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JASEHN
Joint Action to Support the eHealth Network

REPORT

on

The Implementation of ePrescription Guidelines in EU Member States[1]

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Stakeholder Contributor(s):	

[1] Including Norway and Switzerland

TABLE OF CHANGE HISTORY

VERSION	DATE	SUBJECT	MODIFIED BY
0.1	2016-09-09	Basic draft document produced after questionnaire analysis and sent for review to CG and WP partners	Vanja Pajić, Ana Vrančić-Mikić (HZZO)
0.2	2016-10-14	Final draft document produced based on the documents from CG and WP partners	Vanja Pajić, Ana Vrančić-Mikić (HZZO)
1.0	2016-10-27	Approval by sPSC on 27/10/2016 at the sPSC meeting	
2.0	2017-01-30	Formal language and quality check	WP1, WP3

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1. Foreword

The objective of this document is to report on the feedback from the Member State (MS) representatives responsible for the implementation of the ePrescription Guidelines and to identify the barriers to and facilitators of the implementation of these guidelines in Member States. This information is obtained from the questionnaire on the implementation of the ePrescription Guidelines created within the framework of the Joint Action to support the eHealth Network (JAseHN) project. We believe that the results presented in this report will provide a better understanding of the conditions and barriers faced by Member States in the implementation of the guidelines; it will also form a basis for updating the guidelines and establish a roadmap for the future assessment and monitoring of the implementation of the guidelines.

2. Executive summary

This report is based on the answers to questions asked in the questionnaire that was distributed to associated and collaborating partners of the JAseHN. Twenty-seven Member State representatives (excluding Slovakia) and one non-EU Member State representative (Norway) were contacted. The questionnaire was based and focused on implementation of the ePrescription Guidelines in Member States. It was assumed that each country representative was in the best position to evaluate the most suitable response for his/her country.

The aim of the questionnaire was to collect data on the progress and impact of the implementation of the ePrescription Guidelines in Member States and to outline some of the barriers to implementation. Conclusions are based exclusively on the questionnaire results and include the feedback received from JAseHN partners.

3. Introduction

Implementation of the eHealth guidelines was assessed with regard to four interoperability aspects (i.e. levels[2]) in accordance with the European Interoperability Framework (EIF):

1. Legal (Questions 1-5: Information on legal interoperability)
2. Organisational (Questions 6-15: Information on organisational interoperability)
3. Semantic (Questions 16-25: Information on semantic interoperability)
4. Technical (Questions 26-35: Information on technical interoperability)

Member States were asked to answer questions both on the practical aspects of implementation of the ePrescription Guidelines (such as barriers to implementation) and on the factual information regarding the state of implementation.

Out of 29 countries contacted (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia,

[2] The European Interoperability Framework uses the term 'interoperability layer' when discussing the different aspects of interoperability; see more here: http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf

Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovenia, Spain, Sweden, Switzerland and the United Kingdom), a total of 23 countries provided answers to the questionnaire. The countries that answered the questionnaire are Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Norway, Portugal, Romania, Spain, Sweden, Switzerland and the UK. Belgium, Estonia, France, Poland and Slovenia were contacted but provided no answer. There were in total three (3) deadlines for answering the questionnaire – the original deadline and two extensions. After the third extension had passed, we contacted the Member States individually with extended deadlines in order to receive the last-minute questionnaire entries.

The main constraint of this report is its reliance on the questionnaire data gathered from Member States. The conclusions were based on responses gathered from national contact points, consisting of their opinion on matters pertaining to the national and cross-border implementation of the ePrescription Guidelines, and are only a part of the complete picture. That being said, the answers might have been focused on the national capacity for legal, organisational, semantic and technical interoperability, which may or may not have an impact on the cross-border data sharing capability, and thus represent a Member State's subjective opinion.

It should also be noted that some Member States opted to answer most of the questions with 'No' or 'I don't know'. The reason for this could be that the questions were unclear or that there was unwillingness to provide answers on particular aspects of the national ability to share data. It could also be that some of the respondents were not able to answer the question due to its lack of alignment with the current situation within the particular Member State's internal organisation. Other Member States showed willingness for cross-border healthcare data exchange. However, the fact that the prioritisation of eHealth and other healthcare-related projects is still underway is slowing this process down. Another constraint of this report is the tight delivery deadlines and the fact that the questionnaire was conducted during the holiday season.

4. Notes on methodology

As a mechanism for obtaining information and opinions, questionnaires offer a number of advantages and disadvantages when compared to other evaluation tools. In general, questionnaires are effective mechanisms for the efficient collection of certain kinds of information. Although there are also some issues that need to be addressed when using questionnaires for data collection, in that the quality of respondent data is probably not as high as with alternative methods of data collection, such as interviews, there are significant benefits to using questionnaires. One key advantage of using questionnaires to collect data is that they give respondents time to consider their responses carefully without any interference from the interviewer. They are also low-cost, as they can easily be electronically mailed to respondents. Even though the questions need to be both specific and broad, as they need to cover different aspects of a problem and at the same time provide an unambiguous answer, it

is possible to provide questionnaires to large numbers of people simultaneously. Questionnaires provide uniformity because each respondent receives an identical set of questions and they are able to address a large number of issues and cover areas of interest in a relatively efficient way, with the possibility of a high response rate. With closed-form questions, responses are standardised, which can assist in interpreting answers from large numbers of respondents. In this way, the answers are mutually comparable, although they may lack depth and the root cause of the problem may remain hidden. We opted to use a questionnaire as the data collection method due to its high distribution rate, standardisation of answers and ease of analysis.

In this questionnaire, the respondents were asked about their given and family names, the organisation they represent, their role in the organisation and the country to which the organisation belongs. After answering the introductory part containing identification information, the respondents proceeded to the "content" questions regarding implementation of the ePrescription guidelines in their specific country.

5. Report

The following section outlines the results from the ePrescription Guidelines implementation questionnaire. After each question from the questionnaire, a graphical summary of answers is given. As previously stated, the questionnaire was structured in accordance with the European Interoperability Framework and reflects the legal, organisational, semantic and technical levels of interoperability with regard to implementation of the ePrescription guidelines.

5.1. LEVEL 1: Assessing legal preparedness and interoperability

Q1.1 Has your country deployed a national ePrescription system?

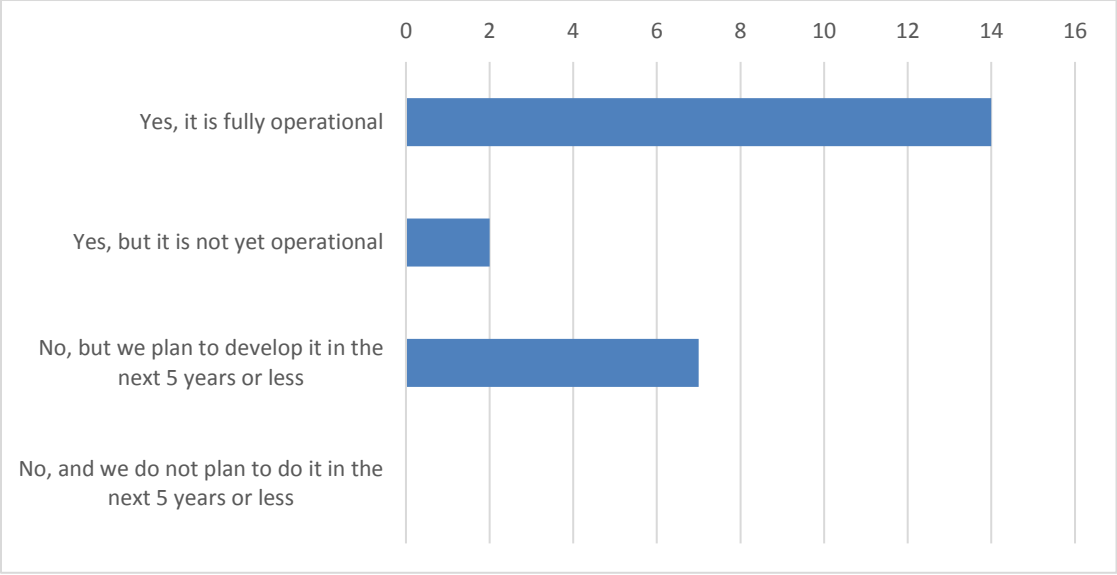

Figure 1. Question 1 on the national ePrescription system

Q1.2 Which procedure is accepted in your national legislation for statutory insured persons with regard to the recovery of costs for issued prescriptions, in the case of prescriptions issued in your country and dispensed in another Member State?

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Q1.3 In your country, is there any specific national legislation on the identification of patients who want to have their prescriptions issued in another Member State?

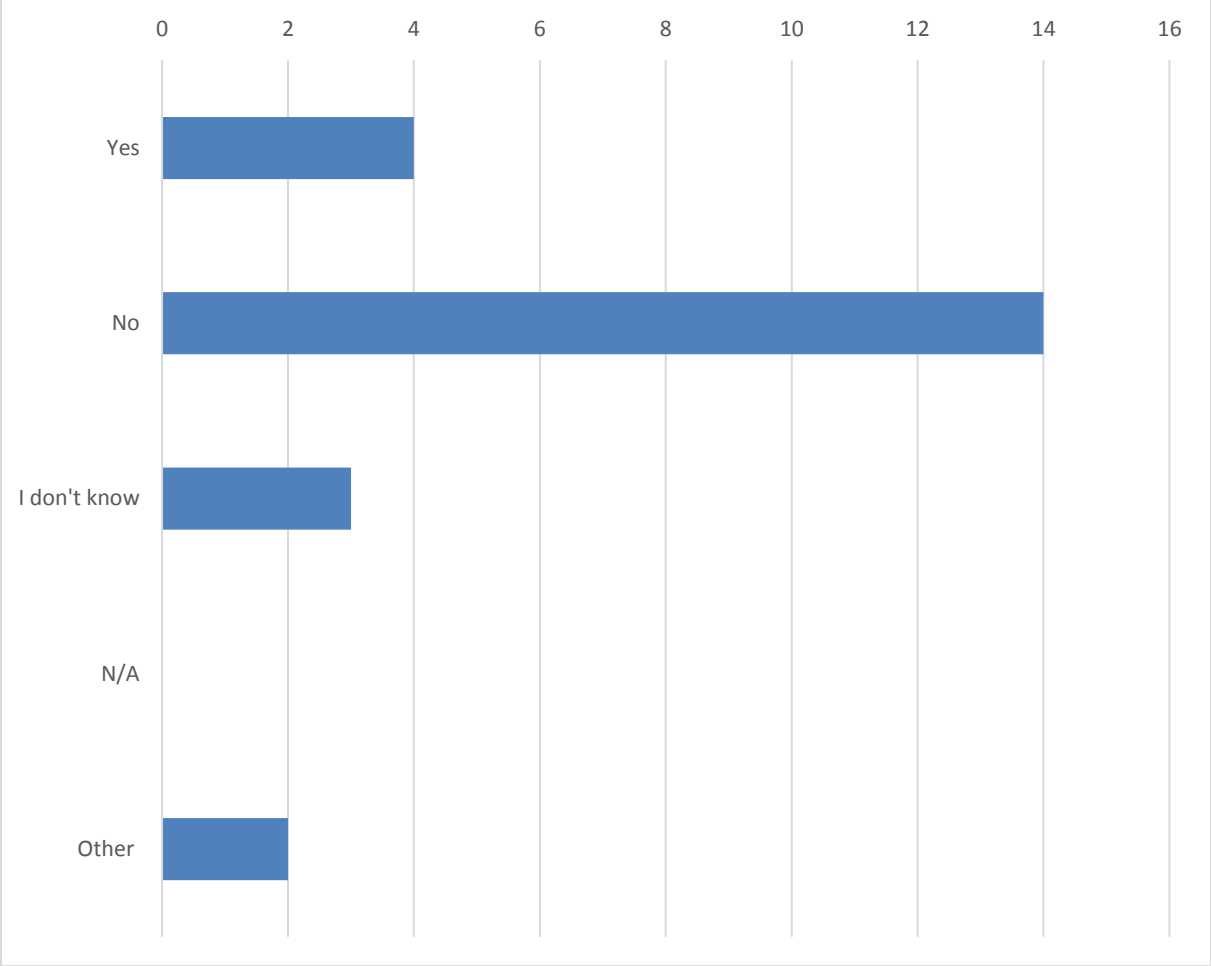

Figure 2. Question 3 on national legislation on the identification of patients who want to have their prescriptions issued in another Member State

Q1.4 In your country, is there any specific national legislation on the identification of health professionals with regard to ePrescriptions?

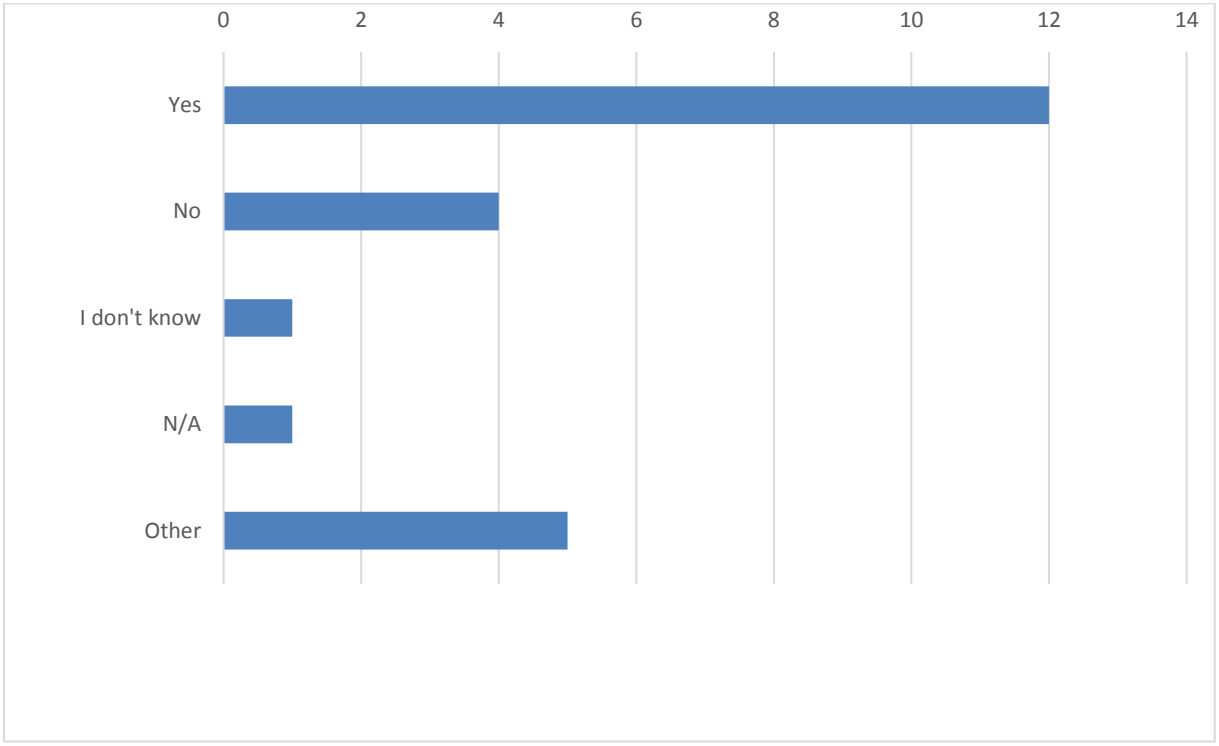

Figure 3. Question 4 on the identification of health professionals with regard to ePrescriptions

Q1.5 Does your country have a legal basis regarding cross-border exchange of ePrescription/eDispensation data?

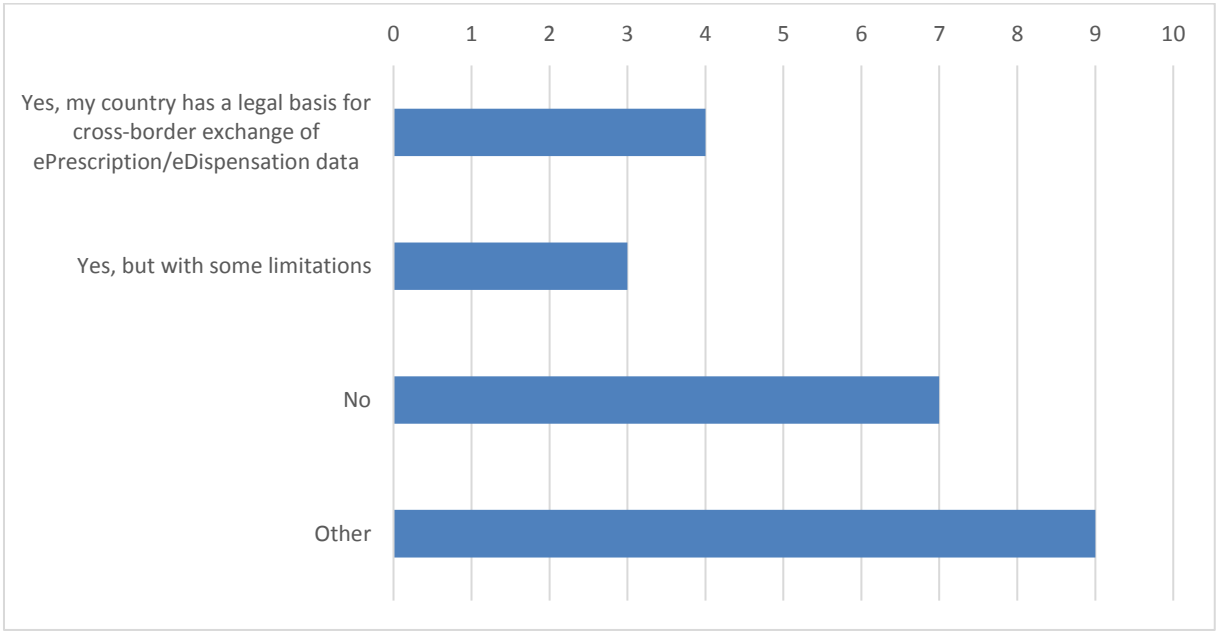

Figure 4. Question 5 on the legal basis regarding cross-border exchange of ePrescription/eDispensation data

Q1.6 How long is national ePrescription/eDispensation data stored in your country for litigation purposes?

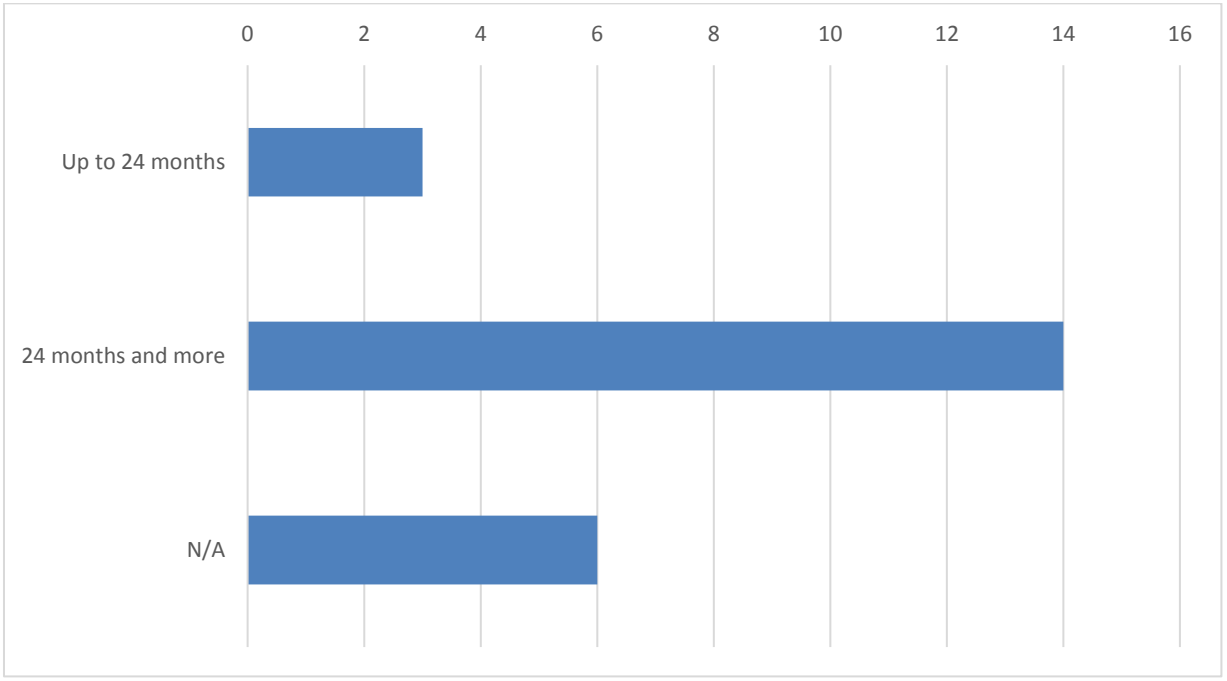

Figure 5. Question 6 on the length of time that national ePrescription/eDispensation data is stored for litigation purposes

Q1.7 How long are national ePrescription/eDispensation log files stored in your country for litigation purposes?

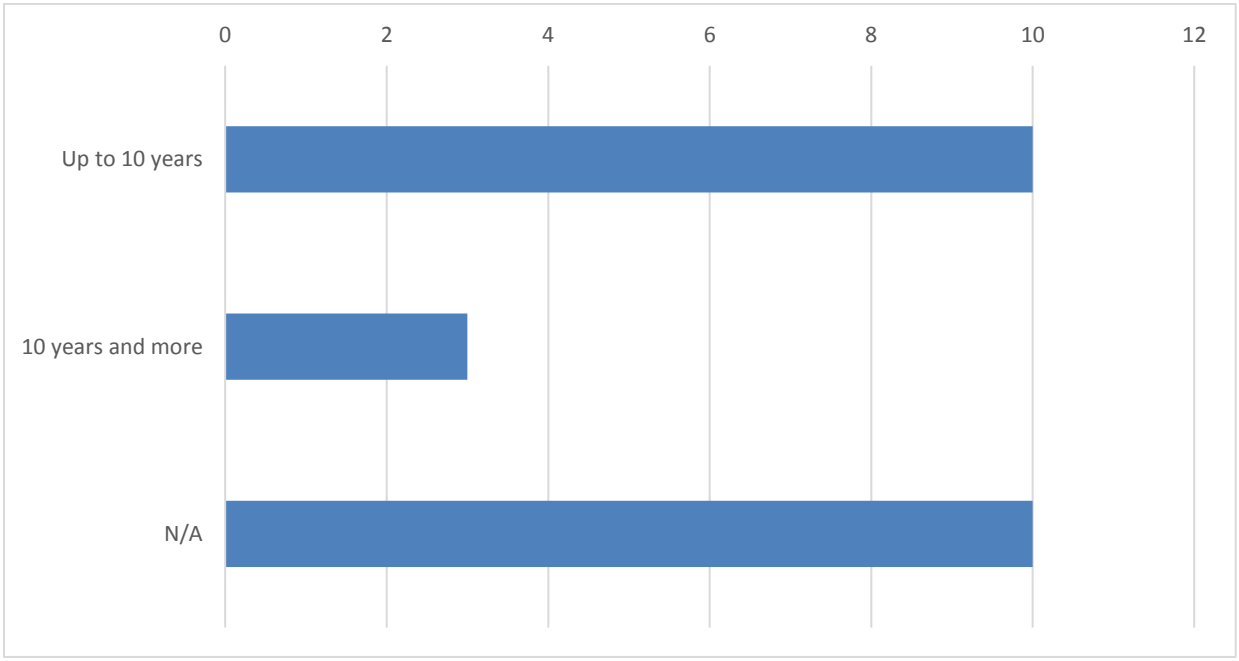

Figure 6. Question 7 on the length of time that national ePrescription/eDispensation log files are stored for litigation purposes

Q1.8 Is any information regarding cross-border ePrescription/eDispensation data received in your country from a different country treated in the same manner as ePrescription/eDispensation data obtained under your national law?

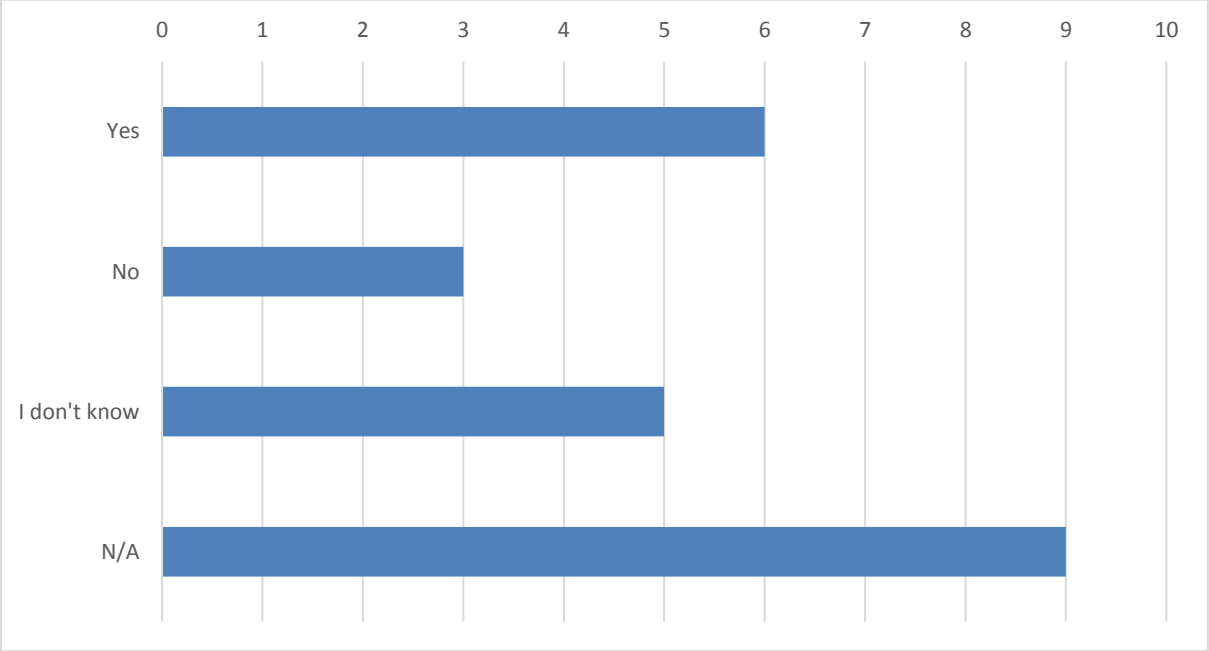

Figure 7. Question 8 on information regarding cross-border ePrescription/eDispensation data received from a different country

Q1.9 Under your national legislation, can information on cross-border ePrescription/eDispensation data be disclosed only by persons and authorities (including courts and administrative bodies) in the jurisdiction of your country?

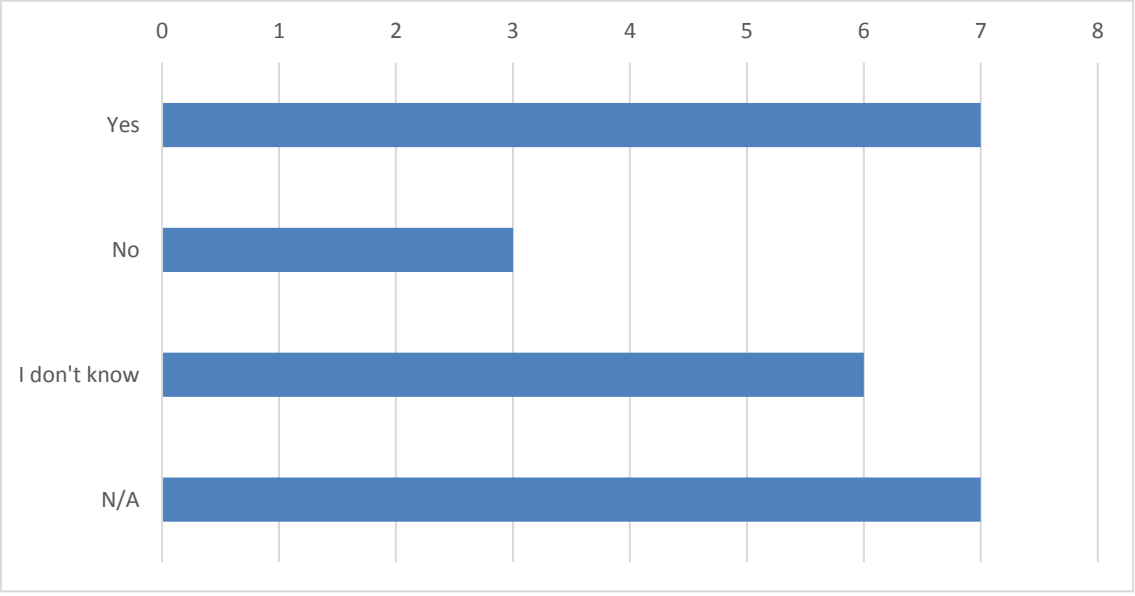

Figure 8. Question 9 on ePrescription/eDispensation data disclosure

Q1.10 Must the patients involved in national ePrescription/eDispensation give their consent to the use of their personal data?

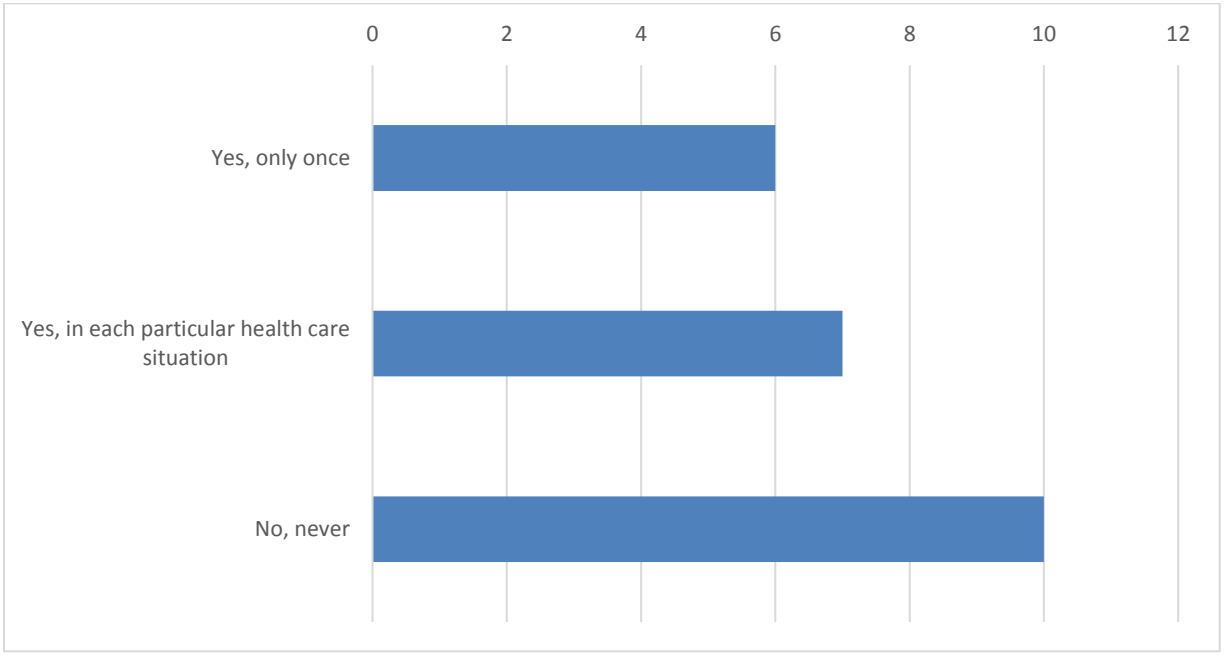

Figure 9. Question 10 on ePrescription/eDispensation data consent to the use of personal patient data

Q1.11 In your country, is patient consent for national prescription purposes also valid for cross-border exchange of ePrescription/eDispensation data?

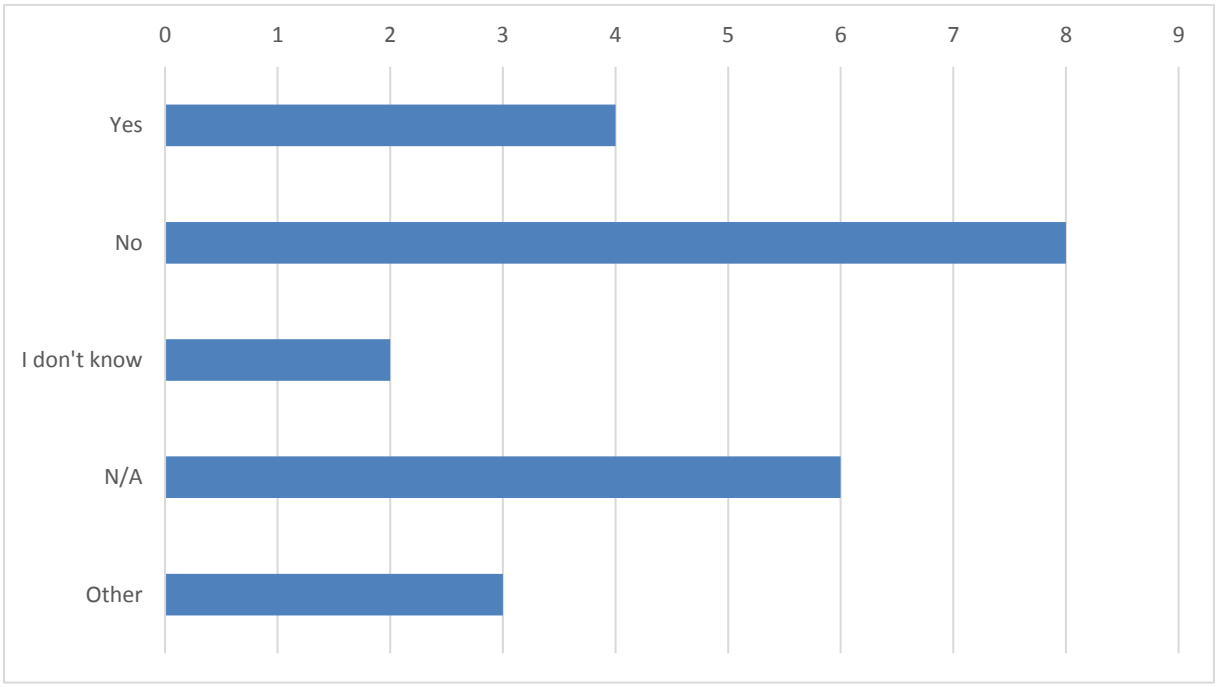

Figure 10. Question 11 on ePrescription/eDispensation data consent for the purpose of ePrescription/eDispensation cross-border data exchange

Q1.12 What are the legal obstacles to cross-border exchange of ePrescription/eDispensation data in your country, if any?

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5.2. LEVEL 2: Assessing organisational preparedness and interoperability

Q2.1 Has your country implemented the national ePrescription in a way defined by the ePrescription Guidelines?

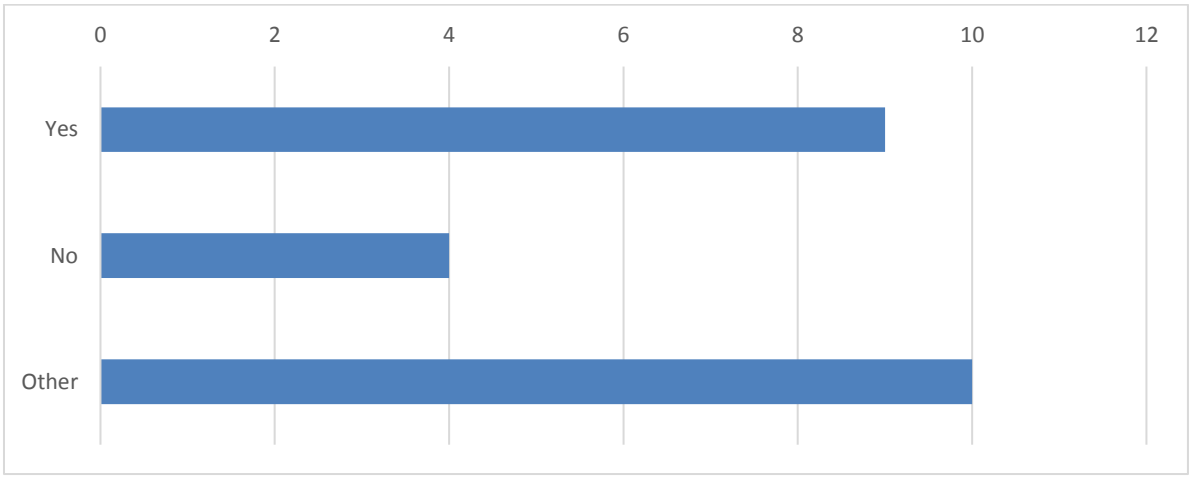

Figure 11. Question 13 on the implementation of national ePrescriptions

Q2.2. If you implemented the ePrescription as defined by the ePrescription Guidelines, on which level did you implement it in terms of geographic coverage?

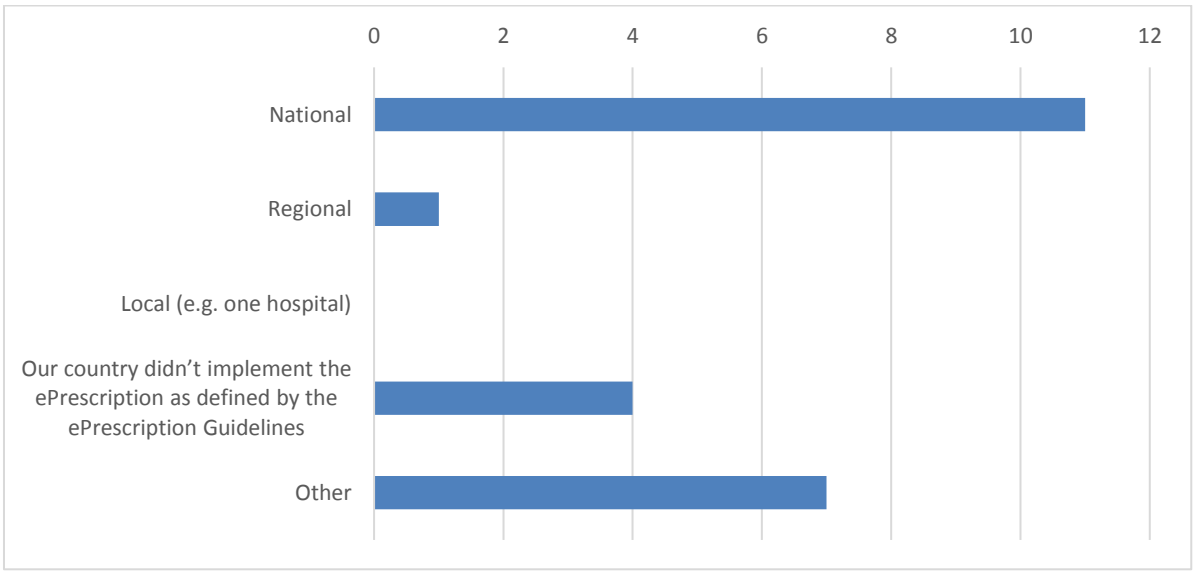

Figure 12. Question 14 on the level and geographic coverage of national ePrescriptions

Q2.3 Did your country establish an eHealth National Contact Point (NCPeH) for the purposes of ensuring interoperability across national borders towards other Member States?

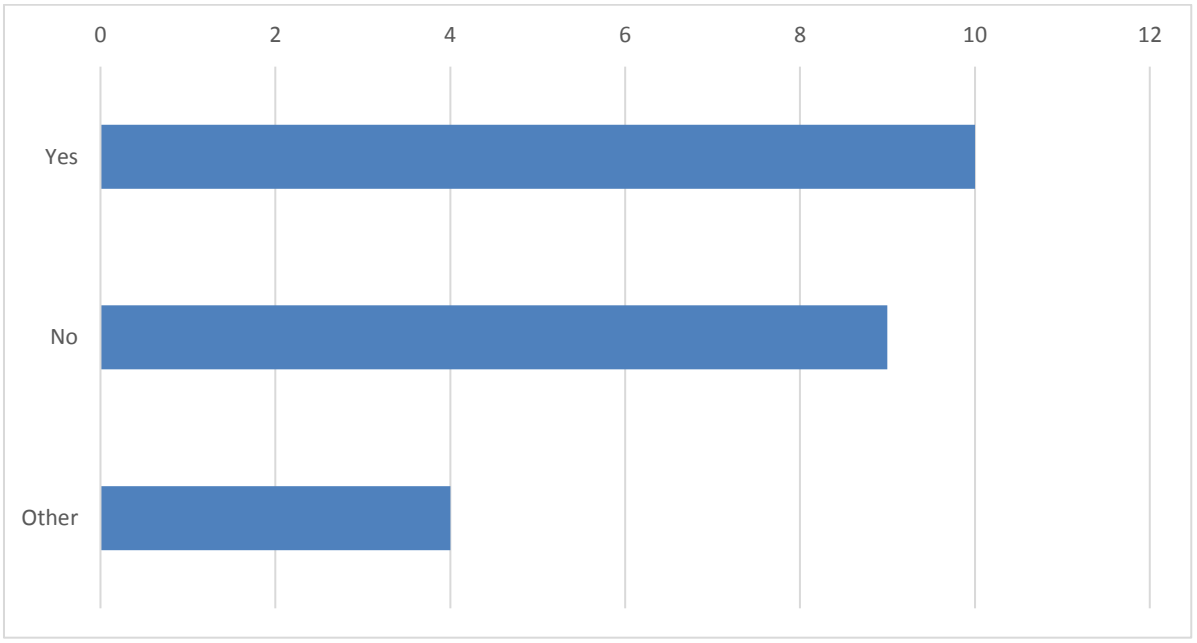

Figure 13. Question 15 on establishment of the eHealth National Contact Point (NCPeH)

Q2.4 Are ePrescriptions in your country issued only by registered persons with the appropriate health professional role?

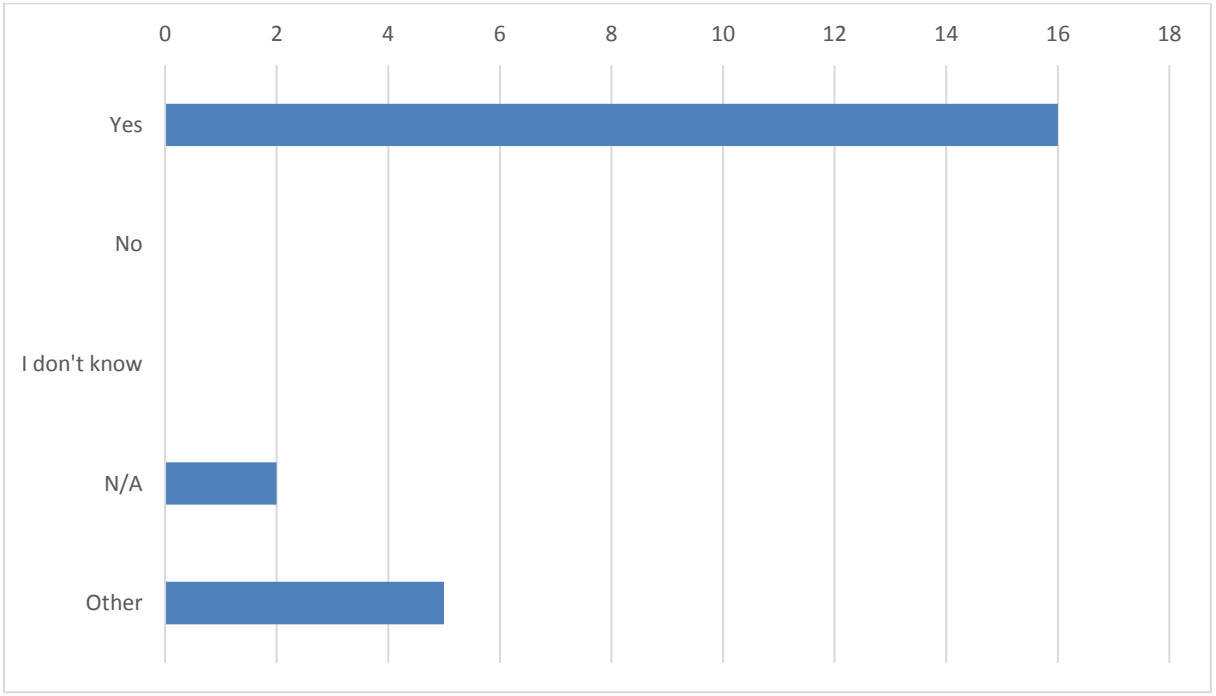

Figure 14. Question 16 on the issuing of national ePrescriptions by health professionals

Q2.5 Are there any national rules regarding the identification of health professionals with regard to ePrescription/eDispensation?

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Q2.6 Does your country ensure that ePrescription drugs are not dispensed without appropriate identification of the health professional?

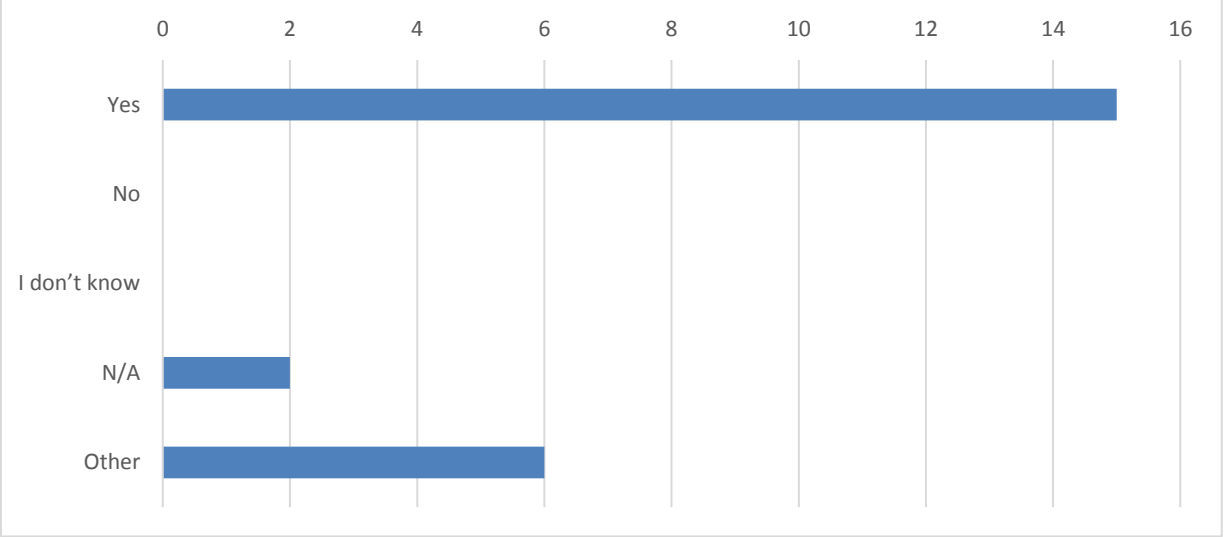

Figure 15. Question 18 on the issuing of ePrescription drugs not being dispensed without appropriate identification of the health professional

Q2.7 In your country, are ePrescriptions allowed to accommodate multiple dispensations?

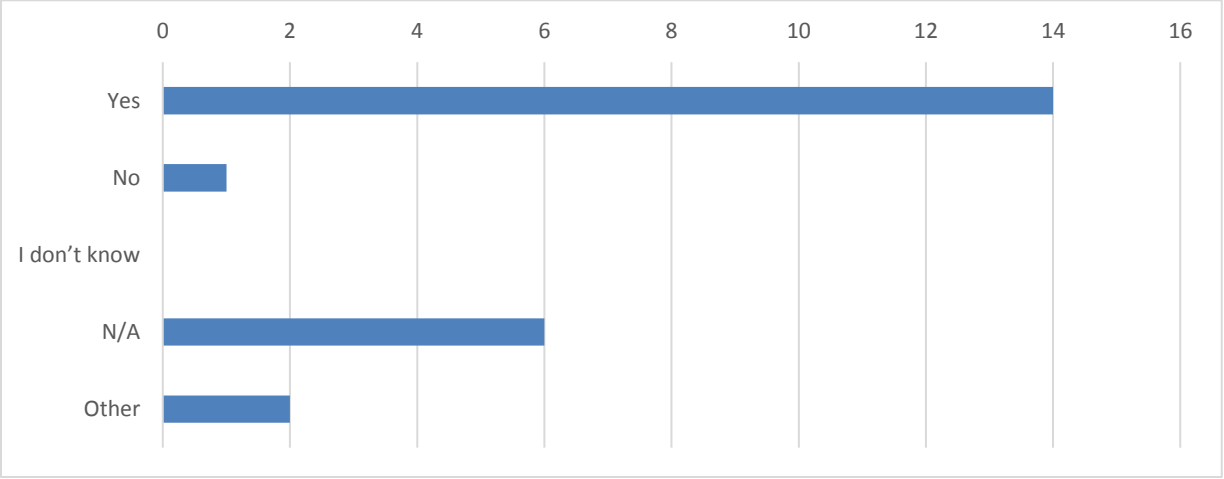

Figure 16. Question 19 on the multiple dispensation allowance for ePrescriptions

Q2.8 What are the organisational obstacles to cross-border exchange of ePrescription/eDispensation data in your country, if any?

Free text.

5.3. LEVEL 3: Assessing semantic preparedness and interoperability

Q3.1 Does your country use the ATC classification system of active substances in drugs developed by WHO with regard to coding ePrescriptions?

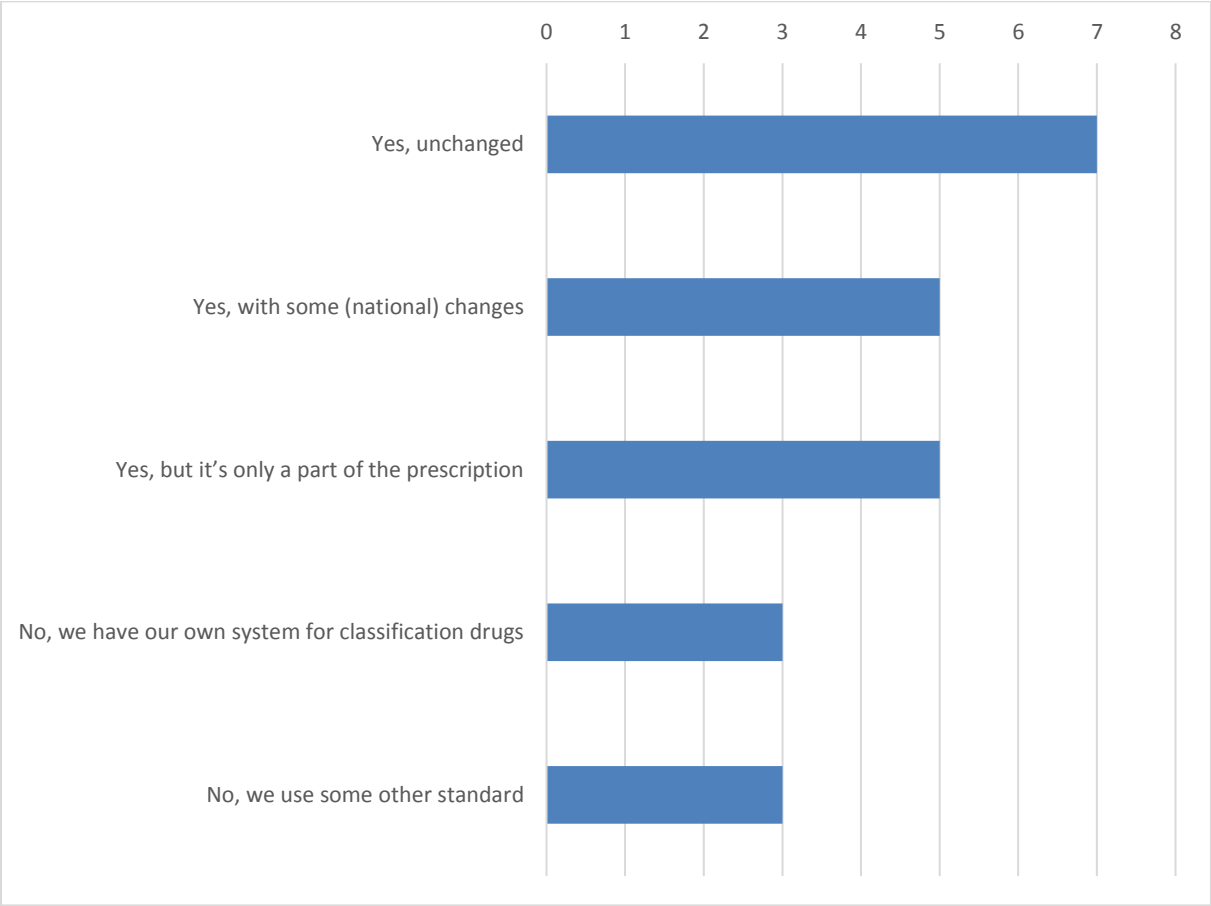

Figure 17. Question 16 on the usage of the ATC classification system

Q3.2 Does your country use the inventory of medicinal products as suggested by the European Medicines Agency (EMA), i.e. maintain a database which provides references and terminology for medical products (including information about therapeutic indications, strength, pharmaceutical form and route of administration)?

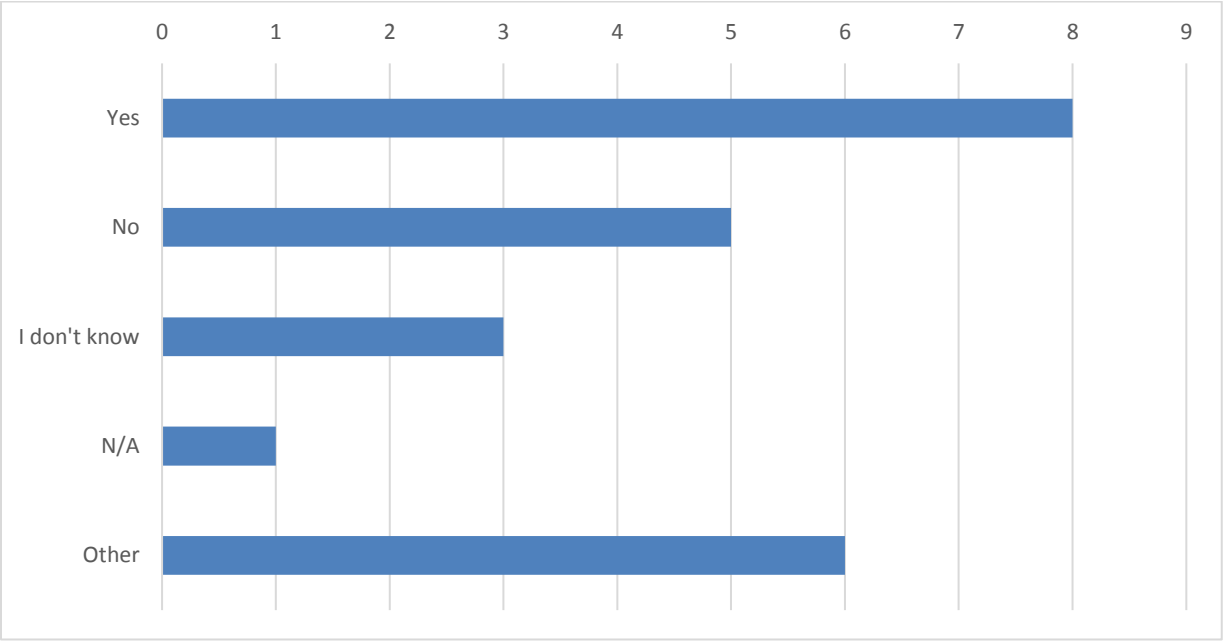

Figure 18. Question 17 on the use of the inventory of medicinal products as suggested by the European Medicines Agency (EMA)

Q3.3 In the event of semantic transformation of cross-border ePrescriptions, are both the transformed and the original documents available to all persons who are authorised to use this data?

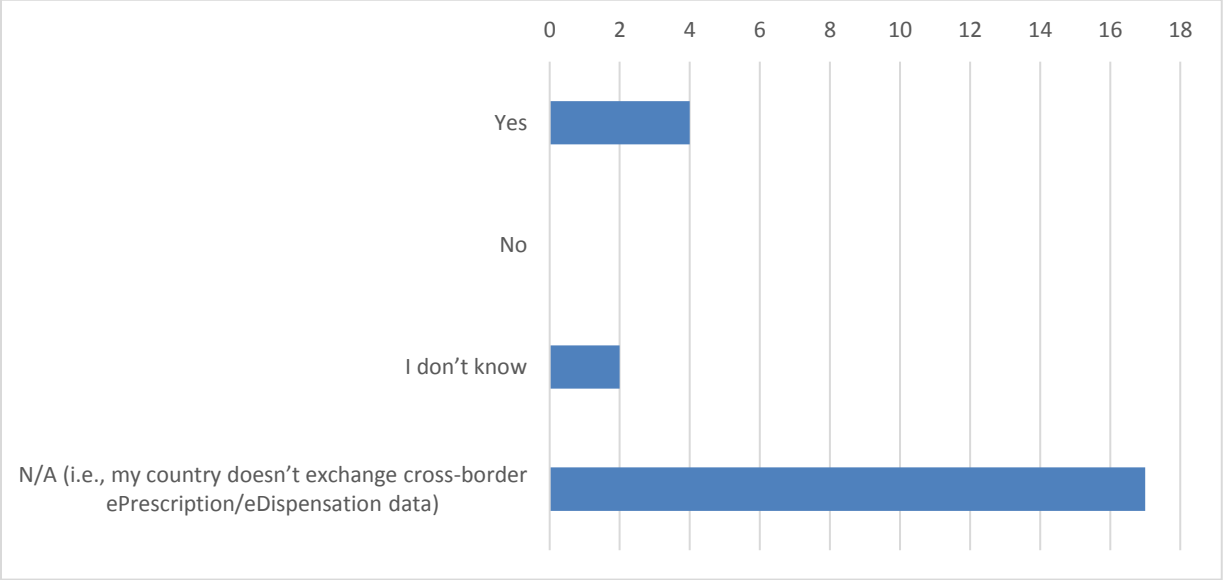

Figure 19. Question 18 on authorized use of personal data in the event of semantic transformation of cross-border ePrescriptions

Q3.4 Are all healthcare professionals who issue ePrescriptions/eDispensations in your country registered in at least one healthcare professional organisation or health authority belonging to the country?

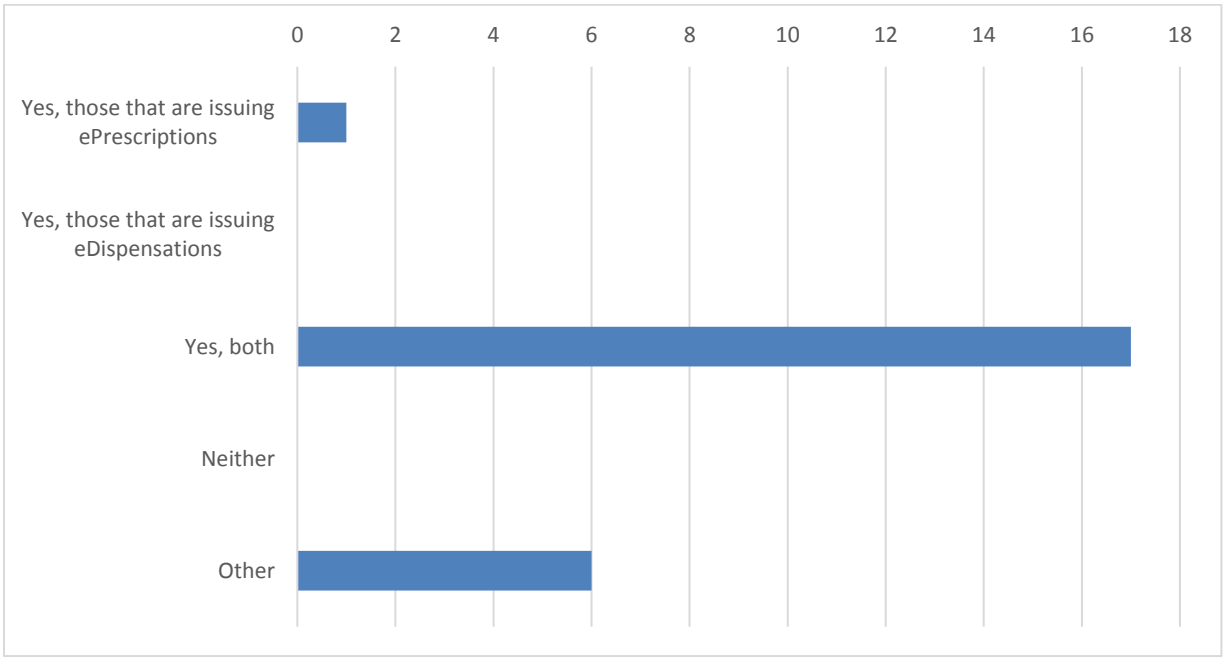

Figure 20. Question 19 regarding the healthcare professional organisation or health authority registration for the purpose of issuing ePrescriptions/eDispensations

Q3.5 Does your country have a system to check the information access rights of the end user (i.e. health professional responsible for dispensation) who requests data from ePrescriptions?

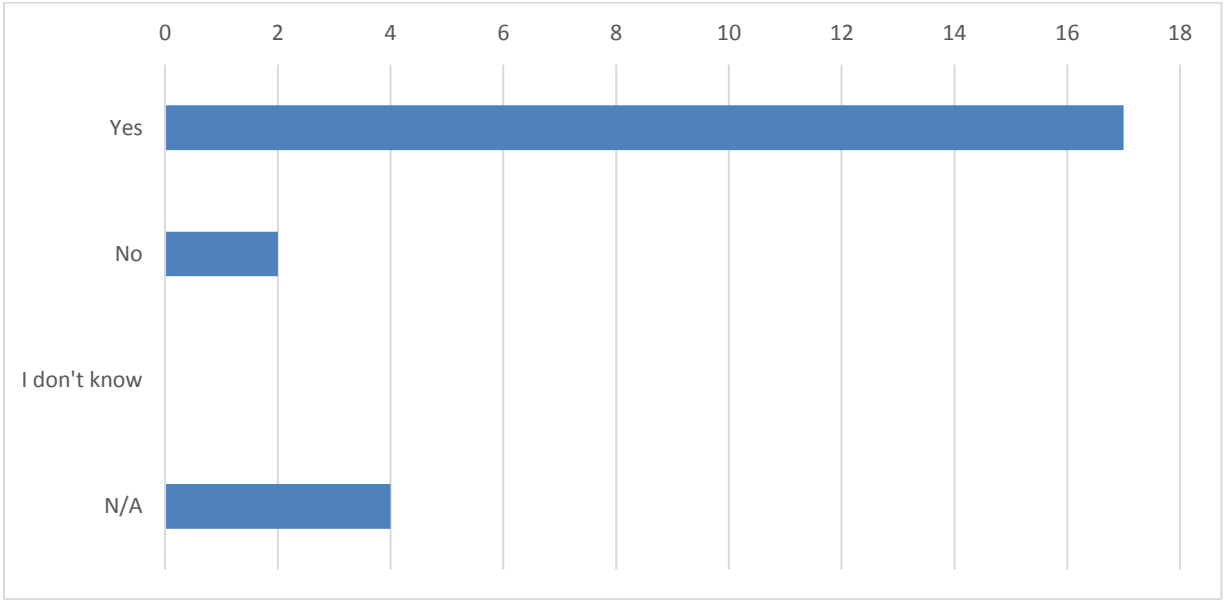

Figure 21. Question 20 on the existence of a system to check the information access rights of the end user

Q3.6 In the case of eDispensations, which of the following data can be sent to the prescriber? (Multiple-answer question)

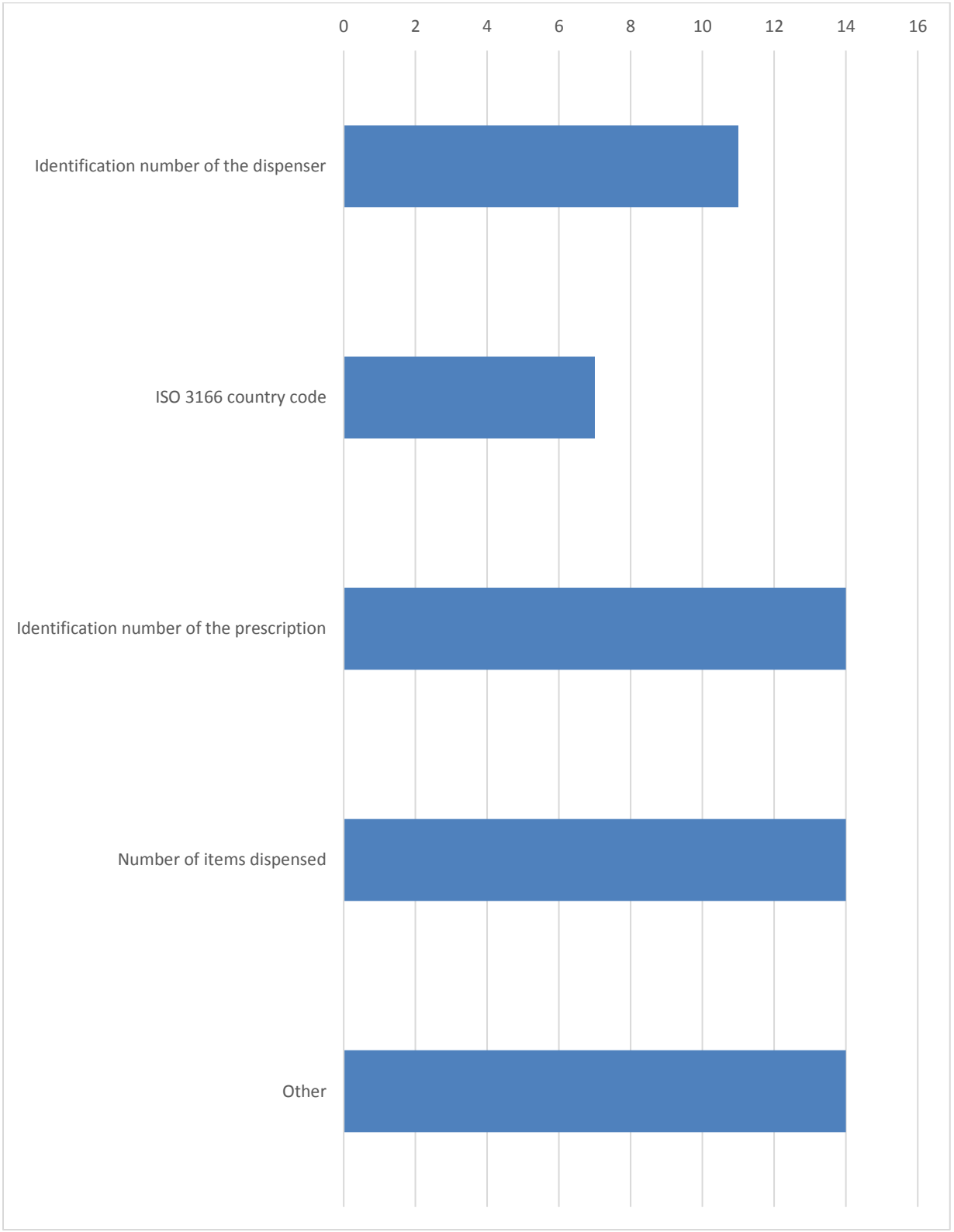

Figure 22. Question 21 on the eDispensation data that can be sent to the prescriber

Q3.7 What are the semantic obstacles to cross-border exchange of ePrescription/eDispensation data in your country, if any?

Free text.

5.4. LEVEL 4: Assessing technical preparedness and interoperability

Q4.1 In your opinion, can your country ensure the technical requirements for cross-border exchange of ePrescriptions based on the ePrescription Guidelines?

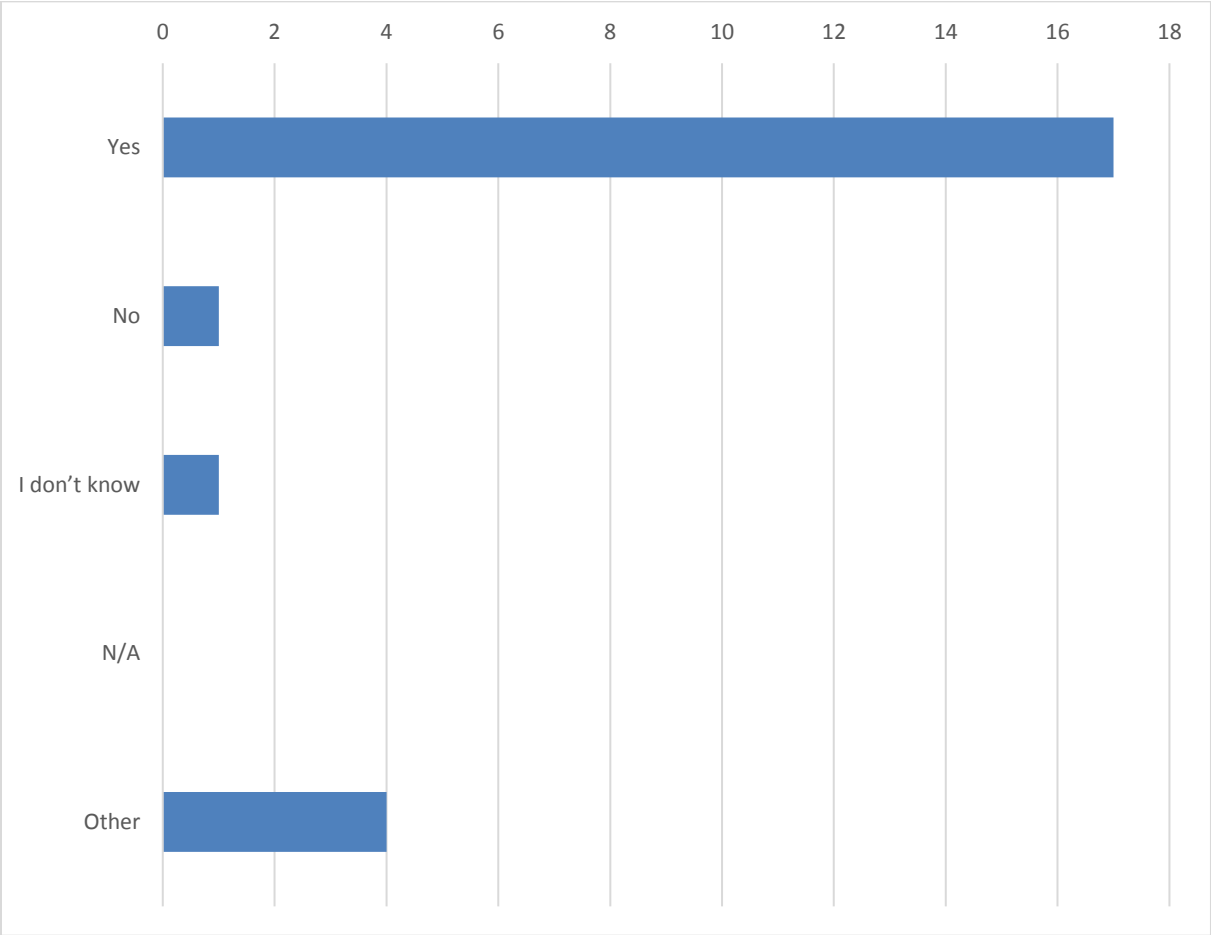

Figure 23. Question 26 regarding the country's technical requirements for cross-border exchange of ePrescriptions based on the ePrescription Guidelines

Q4.2 Can your country ensure that communication of identifiable personal health data is subject to secure communication and end-to-end security measures for cross-border purposes?

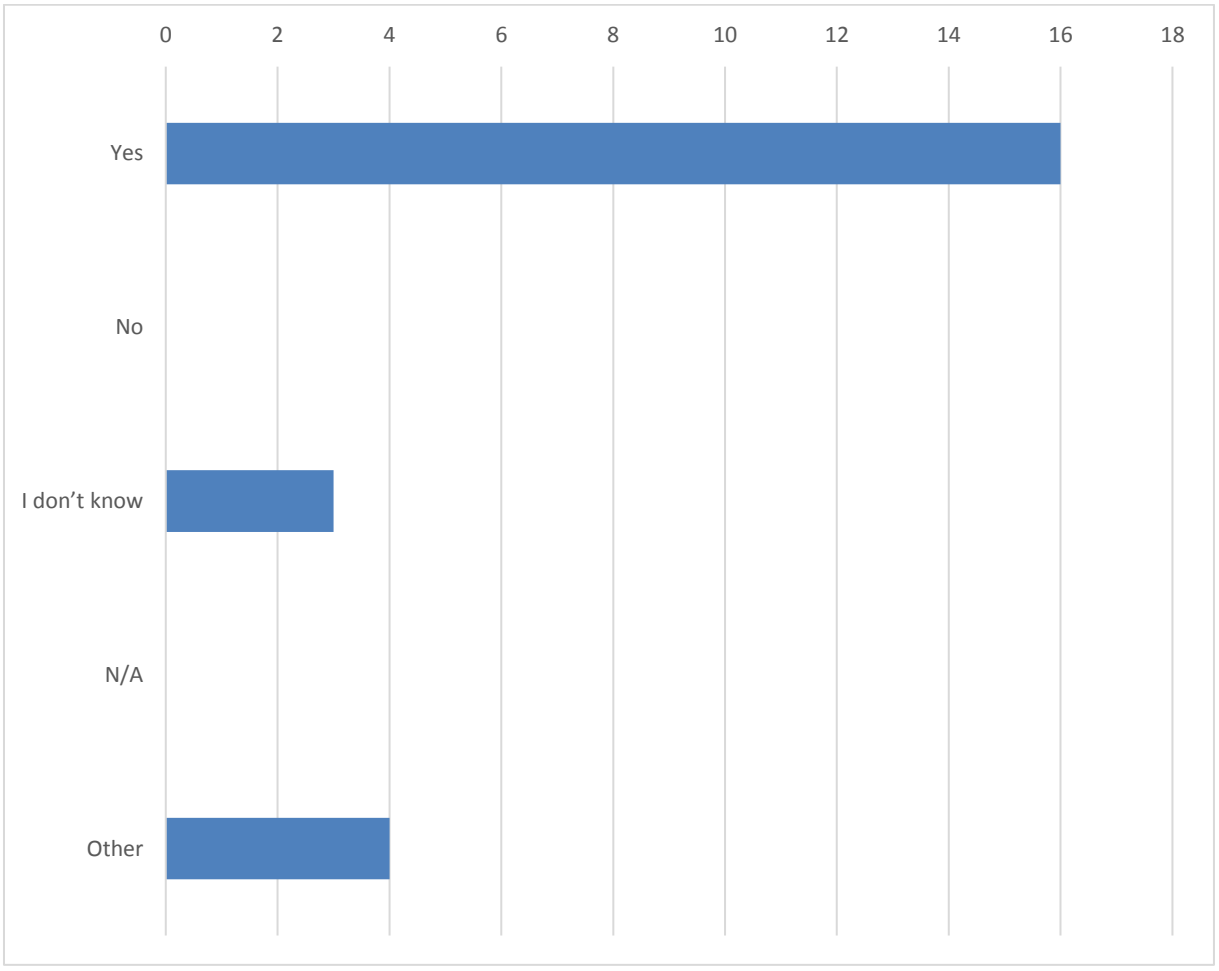

Figure 24. Question 27 on the country's secure communication and end-to-end security measures for cross-border purposes

Q4.3 Concerning authentication and authorisation, which of the following applies to your country? Please select all that apply.

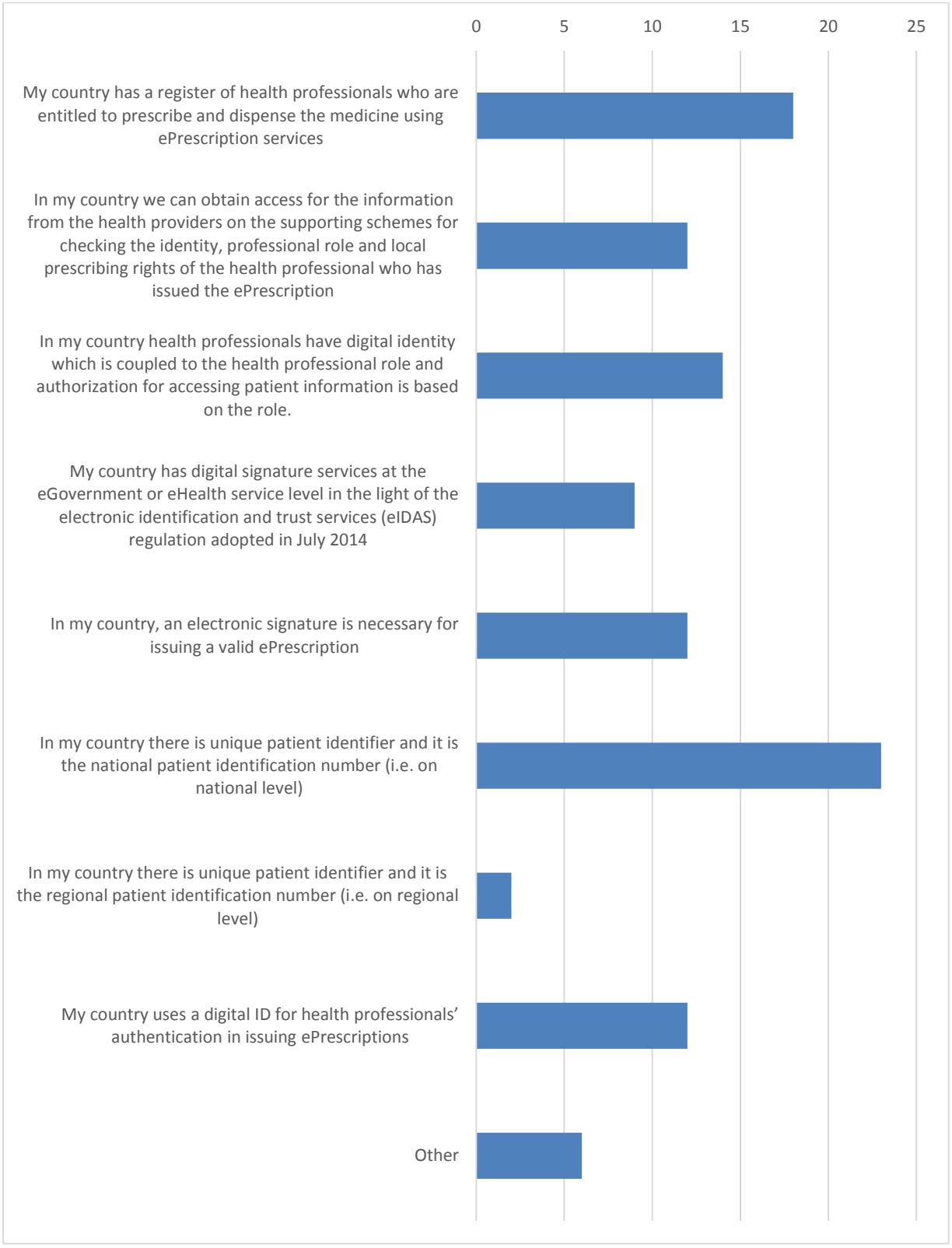

Figure 25. Question 28 on authentication and authorisation

Q4.4 Does your country use any of the following security principles for ePrescription purposes?

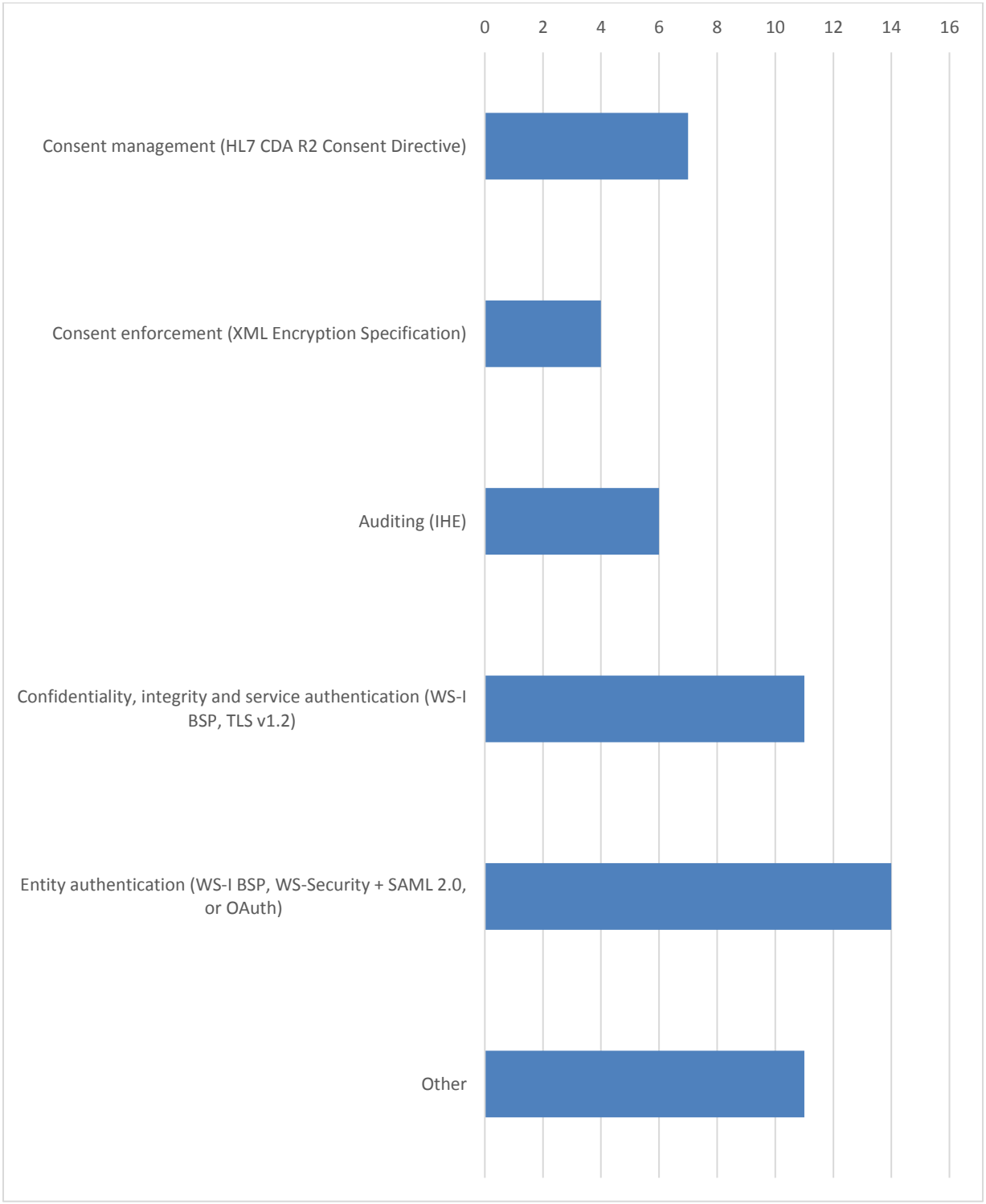

Figure 26. Question 29 regarding the country's use of security principles for ePrescription purposes

Q4.5 Can your country ensure the detection of unauthorised access to ePrescription data in terms of data transactions logging?

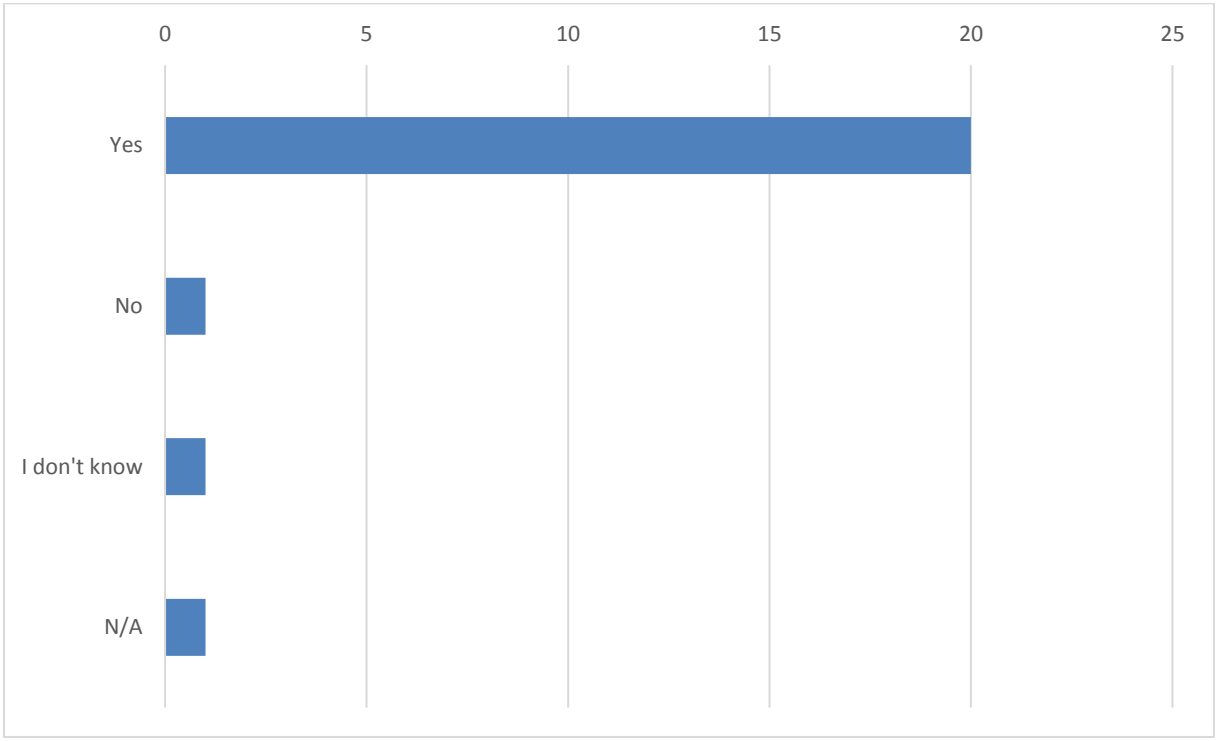

Figure 27. Qu**Fehler! Verweisquelle konnte nicht gefunden werden.**estion 30 regarding the detection of unauthorised access to ePrescription data in terms of data transactions logging

Q4.6 What are the other possible technical obstacles to cross-border exchange of ePrescription/eDispensation data in your country, if any?

Free text.

5.5. Barriers to the implementation of the Patient Summary Guidelines (Appendix)

QA.1 When implementing the ePrescription Guidelines in your respective country which barriers to performing all the tasks did you encounter?

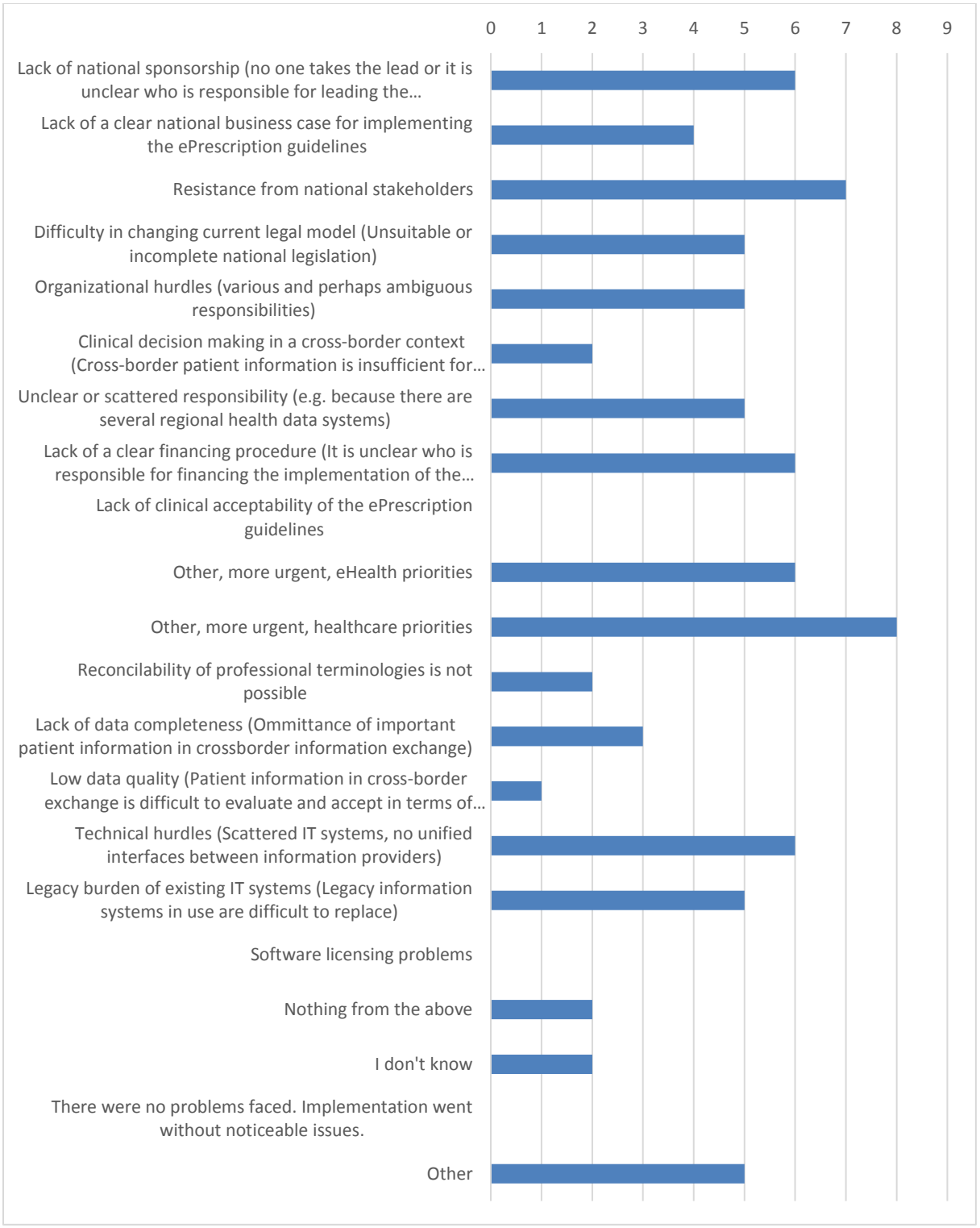

Figure 28. Question 37 on the barriers to implementation of the Patient Summary Guidelines

QA.2 In your professional opinion, are the methods and steps needed for implementing the ePrescription Guidelines clear from the document itself?

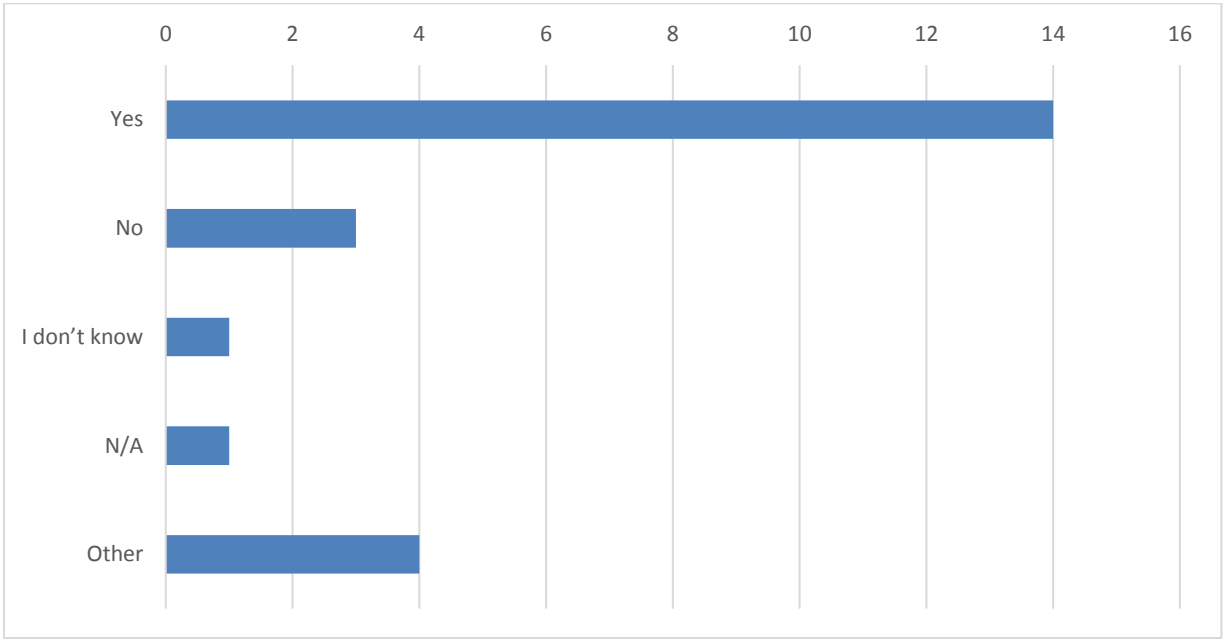

Figure 29. Question 37 on the clarity of methods and steps needed for implementing the ePrescription Guidelines

QA.3 In your personal opinion, was it difficult to prioritise particular elements of the ePrescription Guidelines in order to implement them in an efficient manner?

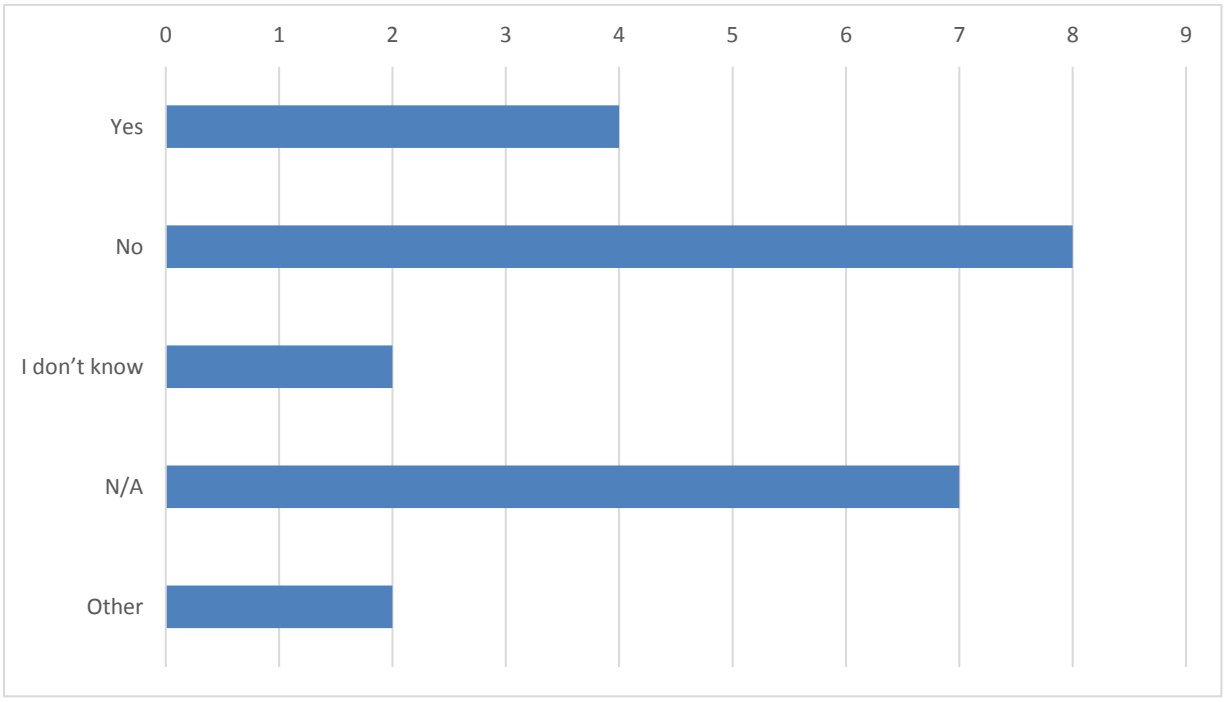

Figure 30. Question 37 on the difficulty of prioritising particular elements of the ePrescription Guidelines in order to implement them in an efficient manner

QA.4 After reading the ePrescription Guidelines, did you detect any problems in dispensing the medicine in your country for patients from other Member States?

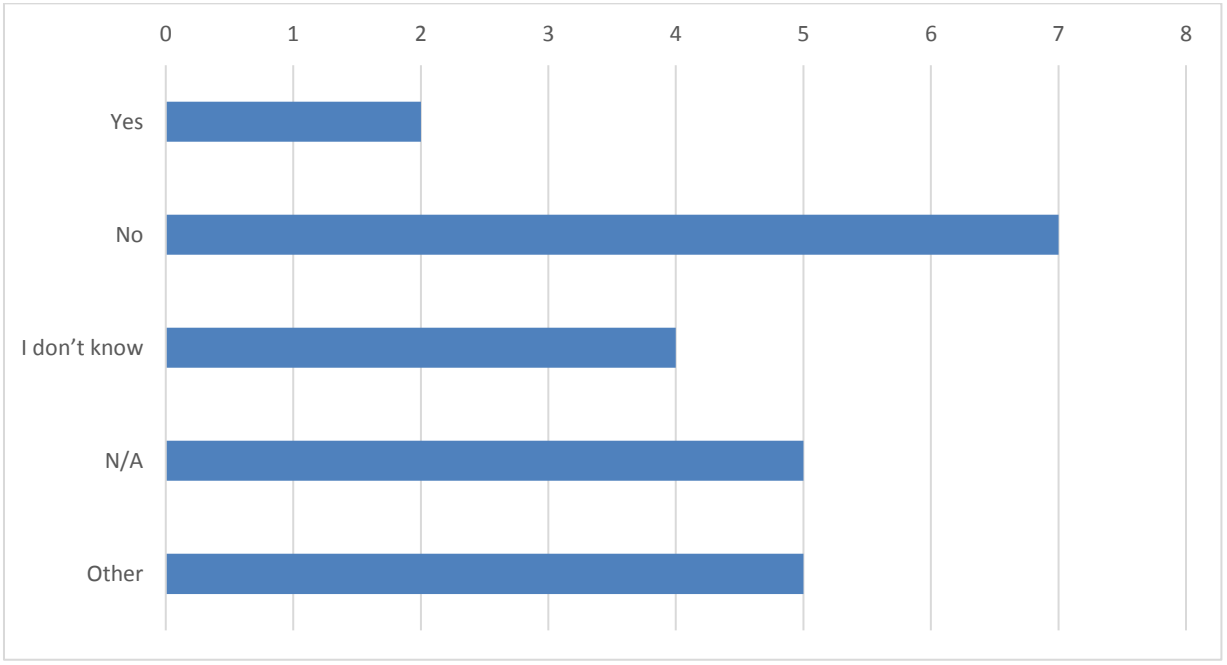

Figure 31. Question 37 on the problems in dispensing medicines for patients from other Member States

QA.5 In terms of education, training and awareness raising of citizens, which of the following applies to your country?

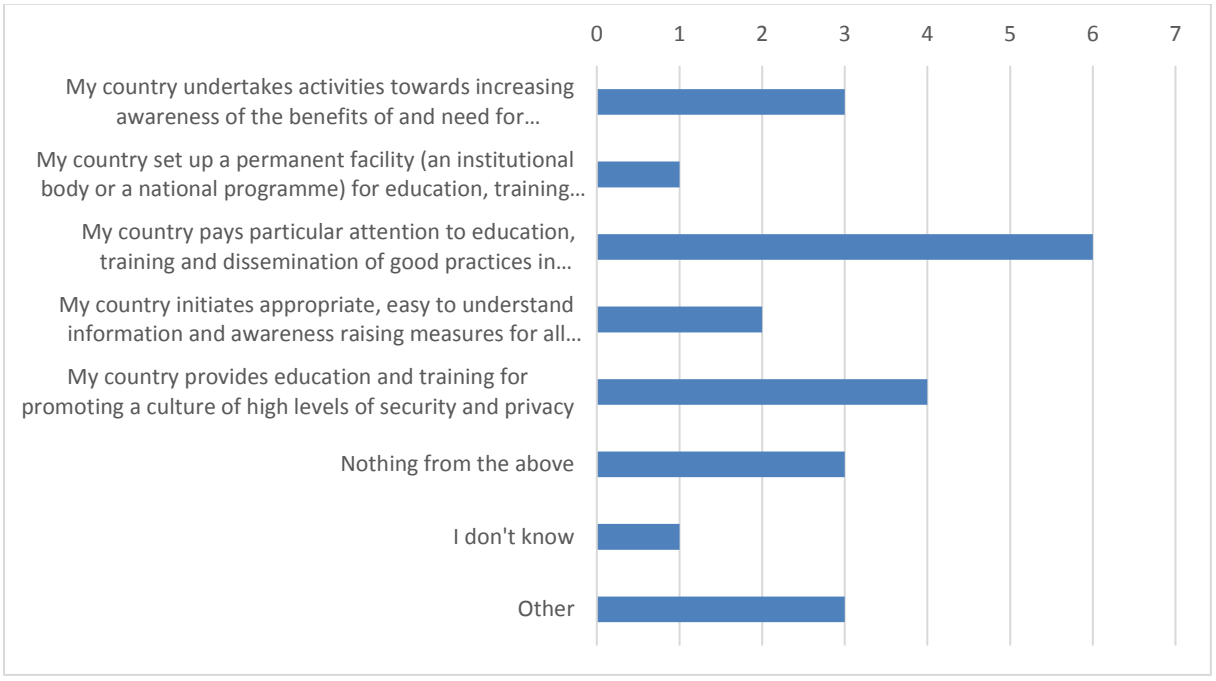

Figure 32. Question 37 on the ePrescription-focused education, training and awareness raising of citizens

QA.6 With regard to the CEF for eHealth call for proposals, when is the planned start of the ePrescription services deployment as Country A?

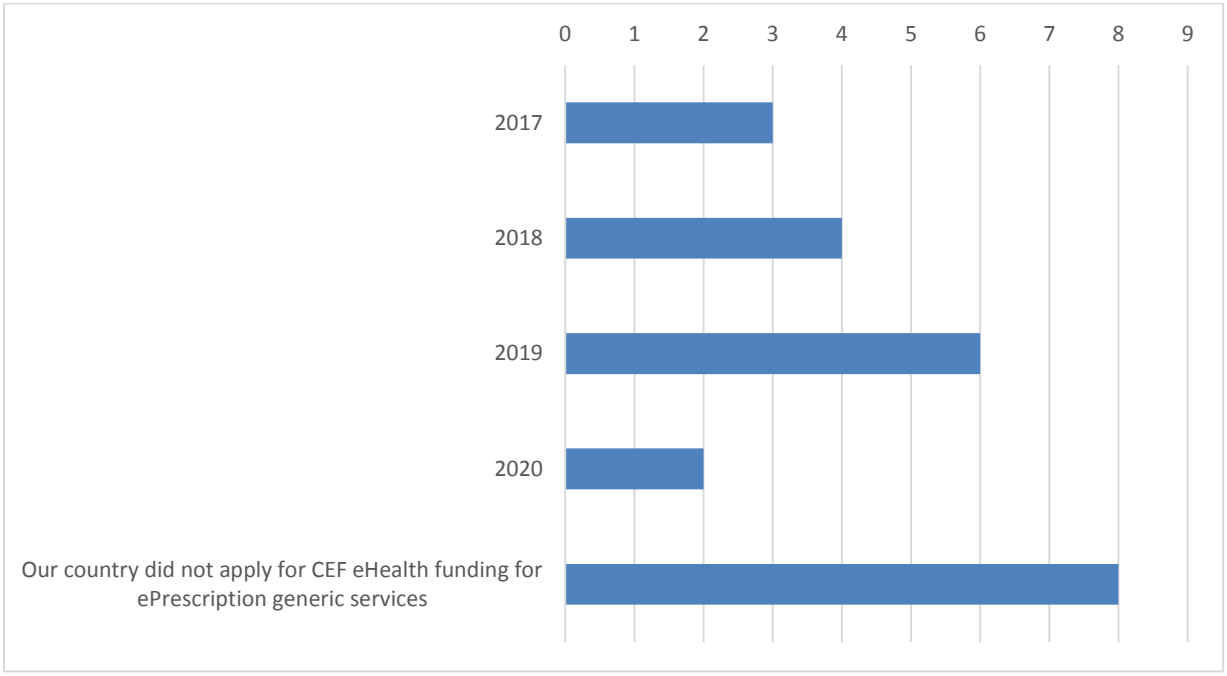

Figure 33. Question 37 on the planned start of the ePrescription services deployment as Country A

QA.7 With regard to the CEF for eHealth call for proposals, when is the planned start of the ePrescription services deployment as Country B?

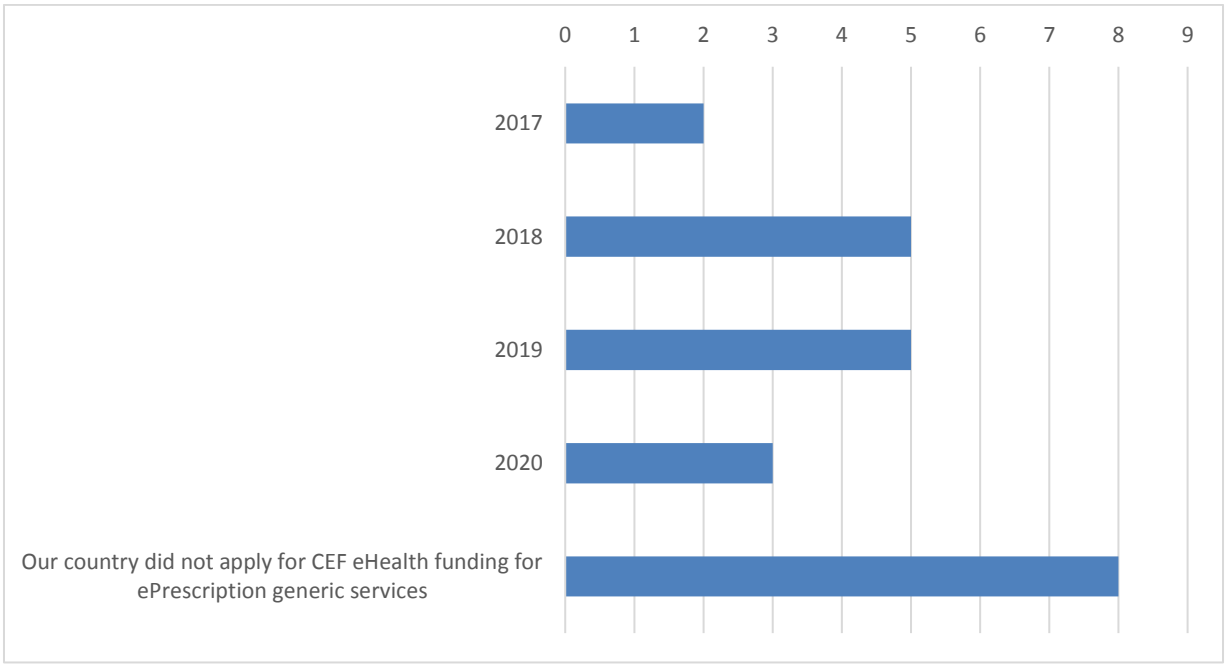

Figure 34. Question 37 on the planned start of the ePrescription services deployment as Country B

QA.8 Please be so kind and share with us any other opinions regarding ePrescription Guidelines implementation in your country.

Free text.

Note on the free text questions:

A number of questions in the Questionnaire were open-ended and answers were provided in free text form. The complexity of answers that were provided in free text form varied greatly and their content covered a multitude of diverse topics, depending on the MS answering the Questionnaire. For this reason and because they were not mandatory, they were not presented graphically like the other answers (single or multiple choice answers) nor were they copied to the Report in their original form. However, all these free form answers were included in the findings of this Report and formed much of its conclusions.

6. Findings

The questionnaire results and responses from countries' representatives indicate that the majority of countries are actively preparing themselves for the upcoming national implementations of eHealth DSI under CEF funding. The majority of countries have already deployed ePrescriptions at a national, regional and/or local level, and the others plan to do so in the next five years. There is usually national legislation on the procedures showing how an insured person can obtain medicine in another EU country. Mostly, reimbursement is requested by the insured person in his/her own country and the amount is determined by the domicile country and by the cost of the medicine in that country. One half of countries do not have any national law defining how to identify patients in other Member States, and there is no strategic approach to pave the way for a good legal basis at EU level. The answers indicate that some countries have made legal preparations for cross-border interoperability for ePrescriptions, but not as much as we might have expected since deployment under the CEF call is quite close.

As expected, the main obstacle from the legislation point of view found by the countries is the lack of a clear bi-/multilateral agreement between the Member States (bi- referring here to an agreement between a non-Member State and the EU). Countries hope that many crucial legislation issues could be solved by this agreement. On the other hand, countries' representatives are aware that this agreement will not be sufficient and that some changes will be necessary at national legislation level.

At organisational level, countries have worked on ePrescription cross-border interoperability according to the Guidelines, or they plan to follow the Guidelines when they start implementing ePrescription cross-border interoperability. More than half of the countries implement it at national level or plan to implement it. Just one of them did so at regional, and none of them at local level (one is planning to pilot it at local level). However, the answers

indicate that countries plan to work on organisational issues after national implementation of eHealth DSI under CEF funding has started.

The issue of authorisation of health professionals who will be involved in the ePrescription/eDispensation procedure is not seen to be a problem in Member States because they have already introduced or plan to introduce a clear procedure under which only registered health professionals will be involved in the ePrescription/eDispensation process. In addition, the majority of countries have a national rule regarding the identification of health professionals involved in ePrescription/eDispensation procedures and the drugs cannot be dispensed without appropriate identification.

The main obstacles to cross-border exchange of ePrescriptions/eDispensations at organisational level are foreseen to be the reimbursement issue, language and change of national habits (patients can nominate their chosen pharmacy and pharmacies operate on an open market principle).

Countries use the ATC system in its original or in a redesigned form; only six Member States use something else or their own system (something similar to ATC or their own database).

It is very interesting to see that in only two countries that answered the questionnaire is there no feedback from the health professional who dispensed the medicine to the patient in the eDispensation process. It is usually possible to send some kind of feedback (identification number of the dispenser and prescription, number of items dispensed, etc.). Furthermore, some countries keep information in a repository and information can be retrieved on demand if necessary.

At any event, the main obstacles at semantic level are foreseen to be mapping and identification of medicines and substitution rules.

At technical level, countries consider themselves to be ready: we can see that this question was answered almost unanimously.

In general, almost every country has started a number of educational procedures and awareness raising activities. The others are probably waiting for the project to start with CEF funding before they carry out a general marketing and education campaign informing citizens about the functionality and security of the ePrescription system.

As a final note, it should be said that the findings from this report were not based on a root-cause analysis and should not be taken as objective recommendations for further actions towards improving the implementation of the ePrescription Guidelines in Member States. However, the questionnaire analysis shows a number of patterns that should be taken into account.

7. Conclusions

The Member States were asked to answer the questionnaire in a very short time period after the first call for Connecting Europe Facility (CEF) funding, and that resulted in the high level of maturity of most of the answers received. A fair number of countries that provided answers to the questionnaire showed a high degree of comprehension of implementing the ePrescription Guidelines. Member States have already implemented their own ePrescriptions on a national, regional or local level. At the same time, the majority of other preconditions necessary to start cross-border data exchange in terms of semantic standards and technical solutions have already been met and as such aligned with the ePrescription Guidelines. On the other hand, the national legislature for national ePrescription/eDispensation purposes can pave the way for cross-border exchange of ePrescriptions, but the countries are aware that this is the burden that has to be tackled before the guidelines are fully implemented. The legal foundations of cross-border healthcare data exchange are still something that needs to be put in place before Member States can actually start sharing data. This is a concern raised by most of the countries, and it holds especially true for non-EU countries.

The next step in building a more robust environment providing cross-border healthcare data is the adoption of the more complete eHealth Guidelines that would advance from the technical and semantic aspects of interoperability towards legal and organisational ones. What is also needed is the strengthening of the eHealth National Contact Points' role in Member States, which should provide continuity and sustainability for all future eHealth implementations. Above all, a sound legal base is required for the Member States to share the data in a way that will achieve sustainability in the European Union concerning eHealth cross border interoperability.

As a final note, judging both from the experience gained through reporting on implementation of the Patient Summary Guidelines and ePrescription Guidelines and having experience in coordinating the Member States during the CEF proposal writing phase, we strongly recommend a joining of efforts in overcoming all the previously stated difficulties in implementing the eHealth Guidelines. All Member States share the same problems and only by uniting their national experts in the areas of legal, organisational, semantic and technical interoperability, we can jointly tackle some of our common issues. This should hold true not only during CEF funding but also as a way of implementing all eHealth services in the future.

8. References

- European Interoperability Framework (EIF) for European public services, available at: http://ec.europa.eu/isa/documents/isa_annex_ii_eif_en.pdf (30/07/2015)
- Guidelines on ePrescriptions Dataset for Electronic Exchange under Cross-border Directive 2011/24/EU, Release 1, http://ec.europa.eu/health/ehealth/docs/eprescription_guidelines_en.pdf
- Guidelines On Minimum/Nonexhaustive Patient Summary Dataset for Electronic Exchange in Accordance With The Cross-Border Directive 2011/24/EU, Release 1, http://ec.europa.eu/health/ehealth/docs/guidelines_patient_summary_en.pdf
- Report on The Implementation of Patient Summary Guidelines in Member States, http://jasehn.eu/wordpress/wp-content/uploads/2016/04/JAseHN_D6.1.1_Report_on_the_implementation_of_PS_Guideline_v2.0_clear.pdf

9. Appendix A: Glossary of terms

CONCEPT	DEFINITION
CBeHIS	Cross-Border eHealth Information Services in the scope of the current document, namely Patient Summaries and ePrescriptions (may include eDispensations)
CEF eHealth	EU financial (€7.5 million) mechanism (based on call for proposals) that will be launched by November 2015, and may be used by MS to support CBeHIS provision (preparation, deployment and operation)
eHealth DSI	eHealth Digital Service Infrastructure
ATC	Anatomical Therapeutic Chemical
EIF	European Interoperability Framework
European public service	A cross-border public sector service provided by public administrations, either to one another or to European businesses and citizens
Guideline	A suggestion on how to perform a certain task. It is visible to those using or supporting the use of a particular service but there are no sanctions if it is not followed.
Interoperability framework	An agreed approach to interoperability for organisations that wish to work together towards the joint delivery of public services. Within its scope of applicability, it specifies a set of common elements such as vocabulary, concepts, principles, policies, guidelines, recommendations, standards, specifications and practices.
National Infrastructure	The healthcare IT infrastructure, which manages patient and HP identification and healthcare records in MS
NCP	National Contact Point as referenced in Article 4 of Directive 2011/24/EU
NCPeH	National Contact Point for eHealth that may act as an organisation and technical gateway for the provision of eHealth Cross-Border Information Services