcome to give their views.

The present document analyses the replies received from respondents to the public consultation.

2. METHODOLOGY

2.1. Question set

The questions, attached at the end of the present report as an annex, concern:

1) Items regarding "patient identification", "prescriber identification", "product identification" as well as "other information" as proposed by the support study SANCO/2010/C5/2010 for the identification and development of a non-exhaustive list of elements to be included in prescriptions. The support study included primarily[1] health professionals, viz. prescribers and dispensers. As such, presenting the item lists from the support study serves not only to (in)validate its findings, but also to enrich them by providing insights from patients and the industry.

2) Issues hampering the recognition of cross-border prescriptions (questions 10-17) as identified from support study EAHC/2010/Health/01/Lot1: Health Reports for the Mutual Recognition of Medical Prescriptions: State of Play. The support study covered a broad sample (some 1,000) of individual pharmacists in seven Member States. As such, gaining a better understanding of the views held by other groups of interest as well by dispensers at the level of organised stakeholders complements the analysis.

3) Questions 38-43 on items possibly improving patient understanding of information in prescription were added specifically with a view to the implementing acts under Art. 11 para. 2 (d) with a view to improved patient understanding of comprehensibility of information to patients.

4) Questions 43-50 on prescriber authentication "tools" were added to directly inform the impact assessment on the relative effectiveness of various authentication tools to improve the recognition of cross-border prescriptions. As such, mainly the dispensers' perspective is of relevance here.

In keeping with support study SANCO/2010/C5/2010 most questions concern scores between 1-9 by respondents to assess the relevance of given items for the (improved) recognition of cross-border prescriptions. Respondents were also given the opportunity to provide additional comments.

2.2. Analysis of replies

2.2.1. Selection of respondents

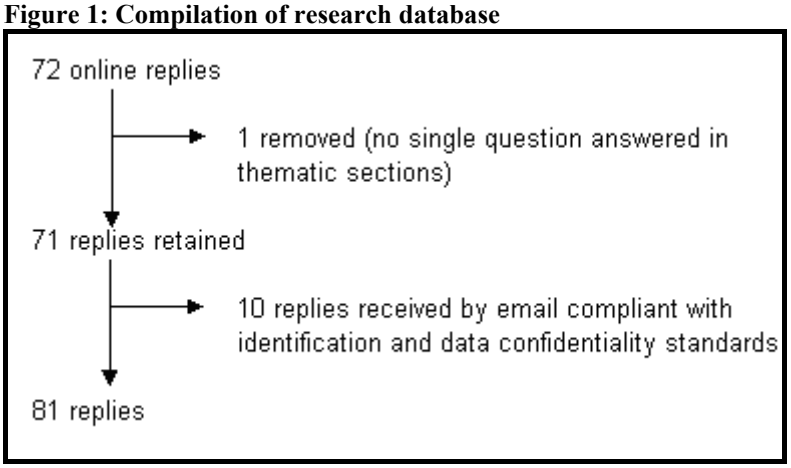
The online survey was filled out by 72 respondents, of which 1 was removed as no questions other than the mandatory respondent identification questions had been answered.

Various other replies were sent by mail. Following further enquiries by email 10 of these respondents complied with necessary information requests on identification and data confidentiality. These replies were added to the research database (81 records, MS

[1] Representative patients' associations were also consulted, but the responses rate was low due to the perceived technical nature of presented issues.

excel® 2003). As such the final research database consisted of 81 respondents (see Figure 1).

Figure 1: Compilation of research database



2.2.2. Presentation of results

All analyses were made with MS excel® 2003.

Scored items (between 1-9 to respectively indicate "least"-"most") are presented in sections 4.1 tot 4.8 below as average scores. When averages for individuals are presented, these are shown with a +/- 2 Standard Error of the Mean (SEM[2]) band. As the SEM is inversely proportional to the number of scores the average is based on, this captures the uncertainty around the average as a result of small sample sizes. Where sample sizes are below 10 individuals, no averages are shown. Scored items are ordered by descending value of related averages in the dispensers' organised stakeholder group where applicable.

Note that the replies by "others" (respondents not belonging to the targeted interest groups) were found to mostly concern public organisation from Member States. Member States are extensively consulted, both informally through designated experts collaborating in the SANCO/2010/C5/2010 support study and formally in the standing committee and related expert groups dealing with the implementing acts in the scope of the public consultation. As such, replies from "others" were not analysed in depth as "others". However, their replies are summarised in an annex attached to this report.

Commentaries, "open label" additions, etc. are presented in a qualitative analysis presenting highlights in section 4.9.

[2] SEM estimated by the sample standard deviation divided by the square root of the number of scores the average is based on.

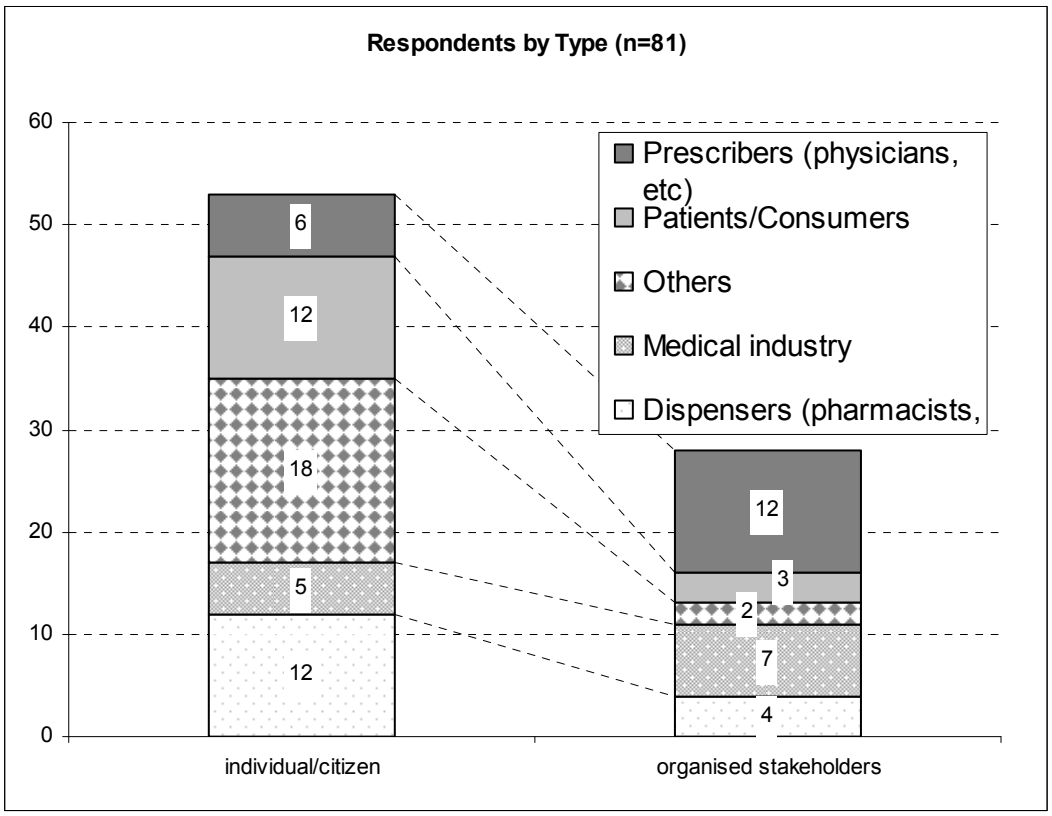
3. RESPONDENTS

The respondents in the research databases are shown below by type and geography. It can be seen that overall numbers are low. As stated above, resulting uncertainty from small sample sizes for individual respondents will be captured by showing a +/-2SEM band along with results.

Note that 22 respondents (mainly in the "others" category) identified themselves as "stakeholders" without referring to an identification number in the Transparency Register[3]. A further two respondents identifying themselves as stakeholders referred to an incorrect identification number. In keeping with European Commission practices these 24 respondents were treated as replying individuals. However, it should be stressed that the true number of individuals having replied is likely to be even lower than shown in Figure 2.

An overview of stakeholders among respondents (except the "others" category) is attached as an annex to this document. It was found that the four targeted consultation groups were sufficiently represented: at least on stakeholder with at least EU-wide coverage and sufficient representative scope (covering all members of target groups in general).

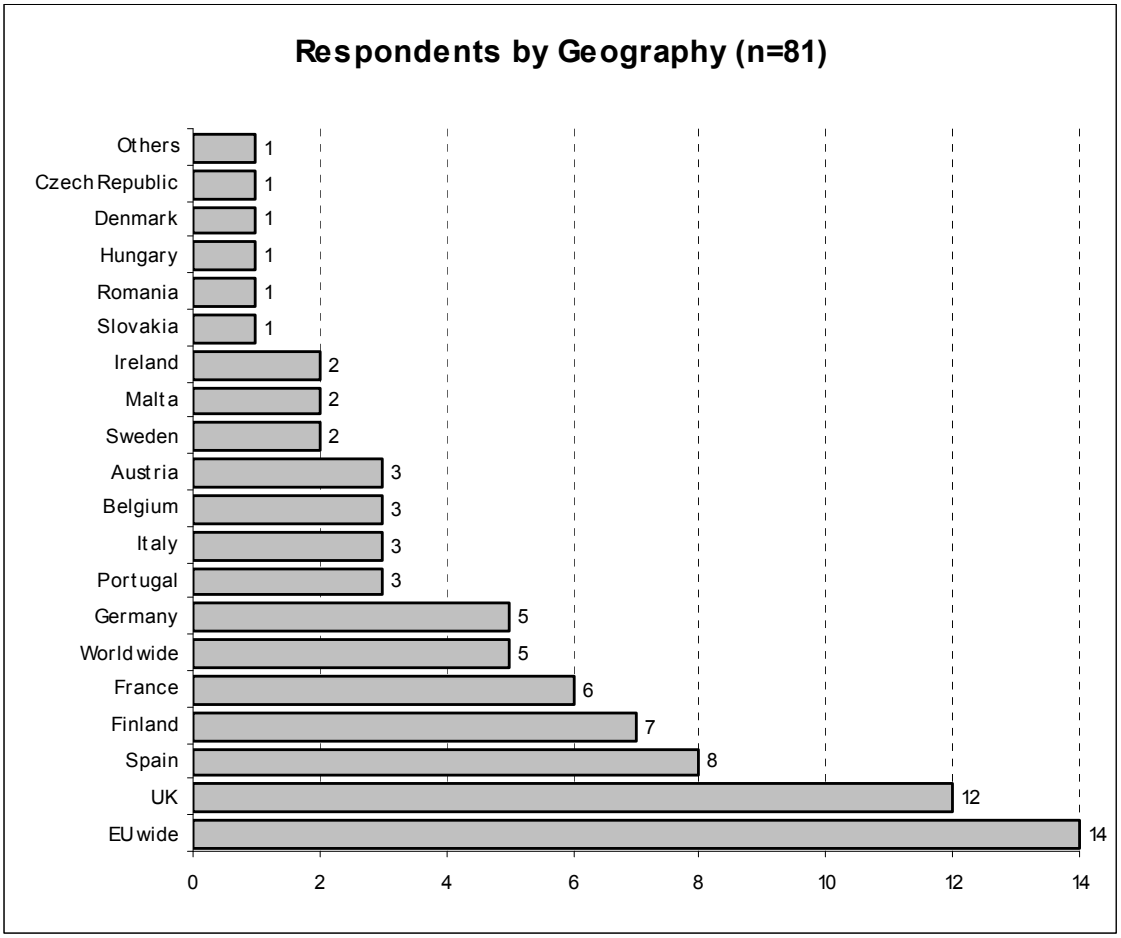
Figure 2: Respondents by type



As regards geographic scope, the most frequently quoted reply was "EU-wide", followed by the United Kingdom. Further, there was a remarkably high number of replies from Finland. One respondent indicated "Others", specifying "Europe, Middle East, Africa".

[3] See http://ec.europa.eu/transparencyregister/public/consultation/search.do?locale=en&reset=

Figure 3: Respondents by geography



4. RESPONSES

4.1. Issues in the recognition of cross-border prescriptions for dispensers

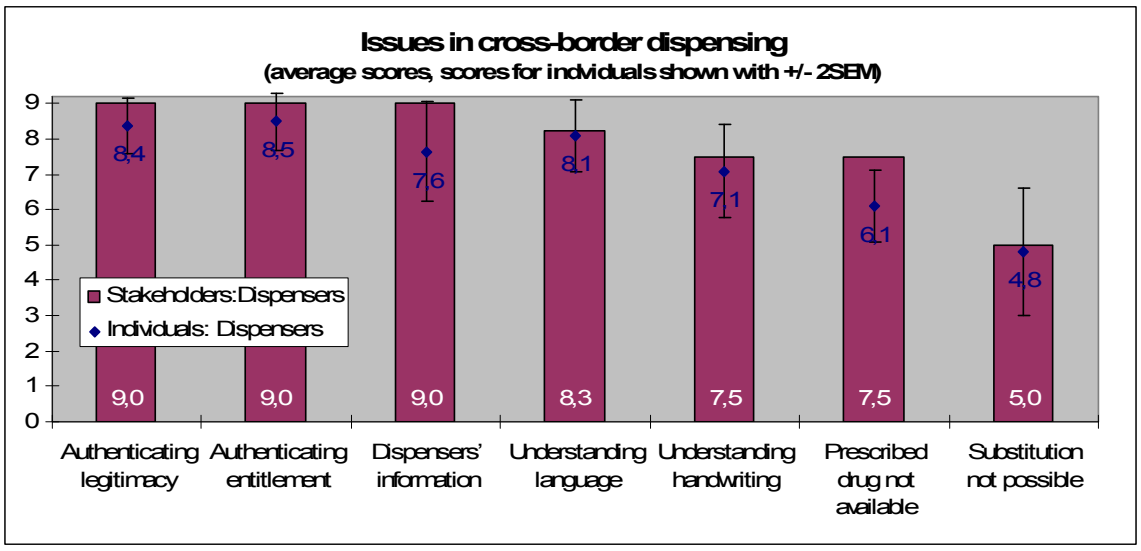
Replies shown below concern dispensers (mainly pharmacists) as this consultation target group makes the actual assessment of the (non-)dispensing of cross-border prescriptions. Figure 4 indicates that:

- Three issues are seen as sure to cause problems. These issues have to do with the authenticity of the cross-border prescription, the entitlement of the cross-border prescriber and the absence of certain items on the prescriptions. As such, these issues are likely to be covered by the implementing acts under consideration.

- Additional issues, however, are also expected to lead to the non-dispensing of cross-border prescriptions. These have to do with understanding the (foreign) language on a prescription and the unavailability of a prescribed product. The latter issues are not covered by the implementing acts under consideration.

Overall, average scores between organised stakeholders and individual dispensers appear to broadly be in line with variance in scores from individual dispensers increasing for items with lower average scores.

Figure 4: Issues in cross-border dispensing



Respondents formulated further comments further specifying the presented issues and not suggesting additional issues.

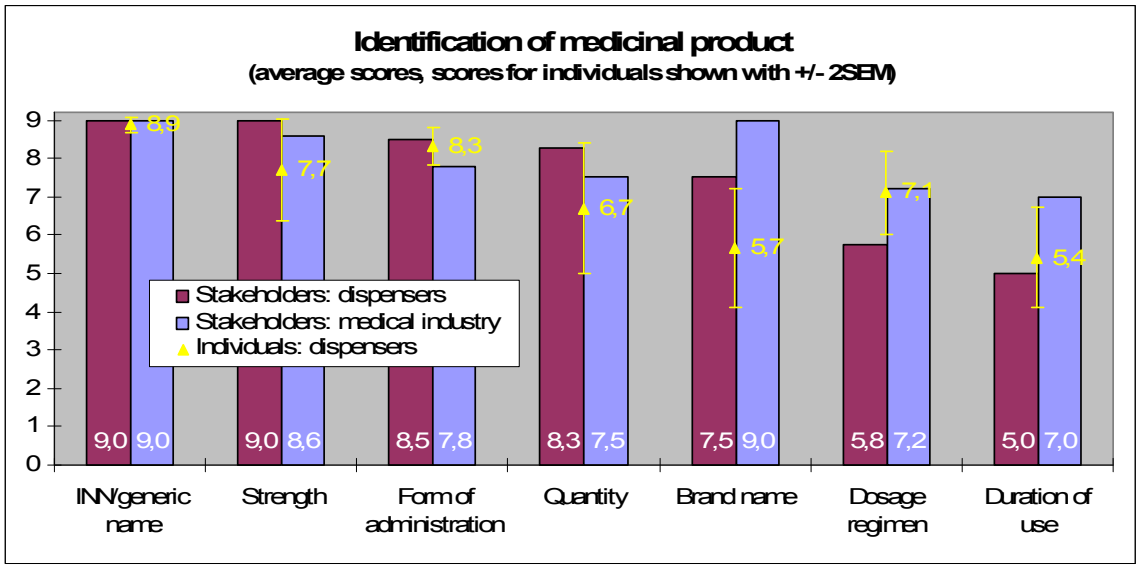
4.2. Identification of medicinal products

Below replies include those by dispensers and the medical industry as both groups are most concerned either as a dispenser having to identify a product or as the producer of said product.

From Figure 5 it can be observed that:

- INN/generic name is seen as the most relevant identifier by all groups, with low variance in scores by individuals.
- Some variability between groups is noted for scored items "strength; form of administration, quantity, duration of use" and "dosage regimen". This may be due to the fact that there is semantic overlap between some of the items. The item sets were taken from the SANCO/2010/C5 support study which was based on an open ranking method and as such did not preclude possible redundancies.
- Strikingly, brand name is ranked as high as INN/generic by the medical industry, an assessment not shared with dispensers.

Figure 5: Identification of medicinal products



"Therapeutic formulation" (pill, solution, etc.) and "use of electronic aids / bar codes" were mentioned as possible additional identification items. Further comments concerned elements that were part of the "other information" question set (see 4.8).

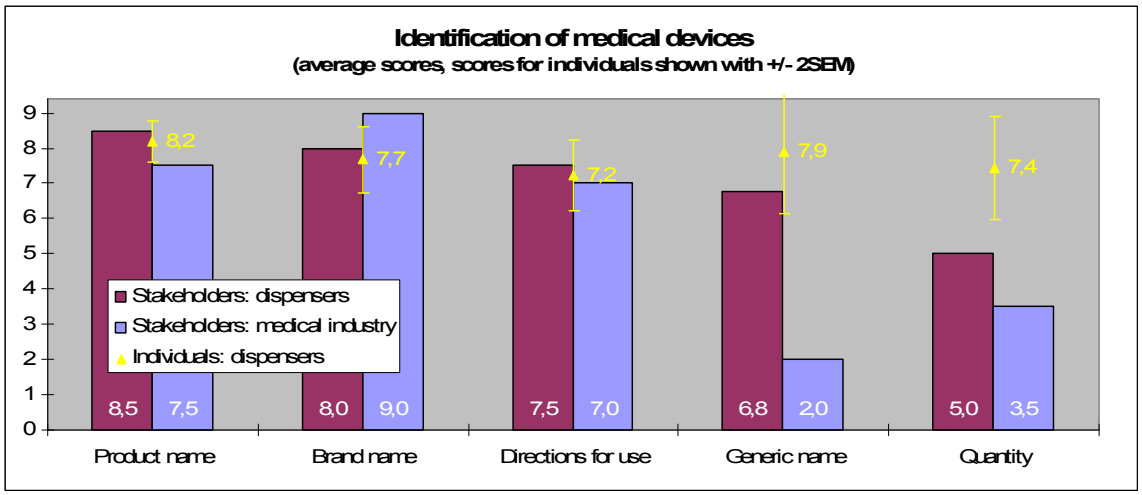
4.3. Identification of medical devices

Below replies include those by dispensers and the medical industry as both groups are most concerned either as a dispenser having to identify a product or as the producer of said product.

From Figure 6 it can be observed that:

- "Product" and "brand name" as well as "directions for use" are seen as relevant identifiers for medical devices by all groups.
- "Generic name" and "quantity" are scored markedly lower by the medical industry and high variance in scores received from individual dispensers.

Figure 6: Identification of medical devices



"Bar codes" were mentioned as a possible additional identification item. Further comments concerned elements that were part of the "other information" question set (see 4.8). Overall, comments seemed to indicate that, given wide variety of possible medical devices, no general assessment could be made, specific product examples would be due.

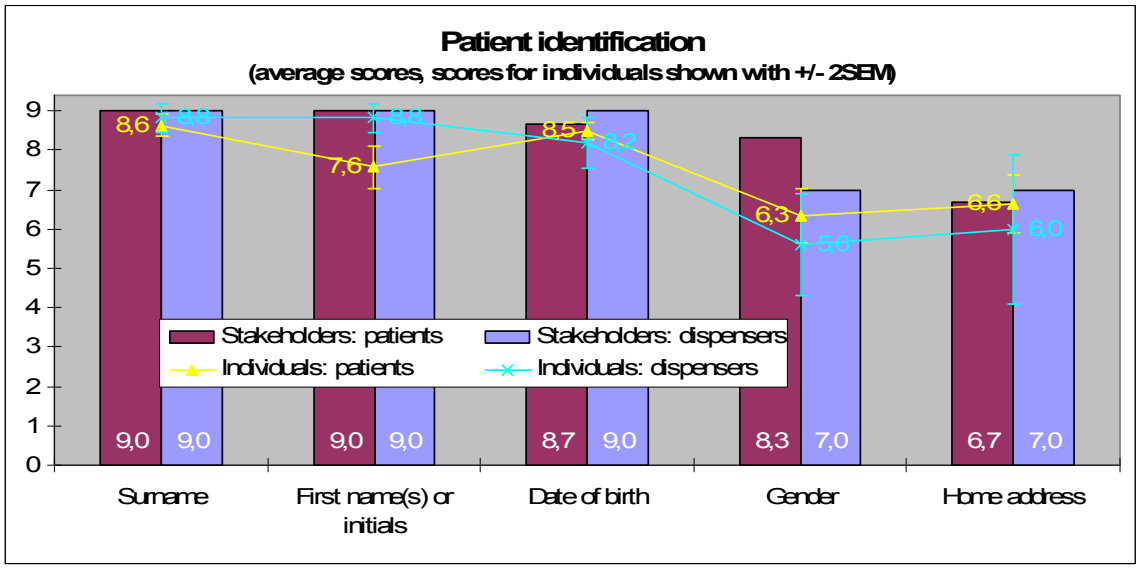
4.4. Identification of patients

Below replies include those by dispensers and patients as both groups are most concerned either as a dispenser having to identify a patient or as the patient him/herself.

From Figure 7 below it can be observed that:

- Three items (surname, name and date of birth) are ranked as most relevant by all groups;
- Gender and home address are ranked lower by all groups (with large variance in answers from individual dispensers as regards "home address", scored by 11 pharmacists).
- The variance in scores is higher for individual pharmacists than for individual patients (both groups being equal in size).

Figure 7: Patient identification



Additional comments suggested a patient identification number / EHIC card as useful identification means. Further elements suggested included patient contact details other than "home address" which is seen as less relevant for patients abroad (phone number, etc.)

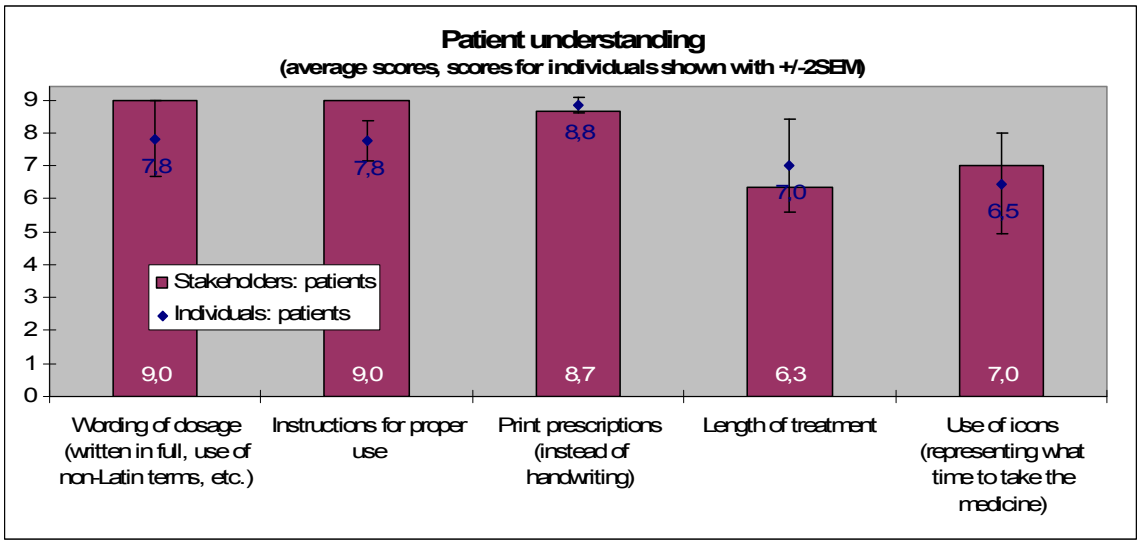
4.5. Improved patient understanding

Patients were asked about which elements would most improve their understanding of the information on prescriptions.

From Figure 8 it can be seen that:

- Three items are ranked as most relevant by organised stakeholders and individuals: wording of dosage (which may actually contradict better understanding by pharmacists of for instance Latin terms), instructions for proper use and print prescriptions. The latter is not within the scope of the implementing acts under consideration.

Figure 8: Items contributing to better patient understanding



Additional comments pointed to the usefulness of investigating how a link between the prescription and leaflets, etc. could be improved.

4.6. Prescriber authentication

Prescriber authentication "tools" as scored by prescribers themselves and dispensers are shown below.

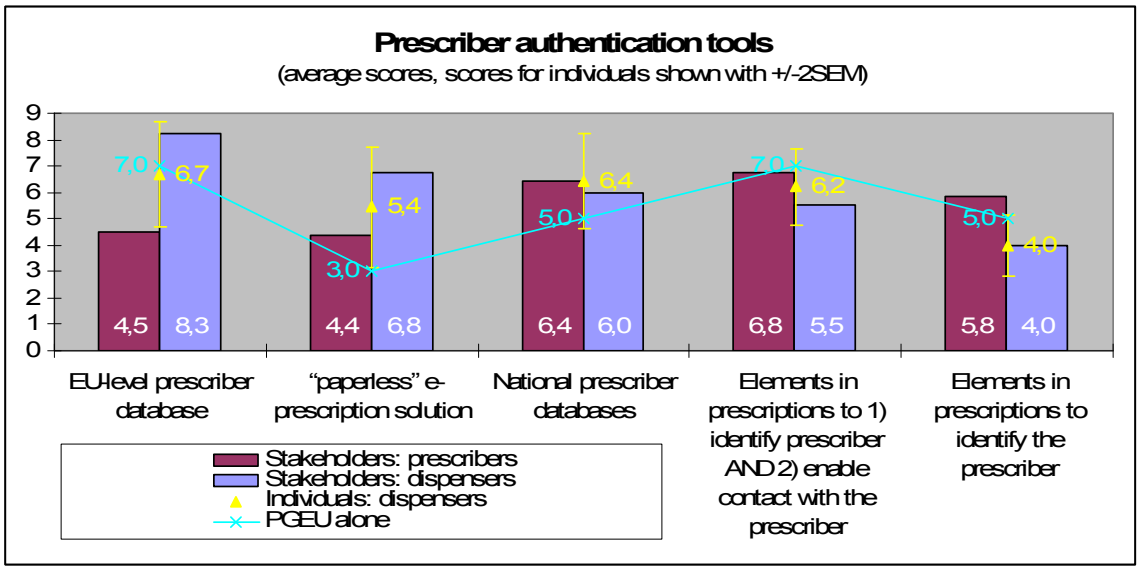
From Figure 9 it can be observed that:

- Overall, prescribers and dispensers as organised stakeholders appear to have opposite views on how to ensure prescriber authentication (correlation of -0,64 for scores between both groups).

- On closer examination it appears that the specific scores attributed by Pharmaceutical Group of the European Union (PGEU), the organised stakeholder for pharmacists with the widest geographic scope[4] are more in line with prescribers (correlation of 0,36).

- The main point of distinction between PGEU and prescribers is the EU-level prescriber database and the uptake of contact details in prescriptions seems to be the consensus option.

Figure 9: Prescriber authentication tools



Additional comments raised the potential costs at play related to some options.

[4] Next to the PGEU, pharmacists' associations for Finland, Spain and the UK submitted replies.

The organised stakeholders for each target group that are considered to have the widest geographical scope and the widest target group coverage (e.g. not focusing specifically on one particular type of medical condition) are shown in Table 1.

Table 1: Organised stakeholders for each target group with widest possible geographical scope and target group coverage

Name	Registration number in the Transparency Register.	Group of interest
Phamaceutical Group of the European Union (PGEU)	00086317186-42	Dispensers (pharmacists, etc)
EGA - EUROPEAN GENERIC MEDICINES ASSOCIATION	48325781850-28	Medical industry
EuropaBio - European Association for Bioindustries	1298286943-59	Medical industry
European Federation of Pharmaceutical Industries and Associations (EFPIA)	38526121292-88	Medical industry
BEUC - The European Consumers Organization	9505781573-45	Patients/Consumers
Council of European Dentists	4885579968-84	Prescribers (physicians, etc)
The Standing Committee of European Doctors (CPME)	9276943405-41	Prescribers (physicians, etc)

In Table 2 the scores given to the presented authentication tools by the organised stakeholders in the table above are shown. From these stakeholders only the dispensers and prescribers submitted scores for the prescriber authentication tools. It can be concluded that:

- Stakeholders across the board agree that inserting physician contact details in prescription forms will help the authentication of presrcibers.
- National prescriber database are not perceived as improving prescriber authentication by the PGEU[5].
- The Council of European Dentists indicated it takes cost proportionality into account when scoring the various authentication tools. This may explain the exceptionally low scores given to the EU-level database and the e-prescription solution.

[5] The following comment was received (personal communication by email on 29 February 2012): "From our point of view, because national databases that are held in national language and hosted on the website by national competent authority, it is difficult to expect that a pharmacist will be able to navigate those and given often very limited time during busy pharmacy hours may be extremely time consuming. We would favour a single port of entry (EU database) which we think would be easier for individual practitioners to navigate. In addition using a registration number in the database or other form of ID number to look up prescribers would be a better solution than searching by name."

Table 2: Scores of authentication tool from organised stakeholders (score of 9 = 100%)

Name	"Paper" solutions using elements in prescriptions to identify the prescriber	"Paper" solutions using elements in prescriptions to 1) identify the prescriber. AND 2) enable contact with the prescriber	National prescriber databases accessible to dispensers	An EU-level prescriber database accessible to dispensers	A "paperless" e-prescription solution
Phamaceutical Group of the European Union (PGEU)	56%	78%	56%	78%	33%
Council of European Dentists	56%	67%	78%	11%	11%[6]
The Standing Committee of European Doctors (CPME)	22%	56%	67%	78%	89%

[6] As an additional comment the Council of European Dentists stated "While we support the idea of e-prescriptions, we do not believe that a central repository on prescriber, prescription and patient should be developed at EU level as we believe this measure to be disproportionate taking into account the volume of cross-border prescriptions. Comment related to question"

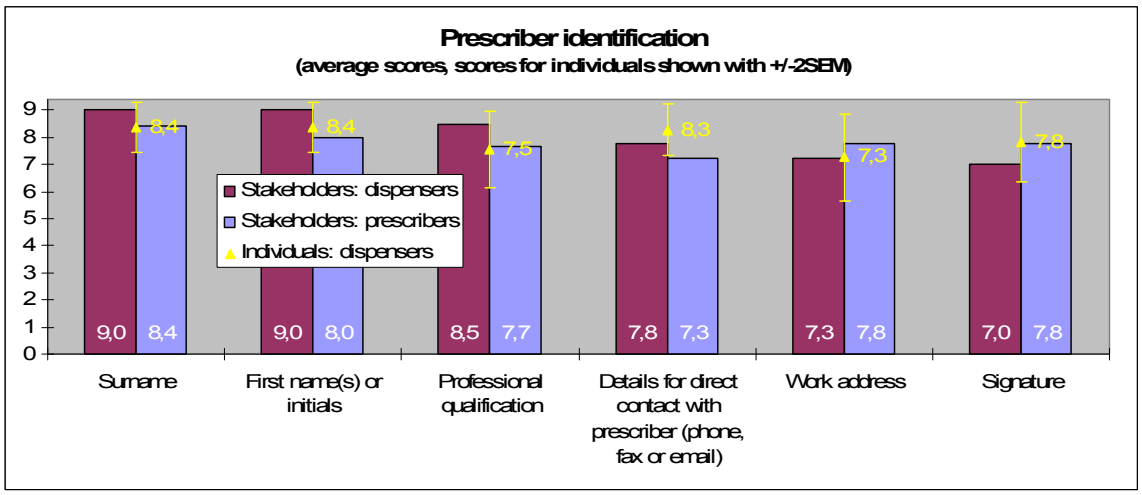
4.7. Prescriber identification

Below replies include those by dispensers and prescribers as both groups are most concerned either as a dispenser having to identify a prescriber or as the prescriber him/herself.

In Figure 10 it can be seen that:

- All items are scored as relevant, with surname and first name ranking first.
- Prescribers appear to attach less importance to contact details in prescriptions than dispensers.

Figure 10: Prescriber identification



The majority of additional comments referred to the use of a unique prescriber identifier code.

4.8. Other information

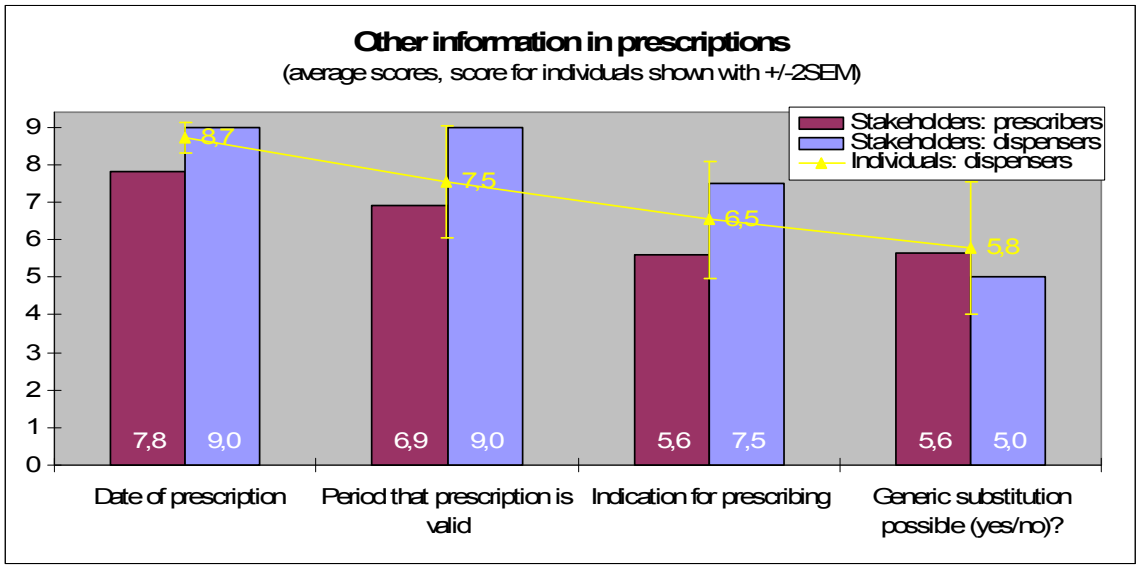
Below replies include those by dispensers and prescribers as both groups are most concerned either as a dispenser having to assess the recognition of a cross-border prescription as the prescriber having written the prescription.

From Figure 11 it van be observed that:

- Groups are in general agreement on the relevance of items: date of prescription and validity period are ranked highest, with lowest reported variance in scores from individual dispensers.

- Generic substitution possible is ranked lowest and scores vary considerably among individual pharmacists for this item.

Figure 11: Other information



Additional comments raised issues with national legislation on generic substitution of drugs as well as possible data protection issues with disclosing indication on prescriptions.

4.9. Other comments

Additional comments were made by 42 respondents, some referring to separate documents that they uploaded. Comments (by respondents agreeing to full data disclosure) are attached as annex to this document.

Main remarks made addressed:

- Issues with prescriptions for medicinal products such as narcotics, psychotropics, etc.

- Recognition of prescribers from another Member State, specifically nurses and midwives.

- Potential role for online databases (prescribers, medicinal products, medical devices) and future ePrescription systems. Often, however, questions were raised about the cost-proportionality of such measures in the context of cross-border prescriptions,

- References to other activities from the European Commission: "Directive on Falsified Medicines", "Directive on Pharmacovigilance", "European Professional Card", "epSOS project (Smart Open Services for European patients)".

Further comments on the items presented for respondent scoring mainly pointed to:

- the role of "brand name" next to "INN/generic name" for the identification of certain medicinal products, in particular biologicals,

- data protection issues associated with items such as "indication",

- Conflicts with national legislation on dispensing for items such as "generic prescription allowed (yes/no)?",

- Suggestions to include items related to the reimbursement of costs for the prescribed product.

5. CONCLUSIONS

The public consultation on the recognition of prescriptions issued in another Member State confirmed certain key findings:

- The implementing acts under consideration will not address all issues at play for the recognition of cross-border prescriptions: understanding of foreign languages by dispensers, difficulty in reading handwritten prescriptions, products not available throughout the EU. However, the main issues appear to be addressed.

- The highest scoring items for the identification of medicinal products, prescribers and patients from the SANCO/C5/2010 support study were confirmed.

It appears certain trade-offs are observed by respondents (as indicated through various additional comments):

- Improved patient understanding (e.g. by avoiding Latin terms) may come at a loss of information for cross-border prescriptions.

- Improved information for dispensers (e.g. reference to diagnosis on prescriptions) may conflict applicable data protection legislation, national legislation on dispensing, etc.

- Fraud-proof prescriber authentication in cross-border context may come at a high cost/administrative burden.

The results of this public consultation both confirmed and deepened the impact assessment work undertaken on implementing measures for the improved recognition of cross-border prescriptions.

Annex: Replies from "others"

Question	Average Score (n=19)
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Authenticating legitimacy	**7,4**
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Authenticating entitlement	7,1
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Understanding language	7,0
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Understanding handwriting	7,8
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Dispensers' information	6,3
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Prescribed drug not available	6,7
Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Substitution not possible	5,4
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Brand name	4,4
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Form of administrtn	8,1
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Quantity	7,4
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Strength	8,2
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Dosage regimen	7,7
Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Duration of use	7,7
Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Generic name	8,4
Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Brand name	4,6
Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Product name	8,1
Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Directions for use	7,5
Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Quantity	6,7
Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Surname	8,5
Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: First name(s) or initials	8,4
Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Gender	6,0
Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Date of birth	7,8
Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Home address	6,0
Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Wording od dosage (written in full, use of non-Latin terms, etc.)	8,1
Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Use of icons (representing what time to take the medicine)	6,1
Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Length of treatment	7,7
Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Instructions for proper use	7,6
Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Print prescriptions (instead of handwriting)	8,2
How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: "Paper" solutions using elements in prescriptions to identify the prescriber such as name, address, qualification, prescriber code etc.	4,7
How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: "Paper" solutions using elements in prescriptions to identify the prescriber such as name, address, qualification, prescriber code etc.	5,1
How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: National prescriber databases accessible to dispensers (e.g. accessed via internet) using information on the prescription as a starting point	7,4
How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: An EU-level prescriber database accessible to dispensers (e.g. via internet) using information on the prescription as a starting point	6,6
How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: A "paperless" e-prescription solution e.g. allowing dispensers to verify information in a central repository on prescriber, prescription and patient	6,9
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Surname	8,4
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: First name(s) or initials	7,9
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Professional qualification	8,2
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Work address	7,3
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Details for direct contact with prescriber (either telephone, fax or email)	7,5
Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Signature	7,9
Which other information is necessary in prescriptions (score 1-9)?: Indication for prescribing	5,5
Which other information is necessary in prescriptions (score 1-9)?: Date of prescription	8,1
Which other information is necessary in prescriptions (score 1-9)?: Period that prescription is valid	8,0
Which other information is necessary in prescriptions (score 1-9)?: Generic substitution possible (yes/no)?	6,3

Annex: Additional comments (only respondents agreeing to full data disclosure)

Group		Additional comments
individual/citizen	Dispensers (pharmacists, etc)	In our opinion especially certain drugs such as narcotics and other psychoactive drugs may lead to problems related to drug abuse and counterfeit presciptions. Some drugs may also require prescription to be stored in a pharmacy or to be written using a special form. Those medicines should be restrained, at least in a national level. How to know the restrictions and rights of the prescribers in another EU-country? Scenario: a medicine is dispensed in another EU-country, with a prescription that would not be valid in the country where it is written. The validity of prescription varies between countires, therefore the validity must be marked on prescription. In our opinion the prescription should be written using brand name. This is needed for the authencity and patientsafety, as the saltform or variety of excipients may influence e.g. on bioavailability and also be potential allergen for some patient. How is ensured that the patient gets the right medicine and enough of information related to the medication when the prescription is in foreign language for the dispenser and the package leaflets are in foreign language for the patient and in worst scenario there are no common language between them? Should the dispenser take the responsibility? The most concerning thing is the patientsafety.
individual/citizen	Dispensers (pharmacists, etc)	make sure all the practical problems involved in actually dispensing such prescriptions in community pharmacy are considered and dealt with before agreeing to proceed with this!
individual/citizen	Dispensers (pharmacists, etc)	This is an impractical proposal which will compromise patient safety, increase misuse of medicines and put profesional at risk as well
organised stakeholders	Dispensers (pharmacists, etc)	A key issues in the ability of the dispensing pharmacist to " authenticate the prescriber " authenticate the prescription " ensure the clinical appropriateness of the item prescribed. " Differences between countries in the way that some medicines are used which may raise concerns for the dispensing pharmacist. Along with authenticating the prescriber, it is also important to authenticate the prescription (to ensure that the prescriber actually prescribed the item). Providing contact details of the prescriber will able the pharmacist to contact the prescriber to verify the prescriptions. Example: a prescription has been presented which contains 3 items, 2 typed and 1 handwritten. The pharmacist would be able to contract the prescriber to ensure that the additional item was written by the prescribed and added by the patient. Although many of the options given would enable authentication of the prescriber, we think this would be at significant cost/burden and not go far enough. The dispenser needs to be able to authenticate the prescription so why incur all the cost of just being able to verify that they are a legitimate prescriber The pharmacist has to balance the professional requirement to do the best for the patient against the legal requirements around accurate dispensing in the UK. If the necessary information to validate the prescription and prescriber is not easily available, they will have no alternative but to refuse to dispense the prescription, with this having consequences for the patient. Language issues between the pharmacist and patient, which may prevent the pharmacist explaining about medicines or why the prescription cannot be dispensed. Further, cultural differneces may make it difficult for the pharmacist to make judgement about the legitamacy of the patient and the pharmacist may not be familiar with drugs/usage/dosage
organised stakeholders	Dispensers (pharmacists, etc)	Recognition of prescriptions is very complicated process, because the regulatory framework in different countries varies a lot. Identification of prescribers rights is an impossible task for pharmacies. It is crucial, that implementation of this directive will not harm patient safety or create new unwanted "business models" in the field of health care.
organised stakeholders	Dispensers (pharmacists, etc)	Please find attached PGEU response to the consultation. We chose not to respond online, due to limited space for comments after each section. In addition, please find PGEU Policy Statement on recognition of cross-border prescriptions.
individual/citizen	Medical industry	In its response, Abbott wishes to only address questions C, and G which are of more direct relevance to research-based pharmaceutical companies which research, develop and manufacture the medicines that are prescribed throughout Europe. C1. Identification of medicinal products Abbott considers most elements to be important to identify a medicinal product. Due to the variability of biologicals and to ensure that products are delivered in accordance with the patients' specific medical needs, biological medicines should only be prescribed by their brand name, and not by their INN, which identifies medicines by their active pharmaceutical ingredients. Abbott would be opposed to a policy of mandatory INN prescribing without reference to the brand name of a medicinal product. In the case of biotech derived medicinal products for example, two biological medicinal products, the reference originator product and the similar biological medicinal products (i.e. products that are similar but not identical to their reference product) that have a similar active ingredient, based on the same amino acid sequence, will often share the same INN but since they are produced using different materials (e.g. cell lines) and manufacturing processes, this may be reflected in a changed side effect or efficacy profile. The same applies to different biosimilar products referencing the same originator product. Unless they rely on the same dossier, different biosimilars referencing the same originator product are also only similar among each other and not identical. Without clear product identification, pharmacovigilance follow-up would be significantly compromised. G1. Other information Automatic substitution is when a

Group		Additional comments
		pharmacist substitutes a generic medicine for the brand name version of the same active ingredient, with no obligation to inform the treating physician. Some countries make generic substitution mandatory under certain conditions, for example where the doctor prescribes by INN. While this may be appropriate for generic small molecule medicines which are identical to their reference product, the siutation is different in the case of biosimilars. A biosimilar is a medicine that is similar – but not identical – to a biological medicine that has already been authorised. Due to the complex way in which biotech-derived medicines are manufactured, biological medicines generally show a higher variability than small molecules which could potentially induce unwanted and even harmful reactions. It is therefore important that any change in treatment is carefully managed by a treating physician in close dialogue with patients, particularly in the case of chronic diseases and long-term treatments. Abbott would recommend that, for the identification of biological medicinal products – including biosimilars – and particularly in the context of the recognition of medical prescriptions issued in another Member States, the following applies: • Add the invented/trade name of biological medicinal products among the list of core elements which must be included in the prescriptions, including those to be used in the cross-border healthcare context; and • Rely on the invented/trade name of biological medicinal products as means (together with the INN) to ensure and/or facilitate the correct identification of medicinal products prescribed, dispensed, or sold in the European Union, including in the cross-border healthcare context. In addition, pharmacovigilance requirements will also need to be taken into consideration, particularly when patients are prescribed a medicine which is not available in their home Member State. Information about the prescribed medicine will need be communicated to the treating physician in the home Member State and pharmacovigilance will need to be conducted and ensured accordingly.
individual/citizen	Medical industry	With regard to section C2 All elements mentioned under C2 are important to identify a medicinal product. Their relative importance would depend on the purpose of the identification and on the product. E.g. brandname is an important identifier but if the brandname between countries differs, the INN becomes an equally important distinguisher. Also, identification for the purpose of pharmacovigilance follow-up or follow-up of product defects requires more details than identification for the purpose of recognizing cross border prescriptions. The different purposes of product identification cannot be separated and should all be taken into account when defining the elements needed on a prescription and subsequent dispensed product. A special situation exists for biologicals, where products with the same INN are similar but not completely identical. For this reason, it is our opinion that when an INN is used, this should always be accompanied by the brandname, to ensure that the products are delivered in accordance with the patients' specific medical needs and to allow robust pharmacovigilance in line with the risk management plan. Moreover, inclusion of the brandname respects any trademark rights associated with the brandname. Furthermore, we would like to refer to the Directive on Falsified Medicines and the Directive on Pharmacovigilance, which both contain provisions related to the better identification of medicinal products. These Directives (and the associated implementation activities) could also provide useful information to assist identification in the context of cross-border prescriptions. With regard to F3 In case of an EU-wide e-prescription, elements under E ("Improving patient understanding of prescriptions") should be made available to the patients separately. The solution chosen should be such that mis-use, which is already a growing problem, e.g. for opiates but also for insomnia drugs, can be countered. On a national level (or regional), alert systems are in place to inform pharmacists on such issues. An internet based EU registry, might need to contain this kind of information (might be relevant for patient identification under D as well). Another factor to be taken into account relates to who might prescribe what. In some countries dentists are allowed to prescribe everything whereas in other countries they are basically only allowed to prescribe antibiotics and analgesics. With regard to G2 Automatic substitution (or generic substitution) is when a pharmacist substitutes a generic medicine for the brand name version of the same active ingredient, with no obligation to inform the treating physician. Some countries make generic substitution mandatory under certain conditions, for example where the doctor prescribes by INN. We would like to underline that generic substitution is not always possible. For example, two biological medicinal products or similar biological medicinal products will often share the same INN but if they are produced using different materials or manufacturing processes, on a molecular level small differences may exist and individual patients may respond differently to the two drugs. A patient stabilized on one product may react differently to another product. It is therefore important to ensure that the substitution of a biological medicinal product by a biosimilar only takes place with the knowledge of the prescribing physician. Therefore it is necessary that the prescription form contains as well contact details of the prescriber so that the dispenser (pharmacist, etc.) can contact the prescriber (physician, etc.) in case of changes (see F.1, second bullet point). Therefore, in the absence of data that demonstrate interchangeability, Merck considers it important to leave the option to the prescriber to indicate whether he/she considers, based on the patients' medical condition, that generic substitution is secure.
organised stakeholders	Medical industry	Automatic substitution (or generic substitution) is when a pharmacist substitutes a generic medicine for the brand name version of the same active ingredient, with no obligation to inform the treating physician. Some countries make generic substitution mandatory under certain

Group		Additional comments
		conditions, for example where the doctor prescribes by INN. Generic substitution is often linked to reimbursement, as some health insurance schemes will only reimburse the patient for the cost of the generic version of a product. Countries that currently allow automatic substitution of biologicals should take the necessary measures to stop this practice in the absence of data that demonstrate interchangeability. Therefore, any change of treatment with a biological medicine should currently only be made under close medical supervision by the physician, with the patient's consent. Until the medicine reaches patient use, biological medicines require specific storage conditions (e.g. to maintain cold chain) that should be communicated to patients by pharmacists or on an additional note to patients. EuropaBio would recommend that, for the identification of biological medicinal products – including biosimilars – and particularly in the context of the recognition of medical prescriptions issued in another Member States, the following applies: • Add the invented/trade name of biological medicinal products among the list of core elements which must be included in the prescriptions, including those to be used in the cross-border healthcare context; and • Rely on the invented/trade name of biological medicinal products as means (together with the INN) to ensure and/or facilitate the correct identification of medicinal products prescribed, dispensed, or sold in the European Union, including in the cross-border healthcare context.
organised stakeholders	Medical industry	Please refer to the attached document.
organised stakeholders	Medical industry	When INN are used, they should always be accompanied by the brand name of the product to ensure that products are delivered in accordance with the patients' specific medical needs. Due to the variability of biologicals, the correct product identification in prescriptions is important. Biological medicines should only be prescribed by their brand name, and not by their INN, which identifies medicines by their active pharmaceutical ingredients. In the case of biotech derived medicinal product for example, two biological medicinal products or similar biological medicinal products (i.e. products that are similar but not identical to their reference product) that have similar active ingredient, based on the same amino acid sequence, will often share the same INN but if they are produced using different materials or manufacturing processes, this may be reflected in a changed side effect or efficacy profile. Without clear product identification, pharmacovigilance follow-up would be significantly compromised. Physician's prior involvement and informed consent should always be included in the decision to substitute a biological medicinal product for a biosimilar, but also switching from a biosimilars to a biological medicinal products. We therefore recommend that healthcare professionals should better be informed about the specifics of biological products and encourages activities and initiatives to this end. Substitution by any other biological medicinal product is subject to consent of the prescribing physician who should record the substitute product in the patient file. Information as set forth in this label can only be warranted for this specific biologic product. Therefore, in order to improve the traceability of the biological medicinal products, the product name should be clearly recorded (or stated) in the patient file and the product should be dispensed to the patient as prescribed by physician. Substitution by any other biological medicinal product is subject to consent of the prescribing physician who should record the substitute product in the patient file. Information as set forth in this label can only be warranted for this specific biologic product. I shoudl also be consider that the directive may allow some illicit process with false prescriptions. Specifically in primary care that might be an issue. Therefore the certification of the prescribers will be key to avoid any illegal business. Patients safety might also be consider in case the prescription cannot be read properly and therefore patients might be delayed or even not have access to the drugs.
organised stakeholders	Medical industry	For med. Devices there are no generic BUT So called "white label" products, which CAN be cheap imports NOT fulfilling quality criteria (i.e. DIN EN ISO 15197*): specifies requirements for SMBG devices, e.g., with regard to system performance, accuracy, and precision. * DIN EN ISO 15197: In Vitro Diagnostic Test Systems– Requirements for Blood Glucose Monitoring Systems for Self-Testing in Managing Diabetes Mellitus (ISO 15197:2003). European Committee for Standardization, Brussels, 2003. File upload: Freckmann Study
organised stakeholders	Medical industry	Similar consideration to those reported in the box C.2 (i.e. Brand name prescription allows immediate identification of the prescribed product; INN-only prescription introduces the risk to dispens a similar, but not identical product) are applicable to the elderly and chronically ill patients who would be at risk - for each prescription - to receive a different product. INN-only prescribing undermines the value of the Brand, which is an instrument for identifying the pharmaceutical company and its products, the outcome of a lengthy and risky process of research, an easily recognizable element and a guarantee for the patient.
individual/citizen	Others	Generic substitution is necessary at EU level because not all brands are available in all MS

Group		Additional comments
individual/citizen	Others	- The prescriber should be informed in case of substitution (consider always to provide feedback) - The prescriber must always allow the change of the route of administration (mainly in case of injectable medicines) - The patient must be aware of adverse drug reactions and should be able to provide information to the pharmacovigilance system - In case of dispensing of injectable drugs, the patient must be informed about the healthcare service that is able to provide the administration of the drug - The patient should be aware of specific storage conditions, if they were different from usual ones - The patient should be aware of expiry date of the medicine after open the recipient (mainly for ophtalmologic drugs)
individual/citizen	Others	very important also to ensure that reimbursement and insurance issues are also included
individual/citizen	Others	The UK is one of the few European countries where nurses and midwives may prescribe following legislative changes. The regulatory standards for nurses and midwives are set out in Standards of Proficiency for Nurses and Midwives Prescribers NMC 2006. There are around 59.000 nurses and midwives in the UK who have recorded their qualification to prescribe with the NMC and who may either prescribe fom a limited Nurse Prescriber Formulary or from the wider British National Formulary. This should be taken into account in any measure developing a EU prescribing rules. We would like to be assured that prescriptions written by an authorised nurse or midwife prescriber in the UK would be recognised in other Member States. Non-recognition could threaten the continuity of care for patients. An EU prescription template could be helpful but it should be supported by robust verification systems to prevent fraud. The existing diversity within Europe with regard to medicines management and prescription rules, as well as in the naming of drugs, their constitution, dosage and availability should be taken into account in any provisions made for the recognition of prescriptions.Inability for professionals to understand a prescription available either in a different language or using different terminology and dosage measures could lead to putting patient safety at risk. We believe that the recognition of cross-border prescriptions should be made via electronic means and shouldn’t involve the recognition of handwritten prescriptions.
organised stakeholders	Others	I have completed the scored questions but please see the attached response for the full NHS response, including textual comments and suggestions.
organised stakeholders	Others	The legal classification status of medications (such as prescription only, over the counter and general sales used in Ireland) for each Member State is a variable that will need to be considered for cross border recognition of prescriptions. Also the issue of payment or reimbursement of medication and devices by Member States may also have significant implications for dispensers and pharmacies, and most importantly the patient. The issue of controlled substances (narcotics) is concerning, again referencing the various schedules of controlled medications based on the medicines legislation and regulations of the Member State. It is suggested that standardisation of terms used for prescription writing also be considered for this current project. For example, elimination of abbreviations in prescriptions. The correct "how-to's for prescription writing should form a part of all health care professionals's education for prescriptive authority. An Bord Altranais has established standards for registered nurse and midwife prescribers for their prescribing practices. Practice Standards and Guidelines for Nurses and Midwives with Prescriptive Authority (2010) details the standards for prescription writing as determined by evidence based practice. The Collaborative Practice Agreement (2007), Decision-Making Framework for Nurse and Midwife Prescribing (2007), and the Requirements and Standards for Education Programmes for Nurses and Midwives with Prescriptive Authority (2007) Guidance to Nurses and Midwives on Medication Management (2007) also published by the Nursing Board provide professional guidance to assist prescribers and other members of the health care team in understanding the regulatory responsibilities of nurses and midwives for prescriptive authority and medication management. An Bord Altranais is aware that other Member States have introduced nurse and/or midwife prescribing of medicines and medical devices. As part of the EU's project for improving the recognition of prescriptions issued in another Member State it is important that the implications of the amendements to the EU Directive 2005/36, particularly the introduction of the European professional card are considered with the expansion of prescriptive authority by health care professionals across the EU. Regular audit of prescription writing and dispensing, inclusive of the clinical decision-making for a patient's plan of care and treatment can also contribute to increase patient safety and practitioner competency particularly with the introduction of cross-border recognition of prescriptions.
organised stakeholders	Others	generic substitution is necessary at EU level because not all brands are available in all member states
organised stakeholders	Others	We think you can consult our experience in the project epSOS (Smart Open Services for European patients. Open eHealth Initiative for a European large scale pilot of patient summary and electronic prescription). And the specific document D.3.1.2. Final definition of functional service requirements-eprescription.
organised stakeholders	Others	Generic substitution is necessary at EU level because not all brands are available in all MS

Group		Additional comments
organised stakeholders	Others	- Wll the prescriptions for "of-label" drugs be done by recipes wich should be expedited abroad? - Classification of narcotics drugs, differences between the countries in EU/EAA?
organised stakeholders	Others	How large amounts of a prescription medicine, that is issued in another Member state, can a patient obtain? Is it meant that he or she can obtain medicines for a longer period of time or just to continue an ongoing medical treatment? There should be an agreement how the pharmacist/dispensers in the Member states write down the amounts of medicines that has been dispensed; otherwise there is a risk that a patient can receive unlimited amounts of medicines with one prescription form. In some countries the pharmacies keeps the prescription but e.g. in Finland the patient normally gets it back. Other critical things should be recorded on the prescription form as well (when the medicine is dispensed, where, who). It would be recommended that all the Member state uses signatures on the medicine packages (a sticker that is attached on the package), were all the important directions for use of the medicine are stated (dosage, indication etc.). It would be recommended that an agreement is made which documents a pharmacist is expected to give to the patient so that he or she later can obtain the reimbursement in his or hers own home-country. When a patient visits a pharmacy in another Member state and receives a medicine it has to be taken into consideration that the leaflet in the package is on another language; a language that the patient does not understand. Patient counseling must be of high quality to be sure that the medicine is used correctly and safety.
organised stakeholders	Others	• There is no central repository of critical information on the medicine; generally we would see this as the Summary of Product Characteristics (SmPC), in all the official European languages of all the products marketed in all of the European states. The European Medicines Agency has this, but only for centrally authorised products. • There is no central repository of critical information on the healthcare professional central to this i.e. the prescriber. Apart from this omission, who can prescribe varies by European state! • The General Pharmaceutical Council (GPhC), the regulator of pharmacists, pharmacy technicians and pharmacy premises in Great Britain, has already commented on the 'health professional card' and indicated its total opposition until regulator authorities share fitness to practice issues across borders. The GPhC has already made this available in the public domain and the Register is annotated where there are fitness to practice issues. We understand that this is not normal practice across the rest of the EU. • We wish to point out that the National electronic Library for Medicines (NeLM) is the largest medicines information portal for healthcare professionals in the UK National Health Service (NHS). NeLM is designed and administered by the e-Communications Team at the London and South East Medicines Information Service based at Guy's Hospital London. It aims to promote the safe, effective and efficient use of medicines. This centre has been designated 'medicines information' centre for the London Olympics, so as well as working with the sports doctors to construct the formulary for the Games, contact has been made with Athens, Barcelona and Sydney with respect to how these countries handled all the medicines issues for visitors to the Games. • The language on labelling/package insert will naturally be for the country in which the medicine is dispensed (leading to the need for further EU legislation). Pharmacists and doctors cannot be expected to be able to translate these details into to all of the official European languages. Telephone translation services are currently available from the East Medicines Information Service, Guy's Hospital London, but this is a major hospital that deals with about 1million patients a year, and therefore a service such as this cannot be expected to be available from a community pharmacist.
individual/citizen	Patients/Consumers	1. English version only Unfortunately only an English version of the questionnaire is provided (even though it is rather short and easy to translate). This might limit responses from patients, one of the prime target groups for a consultaion in the contexts of a directive focussing on patients rights. To avoid the impression that the EC does not really care for the opinion of European citizens (even when patients or consumers or citizens are listed as target groups) it would be helpful to make an effort in the future and provide at least information on the consultation process in all languages, to provide questionnaires not only in Englisch and to invite citizens to comment in the language of their choice if they cannot or do not want to use questionnaires. 2. The questions were focussed on data elements of prescription forms. Assumed business processes and necessary and existing organisational and technical infrastructures were not adressed sufficiently. Examples: - Data fields for identification of medication must be evaluated in the context of information systems for medicines available to prescribers and dispensers - Prescription forms (includinf identification of medication and prescriber)are used in different processes for different purposes: Information for dispenser to ensure correct selection of medication, Information for patients to ensure correct use (in most cases information in separate document is preferrable), basis for reimbursement (for patient or dispenser), archivation for legal reasons. It would have been helpful to state explicitly the indented purposes.
individual/citizen	Patients/Consumers	for medicaments having an autorisation from EMA ,the number of the authorisation given may simplify the understanding of the medicament. For devices the situation may be more complicated, therefore more information is needed. the EU should in paralel ask the gouvernment to instruct better the prescribers concerning ICD. Aspecial attention must be developped toward education of patients (fear for automatic prescription) better participation to the treatment and compliance.

Group		Additional comments
individual/citizen	Patients/Consumers	On the long run only ePrescribing will solve all the problems related to cross-border prescriptions.
organised stakeholders	Patients/Consumers	The cross border prescription works more or less in smaller countries... Finincing/reimbursemet is critical point. Another upgrade could be done in standardised form of prescription in EU and ESPECIALLY initiate at least standard with 3 copies, one for the patient, one for the pharmacy and one for *Health Insurance. Optional could be signature of the patient that he/she took the medicaments.
individual/citizen	Prescribers (physicians, etc)	Since I am working in the diagnosis and treatment of a group of "Orphan Diseases" a correct information is mandatory
organised stakeholders	Prescribers (physicians, etc)	Anthroposophic medicinal products (AMPs) are produced according to anthroposophic pharmaceutical principles and processes, some of which they share with homeopathy and some of which are specific non-homeopathic processes that reflect the interrelationship between human beings and the world of nature. They are manufactured according to the standards of Good Manufacturing Practice (GMP), and their quality is controlled by the criteria and parameters of official pharmacopoeias. AMPs are prescribed in Europe for more than 90 years with well documented effectiveness and safety. AMPs have been on the market in many EU member states under registration procedures that predate EU-legislation. The situation has changed with EU legislation, as the EU Community Code relating to medicinal products for human use (Directive 2001/83/EC and Directive 2004/24/EC) covers only those anthroposophic medicinal products manufactured according to homoeopathic technology or fall within the scope of traditional herbal medicinal products. However, these groups of products represent only a part of AMPs, as in anthroposophic medicine AMPs mainly are used on prescription by a physician, with indications and by any route of application including injections. Due to the nature of anthroposophic medicine as a holistic medical system with highly individualized therapy schemes a broad spectrum of AMPs is necessary, whereas the turnover of the single medical product may be low from an economical point of view. In this respect simplified registrations procedures for AMPs as a group are indicated similarly to homeopathic or traditional herbal medicinal products. The situation for marketing of AMPs inside the EU is, as for every pharmaceutical product in the EU, complicated by the fact that the principle of the EU Single Market is still not extended to the markets for all medicinal products such as AMPs. Therefore, each pharmaceutical product has to be registered one at a time in each Member State in order to be available inside the EU. This is a disproportionate high burden and will prevent free circulation and free choice for the EU patients. Current EU legislation causes significant impact on availability of AMPs across Europe. With the exception of Germany, where AM is defined as “special therapeutic system” [Besondere Therapierichtung] in the Code of Social Law (Sozialgesetzbuch V), and Switzerland, where AM is defined as part of CAM under constitutional law, the legal situation of AMP is unsatisfactory in the majority of Member states. Both problems - the lack of adequate registration procedures for Anthroposophic medicinal products in the Community Code relating to medicinal products for human use (Directive 2001/83/EC and Directive 2004/24/EC) and the obstacles the lack of a Single Market causes for pharmaceutical products in the EU – need to be addressed and resolved by EU pharmaceutical policy. This is significant within the scope of this consultation: Despite the unsatisfactory legal and regulatory situation of AMPs, anthroposophic medicine is broadly used by patients in the EU and provided in 24 hospitals in 5 EU member states and Switzerland (14 of those have Accident&Emergency services, 2 of those are university teaching hospitals), in more than 120 outpatient centres (physician and at least 1 anthroposophic therapist) in 14 EU member states, Norway and Switzerland. Anthroposophic physicians practice in 22 EU member states. Therefore patients travel and cross border medical services of anthroposophic medicine are very common in Europe. This means that patients may be treated in one of the hospitals in Germany, Switzerland, Sweden, United Kingdom or Italy – get prescriptions for follow up treatments and run into difficulties, if they have to renew their prescriptions in Finland, Spain or Holland. Here all the problems addressed above are most likely to occur: 1. The remedy which was prescribed in member state A may not be available in member state B 2. Substitution is most cased not possible for highly individualized anthroposophic therapies 3. The dispensing pharmacy may not have sufficient information about the legal situation of products like AMPs. 4. The purchasing pharmacy in member state B may not have appropriate raw materials available, low level know-how and lack of information to dispense ex tempore prescriptions which were provided in member state A. IVAA therefore calls for an adequate European legislation for all AMPs, i.e. all medical products necessary for the practice of the system of anthroposophic medicine as the precondition for facilitating the equal accessibility of anthroposophic medical services to any citizen in the European Union. Due to the inhomogeneous distribution of anthroposophic medical services across Europe cross border prescriptions are frequent for AMPs. Standardized records for the authentication of the prescriber´s identity, qualification and contact details are welcomed
organised stakeholders	Prescribers (physicians, etc)	We have included our additional comments, in numbered paragraphs 1-35 in the attached MS Word document. Many thanks for the opportunity to comment on the proposals.

Group		Additional comments
organised stakeholders	Prescribers (physicians, etc)	Brand name prescription: 1) allow immediate identification of the prescribed product. 2) avoid the not exactly bioavailability between similar but not identical products. 3) avoid health risk in elderly and chronically patients, who, with INN-only prescription, could get “different” products also. 4) in case of need, for instance if an adverse drug reaction occurs, patients can easily indicate the product at issue. 5) Every product must have its “specific name” to allow the patient to identify specifically what he takes.
organised stakeholders	Prescribers (physicians, etc)	The e-prescription is a tool which improves the security and the quality of the prescriptions. As far as the French Medical Council is concerned, the e-prescription can be described as a service including the following elements: -the prescription dematerialized of drugs, devices, examinations in particular biologics or care provided by a health professional legally authorized to practice. -the secure deposit in a regulated database. -the research of the prescription for its execution -a package of software allowing: the access by identification and authentication of the prescriber the deposit and to find an e-prescription in the database. - to update the statute of execution of the prescription (entirely carried out, partially carried out, to be renewed, etc). -to communicate to the prescriber any risk or anomaly detected during the execution of the e-prescription.
organised stakeholders	Prescribers (physicians, etc)	Comment related to question B.1: Many of the problems in recognition of prescriptions for dispensers listed in this section are not specifically linked to cross-border prescriptions but are just as problematic at the national level. Comments related to question C.1: While quantity is not the most important element in prescription forms contributing to the identification of medicinal products, it is absolutely crucial to include it in prescriptions as a way of avoiding abuse of prescriptions and illegal trade in medicinal products, within or between countries. We consider dosage regimen and intended duration for use to be qualifying elements of the prescription. Comment related to question D.1: Should an EU common system for identification of the patient be developed and put in to practice it is very important that it reflects the cultural variations between the Member States in terms of how names and initials are applied. We do not believe that initials are enough to form the basis for identification. As an example of good practice, the system for identification of the patient in a number of Member States, including Belgium, France and Sweden, is based on the personal identification number. Comment related to question F.2: While we support the idea of e-prescriptions, we do not believe that a central repository on prescriber, prescription and patient should be developed at EU level as we believe this measure to be disproportionate taking into account the volume of cross-border prescriptions. Comment related to question G.1: Please note that including indication for prescribing in prescriptions can sometimes be limited as a result of national privacy protection laws. In the same vein, information about generic substitution depends on national regulation. General comment: Patient privacy is an important element which should be taken into consideration in all further work on prescriptions. For dentists, patient privacy should be respected both on the basis of applicable national legislation and in line with ethical norms of health professionals.
organised stakeholders	Prescribers (physicians, etc)	Die unter D. aufgeführten Elemente "Angabe des Geschlechts" und "Angabe des Geburtsdatums" sind eher unter Sicherheitsaspekten (Arzneimittelsicherheit) wichtig als für die Identifizierung des Patienten. Für die unter F.2 angesprochenen nationalen und EU-weiten Datenbanken wären über verschiedene Stellen (in Deutschland beispielsweise über alle Landesärztekammern) entsprechende Daten zusammenzuführen und regelmäßig zu aktualisieren. Fraglich ist hierbei, ob der zu betreibende Aufwand noch in einem angemessenen Verhältnis zum Nutzen steht. Bei der elektronischen Variante, bei der die Apotheken über einen Server Zugriff auf die Daten der Verordnung des Arztes und des Patienten haben, sind neben Datenschutzaspekten zur Beurteilung auch eine Bewertung des Verhältnisses von Aufwand und Nutzen (Beispiel: Serverkapazität, Pflege) erforderlich.
organised stakeholders	Prescribers (physicians, etc)	The "Consejo General de Colegios Medicos de España" is the competent authority for the safe identification of the prescribing physician: -registration of doctors in Spain -certificate of good standing (electronic/print) -standardization and description of standards for safe print and electronic prescription forms (recognised electronic signature).
organised stakeholders	Prescribers (physicians, etc)	Justification of CPME reply to Question B1: Problems in the recognition of cross-border prescriptions for dispensers: Authenticating the legitimacy of cross-border prescriptions is certainly a potential concern for the patients’ safety as dispensers may become the target of counterfeited prescriptions. CPME supports the inclusion of recognition elements clearly identifiable in all prescription formats across the EU. Allowing contact between the prescribing party and the dispensing party is to be welcome. It should be, however, only a complementary measure (accompanying recognition elements as referred to above) to ensure the authentication of the prescription due to potential limitations based on language reasons. As regards the availability of the prescribed drug on the local market, CPME does not consider this scenario as particularly problematic, as most of the major drugs/medical devices are widely available across the EU. Justification of CPME reply to Question E: Improving patient understanding of prescriptions: CPME understands the ‘wording of dosage (written out in full, use of non-Latin terms, etc) as quite important to contribute to a better patient understanding of what is prescribed (rated 7/9). As regard the ‘Latin terms’, CPME is of the opinion that they should not be completely excluded in case of need. They should be addressed, however, to the dispenser, rather than to the patient. With

Group		Additional comments
		regard to the Commission suggestion to 'use icons (representing what time to take the medicine)', this option have not proved to be helpful for different reasons (e.g. the interpretation of icons used so far has been very subjective, the small size of the icon, etc). CPME believes that full wording to indicate the timing of the intake is preferable. E2. Which other elements could contribute to a better patient understanding of what is prescribed? Complementary information (not always possible to duly indicate it in a prescription, due to different reasons): § Main purpose of the prescription § Particular indications for a concrete patient (e.g. avoid mixing with other medicines, ensure adherence to treatment, indications for chronic treatments, etc) Justification of CPME reply to Question F2: How can prescriber authentication best be guaranteed? (In order of preference, from best to least solution): Option e) 'Paperless e-prescription solution' is in principle the best solution to guarantee the authentication of the prescriber. The main objective of ePrescribing both within Member States and across borders is to improve convenience for doctors and patients, while not reducing patient safety. CPME supports initiatives such as epSOS, which is establishing technical and semantic interoperability in cross-border ePrescribing, and stresses the importance of adequate identification (eID) measures that support security and data protection of identifiable patient data. So far, only several Member States have (partially) implemented these services in their national healthcare systems (i.e. FIN, S, E, I, DK, EL) and several others are about to do so. However, many of them cannot currently communicate with each other. E-prescription will only be widely used if it is trusted by both patients and healthcare professionals. Furthermore, appropriate data protection, system security and performance criteria need to be ensured in any cross border e-prescription application. Options d) 'EU level prescribed database' and c) 'National prescriber database) could also guarantee the authentication of the prescriber. Should the national database be the chosen solution the database should be accessible to prescribers based in other EU Member States. These options, however, might pose some concerns due to patients' data protection. CPME is of the opinion that, in addition to the prescriber database, details about the prescriber (e.g. name, qualification, identification code, etc) should also appear on the prescription.
organised stakeholders	Prescribers (physicians, etc)	This issue has been debated in meetings of European doctors and it has become apparent that the differences in practice among the EU countries represented in such meetings was such that agreement was difficult. For example, the UK prescribes generic medicines to a much greater extent than other European countries. Moreover, some drugs which may be in common use in one country, may not be used in other countries. On balance there are a number of concerns with this proposal: • Transcription errors by the pharmacist • Different trade names of the drugs in different countries • Translation issues for instructions and dosages • Health tourism for prescriptions – some for cost-savings / some for fraudulent reasons • Confusion about charges for scripts in different countries • Concerns about the handling of Personal Identifiable Information
organised stakeholders	Prescribers (physicians, etc)	• Comment D1a+b: As far as included in the EU ID card or passport. • Comment E1a+b: Question E is worded incorrectly: it is not up to the patient to understand the prescription, it is up to the dispenser. Correct: "What elements of the dispenser's instructions for the patient contribute to a better understanding of what is prescribed?" Important for the patient but cross-border issues only if dispenser has to write these instructions on the package • Comment E1c+d+e: Question E is worded incorrectly: it is not up to the patient to understand the prescription, it is up to the dispenser. Correct: "What elements of the dispenser's instructions for the patient contribute to a better understanding of what is prescribed?" Important for the patient but cross-border issues only if dispenser has to write these instructions on the package • Comment F2a+b: Not feasible for actively checking the authentication. • Comment F2e: „Central repository" is not necessary if e-prescription includes a qualified certificate to verify the prescribers authentication. • Comment G1c: If mandatory in member states.• Comment G1d: Depends on type of drug/ social security system. • Questionnaire is ill structured and partly mixes up dispensers' and patients' best interests. Everyday needs in real world practice are neglected. Questionnaire insufficiently distinguishing between what could be helpful in theory (in an ideal EU-world) and in practice. Also disregard of crucial differences between types of drugs where cross-border issues could be important (e.g. a) drugs for chronic use in patients living for longer periods in other countries vs. those for short-term use, b) OTC vs. POM vs. narcotic drugs). Also disregard of the issue of duration of validity of prescriptions (renewable or not renewable) which differs between countries.
organised stakeholders	Prescribers (physicians, etc)	Patients should receive appropriate, safe and cost effective treatment. Substitution is more a financial issue than a medical issue. As generic prescribing is the most exact and safe solution, substitution should not be an issue.

Annex: stakeholders consenting to full data disclosure (excl. "Others" group)

Name	Registration Transparency Register.	Group of interest	Geographical area
Phamaceutical Group of the European Union (PGEU)	00086317186-42	Dispensers (pharmacists, etc)	EU wide
Sirpa Peura The association of Finnish Pharmacies	65416077600-17	Dispensers (pharmacists, etc)	Finland
Consejo General de Colegios Oficiales de Farmacéuticos de España (General Council of Spanish Pharmacists)	86233805607-24	Dispensers (pharmacists, etc)	Spain
Royal Pharmaceutical Society of Great Britain	26683956563-83	Dispensers (pharmacists, etc)	United Kingdom
EGA - EUROPEAN GENERIC MEDICINES ASSOCIATION	48325781850-28	Medical industry	Belgium[7]
EuropaBio - European Association for Bioindustries	1298286943-59	Medical industry	EU wide
European Federation of Pharmaceutical Industries and Associations (EFPIA)	38526121292-88	Medical industry	EU wide
Government Affairs Corporate Law Bldg	18940431725-51	Medical industry	World wide
EMEA/LatAm Roche Diagnostics Deutschland GmbH	18940431725-51	Medical industry	World wide
Robert Bruchet Director, International Public Affairs Pfizer Inc.	4263301811-33	Medical industry	World wide
Johnsons & Johnson (Corporate Government Affairs and Policy Medical Devices & Diagnostics EMEA)	75617941310-89	Medical Industry	
European Federation of Patients' Associations for Anthroposophic Medicine (EFPAM)	28735567576-83	Patients/Consumers	EU wide
BEUC - The European Consumers Organization	9505781573-45	Patients/Consumers	EU wide
Joint contribution from the European Region of the International Lesbian, Gay, Bisexual, Trans and Intersex Association (ILGA-Europe) [Transparency Register ID 11977456675-84] and Transgender Europe (TGEU).	11977456675-84	Patients/Consumers	EU wide
European Council of Optometry and Optics, EUROM I and EUROMCONTACT	03999415319-19	Prescribers (physicians, etc)	EU wide
Council of European Dentists	4885579968-84	Prescribers (physicians, etc)	EU wide
European Glaucoma Society	05697037283-66	Prescribers (physicians, etc)	EU wide
The Standing Committee of European Doctors (CPME)	9276943405-41	Prescribers (physicians, etc)	EU wide
Conseil National de l'Ordre des Médecins/French Medical Council	46314992900-82	Prescribers (physicians, etc)	France
Kassenärztliche Bundesvereinigung	82797211999-77	Prescribers (physicians, etc)	Germany
Bundesärztekammer Berlin Germany	89648243865-50	Prescribers (physicians, etc)	Germany
Federazione Italiana Medici di Medicina Generale (Fimmg) Italian General Practitioners Union	60456307611-13	Prescribers (physicians, etc)	Italy
National Institute of Infectious Diseases	60070063723-48	Prescribers (physicians, etc)	Romania
Consejo General de Colegios Medicos de España	59366517539-54	Prescribers (physicians, etc)	Spain
British Medical Association (BMA)	59537502076-56	Prescribers (physicians, etc)	United Kingdom
IVAA International Federation of Anthroposophic Medical Associations	60399267990-31	Prescribers (physicians, etc)	World wide

[7] "Belgium" indicated by respondent. However, "EU-wide" appears to apply.

Annex: Question List

Export Name	Number	Section	Question
Q A1 name	1	A1	Please, enter your name and, where relevant, the name of the organisation you represent.
Q A2 email	2	A2	Please include also your E-mail address for contact purposes. This is for use only if we need clarification about your response.
Q A3 Ind/stake	3	A3	I am replying as / on behalf of:
Q A4 SH Reg	4	A4	Please enter your registration number in the Transparency Register. It is Commission policy to treat submissions from organisations that choose not to register as individual contributions (see exceptions). Please check the validity of your entry via the search function in the Transparency register — invalid entries will by default be regarded as unregistered.
Q A5 pat/pres/dis/ind	5	A5	Please indicate which group your respresent/belong to (maximum of one choice)
Q A6 med/dev	6	A6	You deal with/have experience with (at least one box to be checked)
Q A7 Other	7	A7	Please briefly describe "others"
Q A8 loc	8	A8	Please indicate your country or, where relevant, the geographical area you represent*
Q A9 CONF	9	A9	We will publish your response, together with your Identity, on the Commission website, where it will be publicly accessible. Though if you request it, publication will be anonymous. Flow would you prefer your contribution to be published, if at ail?
Q B1 Mat Pres	10	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Authenticating legitimacy
Q B1 Mat prescr	11	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Authenticating entitlement
Q B1 Mat lang	12	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Understanding language
Q B1 Mat hand	13	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Understanding handwriting
Q B1 Mat nat	14	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Dispensers' information
Q B1 Mat prod	15	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Prescribed drug not available
Q B1 Mat subst	16	B1	Problems in the recognition of cross-border prescriptions for dispensers (score 1-9):Substitution not possible
Q B2 Other	17	B2	Which other elements could cause problems in the dispensing of cross-border prescriptions?
Q C1 Mat INN	18	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: INN/generic name
Q C1 Mat Brand	19	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Brand name
Q C1 Mat Form	20	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Form of administrtn
Q C1 Mat quant	21	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Quantity
Q C1 Mat stren	22	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Strength

Export Name	Number	Section	Question
Q C1 Mat dos	23	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Dosage regimen
Q C1 Mat dur	24	C1	Which elements in prescription forms contribute to the identification of medicinal products (score 1*9)?: Duration of use
Q C2 Other	25	C2	Which other elements could contribute to a better identifying the medicinal product?
Q C3 Mat Gen	26	C3	Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Generic name
Q C3 Mat Brand	27	C3	Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Brand name
Q C3 Mat ProTyp	28	C3	Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Product name
Q C3 Mat Dir	29	C3	Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Directions for use
Q C3 Mat Quant	30	C3	Which elements in prescription forms contribute to the identification of medical devices (score 1-9)?: Quantity
Q C4 Other	31	C4	Which other elements could contribute to better identifying a prescribed medical device?
Q D1 Mat Surn	32	D1	Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Surname
Q D1 Mat FiNa	33	D1	Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: First name(s) or initials
Q D1 Mat Gend	34	D1	Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Gender
Q D1 Mat DoB	35	D1	Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Date of birth
Q D1 Mat Home	36	D1	Which elements in prescriptions contribute to the identification of the patient (score 1-9)?: Home address
Q D2 Other	37	D2	Which other elements could contribute to a better identification of the patient?
Q E1 Mat dos	38	E1	Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Wording od dosage (written in full, use of non-Latin terms, etc.)
Q E1 Mat icons	39	E1	Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Use of icons (representing what time to take the medicine)
Q E1 Mat Len	40	E1	Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Length of treatment
Q E1 Mat Ins	41	E1	Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Instructions for proper use
Q E1 Mat Print	42	E1	Which elements in prescription forms contribute to a better patient understanding of what is prescribed (score 1-9)?: Print prescriptions (instead of handwriting)
Q E2 Other	43	E2	Which other elements could contribute to a better patient understanding of what is prescribed?
Q F1 Why Pres?	44	F1	What are the main reasons to have clear prescriber identification in prescription forms (minimum of one choice)?
Q F2 Mat paper	45	F2	How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: “Paper” solutions using elements in prescriptions to identify the prescriber such as name, address,

Export Name	Number	Section	Question
			qualification, prescriber code etc.
Q F2 MAT Paper_2	46	F2	How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: "Paper" solutions using elements in prescriptions to identify the prescriber such as name, address, qualification, prescriber code etc.
Q F2 Mat Nat DB	47	F2	How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: National prescriber databases accessible to dispensers (e.g. accessed via internet) using information on the prescription as a starting point
Q F2 MAT EU DB	48	F2	How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: An EU-level prescriber database accessible to dispensers (e.g. via internet) using information on the prescription as a starting point
Q F2 Mat Paperless	49	F2	How can Prescriber Authentication Best to be Guaranteed (score 1-9)?: A "paperless" e-prescription solution e.g. allowing dispensers to verify information in a central repository on prescriber, prescription and patient
Q F3 OtherSol	50	F3	Which other solutions could improve prescriber authentication?
Q F4 other?	51	F4	can you briefly explain "Other" in Question F.1?
Q F4 Mat Surn	52	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Surname
Q F4 Mat FiNa	53	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: First name(s) or initials
Q F4 Mat ProfQual	54	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Professional qualification
Q F4 Mat WorkAddress	55	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Work address
Q F4 Mat ContDetails	56	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Details for direct contact with prescriber (either telephone, fax or email)
Q F4 Mat Signature	57	F4	Which elements in prescription forms contribute to the identification of the Prescriber (score 1-9)?: Signature
Q F5 PresOther	58	F5	Which other elements could contribute to a better identification of the prescriber (optional)?
Q G1 Mat Ind	59	G1	Which other information is necessary in prescriptions (score 1-9)?: Indication for prescribing
Q F1 Mat DoP	60	F1	Which other information is necessary in prescriptions (score 1-9)?: Date of prescription
Q G1 Mat valid	61	G1	Which other information is necessary in prescriptions (score 1-9)?: Period that prescription is valid
Q G1 Mat gen Sub	62	G1	Which other information is necessary in prescriptions (score 1-9)?: Generic substitution possible (yes/no)?
Q G2 Other	63	G2	Which other elements would you add?
Q H1 com	64	H1	Please include any additional comments you might have