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IMPACT ASSESSMENT

Accompanying the document

COMMISSION IMPLEMENTING DIRECTIVE 2012/52/EU

of 20 December 2012

laying down measures to facilitate the recognition of medical prescriptions issued in another Member State

Disclaimer

This impact assessment report commits only the Commission's services involved in its preparation and the text is prepared as a basis for comment and does not prejudge the final form of any decision to be taken by the Commission.

Table of contents

1. Procedural issues and consultation of interested parties 6
   1.1 Background 6
   1.2 Impact Assessment Steering Group (IASG) 8
   1.3 Impact Assessment Board (IAB) 8
   1.4 Consultation 8
   1.5 External Expertise 13
2. Problem definition 14
   2.1 Recognition of prescriptions issued in another Member State 14
   2.2 Concerned groups 18
   2.3 Expected baseline evolution 20
   2.4 Rationale for EU action 23
3. Objectives 24
   3.1 General policy objectives 24
   3.2 Specific objectives 24
4. Policy options 25
   4.1 Assessed options 25
   4.2 Selection criteria 26
5. Analysis of impacts 28
   5.1 Option 1: "no further policy action" 29
   5.2 Option 2: "non-exhaustive list" 31
   5.3 Option 3: "non-exhaustive list combined with national prescriber registers" 34
   5.4 Option 4: "non-exhaustive list combined with EU-level prescriber register" 36
   5.5 Comparing impacts across the options 39
6. Cost-minimisation analysis 43
   6.1 Methods 43
   6.2 Results 45
7. Monitoring and evaluation 49
   7.1 Progress indicators 49
   7.2 Methods 50
   7.3 Timing 51
8. Annexes 53
   8.1 Economic Evaluation 54
   8.2 Web-links to background documents 92
   8.3 Compliance with Commission consultation standards 93
   8.4 Ex ante evaluation check of option 4 94

Table of tables

Table 1: Product non-dispensing for handwritten cross-border prescriptions 21
Table 2: Product non-dispensing for non-handwritten cross-border prescriptions 21
Table 3: Options/Objectives Matrix (crosses reflect relevance of option for objective) 26
Table 4: Organised stakeholders with widest geographical scope and target group coverage 28
Table 5: Cost of a doctor consultation 30
Table 6: stakeholder views for option 1 30
Table 7: stakeholder views for option 2 34
Table 8: stakeholder views for option 3 36
Table 9: Cost of EU-level prescriber register 38
Table 10: stakeholder views for option 4 38
Table 11: Main impacts by option (+/- to indicate positive/negative outcome on group). 39
Table 12: Cost impacts per option 39
Table 13: Non-dispensing probabilities for handwritten cross-border prescriptions 41
Table 14: Non-dispensing probabilities for non-handwritten cross-border prescriptions 42
Table 15: Model results 45
Table 16: Estimated cost savings 46
Table 17: Estimated increase in number of dispensed cross-border prescriptions 46
Table 18: Options/Objectives Matrix (crossed to measure relevance of option to objective) . 55
Table 19: Matrix 2012 average scores (full sample of score prescriptions) 61
Table 20: Matrix 2012 derived non-dispensing probabilities for cross-border probabilities ... 62
Table 21: Break-down by assumed reason in case of non-dispensing common products 62
Table 22: Break-down by assumed reason in case of non-dispensing common products 62
Table 23: NIVEL 2011 survey replies on percentage of handwritten prescriptions 63
Table 24: Work-up of estimated share of handwritten prescriptions 63
Table 25: Organised Stakeholders (pharmacists, all agreed to full data disclosure) 64
Table 26: SANCO 2012: work-up of authentication effectiveness by option 65
Table 27: Non-dispensing probabilities for handwritten cross-border prescriptions 67
Table 28: Non-dispensing probabilities for non-handwritten cross-border prescriptions 68
Table 29: Cost Inputs 70
Table 30: SANCO 2011 survey on electronic prescriber registers in Member States 71
Table 31: Deterministic model results 72
Table 32: Estimated cost savings 72
Table 33: Estimated extra dispensed cross-border prescriptions 72
Table 34: distributions used in the probabilistic model 73
Table 35: Probabilistic results (observations not clustered by simulation) 74

Table of figures

Figure 1: Respondents by type 11
Figure 2: Problem tree 17
Figure 3: Tree Diagram of Cross-border Prescription Model 44
Figure 4: Tree Diagram of Cross-border Prescription Model 57
Figure 5: Organised stakeholder (pharmacists) scores for prescriber authentication tools 65
Figure 6: Probabilistic results as boxplots (observations not clustered by simulation) 74
Figure 7: Probabilistic results as a scatterplot 75
Figure 8: Probabilistic results as a scatterplot with simulations ranked by cost of option 1 75
Figure 9: Tornado diagram 76
Figure 10: Spider plot 77
Figure 11: Univariate Sensitivity scenario: number of cross-border prescriptions increases to 8 million 78
Figure 12: Univariate Sensitivity scenario: GP cost of EUR 28 assumed 79
Figure 13: Univariate Sensitivity scenario: authentication effectiveness relative to status quo 79
Figure 14: Worst case scenario 80

List of abbreviations and acronyms

2012 EUR	Euro, in 2012 value
BEUC	The European Consumers Organization
BIG	Beroepen in de Individuele Gezondheidszorg
CED	Council of European Dentists
CI	Confidence Interval
COPD	Chronic Obstructive Pulmonary Disease
CPME	Standing Committee of European Doctors
DG SANCO	Directorate General for Health and Consumers
EFPIA	European Federation of Pharmaceutical Industries and Associations
EGA	European Generic medicines Association
epSOS	European Patients - Smart open Services
EuropaBio	European Association for Bioindustries
FTE:	Full Time Equivalent
GP:	General Practitioner
HPRO	Health PROfessionals
IA, IAB, IASG	Impact Assessment / Board / Steering Group
INN	International Non-proprietary Name
MS:	Member State
NIVEL	Nederlands instituut voor onderzoek van de gezondheidszorg
OECD`	Organisation for Economic Co-operation and Development
PGEU`	Pharmaceutical Group of the European Union
SCM (network)	Standard Cost Model (network)
SME	Small and Medium-sized Enterprise
TFEU	Treaty of the Functioning of the European Union

1. Procedural issues and consultation of interested parties

1.1 Background

In April 2011 the Directive 2011/24/EU on patients' rights in cross-border healthcare entered into force[1]. This Directive provides rules for facilitating the access to safe and high-quality cross-border healthcare and for the reimbursement of such healthcare. It also promotes cooperation on healthcare between Member States. The transposition of the Directive by Member States into national legislation is foreseen by 25 October 2013. Moreover, the cooperation between Member States is enhanced in key areas for cross-border healthcare on:

- standards and guidelines on quality and safety (Article 10),
- measures to improve the recognition of prescriptions issued in another Member State (Article 11),
- European reference networks between healthcare providers and centres of expertise (Article 12),
- the development of diagnosis and treatment capacity of rare diseases (Article 13),
- a network connecting national authorities responsible for eHealth designated by Member States (Article 14),
- a network connecting national authorities or bodies responsible for health technology assessment designated by Member States (Article 15).

This impact assessment (IA) focuses on the above measures to improve the recognition of prescriptions issued in another Member State ("cross-border prescriptions"). Cross-border prescriptions relate to situations where patients seek to have a prescribed medical product dispensed in a Member State other than the Member State in which the prescription was made. This includes prescriptions both for medicinal products ("pharmaceuticals") and for medical devices.

Further implementing measures contained within the Directive 2011/24/EU regard:

- Article 11(2) (c) requires the Commission to adopt implementing acts covering guidelines to support Member States in developing interoperable ePrescriptions. These are non-binding recommendations and do not imply any obligation on the part of Member States to set up new systems or change existing ones.
- Article 12(4) requires the Commission to develop and publish criteria for establishing and evaluating European reference networks. And it must facilitate the exchange of information and expertise on the establishment of the networks and of their evaluation. These two points are to be done via implementing acts.
- Article 14 requires the Union to support and facilitate cooperation amongst Member States on eHealth. This is to be done via a network of national authorities, participating on a voluntary basis and designated by the Member States. Article 14(3) requires the Commission to adopt, via implementing acts, the measures necessary to set up, manage, and run (in a transparent manner) this network.

[1] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF (last accessed on 9 July 2012).

- Article 15 requires the Union to support cooperation between Member States on health technology assessment. This cooperation is to take place within a network of national authorities who participate on a voluntary basis and are designated by the Member States.
- Article 15(4) requires the Commission to adopt, via implementing acts, the measures necessary to set up, manage, and transparently run this network.

Note that the above implementing measures are only interlinked with the present initiative in the sense that the guidelines to support Member States in developing interoperable ePrescriptions under Article 11(2) (c) will need to account for the possible impact of the non-exhaustive list on ePrescriptions (e.g. certain items may imply the use of certain databases).

The detailed measures assessed are contained in the second paragraph of Article 11 of the Directive, where it is states that the "*Commission shall adopt the following measures:*

(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;

(c) measures to facilitate the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, including measures to address patient safety concerns in relation to their substitution in cross border healthcare where the legislation of the dispensing Member State permits such substitution. The Commission shall consider, inter alia, using the International Non-proprietary Name and the dosage of medicinal products;

(d) measures to facilitate the comprehensibility of the information to patients concerning the prescription and the instructions included on the use of the product, including an indication of active substance and dosage."

In paragraph 4 of the same Article it is stated that, in adopting the above measures, the Commission shall have regard to the proportionality of compliance costs as well likely benefits. In line with this, an IA has been performed. This IA presents evidence for decision-makers on the advantages and disadvantages of possible policy options for implementing the above measures by assessing the main potential impacts that can be expected.

The type of initiative assessed concerns implementing acts under the Examination Procedure[2]. The expected date of adoption of the implementing acts is by November 2012.

[2] See Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

1.2 Impact Assessment Steering Group (IASG)

In September 2011, DG Health and Consumers set up an IA Steering Group in which the Directorates General for Competition, Enterprise and Industry, Justice, Information Society and Media, Internal Market and Services and the Secretariat General participated. The IASG met 3 times (on 27 September 2011, 16 January and 6 March 2012).

In addition, DG Health and Consumers consulted the Directorate-General for Budget in writing, specifically on the potential EU budget impact of policy option 4 (EU-level register of prescribers, see also the ex ante evaluation checklist in the annexes to the IA). The European Data Protection Supervisor was consulted in general on the implementation of the Directive 2011/24/EU and informed on the proposed measures (meeting of 22 November 2011).

1.3 Impact Assessment Board (IAB)

A draft IA was submitted to the IAB on 4 April 2012 and discussed in a meeting on 2 May 2012. Following this meeting in its Opinion of 4 May 2012 the Impact Assessment Board expressed a positive opinion whilst requesting following improvements to be made:

1. Strengthen the problem definition and baseline scenario, including a better explanation of applicable limitations.
2. Improve the description of options, specifically as regards differences vis-à-vis the status quo option 1.
3. Better assess the impacts by strengthening their qualitative analysis.
4. Improve the comparison of option and include a worst case scenario.
5. Outline clearer monitoring and evaluation arrangements, including links with the compliance reporting foreseen under Directive 2011/24/EU.

The present version of the IA addresses all of the above points.

1.4 Consultation

1.4.1 Background

In order to inform the impact assessment, a public stakeholder consultation was carried out[3]: This web-based open consultation was organised between 28 October 2011 and 8 January 2012. The accompanying consultation document was the impact assessment roadmap "Implementing measures for improving the recognition of prescriptions issued in another Member State under Article 11 paragraph 2 of the Directive on the Application of Patients'

[3] Public consultation on measures for improving the recognition of prescriptions issued in another Member State, available at: http://ec.europa.eu/health/cross_border_care/consultations/cons_prescriptions_en.htm (last accessed on 9 July 2012).

Rights in Cross-Border Healthcare (CBHC)"[4]. A full analytic report of the consultation report is featured on DG SANCO website[5] as referenced in annex to this IA.

Target groups included were:

- patients/citizens/consumers,
- health professionals prescribing medicinal products and/or medical devices ("prescribers"),
- health professionals dispensing prescriptions for medicinal products and/or medical devices ("dispensers"), and the
- medical industry involved in manufacturing and wholesale dealing of medicinal products and/or medical devices.

Further, it was possible for "others" (with further specification requested in the survey) to reply.

Public healthcare payers (public organisations, social security funds) were not explicitly targeted in the public consultation as they had been consulted in a prior stage for the NIVEL 2011 support study (see also below in section 1.5 "Procedural issues and consultation of interested parties"). For this study, Member States had been contacted in July 2010 via their Permanent Representations to the EU with the request to submit expert names. In all, 17 Member States submitted names by January 2011. The NIVEL research team contacted additional experts. In total, experts submitted information for 21 Member States, with 6 Member States[6] not included in the full study scope of NIVEL 2011. Moreover, detailed measures are formally discussed with Member States in the "Committee on cross-border healthcare" (committee code C40200[7]).

As demonstrated in the annexes to this IA, this public consultation met with all Commission consultation standards at the time of the launching date of the public consultation.

[4] Roadmap "Implementing measures for improving the recognition of prescriptions issued in another Member State under Article 11 para. 2 of the Directive on the Application of Patients' Rights in Cross-Border Healthcare. (CBHC)", available at: http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_004_mutual_recognition_of_prescriptions_en.pdf (last accessed on 9 July 2012).

[5] See http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_report_en.pdf (last accessed on 9 July 2012).

[6] Non-responding Member States were Cyprus, Luxembourg, Romania, Greece, Slovakia and the United Kingdom. For the three latter countries, more extensive information was provided for these countries at a later stage of the NIVEL study.

[7] See http://ec.europa.eu/transparency/regcomitology/index.cfm (last accessed on 9 July 2012).

1.4.2 Content and methodology

Questions included in the consultation concerned:

- Proposed prescription form items targeting better "patient identification", "prescriber identification" and "product identification" as well as questions on possible "other information". These questions are based on the outcome from the support study NIVEL 2011 (see below in section 1.5 "External Expertise"). NIVEL 2011 included primarily[8] prescribers and dispensers. Presenting the item lists (containing items such as "Prescriber telephone number" "International non-proprietary name (INN)", etc.) from the support study serves not only helped to validate its findings, but also deepened them by providing insights from patients and the industry.
- Issues hampering the recognition of cross-border prescriptions. These issues were identified through the support study Matrix 2012 (see below in section 1.5 "External Expertise"). The support study covered a broad sample of individual pharmacists in seven Member States. Gaining a better understanding of the views held by other groups of interest as well by dispensers at the level of organised stakeholders complemented these findings.
- Additional questions on items possibly improving patient understanding of information in prescription were added specifically with a view to the implementing acts under Article 11 paragraph 2(d) targeting better patient comprehensibility.
- Additional questions on prescriber authentication "tools" (such as on-line prescriber databases) were added to inform the impact assessment on the relative effectiveness of various authentication tools to improve the recognition of cross-border prescriptions. Replies to these questions were of direct relevance to the IA as the assumed differences in dispensing rates between police options 2, 3 and 4 are based on them.

In line with NIVEL 2011 most questions concerned 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.

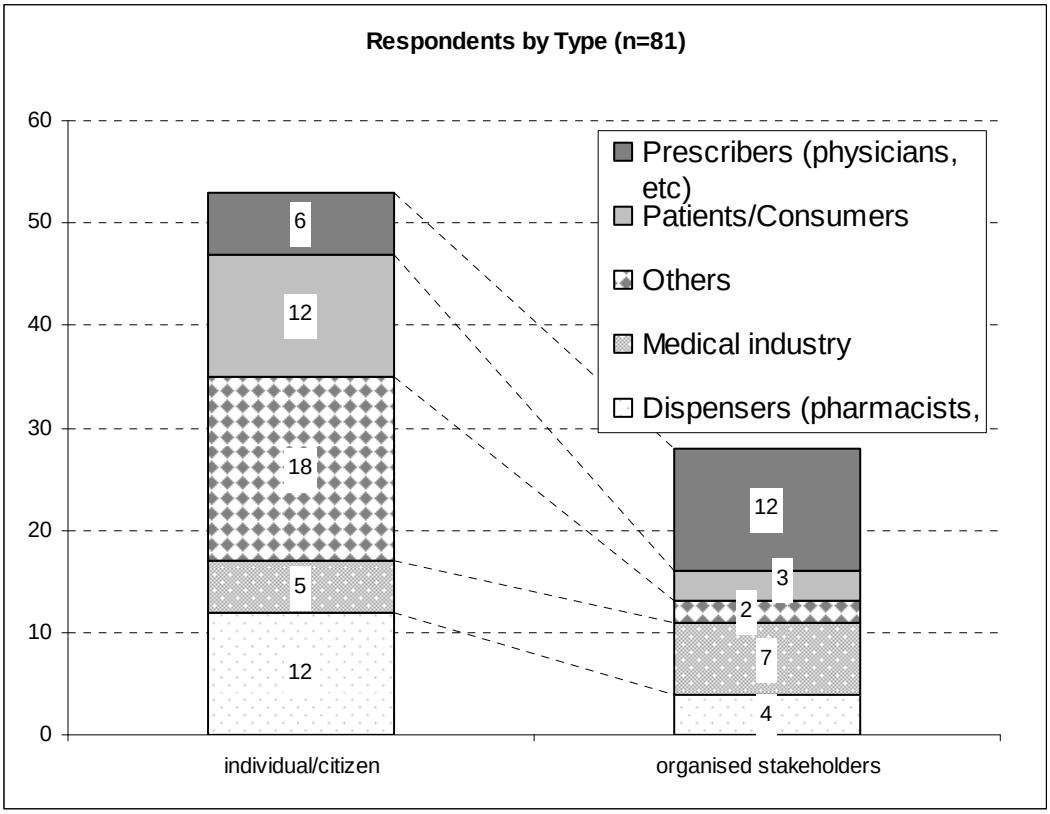
[8] Representative patients' associations were also consulted, but the responses rate was low due to the perceived technical nature of presented issues.

1.4.3 Main results

1.4.3.1 Respondents

In total 81 responses were received. The respondents are shown in Figure 1 below by type. Further details can be found in the Consultation Report[9].

Figure 1: Respondents by type



It was found that the four targeted consultation groups were sufficiently represented by replying organised stakeholder groups: at least one organised stakeholder with at least EU-wide coverage and sufficient representative scope (covering all members of target groups in general) replied on behalf of each target group.

[9] See http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_report_en.pdf (last accessed on 18 July 2012).

1.4.3.2 Result of the public consultation

The public consultation led to the following key findings:

- The proposed implementing acts will not address all issues hampering the dispensing of prescribed products in cross-border settings: understanding of foreign languages by dispensers (combined with) difficulty in reading handwritten prescriptions, products not available throughout the EU. However, the main issues appear to be addressed: prescriber authentication and minimum data needed in prescriptions to comply with local dispensing rules.
- 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 dispensers.
    - Improved information for dispensers (e.g. reference to diagnosis) may conflict with 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.

In respect to stakeholder positions on various possible ways of authenticating foreign prescribers, the following was found:

- The patients/consumers and the medical industry did not express an explicit preference for a particular way of prescriber authentication (i.e. they did not submit scores).
- Pharmacists indicated a preference for using an EU-level database of prescribers as compared to national prescriber databases.
- Similarly to the pharmacists, doctors indicated a preference for using an EU-level database of prescribers as compared to national prescriber databases.
- The dentists[10] indicated a preference for national prescriber databases compared to an EU-level database. However, the dentists indicated they took cost proportionality into account when scoring the various authentication tools.

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.

[10] Terminology used in in Directive 2005/36/EU on the Recognition of Prrofessional Qualifications includes both "dental practitioners" as well as "dentists", see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:255:0022:0142:en:PDF (last accessed on 9 July 2012).

1.5 External Expertise

Two external studies in preparation to this IA have been completed. These studies are available on-line as referred to in the annexes to this IA:

- SANCO/2010/C5/2010 ("NIVEL 2011"): "The identification and development of a non-exhaustive list of elements to be included in prescriptions", based on desk research and expert consultation. This study was finalised in November 2011 and delivered a basis for the actual core set of prescription form items.
- EAHC/2010/Health/01/Lot1 ("MATRIX 2012"): "Health Reports for the Mutual Recognition of Medical Prescriptions: State of Play." This study was delivered in January 2012. This concerns a report that captures the nature and scale of cross-border prescriptions. Based on desk research, expert input and a survey among pharmacists a statistically robust measurement of the recognition of cross-border prescriptions and possible patient outcomes was presented.

Both studies were used to inform the IA, in particular the economic evaluation attached in the annexes to the IA.

2. Problem definition

Overall, the size of cross-border healthcare is estimated to be limited at around 1% of public healthcare budgets[11]. This amounts to over 9 billion euro for the European Union or 0.08%[12] of the EU's GDP based on Eurostat data for 2009.

The total number of medical prescriptions in the EU each year is estimated between 6.5 and 10 billion. The total number of cross-border prescriptions (prescriptions issued in another Member State than the Member State where a patient seeks to have them dispensed) is estimated to be between 1.1 million and 8 million in the EU each year. Consequently, cross-border prescriptions are assumed to currently account for a small proportion of all prescriptions in the EU in the range of 0.02% to 0.04%[13] (MATRIX 2012). As the Matrix 2012 study selected Member States based on likelihood to find cross-border prescriptions, the estimated range is considered to be a "maximalist" approximation of the true number of cross-border prescriptions in the EU.

2.1 Recognition of prescriptions issued in another Member State

The principle of mutual recognition of medical prescriptions derives directly from the Treaty of the Functioning of the European Union (TFEU). Under EU rules on freedom to provide services, Member States should recognise medical prescriptions issued by medical doctors from other Member States. As stated by the Court of Justice of the European Union[14], the requirements for admission to the profession of doctor have been harmonised and have to be recognised in other Member States. As a result, the prescribing of a medicinal product by a doctor established in another Member State offers the same guarantee for the patient as a prescription issued by a doctor in the Member State where the pharmacy in question is located.

This principle clearly predates the Directive 2011/24/EU. Nevertheless, there is evidence that the real life application of this principle to cross-border prescriptions to date is suboptimal.

Research by Mäkinen 2007[15] found that the recognition of prescriptions issued in another Member State is hampered by (among other reasons) the fact that:

- effective recognition is limited to prescriptions issued only in certain countries depending on the country of the dispensing pharmacist,
- it is not always possible to verify the validity of the prescriber prior to dispensing, as required by local law.

11 See Impact Assessment accompanying the Directive on the application of patients' rights in cross-border healthcare(SEC(2008) 2164), available at: http://ec.europa.eu/health/archive/ph_overview/co_operation/healthcare/docs/impact_assessment_en.pdf (last accessed on 9 July 2012).

12 Calculated as 1% of 7.8% of the EU GDP (11 752 175 million euro) in 2009.

13 Range based on point estimate of 2.3 million cross-border prescriptions by MATRIX 2012.

14 European Court of Justice, judgments of 7 March 1989 (C-215/87, *Schumacher* should there be no ECR reference to cases?) and 8 April 1992 (C-62/90, *Commission* v. *Germany*).

15 Web-published dissertation by Mäkinen 2007, Delivery of European cross-border healthcare and the relevance and effects of EU regulations and judicial processes, available at: http://www.doria.fi/bitstream/handle/10024/33603/D790.pdf?sequence=1 (last accessed on 9 July 2012).

Further, this research illustrated that product substitution is commonly applied to overcome problems with the local availability of prescribed products. Restrictions on dispensing of foreign prescriptions in practice have to do with the type of prescribed product, the authenticity of the prescription and the medium of the prescription ("paper, fax, etc.").

Two literature reviews carried out for the support studies NIVEL 2011 and MATRIX 2012, did not identify any further relevant studies beyond Mäkinen 2007 on this topic. Moreover, the prospective research in the Mäkinen study concerned only a limited sample: "29 prescriptions were tested, consisting of 15 Finnish and 14 Luxembourgian prescriptions in 14 Member States".

In order to have a statistically robust base for the IA, primary research on the effective recognition of cross-border prescriptions was done in the Matrix 2012 study. This study included a survey completed by nearly 1000 pharmacists across seven Member States (Denmark, Germany, Greece, France, Netherlands, Poland, UK) sharing their views on dealing with foreign prescriptions across eight pathologies (Asthma, Chronic Obstructive Pulmonary Disease (COPD), Depression, Diabetes, Epilepsy, Hypertension, Ischemic Heart Disease, Osteoarthritis/Rheumatoid Arthritis).

The seven sampled Member States represent 56% of the EU population and account for an estimated 53% of all prescriptions in the EU. The sampled pathologies account for 25% of the disease burden in men and 29% of the disease burden in women[16]. In all, 7 440 hypothetical prescriptions were scored by pharmacists. This has vastly improved the statistical validity[17] and depth of the state-of-the-art knowledge in this field.

Findings by Matrix 2012 suggest that 55% of cross-border prescribed products will face difficulties in being dispensed. The key challenge is the verification of the prescriber in 24% of problematic cases. This may possibly be exacerbated for handwritten[18] prescriptions, those presented in an unfamiliar language, or missing information (all three factors each accounting for around 20% of problematic cases). The availability of (substitute) products has been mentioned as a problem less often (16% of problematic cases). The latter is a problem driver that is not related to the actual recognition of the prescription. Problem drivers related to the language/handwriting are not tackled by the proposed measures either.

The problem drivers that will be impacted by the measures concern issues with authentication (verifying the entitlement of a cross-border prescriber in particular) and issues with "missing data" (prescription form containing insufficient data to comply with local dispensing rules) in accordance with the mandate received by the Commission under Article 11 of the Directive.

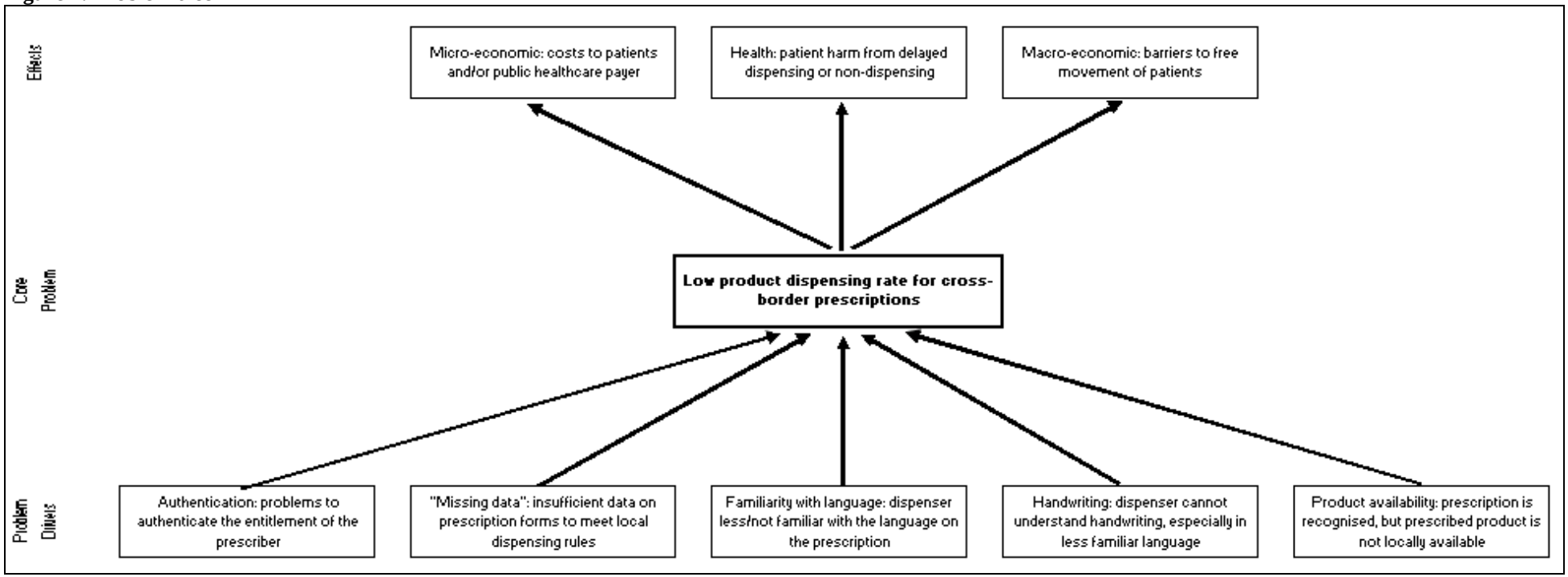
The main effects that can be anticipated as a result of the lower dispensing rate of cross-border prescriptions are:

[16] WHO burden of diseases statistics, see http://www.who.int/healthinfo/global_burden_disease/en/ (last accessed on 9 July 2012).
[17] 95% Confidence intervals as narrow as +/- 0.5% apply to the Matrix 2012 results on average dispensing rates.
[18] Handwritten prescriptions of course also apply outside of cross-border settings. However, the issue of understanding handwriting is particularly relevant for languages with which the dispenser is less familiar.

- negative health effects for patients not receiving a prescribed product or only receiving it with a delay (for instance after having obtained a prescription with a local prescriber),
- negative financial effects for patients and/or reimbursing third parties related to the cost of an extra visit to a local doctor,
- overall negative effects on patient mobility as patients (especially those with a chronic condition) may be less inclined to travel to other Member States for longer periods.

The problem tree in Figure 2 captures the above discussion of problem, problem drivers and problem effects.

Figure 2: Problem tree



2.2 Concerned groups

Cross-border Patients

As explained in the preceding section, it can be expected that the number of patients seeking to have a prescription dispensed in a Member State other than the Member State in which the prescriptions was made out, will be limited.

Nevertheless, the improved recognition of cross-border prescriptions will benefit specific groups. This was already established in the Commission's 2008 Impact Assessment accompanying the proposal for a Directive on the application of patients' rights in cross-border healthcare. The public consultation held for this impact assessment indicated that cross-border healthcare is of specific relevance to:

- Border regions: the impact of cross-border healthcare is likely to be greater for European citizens living in border regions.
- "Smaller" Member States: in less populated Member States it may be necessary for patients to go abroad to receive specialised treatments.
- Rare diseases: patients with rare diseases may need to rely more on cross-border care to obtain appropriate treatment than patients with more common conditions.
- Areas attracting large numbers of tourists.
- Further, demographic (e.g. the retired) and medical (e.g. chronic conditions) factors at play may imply the relevance of improving the recognition of cross-border prescriptions is far-reaching for specific patient groups.

Moreover, a crucial success factor for the implementation of Directive 2011/24/EU will be the confidence patients have that continuity of care will be guaranteed once they return "home" (or once they choose to travel following a healthcare intervention "at home"). In this respect, the recognition of cross-border prescriptions (e.g. as part of the follow-up treatment) is of relevance to all patients seeking all forms of cross-border healthcare.

Dispensers

In principle all dispensers would be impacted. In practice this will mainly concern pharmacists, although health professions such as opticians, orthopaedic technicians, etc. may also be impacted. Note, however, that prescriptions for medical devices are less common[19] than prescriptions for medicinal products.

Based on Eurostat data for 2008 the number of practising pharmacists in the EU is estimated at 325 000. Further, there are approximately 150 000 pharmacies in the EU. With some exceptions, notably in the UK, the large majority of pharmacies are Small and Medium-sized Enterprises (SMEs)[20]. Given a total expenditure on (outpatient) pharmaceuticals of 1.7%[21] of

[19] NIVEL 2011 study found that "not all countries use prescriptions for medical devices".

20 Impact assessment accompanying the proposal for a Directive amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source, (SEC (2008) 2674) available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2674:FIN:EN:PDF (last accessed on 9 July 2012).

[21] OECD 2010 "Health at a Glance", available at: http://ec.europa.eu/health/reports/docs/health_glance_en.pdf (last accessed on 9 July 2012).

GDP in the EU, an estimated total of EUR 200 billion is spent on medicinal products in the EU each year.

From the above it is concluded that the average pharmacy will employ around 2 pharmacists (and will probably also employ ancillary staff) and will have a maximum turnover of EUR 1.3 million on average from the sales of medicinal products. Consequently, most pharmacies meet the definition of a "micro-business": "enterprises with less than 10 employees and a turnover or balance sheet total equal to or less than EUR 2 million."

Similarly, as was the case for patients, dispensers in border regions and touristic areas are more likely to be impacted than the average dispenser.

Prescribers

Given the wording in Directive 2011/24/EU "prescribers" concern anyone who is "a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued." This could cover medical doctors, nurses, midwives, dentists and pharmacists.

In practice[22] this will mainly concern doctors ("doctors of medicine" in Directive 2005/36/EU) and dentists ("dental practitioners" in Directive 2005/36/EU). Based on Eurostat data for 2008/2009 the number of practising doctors and dentists is estimated at respectively 1 600 000 and 300 000.

Total expenditure on "outpatient care" represents 32% of total healthcare expenditure in the EU[23]. This implies an average maximum turnover of some EUR 200 000 per doctor or dentist. Arguably, most dispensers affected, when not employed in a National Health Service-type system as a public servant, will work for a micro-enterprise or work as a self-employed owner of the enterprise.

Similarly, as was the case for patients, prescribers in border regions and "smaller" countries are more likely to be impacted than the average prescriber.

Medical industry

This group covers the industry involved in manufacturing and wholesale dealing of medicinal products and/or medical devices. Indirectly the medical industry may be impacted by specific choices made. For instance, the consideration to introduce the active substance by generic denomination on prescriptions as a mandatory element may be seen as facilitating legislative measures at MS level in the field of mandatory prescribing by generic name. These issues can be very sensitive from the industry's perspective.

Others

Further groups that are impacted by the assessed measures concern third party healthcare payers, mainly regulatory bodies in the Member States as well as social security funds.

[22] NIVEL 2011 reports for 21 surveyed Member States that " Next to doctors (who are – naturally – authorised to prescribe everywhere), dentists have prescribing authorisation in a large majority of Member States (n=19). Midwives and nurses have authorisation to prescribe in a minority of Member States and pharmacists in none of the states that participated in the survey".

[23] Based on Eurostat data for 2008: Systems of Health Accounts (SHA).

2.3 Expected baseline evolution

The anticipated evolution of the current level of recognition of cross-border prescriptions, assuming unchanged policy, is based on Matrix 2012. This study provided a baseline measurement of existing problems associated with the mutual recognition of cross-border medical prescriptions.

The Pharmaceutical Group of the European Union (PGEU), representing pharmacists at the EU level, has proposed[24] "a list of essential element for cross-border prescriptions" in its policy position paper on the recognition of cross-border prescriptions under Article 11 of the Directive 2011/24/EU. Currently there are many prescription form models in use in the EU. Often within a given Member States there are different models. However, there appears to be no specific form for cross-border purposes in current use (based on unpublished report by the PGEU documenting prescribing practices for 22 EU member states).

It is important to underline that the wording of Article 11 (2) does not allow to conclude that the Commission has a mandate to impose changes in all medical prescriptions in use in Member States. Hence, the principle of subsidiarity holds. Therefore, strictly speaking, Member States could choose to apply the proposed implementing acts exclusively to prescription forms for "planned" cross-border prescriptions, i.e. prescriptions for which it is known beforehand they will be used in a cross-border setting. In practice this would regard situations in which a patient explicitly indicates to a prescribers that (s)he intends to take the prescription to another Member State. However, as pointed out by Member State designated experts in NIVEL 2011 "the development of separate "cross border prescription forms" does not seem to be reasonable as it might not be foreseeable at the time of prescription neither for the doctor nor for the patient whether the prescription will be used in the home country or another country." In such a case, the general principle of the mutual recognition of prescriptions will still apply undiminished. In other words one would expect current "status quo dispensing rates" (to continue) to apply for these prescriptions. This, however, would warrant follow-up in future evaluation exercises (see under heading 7 "Monitoring and evaluation").

Table 1 and Table 2 summarise the current state of recognition of cross-border prescriptions as based on Matrix 2012. All calculations and data sources applied can be found in the economic evaluation. By "common products" are meant products commonly used and available in all Member States (but not necessarily available in all pharmacies of a given Member State). By "less common products" are meant products available in less than half the Member States and/or less frequently used products. Further, based on NIVEL 2011 an estimate was made for the percentage handwritten[25] prescriptions represent in the EU. This was estimated[26] at 26% of all prescriptions. It should be noted that possible types of medium cover print (fully printed) prescriptions with paper forms as a medium, handwritten (printed template completed in handwriting) prescriptions with paper forms as a medium and ePrescriptions that are fully "paperless" and electronic. Remark, however, that patients may be given a print (paper) copy of their ePrescription.

[24] See http://www.pgeu.org/en/policy/8-cross-border-health-care.html (last accessed on 9 July 2012).
[25] "Handwritten" defined as either fully or partially handwritten. The latter is the case when a prescriber fills out a pre-printed standard form in handwriting.
[26] Estimations were confirmed by the PGEU (personal email, 23 March 2012).

The tables below should are based on the Matrix 2012 study. A detailed explanation on the calculation of the applying percentages is presented in the economic evaluation annexed to this IA. The tables should be read in the following manner: a handwritten cross-border prescription for commonly available products has a 50% probability of not being dispensed. The main reasons for non-dispensing have to do with authentication of the foreign prescriber's professional entitlement (25% of non-dispensed cases), understanding the language in which the prescriptions are drafted (23% of cases), missing information on the prescriptions (20% of cases) and difficulty in reading handwriting, which is aggravated in case of a less known language (also 20% of cases).

Table 1: Product non-dispensing for handwritten cross-border prescriptions

Common Products		Less common products	
Non-dispensing rate	**50%**	Non-dispensing rate	**59%**
Authentication	25%	Authentication	22%
Information Missing	20%	Information Missing	18%
Handwriting	20%	Handwriting	19%
Language	23%	Language	20%
Product Unavailable	12%	Product Unavailable	21%

Table 2: Product non-dispensing for non-handwritten cross-border prescriptions

Common Products		Less common products	
Non-dispensing rate	**40%**	Non-dispensing rate	**48%**
Authentication	32%	Authentication	27%
Information Missing	25%	Information Missing	23%
Handwriting	0%	Handwriting	0%
Language	29%	Language	25%
Product Unavailable	14%	Product Unavailable	26%

From the tables above the following observations are made:

- less common products meet with higher non-dispensing rates as a result of non-availability of the prescribed products,
- handwritten prescriptions meet with higher non-dispensing rates due to non-understanding of the prescription by dispensers.

The measures considered in this impact assessment would only impact issues related to the prescriber authentication and missing data on prescriptions. As regards the other factors (language, product availability, handwriting) it appears logical to assume that only the latter factor, proportion of handwritten prescriptions, might evolve under unchanged policy. Given the continuing[27] computerisation of the prescription process the percentage of handwritten prescriptions will probably decrease (further) from the present 26%. However it is not sure that -nor when- all prescriptions will become non-handwritten. This evolution in itself has no impact on the present analysis (as it would not affect the ranking of options). Nevertheless, it is important to take it into account for future evaluation exercises to make sure a baseline improvement in dispensing rates is not mistakenly attributed to the proposed measures.

Should in the future prescriptions in the EU become "ePrescriptions" and integrated in interoperable cross-border IT systems, issues related to authentication, handwriting, missing

[27] Examples can be found in recent legal proposals for the further uptake of "ePrescribing" in Portugal and Greece.

information could be fully solved. Cross-border ePrescriptions are tested in the "European Patients – Smart Open Services" epSOS project[28], an EU-wide initiative for a large scale European pilot of patient summaries and electronic prescriptions. However, the project (ending by December 2013) foresees testing pilot applications, but no EU-wide roll-out is planned. It should be underlined that it is unlikely ePrescriptions will be widely rolled out in the foreseeable future. At present[29] only Denmark, Sweden and Estonia use nation-wide ePrescribing systems. The literature[30] reports that evolution in this field is progressing slowly. This implies that, particularly in cross-border settings, the use of ePrescriptions will not be part of the foreseeable future. Successful cross-border ePrescribing would not only require national ePrescribing systems to be in place, but would also require them to be interoperable.

Finally, it is likely that Member States will use publicly accessible registers of health professionals to comply with Article 6(3) of the Directive 2011/24/EU. The Directive strengthens the rights of patients to information about a health professional and his/her right to provide services (including the right to prescribe). This information should be made easily accessible by electronic means according to the Directive. Arguably, the most rational (cost-effective as we demonstrate in an annex to the IA) way for Member States to do so, is by using publicly accessible registers. This means that we expect websites with information on – among other- who can prescribe to become widely available. Theoretically, this may improve prescriber authentication in the status quo evolution. However, at present a majority of Member States already have similar online databases in use. Therefore, without an added requirement (either directly or indirectly) for cross-border dispensers to consult these databases, it is assumed the expected baseline evolution is not impact by this factor.

Given the above the anticipated evolution for the foreseeable future with current policy unchanged is for the dispensing of products in cross-border prescriptions to maximally improve by 10[31] percentage points. This equates to the difference in dispensing rates for handwritten versus other prescriptions for 26% of related cases (i.e. the current proportion of handwritten prescriptions). This would correspond to a situation in which all handwritten prescriptions have disappeared (see Table 2). The "no policy action" baseline is explicitly included in 6.2 "Results". As the cost-minimisation analysis is reported both for handwritten and non-handwritten prescriptions, the latter scenario is equivalent to the "maximum" anticipated evolution for the foreseeable future. However, non-dispensing due to dispensers not being able to understand prescriber handwriting is not impacted by the assessed measures. Therefore, possible changes in the proportion of handwritten prescriptions do not impact the present cost ranking of options, nor the estimated overall savings.

[28] See http://www.epsos.eu/.
[29] See for instance http://eprescription-xborder.eu/eprescription-status/ (last accessed on 26 July 2012)
[30] See Mäkinen et al 2011, Telemed J E Health. 2011 Apr;17(3):217-22. Epub 2011 Mar 5, Electronic prescriptions are slowly spreading in the European Union,Mäkinen M, Rautava P, Forsström J, Äärimaa M.
[31] E.g. the calculation for a prescribed "common" product. For handwritten prescriptions the non-dispensing rate is 50% with 20% of non-dispensed cases accounted for by problems with understanding handwriting (Matrix 2012). In other words, for handwritten prescriptions out of a 100 prescriptions 10 would not be dispensed on account of the handwriting. In case of a non-handwritten prescription the non-description rate should therefore drop with 10 percentage points (or 20% of 50%) from 50% to 40%. Also it can be seen that the 10 handwritten prescriptions not dispensed due to "data issues" (or 20% of non-dispensed handwritten prescriptions) in case of non-handwritten prescriptions will account for 25% (or 10 out of 40) of non-dispensed prescriptions.

2.4 Rationale for EU action

A dual legal basis applies for EU action in this field, explicitly in the Directive 2011/24/EU implicitly in Article 56 TFEU on the liberalisation of services.

The proposed implementing act is intended to implement Article 11 paragraph 2 of the Directive 2011/24/EU. Uniform conditions are needed to do so (Article 291 paragraph 2 TFEU). The rationale for these measures is explained in recital 53 of the Directive:

"Where medicinal products are authorised within a Member State and have been prescribed in that Member State by a member of a regulated health profession within the meaning of Directive 2005/36/EC for an individual named patient, it should, in principle, be possible for such prescriptions to be medically recognised and for the medicinal products to be dispensed in another Member State in which the medicinal products are authorised. […]

The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions. […]" The common list of elements provides the basis for recognition of prescriptions.

Moreover, the principle of the mutual recognition of prescriptions predates Directive 2011/24/EU as it derives directly from EU rules on freedom to provide services (Article 56 TFEU).

As the overall impact of cross-border healthcare is limited, it is appropriate to require the application of the non-exhaustive list only to cross-border prescriptions (e.g. prescriptions issued by a health professional, further to an explicit request of a patient who intends to use the prescription in another Member State).

3. Objectives

3.1 General policy objectives

Two general objectives apply:

- To ensure that cross-border healthcare is as safe and efficient as possible.

  This objective is crucial to guarantee that the Directive 2011/24/EU is successfully implemented. The proposed implementing acts are of specific relevance as the improved recognition of cross-border prescriptions will contribute to the overall continuity of care (e.g. in case of prescriptions carried by a patient for follow-up treatment returning "home" after cross-border surgery).

- Remove barriers to free movement of patients and health products

  The proposed implementing acts aim to improve the effective recognition of prescriptions issued in another Member State. In that sense it will contribute to the completion of the internal market by reinforcing the application of the general principle of mutual recognition between Member States.

3.2 Specific objectives

The below specific objectives are distinguished in line with the measures presented in Article 11, paragraph 2 of the Directive 2011/24/EU:

- Ensure that the prescriber's entitlement to prescribe from one Member State can easily be verified in all Member States.

- Ensure the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, in respect of patient safety concerns in relation to possible product substitution.

- Ensure the comprehensibility of the information to patients concerning the prescription.

The objectives imply EU policy making on the content of medical prescriptions, which is a policy field at EU level regulated by Article 11 of the Directive 2011/24/EU.

4. Policy options

4.1 Assessed options

Four options are considered.

Option 1 is the "no policy change approach". The baseline evolution given the current state-of-play is informed by the Matrix 2012 study (see above: 2.3 " Expected baseline evolution"). This option is the comparator against which the policy intervention options 2, 3 and 4 are evaluated.

Option 2 concerns the adoption of a non-exhaustive list of elements for cross-border prescriptions to be included in the prescriptions and which must be clearly identifiable in all prescription formats ("core set"). This core set is to be seen independently of the actual prescription medium (paper and/or electronic). This core set addresses the specific objectives set out above: prescriber authentication, product identification and patient understanding of information. The latter objective is interpreted in the sense that the information needed to ensure the product identification (objective 2) will be made as comprehensible to patients as possible. Consequently, it is considered that the measures described under Article 11 paragraph 2 (a), (c) and (d) of the Directive 2011/24/EU can be simultaneously addressed through the core set allowing for:

- the authentication of prescribers, e.g. by including name, work address, phone number, signature, etc. of the prescriber,
- correct product/device identification and safe substitution practices, e.g. by including codes referring to the Anatomical Therapeutic Chemical classification of drugs, the International Non-proprietary Name (INN) of a medicinal product, the intended dosage, etc.,
- comprehensibility to patients, e.g. by using icons to indicate the time when to take a medicinal product.

As can be seen in the NIVEL 2011 report, the main possible differences between the eventual non-exhaustive list and the content of existing prescriptions in Member States would lie in potentially proposed elements such as direct prescriber contact details, prescriber work address as well as product identification through the INN.

Option 3 combines option 2 with the requirement to establish prescriber databases at Member State level and the requirement for the dispenser to consult these newly established databases or to consult already existing databases. It must be underlined that many Member States already have some type of prescriber/health professional database in use. The main difference between option 3 and the current status quo would therefore lie in the requirement for cross-border dispensers to consult these databases. This requirement could either be by direct obligation or by indirect necessity (e.g. by only mentioning a prescriber code on the prescription that the dispenser needs to enter into the database to access the information on the prescriber contained in the non-exhaustive list under option 2).

Option 4 combines option 2 with the creation of a prescriber database at EU-level. Similar to option 3, option 4 starts from the assumption that in order for a dispenser (such as a pharmacist) to effectively verify the legal entitlement of the prescribing health professional,

an electronic prescriber register, that can be consulted by cross-border dispensers, should be established. Under option 4 a central register at EU-level would be established. Further, option 3 is different from option 4, as centralisation of prescriber data would allow to improve the usefulness of data for dispensers. Information could be presented in (a) language(s) accessible to dispensers. Moreover, to a certain extent nationally applicable terminologies for professional qualifications appearing on prescriptions could be made more comparable and understandable for dispensers. The latter may be necessary when a dispenser has to make an assessment in case a certain product can only be dispensed when prescribed by a practitioner who holds a specific specialised qualification (e.g. anticoagulants prescribed by a cardiologist). Finally, similar to option 3, a requirement would be created for cross-border dispensers to consult this central register. This requirement could either be by direct obligation or by indirect necessity (e.g. by only mentioning a prescriber code on the prescription that the dispenser needs to enter into the register to access the information on the prescriber contained in the non-exhaustive list under option 2).

4.2 Selection criteria

The considered options were selected for their expected relevance to the specific objectives targeted. In Table 3 the relevance of the operational components in options 2-3 for the specific objectives is shown.

The following arguments were considered in choosing policy options:

- The "no policy change" option serves as the comparator against which the costs and/or effectiveness of policy options 2-4 are evaluated.
- Option 2 is steered by the wording in Directive 2011/24/EU, Recital 53: "The implementation of the principle of recognition should be facilitated by the adoption of measures necessary for safeguarding the safety of a patient, and avoiding the misuse or confusion of medicinal products. These measures should include the adoption of a non-exhaustive list of elements to be included in prescriptions." Note that further in Recital 53 it is stated that "The recognition of prescriptions should also apply for medical devices that are legally placed on the market in the Member State where the device will be dispensed."
- Options 3 and 4 are included as stakeholder groups across the board, in reply to the public consultation as well as in consultations as part of support studies NIVEL 2011 and MATRIX 2012 suggested the use of electronic registers to ensure the authentication of prescribers. Note also that in the public consultation various respondents raised the issue of cost-proportionality in this respect.

Table 3: Options/Objectives Matrix (crosses reflect relevance of option for objective)

Operational components	Prescriber Authentication	Product Identification	Patient Understanding
Non-exhaustive List of Elements in (Cross-border) Prescriptions	XX	XXX	XX
Member State Prescriber Databases	XXX		
Central EU Prescriber Database	XXX		

In a prior stage alternative options were considered:

- The option to foresee separate prescription core sets for medicinal products and medical devices. This option did not receive further consideration for the following reasons:
    - feedback received in the NIVEL 2011 study (reporting that various Member States[32] at present do not have prescriptions for medical devices as a rule),
    - the wide variability in existing types of medical devices, hampering the possible identification of products by means of a uniform set of information items.
- The option to foresee a permanent monitoring tool. This option did not receive explicit consideration as experiences with the Matrix 2012 study proved the effectiveness of an ad hoc evaluation tool (i.e. ideally a one-time repeat survey).
- The option to consider that Member States would either fully integrate the core set in all prescriptions or would restrict them to a parallel set of "cross-border only" forms. It was decided that this assessment could be done implicitly through the design of the options comparison (see below). This is explicitly addressed in section 6.2 'Results'.

[32] NIVEL 2011 reports that "Cyprus and Denmark are excluded because their experts stated that prescription forms are not used for medical devices". Further, in practice Finland, the Netherlands, Poland, Belgium, the United Kingdom, Ireland and Slovenia in practice use no or few prescriptions for medical devices (Cross-border Member State expert group on 14 February 2012).

5. Analysis of impacts

The following expected impacts are assessed below:

- Social impacts:
  - Health impacts expected when patients do not receive a prescribed product (or receive it with a delay).
  - Personal data protection impacts expected for options 3 and 4, which include the use of registers containing data on prescribers.
- Regulatory burdens imposed on prescribers and dispensers (as demonstrated in section 2.2 "Concerned groups" these are in majority micro-enterprises[33])
  - Additional information obligations from future monitoring/evaluation exercises.
  - Overall business practice impacts (changes in business software used, time spent dispensing/prescribing).
- Economic impacts
  - Cost impacts on patients and/or public healthcare payers paying the cost of an extra doctor consultation abroad.
  - Cost impacts on Member States and the Commission in options 3 and 4 respectively for the set-up and running of prescriber registers.

Below, these impacts are discussed, where relevant, for each distinct option.

Further, for each option, stakeholder views (if expressed) are referred to explicitly by summarizing views expressed by stakeholders in Table 4. The 4 targeted stakeholder groups in the consultation from the DG Health and Consumers were sufficiently represented by replying organised stakeholder groups: at least one organised stakeholder with at least EU-wide coverage and sufficient representative scope (covering all members of target groups in general) replied on behalf of each target group (see Table 4).

Table 4: Organised stakeholders with widest geographical scope and target group coverage

Name	Number in Transparency Register[34]	Stakeholder Group
Phamaceutical Group of the European Union (PGEU)	00086317186-42	Dispensers (pharmacists, etc)
European Generic Medicines Association (EGA)	48325781850-28	Medical industry
European Association for Bioindustries (Europabio)	1298286943-59	Medical industry
European Federation of Pharmaceutical Industries and Associations (EFPIA)	38526121292-88	Medical industry
The European Consumers Organization (BEUC)	9505781573-45	Patients/Consumers
Council of European Dentists (CED)	4885579968-84	Prescribers (doctors, etc)
The Standing Committee of European Doctors (CPME)	9276943405-41	Prescribers (doctors, etc)

[33] In order to reinforce efforts to minimise the regulatory burden on very small companies to the absolute minimum, the Commission outlined in November 2011 its new policy on "Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises" (COM(20i 1)803). Legislative proposals affecting enterprises, including revisions, start from the premise that micro-companies should be excluded from the scope of the proposed legislation, unless the necessity and proportionality of their being covered can be demonstrated. The necessity is evident as the proposed measures must include prescribers and dispensers and these groups concern mainly micro-enterprises.

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

5.1 Option 1: "no further policy action"

Negative health and cost effects in the current baseline situation are discussed. Options 2, 3, 4 aim to lower these negative effects by improving the dispensing rate of cross-border prescriptions. This way they aim to deliver positive impacts compared to option 1.

5.1.1 Health effects

It is clear that the non-dispensing (or delayed) dispensing of medical products entails negative health effects for patients.

Matrix 2012 looked extensively into possible harm resulting from the non-dispensing or delayed dispensing of prescribed products in cross-border patient cases. For the patient cases included by Matrix 2012 the below symptoms were reported as result of a time gap in prescribed therapy:

- Chronic obstructive pulmonary disease: an increase in shortness of breath, lowered lung function and worse health status.
- Depression and Bipolar Disease: influenza-like symptoms, psychic symptoms, gastrointestinal symptoms, sleep disorders, equilibrium disorders, etc.
- Epilepsy: increased risk of hospitalisation among patients.
- Hypertension: substantial increase in blood pressure.
- Ischemic heart disease: in one instance an acute myocardial infraction was reported.

However, it was found, after an exhaustive[35] literature review, "that although a short-term health effect following a medication gap cannot be ruled out for the majority of pathologies, the relative frequency of it is not clear and the anticipated level of harm tends to be low." Consequently, possible health impacts are not considered among the impacts in the economic evaluation as there is no firm evidence base (to be found) for quantifying them. It should also be remarked that the more severe the expected patient harm is from a medication gap, the more patients will themselves ensure a timely alternative treatment (e.g. a diabetes patients will try to find a local doctor to have insulin prescribed or will go directly to a local hospital).

5.1.2 Cost effects

In line with the figures mentioned under section 2.2 " Concerned groups" at macro-level the overall size of the issue is small. Possible sector impacts for the medical industry, in terms of improved patient compliance and improved free movement of goods, are therefore also likely to be limited. However, the intended measures are expected to benefit the movement of specific groups of citizens (with particular chronic diseases, allergies, etc.) and services (e.g. short-term posted workers abroad). It is likely that geographic, seasonal and demographic patterns are at play. Nevertheless, no significant macro-economic impacts are assumed to apply.

[35] 5 224 unique references were screened on title and abstract, and 5 193 were excluded. The remaining 31 references proceeded to full text screening. Four could not be retrieved, so 27 were included in the final review.

Consequently, the economic impacts are considered to be limited to cost impacts on individual actors such as patients and public organisations. In line with the former, the below cost assumptions apply. In the economic evaluation they are explained in greater detail:

- In case of dispensing, no (additional) costs are assumed for patients and/or public healthcare payers covering the patients.
- In case of non-dispensing the financial effect on the patient (and ultimately public healthcare payers) will be limited to the cost of a doctor visit. This cost was estimated at EUR 34 as an EU average in the Matrix 2012 study (see Table 4). The uncertainty regarding this cost estimate is discussed extensively in the economic evaluation (see annex 1).

Table 5: Cost of a doctor consultation

Cost	Value (2012 EUR)	Source
Cost of visiting local GP	34	MATRIX 2012: calculations made based on OECD data for GP salaries in 7 EU MS (Austria, Czech Republic, Finland, France, Germany, Luxembourg and the Netherlands)

5.1.3 Stakeholder views (public consultation)

Stakeholders were requested to provide feedback on what they saw as the main issues with the recognition of cross-border prescriptions (see Table 6). By and large it was acknowledged that the current recognition of cross-border prescriptions could be improved.

Patients would see a better product identification as an improvement to the status quo. Health professionals are of the opinion that the identification/authentication of the prescriber could be improved.

Table 6: stakeholder views for option 1

	Current Issues with recognition of cross-border prescriptions
Patients	Product identification (INN should be included)
Prescribers	Verification of legitimacy of the prescriptions and in particular the entitlement of the prescriber (CPME) Understanding of handwriting and product availability (CED)
Dispensers	Verification of the authenticity of the cross-border prescription and in particular the entitlement of the cross-border prescriber and the absence of certain items on the prescriptions.
Industry	No indication given

5.2 Option 2: "non-exhaustive list"

Impacts under option 2 are discussed. The impacts concern expected differences in comparison to option 1, the baseline comparator. It is assumed that the dispensing rate for cross-border prescriptions improves under option 2 as:

- All "missing data" issues for dispensers are solved under option 2. This "maximalist" hypothesis corresponds to the overall goal that will be targeted in discussions with Member States on the precise content of the non-exhaustive list. The purpose of the political debate will be to agree with Member States on a non-exhaustive list that minimizes "missing data" issues.
- All "prescriber authentication" issues for dispensers are improved in proportion to scores attributed by the PGEU in the SANCO 2012 public consultation. As the PGEU is an important stakeholder representing the majority of dispensers (pharmacists), the PGEU input is taken as a reference. Also, following the Matrix 2012 study it is assumed that prescription authentication issues mainly equate to prescriber authentication issues: an intra-rater correlation of 85% was found between scores for both authentication issues. Hence, prescriber authentication is assumed to determine overall prescription authentication.

Non-dispensing rates therefore drop by about 20 percentage points. Taking the example of handwritten prescriptions for common products (see Table 8), we find that there is a non-dispensing rate of 50% at baseline (Matrix 2012). This then drops to around 30% under option 2 as:

- There is no more non-dispensing due to "missing data" issues (which accounts for around 20% of non-dispensed prescriptions under option 1 (Matrix 2012). In other words, out of 100 cross-border prescriptions, around 10 more (20% of 50%) will be dispensed.
- There is 78% percent less non-dispensing due to "authentication" issues (which accounts for around 25% of non-dispensed prescriptions under option 1 (Matrix 2012). This drop is based on the authentication effectiveness score (7 out of maximum of 9) given by dispensers in the public consultation. In other words, out of 100 cross-border prescriptions, around 10 more (78% of 25% of half of prescriptions) will be dispensed.

Given the above one can estimate that an extra 10% of prescriptions will be dispensed if "missing data" issues are solved and another extra 10% of prescriptions will be dispensed if the frequency of authentication issues drops by 78%. Taken together, this accounts for the expected drop in non-dispensing rate of around 20 percentage points. It must be stressed that this drop concern a "maximalist" improvement as it is grounded in the 1) explicit assumption that missing data issues are fully minimised and 2) implicit assumption that the current prescriber authentication is fully insufficient. The robustness of results for changes in the latter assumption is extensively tested in the economic evaluation (see annex 1).

5.2.1 Health impacts

In proportion to the improved dispensing rate negative health effects will be avoided, creating an overall positive health impact under option 2. However, these impacts are not quantified as discussed above.

5.2.2 Cost impacts

Doctor consultations

Proportional to the improved dispensing rate on average a positive cost impact (from avoided doctor consultation costs) of around EUR 7 is expected (or 20% of the doctor cost of EUR 34).

Changing prescription forms

No extra costs for the introduction of a list of elements in prescriptions are assumed (e.g. current paper forms are likely to run out in the future and would require reprints on any account). This implies no start-up costs are considered[36]. This is counterbalanced by the fact that:

- No dynamic beneficial spill-over effects are assumed either (improved intra-regional recognition of prescriptions within a given Member State, lower purchasing cost of prescription-related software packages through partial harmonisation of prescriptions across the EU,…).
- There is a trade-off between the transition time left to Member States and start-up cost in line with the time it takes to clear stocks of already printed prescriptions, write off software packages, etc.
- The scope is limited to cross-border prescriptions (i.e. for instance prescription cases where a patient explicitly indicates to the prescriber dispensing of the prescriptions will be sought in another Member States). Based on the NIVEL 2011 Member States are likely to prefer incorporating the non-exhaustive list into all existing prescriptions, but given the restricted scope this non-exhaustive list can be phased in gradually, starting out with cross-border only prescriptions at first.

Further, in reference to a recent legislative initiative from the Spanish government to harmonise prescription forms, it is found that the "MEMORIA ECONÓMICA"[37] accompanying the initial proposal did not anticipate an increase in expenditure for the public budget. Note that a transposition time of 24 months was foreseen for ePrescriptions, 12 months specifically to clear the stock of existing paper prescriptions

In light of the above considerations, only "business as usual" costs are assumed.

[36] Note that the point "Member State experiences (if any) in changing national prescription forms" was put on the agenda of the Cross-border Healthcare Expert Group "Recognition of Prescriptions – implementing acts" on 14 February 2012. The point, however, was not taken up by any of the present experts.

[37] See page 18 (last accessed on 27 July 2012) http://www.cofpo.org/tl_files/Legislacion/Proyecto%20de%20RD%20sobre%20receta%20medica%20y%20etc.pdf

5.2.3 Business impacts

Both for dispensers and prescribers no (additional) future reporting or data collection are foreseen as explained in section in section **Error! Reference source not found.** "**Error! Reference source not found.**". Further possible impacts are explored below.

Dispensers

For dispensers an overall improvement of their business practices is expected[38] due to the proposed measures. A faster recognition of cross-border prescriptions will imply time gains for dispensers during business hours.

Prescribers

For prescribers the impact is less unequivocally positive:

- Changes in "prescribing habits" may take time,
- There may be costs involved with changes to prescription forms or related software.

However, the above impacts are only temporary (e.g. the purchasing cost of small business software is usually written off over a short period) and might be compensated by positive long-term effects such as lower prescription software prices as a result of increased competition among vendors following an EU-wide (partial) harmonisation of prescriptions. The organised stakeholders responding on behalf of prescribers to the public consultation did not signal any particular concerns in this regard. This was confirmed in follow-up communication exchanges with the CPME.

5.2.4 Stakeholder views (public consultation)

Stakeholders were requested to provide feedback on what they saw as the main issues with the Prescription items addressing prescriber identification/authentication and product identification (see Table 7). Replies mentioned specific items to be considered for inclusion in a possible non-exhaustive list for cross-border prescriptions. By and large no comments were received stating the uptake of a non-exhaustive list would not improve the current recognition of cross-border prescriptions.

Patients and prescribers stressed the use of the International Non-proprietary Name for medicinal products. Industry representatives stressed brand name should be included. As regards patient understanding, the suggested use of non-handwritten prescriptions is beyond the scope of the currently assessed measures.

[38] See for instance the response to the public consultation by the PGEU, emphasising that the proposed measures for the recognition of cross-border prescriptions "could help to facilitate this recognition, including a proposal for development of a non-exhaustive list of elements to be included in the cross-border prescription" (http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_pgeu_en.pdf, as last accessed on 27 July 2012).

Table 7: stakeholder views for option 2

	Main comments for non-exhaustive list
Patients	INN to be included both with a view to product identification and patient understanding
Prescribers	INN to be included for product identification. Prescriber contact details to be included for better prescriber authentication. Use of electronic prescriptions will help patient understanding.
Dispensers	Clinical indication would improve product identification. Non-handwritten prescriptions would benefit patient understanding. Using registration numbers would improve prescriber authentication.
Industry	INN should always be accompanied by brand name for product identification.

5.3 Option 3: "non-exhaustive list combined with national prescriber registers"

Impacts under option 3 are discussed. The impacts concern expected differences in comparison to option 1, the baseline comparator. It is assumed that the dispensing rate for cross-border prescriptions improves under option 3 as:

- All "missing data" issues for dispensers are solved under option 3 (see discussion for option 2 as above)
- All "prescriber authentication" issues for dispensers are improved in proportion to scores attributed by the PGEU in the SANCO 2012 public consultation. The authentication effectiveness of option 3 is lower than for option 2 as dispensers expect the use of national prescriber registers to be time-consuming and confusing due to language/terminology issues (see also below).

Non-dispensing rates therefore drop by about 17 percentage points, less than was the case for option 2. The calculation is similar to the one explained under option 2 and further explained in detail in the economic evaluation annexed to the IA.

5.3.1 Health impacts

In proportion to the improved dispensing rate negative health effects will be avoided, creating an overall positive health impact under option 3. However, these impacts are not quantified as discussed above.

5.3.2 Cost impacts

Similarly as for option 2, only "business as usual" costs are considered.

Doctor consultations

Proportional to the improved dispensing rate on average a positive cost impact (from avoided doctor consultation costs) of around EUR 6 is expected (or 17% of the doctor cost of EUR 34).

National electronic prescriber registers

Under option 3 no (additional) costs for prescriber registers accessible to dispensers at the level of Member States are assumed. Based on findings from the Health Professional (HPRO) card project it appears most Member States already have some form of electronic health professional register that is available online (HPRO 2010). Further to this, the NIVEL 2011 study reported that from a total of 21 surveyed Member States, "Nineteen Member States have a registration or up to date list of qualified healthcare professionals with authorisation to prescribe. Seven Member States do not provide this information to dispensing healthcare professionals in other countries. In the other 12 Member States websites are the most common form to verify whether or not a professional is registered." In the annexes to the economic evaluation a non-exhaustive list of existing online prescriber registers (accessible to dispensers) is presented.

Further, Article 6 (3) of the Directive 2011/24 states that "In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice". Moreover, in Article 6 (5) it is stated that "the information referred to in this Article shall be easily accessible and shall be made available by electronic means." Consequently:

- Member States will be required to make a data collection effort if they have not done so already and
- Arguably the most cost-effective way of providing foreign patients with such information by electronic means is through a publicly accessible website as compared to replying to individual phone calls, emails, etc. In the annexes to the economic evaluation it is shown that, given the annually expected number planned cross-border healthcare interventions it is extremely unlikely (e.g. assumed staff time of as little as 40 seconds per patient information request) that meeting related patient information requests on healthcare providers would be more cost-effective by use of ad hoc email replies by staff instead of by use of publicly accessible electronic registers.

The related cost is therefore assumed not to be attributable to option 3 as it is already part of the baseline situation following the overall transposition of Directive 2011/24/EU by 25 October 2013. Moreover, the use of publicly accessible constitutes the most rational (i.e. most cost-effective) manner for Member States to act. The difference between option 3 and option 1 lies in the requirement (either direct or indirect) to be created for cross-border dispensers to consult these national registers.

5.3.3 Business impacts

Expected impacts are similar to those for option 2, with the exception of business practice impacts for dispensers, who indicated the consultation of cross-border national registers may be time-consuming and inefficient. The following explanatory comment was received following an additional request for information (PGEU, 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." Dispensers suggest issues regarding the dispenser's proficiency in foreign languages, nationally applicable terminologies (such as for medical qualifications), etc. will have negative implications on dispensers' operational efficiency.

5.3.4 Personal data

Possible implications are direct for prescribers as their personal data would be included in registers accessible to dispensers. However, no (extra) impact on personal data protection is expected following the same reasoning as applied above for the cost of national registers.

5.3.5 Stakeholder views (public consultation)

Stakeholders were requested to provide feedback on what they saw as the main issues with the use of national prescriber registers. (see Table 8). Especially from the side of dispensers a negative opinion was voiced on option 3 (see also in preceding sections).

Table 8: stakeholder views for option 3

	Main comments for use of national prescriber registers
Patients	No indication given
Prescribers	Option 3 is preferable to option 2. National databases should be accessible to prescribers based in other EU Member States. This may pose some concerns due to patient data protection. Details about the prescriber (e.g. name, qualification, identification code, etc) should also appear on the prescription.
Dispensers	Direct contact with prescribers (option 2) is preferable. Use of national registers in particular is perceived as added burden.
Industry	No indication given

5.4 Option 4: "non-exhaustive list combined with EU-level prescriber register"

Impacts under option 4 are discussed. The impacts concern expected differences in comparison to option 1, the baseline comparator. It is assumed that the dispensing rate for cross-border prescriptions improves under option 4 as:

- All "missing data" issues for dispensers are solved under option 3 (see discussion for option 2 as above)
- All "prescriber authentication" issues for dispensers are improved in proportion to scores attributed by the PGEU in the SANCO 2012 public consultation.

Non-dispensing rates therefore drop by about 20 percentage points, as was the case for option 2. The calculation is similar to the one explained under option 2 and further explained in detail in the economic evaluation annexed to the IA.

5.4.1 Health impacts

In proportion to the improved dispensing rate negative health effects will be avoided, creating an overall positive health impact under option 4. However, these impacts are not quantified as discussed above.

5.4.2 Cost impacts

As was the case for options 2 and 3, only "business as usual" costs are considered.

Doctor consultations

Proportional to the improved dispensing rate on average a positive cost impact (from avoided doctor consultation costs) of around EUR 7 is expected (or 20% of the doctor cost of EUR 34).

EU-level electronic prescriber register

Under option 4 an additional cost is assumed for the maintaining of a central prescriber database at the EU level. This cost is derived from an activity-based breakdown in the 2011 financial statement of the Dutch Ministry of Health (CIBG 2011). The corresponding activity, "BIG register", is that of maintaining a register containing data on some 400 000 health professionals to which a website[39] is attached that can be consulted by a wider audience.

A search for relevant publications and data did not yield any comparable reference costs for other Member States. Member of the epSOS[40] board were also contacted with the request to transmit relevant reference costs. One Member State expert submitted (qualitative) comments[41].

This cost is extrapolated to the EU-level by assuming it is proportional to the number of health professionals most likely to be included: some 1 600 000 doctors and 300 000 dentists for the EU. In NIVEL 2011 for 21 surveyed Member States it was found that doctors are allowed to prescribe in all MS, dentists have prescribing authorisation in a large majority of MS (n=19). Midwives and nurses have authorisation to prescribe in a minority of Member States and pharmacists in none of the MS that participated.

This way, the annual "business as usual" cost of the EU-level central register is estimated at EUR 8 million. Divided by the estimated current number of cross-border prescriptions (Matrix 2012) this means a cost of EUR 7 is added to each cross-border prescription under option 4.

[39] See http://www.bigregister.nl/.

[40] epSOS – Smart Open Services for European Patients: epSOS is the main European electronic Health interoperability project co-funded by the European Commission and the partners, see http://www.epsos.eu/.

[41] Following expenditure posts were identified: development for inputting the central database, user support, server hosting, (content) update of database, IT maintenance, user interface, adapting of software (doctors and pharmacists) to enable links to servers; certified access for doctors/pharmacists.

Table 9: Cost of EU-level prescriber register

Cost	Value (2012 EUR)	Source
Cost of option 4: central EU-level prescriber register (online accessible)	8 000 000	Based on published cost for the Dutch BIG-register, extrapolation made for number of registered health professionals to cover all doctors in the EU (CIBG 2011)
Cost of register per cross-border prescription	7	Calculation based on above and MATRIX 2012 estimations of annual number of 1,14 million intra-EU cross-border prescriptions

5.4.3 Business impacts

Expected impacts are similar to those for option 2. Dispensers did not raise any possible negative impact here (contrary to option 3). However, note that the PGEU assesses the authentication effectiveness of option 4 to be at the same level of that of option 2: potential issues regarding language barriers and non-standardised terminologies are likely to be solved via an EU-level register, but the requirement to consult this register during business hours may still exert a negative impact on dispensers' operational efficiency. This negative influence may counterbalance the improved prescriber authentication via an EU-level register to the extent that authentication effectiveness does not exceed the level attained under option 2.

5.4.4 Personal data

Possible implications are direct for prescribers as their personal data would be included in registers accessible to dispensers. However, no (extra) impact on personal data protection is expected following the same reasoning as applied above for option 3.

5.4.5 Stakeholder views (public consultation)

Stakeholders were requested to provide feedback on what they saw as the main issues with the use of national prescriber registers. (see Table 10). Stakeholders rated option 4 at least as equivalent to option 2, if not as the best option. It should be noted, however, that their assessment concerned perceived effectiveness in identifying/authenticating prescribers, which did not include cost-effectiveness considerations. Additional comments from stakeholders indicated a concern about possible costs at play for option4.

Table 10: stakeholder views for option 4

	Main comments for use of EU central prescriber register
Patients	No indication given
Prescribers	Option 4 is preferable to option 3. Details about the prescriber (e.g. name, qualification, identification code, etc.) should also appear on the prescription.
Dispensers	The use of an EU-level register is seen as equally effective as direct contact with prescribers.
Industry	No indication given

5.5 Comparing impacts across the options

5.5.1 Qualitative impacts

The various impacts compared to the status quo option that were confirmed as applicable are shown in Table 11 below. This table summarises the preceding sections.

Table 11: Main impacts by option (+/- to indicate positive/negative outcome on group).

Impacted group	Option 2	Option 3*	Option 4
Patients			
Health impacts	++	+	++
Cost of doctor (out of pocket share)	++	+	++
Dispensers			
Business practice	+	-	+
Public budgets			
Electronic registers			-
Cost of doctor (publicly reimbursed share)	++	+	++

*Note that dispensing rates are slightly lower for option 3 compared to options 2 and 4, hence the different health/ doctor cost impacts.

5.5.2 Quantified impacts

For the impacts in Table 11 sufficient data were collected to quantify the cost of a doctor consultation and the cost of an EU-level electronic prescriber register. Further, assumed differences in dispensing rates per option were also quantified. These differences determine the total impact per option of (avoided) doctor consultation costs.

Costs

The below cost impacts are assumed (see Table 12). A full methodological discussion is contained in the economic evaluation. The cost of visiting a local doctor will apply for all options, but the frequency of this cost will be different depending on the dispensing rates for each option. The cost of a central prescriber register only applies for option 4 and is calculated as a cost per cross-border prescription, whether dispensed or not.

Table 12: Cost impacts per option

Impacted group	Option 2	Option 3	Option 4
Patients			
Cost of doctor (out of pocket share)	EUR 34 per non-dispensed cross-border prescription		
Public budgets			
Electronic registers	EUR 0	EUR 0	EUR 7 per cross-border prescription
Cost of doctor (publicly reimbursed share)	EUR 34 per non-dispensed cross-border prescription		

Dispensing rates by option

As presented above, the non-dispensing of a cross-border prescription will incur the cost of a doctor visit for patient and/or public healthcare payers. This implies that the main driver of (cost) difference between the 4 options will the non-dispensing rates assumed for each option. In other words this relates to the impact each option has on the dispensing of a cross-border prescription.

In Table 13 and Table 14 the non-dispensing rates and breakdown by reasons are shown for respectively handwritten and other prescriptions. The work-up of these input probabilities is based on NIVEL 2011 (% of handwritten prescriptions), MATRIX 2012 (reasons for non-dispensing by % breakdown) and the 2012 public consultation carried out for the purpose of this impact assessment (authentication effectiveness). Detailed calculations can be found in the economic evaluation.

The main assumptions as presented above for each option are reiterated:

- The starting points are the Matrix 2012 derived probabilities for non-dispensing of a handwritten cross-border prescription.
- The probabilities for non-dispensing due to "missing data" were put to 0% for options 2-4 in both tables. It is assumed that the non-exhaustive list of elements addresses issues related to data requirements for prescription forms under rules in the Member State of the dispenser.
- A downward correction for the probability of non-dispensing due to authentication issues for options 2-4 in both tables. This correction is proportional to the scores the PGEU attributed to various authentication tools in the public consultation.
- Finally, in Table 14 (probabilities for non-handwritten prescriptions) the probability of non-dispensing as a result of handwriting was set to 0%.

After applying the above corrections, the remaining non-dispensing rates (by reason for non-dispensing) are adapted. For instance, in Table 13, under option 1 for prescribed common products the percentage of non-dispensed prescriptions due to "language issues" is around 20% or 10 (20% of 50%) prescriptions out of every 100. If the overall non-dispensing rate drops by some 20 percentage points from 50% to 30% under option 2, the share of prescriptions not dispensed due to "language reasons" will increase to around 33% (or 10 prescriptions out of 30) under option 2.

Table 13: Non-dispensing probabilities for handwritten cross-border prescriptions

Probabilities for Common Products

Variable	Value	Source
Non-dispensing rate option 1	**50,0%**	MATRIX 2012
Authentication	25,3%	based on MATRIX 2012
Information Missing	20,1%	
Handwriting	20,3%	
Language	22,8%	
Product Unavailable	11,5%	
Non-dispensing rate option 2	**30,1%**	MATRIX 2012
Authentication	9,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	33,7%	
Language	37,9%	
Product Unavailable	19,1%	
Non-dispensing rate option 3	**32,9%**	MATRIX 2012
Authentication	17,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	30,8%	
Language	34,6%	
Product Unavailable	17,5%	
Non-dispensing rate option 4	**30,1%**	MATRIX 2012
Authentication	9,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	33,7%	
Language	37,9%	
Product Unavailable	19,1%	

Probabilities for Uncommon Products

Variable	Value	Source
Non-dispensing rate option 1	**59,4%**	MATRIX 2012
Authentication	22,0%	based on MATRIX 2012
Information Missing	18,4%	
Handwriting	18,8%	
Language	20,1%	
Product Unavailable	20,8%	
Non-dispensing rate option 2	**38,3%**	MATRIX 2012
Authentication	7,6%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	29,0%	
Language	31,2%	
Product Unavailable	32,2%	
Non-dispensing rate option 3	**41,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	27,0%	
Language	29,0%	
Product Unavailable	30,0%	
Non-dispensing rate option 4	**38,3%**	MATRIX 2012
Authentication	7,6%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	29,0%	
Language	31,2%	
Product Unavailable	32,2%	

Table 14: Non-dispensing probabilities for non-handwritten cross-border prescriptions

Probabilities for Common Products			Probabilities for Uncommon Products		
Variable	**Value**	**Source**	**Variable**	**Value**	**Source**
Non-dispensing rate option 1	**39,8%**	MATRIX 2012	Non-dispensing rate option 1	**48,3%**	MATRIX 2012
Authentication	31,8%	based on MATRIX 2012 and hypothesis for not handwritten	Authentication	27,0%	based on MATRIX 2012 and hypothesis for not handwritten
Information Missing	25,2%		Information Missing	22,6%	
Handwriting	0,0%		Handwriting	0,0%	
Language	28,6%		Language	24,8%	
Product Unavailable	14,4%		Product Unavailable	25,6%	
Non-dispensing rate option 2	**20,0%**	MATRIX 2012	Non-dispensing rate option 2	**27,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	10,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	57,1%		Language	43,9%	
Product Unavailable	28,8%		Product Unavailable	45,4%	
Non-dispensing rate option 3	**22,8%**	MATRIX 2012	Non-dispensing rate option 3	**30,1%**	MATRIX 2012
Authentication	24,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	19,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	50,0%		Language	39,7%	
Product Unavailable	25,3%		Product Unavailable	41,1%	
Non-dispensing rate option 4	**20,0%**	MATRIX 2012	Non-dispensing rate option 4	**27,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	10,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	57,1%		Language	43,9%	
Product Unavailable	28,8%		Product Unavailable	45,4%	

6. Cost-minimisation analysis

The economic evaluation includes an extensive presentation and discussion of model structures, hypotheses, data sources, calculations and results. Below a summary is presented.

6.1 Methods

A probabilistic cost minimisation analysis was made in Microsoft Excel® (programming language Visual Basic for Applications®). This analysis compares the cost per cross-border prescription for patients and/or public payers as a result of non-dispensing of cross-border prescriptions under the 4 options.

The main data sources are:

- Matrix 2012 study for comparator ("baseline") dispensing probabilities and the cost of a doctor consultation,
- the 2012 public consultation for the assumed effectiveness of prescriber authentication tools for options 2, 3 and 4,
- NIVEL 2011 study for the percentage of handwritten prescriptions,
- CIBG, Dutch Ministry of Health, for estimating the cost of an EU-level database,
- Eurostat and OECD for various data: number of doctors, population data, etc.

The main model assumptions are:

- The non-dispensing of a prescribed product will incur the cost of a doctor visit,
- For options 2-4 it is assumed that there is no non-dispensing due to "missing data" and lower non-dispensing due to "authentication issues". The "authentication effectiveness" for options 2, 3 and 4 is directly based on findings

To assess model robustness, 1 000 probabilistic simulations were performed and additional univariate scenarios assumed.

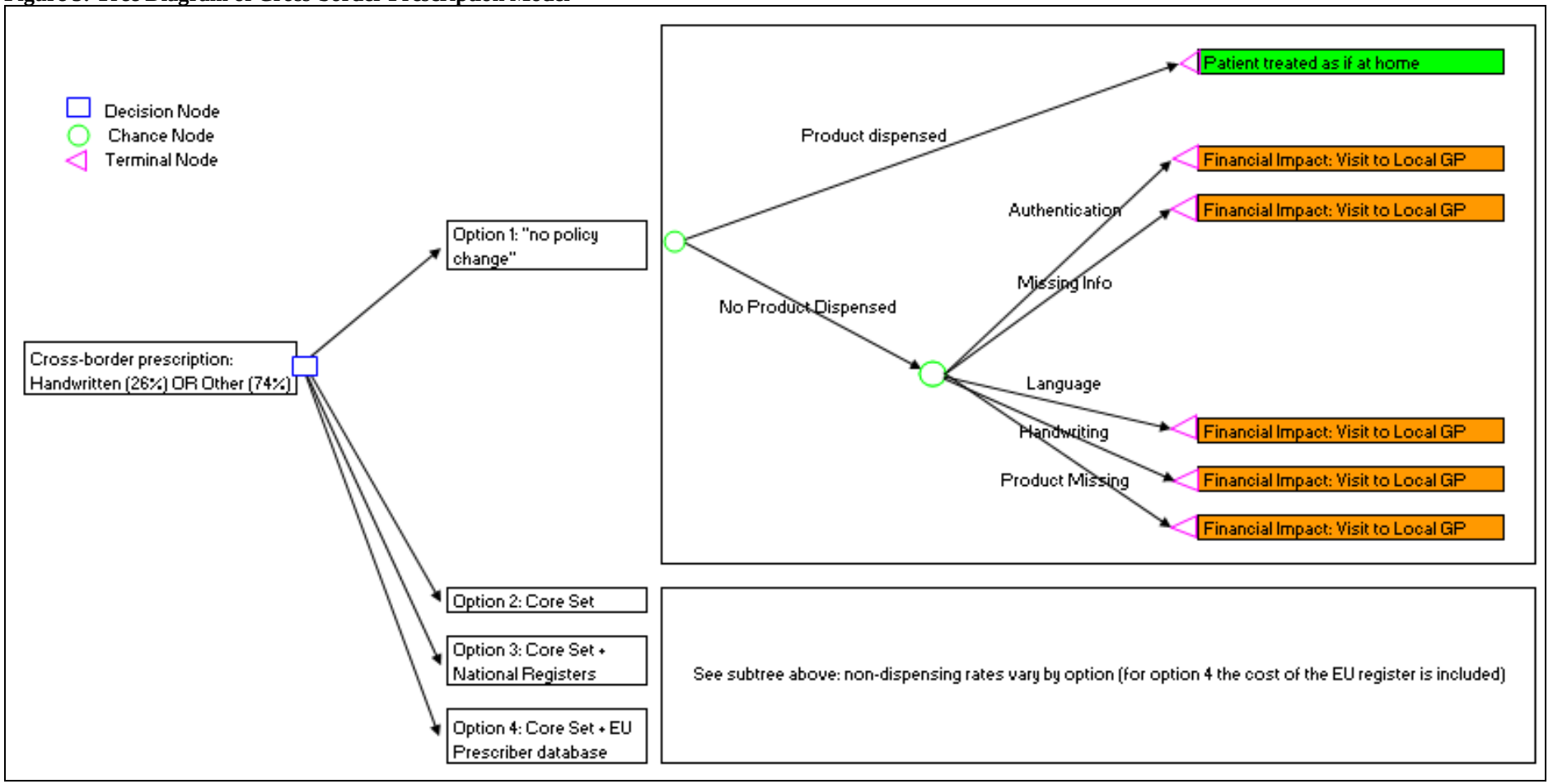
The model outcomes apply to the average cross-border prescription patient case. In a further step assumptions are applied to extrapolate effects to the full population of cross-border prescription patients in any given year in the European Union.

In Figure 3 the pathway a given cross-border prescription follows is shown as a tree diagram:

- In case a product is dispensed no (additional) effects are assumed, i.e. the patient is treated as if (s)he were "at home".
- In case no product is dispensed:
    - a negative financial effect directly for the patient and/or indirectly for the reimbursing public payer, equivalent to the cost of one doctor consultation.
    - based on Matrix 2012 five reasons for non-dispensing are assumed: prescription issues with authentication, missing information, foreign language on the prescription, understanding handwritten prescriptions

The dispensing rates vary under the different options as already shown above in Table 13 and Table 14.

Figure 3: Tree Diagram of Cross-border Prescription Model



6.2 Results

6.2.1 Main results

In Table 10, the main (non-probabilistic) results are presented:

- Option 2 minimises costs in all cases at a cost between EUR 6,8 (for commonly available products, non-handwritten prescriptions) and EUR 13 (for less common products, handwritten prescriptions) per cross-border prescription. This corresponds for instance to a drop in the non-dispensing probability for a handwritten cross-border prescription from around 50% to 30% for a commonly available product. This in turn implies a decrease in costs (20% of the cost a doctor consultation avoided per cross-border prescription).
- Options 3, 1 and 4 respectively complete the ranking by ascending cost impact:
    - Option 3 is less effective in terms of prescriber authentication based on the dispenser (PGEU) feedback to the public consultations. Option 3 has a dispensing rate that is higher than the baseline, but lower than for option 2.
    - Option 4 has the same dispensing rate as option 2, but comes at a higher cost given the budget required for maintaining an EU-level prescriber register that can be consulted by dispensers.
- As can be expected costs are higher across the board for:
    - handwritten prescriptions due to higher non-dispensing rates.
    - less common products due to higher non-dispensing rates as a result from non-availability of the prescribed products

Table 15: Model results

Calculated Cost per Cross-border Prescription: Common Products

PRESCRIPTION TYPE (26% HANDWRITTEN)	VARIABLE	OPTIONS			
		Option 1: status quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Handwritten Prescription	Probability of non-dispensing	50,0%	30,1%	32,9%	30,1%
	Cost of visiting local GP (EUR 2012)	17,0	10,2	11,2	10,2
	Cost of EU prescriber register (EUR 2012)				7,0
Other Prescription	Probability of non-dispensing	39,8%	20,0%	22,8%	20,0%
	Cost of visiting local GP (EUR 2012)	13,5	6,8	7,7	6,8
	Cost of EU prescriber register (EUR 2012)				7,0
All Types	Probability of non-dispensing	42,5%	22,6%	25,4%	22,6%
	Cost of visiting local GP (EUR 2012)	14,4	7,7	8,6	7,7
	Cost of EU prescriber register (EUR 2012)				7,0
Total Cost per Cross-border Prescription (EUR 2012)		**14,4**	**7,7**	**8,6**	**14,7**

Calculated Cost per Cross-border Prescription: Less common Products

PRESCRIPTION TYPE (26% HANDWRITTEN))	VARIABLE	OPTIONS			
		Option 1: status quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Handwritten Prescription	Probability of non-dispensing	59,4%	38,3%	41,2%	38,3%
	Cost of visiting local GP (EUR 2012)	20,2	13,0	14,0	13,0
	Cost of EU prescriber register (EUR 2012)				7,0
Other Prescription	Probability of non-dispensing	48,3%	27,2%	30,1%	27,2%
	Cost of visiting local GP (EUR 2012)	16,4	9,3	10,2	9,3
	Cost of EU prescriber register (EUR 2012)				7,0
All Types	Probability of non-dispensing	51,2%	30,1%	33,0%	30,1%
	Cost of visiting local GP (EUR 2012)	17,4	10,2	11,2	10,2
	Cost of EU prescriber register (EUR 2012)				7,0
Total Cost per Cross-border Prescription (EUR 2012)		**17,4**	**10,2**	**11,2**	**17,2**

In Table 11 we compare the cost per cross-border prescriptions of the policy options 2-4 to the comparator baseline and multiply this with the estimated total number of cross-border prescriptions to obtain the overall yearly savings under each option. The savings per prescription from adopting option 2 compared to option 1 equates to some EUR 8 per cross-border prescription. Multiplied with the Matrix 2012 estimate of some 1.14 million cross-border prescriptions annually in the EU this implies savings of around EUR 8 million per year should be expected under option 2. In line with the ranking above around EUR 7 million savings would be expected under option 3 and no savings (or even minor added costs) under option 4. The number of added cross-border prescriptions that are dispensed is estimated to be well over 200 000 each year (see Table 17).

Table 16: Estimated cost savings

Scenarios (1,145 million cross-border prescriptions)	Option 1: Status Quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Common products	17.000.000	9.000.000	10.000.000	17.000.000
Less common products	20.000.000	12.000.000	13.000.000	20.000.000
Common products	**SAVINGS**	**8.000.000**	**7.000.000**	**0**
Less common products		**8.000.000**	**7.000.000**	**0**

Table 17: Estimated increase in number of dispensed cross-border prescriptions

Scenarios (1,145 million cross-border prescriptions presented)	Option 1: Status Quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Common products	660.000	890.000	850.000	890.000
Uncommon products	560.000	800.000	770.000	800.000
Common products	**EXTRA DISPENSED PRESCRIPTIONS COMPARED TO STATUS QUO**	**230.000**	**190.000**	**230.000**
Uncommon products		**240.000**	**210.000**	**240.000**

6.2.2 Robustness of results

Input variables are subject to wide overall uncertainty. Therefore, a probabilistic model was built. All input variables were assumed to follow probability distributions to best capture the size and type of uncertainty in these variables. Next, 1 000 simulations were ran:

1. Option 2 is confirmed as the preferred, cost-minimising, option and shows up 883 times as the cheapest option (option 3 is the cheapest option for the remainder of cases).
2. Option 4 is the least desirable option, showing up as the most expensive option 560 times (option 1 is the most expensive option the remainder of the time).

Additional univariate scenarios were used to test the robustness of results:

- Assuming a sevenfold increase in the number of cross-border prescriptions. This assumption implies that the cost of the EU-level prescriber register is considerably lowered.
- Assuming a drop in the GP cost from EUR 34 to EUR 28, a variation proportional to differences in GDP per capita between the 7 Member States the reference case cost is based on and the overall EU average.
- Assuming more conservative values for the prescriber authentication effectiveness in options 2-4.

- Combining the above scenario (conservative prescriber authentication effectiveness) with a scenario range as regards possible proportions of prescriptions not containing the non-exhaustive list being presented to dispensers in a cross-border setting ("worst case scenario")

Option 2 was confirmed as the cost-minimising option in all additional model scenarios.

6.2.3 Conclusions

Preferred option

We conclude that the findings from the model are robust for changes in all input variables. This results in a preference ranking of options by expected cost-savings as below:

1. Non-exhaustive list of elements (option 2);
2. Non-exhaustive list combined with national databases (option 3);
3. Status quo (option 1);
4. Non-exhaustive list combined with EU-level database (option 4).

The preferred option is therefore option 2: the use of a non-exhaustive list of common elements in prescriptions, without any further requirement for dispensers to use newly established or existing electronic prescriber registers that are accessible to cross-border dispensers. This policy option is expected to improve the dispensing of cross-border prescriptions compared to the baseline (option 1) by some 20 percentage points (e.g. from some 50% to 70% for handwritten cross-border prescriptions for a commonly available product). This implies on average around EUR 7 will be saved per cross-border prescription as less patients will be obliged to pay for an extra doctor consultation. Given the present volume of cross-border prescriptions this is estimated to lead to annual savings of EUR 8 million for patients and public healthcare payers. Should the number of cross-border prescriptions increase in the future, overall savings will increase in the same proportion.

"Cross-border only" forms

In case a Member State opts to have a separate cross-border prescription form, the general principle of mutual recognition of prescriptions shall continue to apply for "regular" prescriptions presented to a foreign dispenser. As explained under heading **Error! Reference source not found.** "Problem Definition" the general principle of the mutual recognition of prescription should apply undiminished for these prescriptions. Hence, the "status quo" dispensing rates (option 1) should continue to apply. This could be verified as part of a future policy evaluation.

This scenario, at best, is the equivalent of a (suboptimal) combination of option 1 and option 2: an improvement to the status quo, but not delivering the full potential cost savings that option 2 offers (as explored in the "worst case scenario" in the economic evaluation annexed to the IA). The policy implication is that it is advisable for Member States to integrate the non-exhaustive list in all prescription forms and not to restrict it to a separate "cross-border" form. Also, in case some Member States choose to introduce such separate forms, future evaluation should take the recognition of all prescription forms into account. This would include "regular" forms presented to a dispenser abroad. Based on indicative findings in the NIVEL 2011 report it should be assumed that Member States would prefer in the long run to

incorporate the non-exhaustive list in their existing prescriptions. Consequently, this scenario is considered realistic only in a transitional phase.

Non-preferred policy options 3 and 4

As regards option 3, Member States already compile data on authorised prescribers. Further, Directive 2011/24/EU will reinforce patient rights to such information, which should become easily accessible by electronic means. It appears logical to use this information with a view to cross-border dispensing of prescriptions and to make this information publicly available online, also to foreign dispensers. As demonstrated in the IA this policy approach would be the most cost-effective compared to the alternative of replying to all information requests on an ad hoc basis by use of emails. However, dispensers express doubts on the usefulness of such information given likely issues with language, terminology, etc. for option 3. The PGEU in fact assumes that the consultation of national prescriber databases by cross-border dispensers would lead to a less effective authentication of prescribers than the simple use of prescriber contact details in prescription forms (which could then be phoned in case of doubt, etc.). As a result, even though no additional cost for the set-up and maintenance of national prescriber registers is assumed, option 3 is less cost-saving than preferred option 2 given the (slightly) lower dispensing rate of prescriptions in option 3.

In respect to option 4, the low volume of cross-border prescriptions does not justify the set-up of a central EU-register of prescribers, which was estimated to cost EUR 8 million (see under heading 5.4.2 "Cost impacts"). Also, note that as the PGEU scored the authentication effectiveness of option 4 as equal to that of option 2, option 2 will always minimise costs compared to option 4 regardless of the assumed volume of cross-border prescriptions. Even, when assuming ex absurdo that all prescriptions would become cross-border prescriptions, option 4 and 2 would score equally well in terms of prescriptions dispensed, but option 4 would still imply a marginal cost as low as EUR 0,002[42] is added to each cross-border prescription under option 4.

[42] Calculated as the cost of the EU-level prescriber register divided by the maximum estimate of prescriptions in the EU per annum of 10 billion.

7. Monitoring and evaluation

Monitoring and evaluation arrangements aim to assess how the proposed measures will have contributed to achieving their specific objectives as presented under heading 3.2 "Specific objectives":

- Ensure that the prescriber's entitlement to prescribe from one Member State can easily be verified in all Member States.
- Ensure the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, in respect of patient safety concerns in relation to possible product substitution.
- Ensure the comprehensibility of the information to patients concerning the prescription.

7.1 Progress indicators

7.1.1 Verification/identification of prescriber and prescribed product

The main candidate indicator for future assessment of the effectiveness of the proposed measures targeting the verification/identification of prescriber and prescribed product is the product dispensing rate for cross-border prescriptions. This rate could be compared to the Matrix 2012 measurement in order to make an ex post impact evaluation. The results found in Matrix 2012 are statistically robust with a 95% confidence band as narrow as +/-0.5%.

However, from the Matrix 2012 study as well as the public consultation it became clear that factors not impacted by the draft implementing acts strongly influence the dispending rate: the language in which the prescription is made out, whether it is handwritten, local product availability. Moreover there may be a trend toward less handwritten prescriptions (e.g. as a result of computerising prescription practices**)**. This implies that the baseline product dispensing rate could increase, regardless of the proposed measures at hand. In order not to wrongly attribute this expected improvement to the implementing acts it is important that any progress measurement distinguishes changes in the dispensing rate explicitly by underlying reason.

It seems logical to adopt the set of non-dispensing reasons as shown for instance in Table 1 as a basis for future measurement exercises. In summary the non-dispensing rates for cross-border prescribed medical product should be measured for common and less common products, as well as for handwritten and other prescriptions. Non-dispensing rates should be broken down by reasons for non-dispensing due to issues with

- Authentication, in particular of the cross-border prescriber;
- Missing information;
- Handwriting;
- Understanding the language on the prescription;
- Product availability.

Progress will be assessed by measuring changes in non-dispensing rates specifically for the first two reasons above.

7.1.2 Patient understanding

Patient understanding of information related to a medical prescription is relevant with respect to the prescribed product. This may possibly include items such as brand name, active substance, dosage strength, treatment regimen, etc. Items may directly improve patient understanding (e.g. clearer understanding of when/how/how long to take a certain medicine) or indirectly (e.g. patient capable to retrieve information from additional sources on treatment-related adverse events via brand name, active substance, etc. mentioned on a prescription).

A patient understanding score would allow to assess how well current and proposed product identification items are understood by presenting a series of questions measuring understanding of treatment regimen, possible adverse events, etc.

7.2 Methods

7.2.1 Verification/identification of prescriber and prescribed product

The Matrix 2012 study was set up to measure the effective recognition of cross-border prescriptions via a survey presenting pharmacists with hypothetical cross-border prescriptions based on the content of currently used prescription forms.

To base these hypothetical prescriptions on representative patient cases, a selection of pathologies and involved Member States was made following extensive desk research and expert consultation. Further, a sample size analysis was made to estimate the minimum number of pharmacists the study should recruit to increase the probability that resulting findings would be statistically robust with a specific view to follow-up measurements. In other words, the Matrix 2012 provided a "zero-measurement".

Consequently, the best approach to evaluate the effectiveness of the proposed measures is to repeat the 2012 study referring to the same set of sampled patient type-cases. It is, however, likely that the actual names of prescribed products as they appear in the hypothetical prescriptions would require an update. Further, in case some Member States choose to introduce a separate "cross-border" prescriptions, the general principle of mutual recognition would still apply to "regular" prescriptions presented in a cross-border setting. This should then be taken into account in the future evaluation by testing that the recognition of "regular" prescriptions has remained stable despite the co-existence of "cross-border" prescriptions dispensers might have grown accustomed to see.

This evaluation should take place as soon as the implementing acts have been fully implemented (i.e. new prescription forms have been phased in) and dispensers are sufficiently familiar with changed prescription forms. Most likely this will mean an evaluation will be presented at the latest 5 years after the introduction of the measures. Participation by dispensers to the proposed evaluation would be on a voluntary basis, as was the case in the Matrix 2012 study. This study managed to recruit almost 1000 pharmacists in 7 Member States.

7.2.2 Patient understanding

Patient understanding of information related to the prescribed product will be measured over relevant sub-dimensions, such as:

- Understanding of treatment regimen: when/how/how long to follow therapy at which frequency?
- Understanding of possible treatment-related adverse events at play.

Further, this measurement shall distinguish whether patient understanding is based on direct effects (only the prescription is used as an information source) or indirect effects (information on a prescription allowing patients to consult additional information sources). This will help understand whether possible future improvements should include the consideration of additional information sources to be established.

The measurement shall follow a comparative design:

- Two groups of individuals (comparator and intervention group) are selected. The make-up of these groups is statistically similar for characteristics such as patient demographics, socio-economic status, etc.
- Understanding in the comparator/intervention groups is measured presenting groups respectively with current and proposed prescription form items for hypothetical prescriptions cases.

Additionally, it can be verified whether patient understanding in the comparator group is not overestimated as a result of patient familiarity with current prescription form items (this familiarity effect would also occur over time with the proposed prescription form items). To this purpose individuals in the comparator group could for instance be presented ad random with any of prescription form items set presently existing in the EU (i.e. an individual would not necessarily be presented with his/her familiar national prescription form).

7.3 Timing

7.3.1 Verification/identification of prescriber and prescribed product

In Article 20 of Directive 2011/24/EU it is stated that "The Commission shall by 25 October 2015 and subsequently every 3 years thereafter, draw up a report on the operation of this Directive and submit it to the European Parliament and to the Council […]. This report “shall in particular include information on patient flows, financial dimensions of patient mobility, the implementation of Article 7(9) and Article 8, and on the functioning of the European reference networks and national contact points."

As such, the 2015 report shall be based mainly on administrative/billing/reimbursement data by Member States. Moreover, setting up the evaluation study will require some time, even if only an update of an existing study design is required. Further, it is important to measure dispensing rates at a moment where prescribers and dispensers have acquired sufficient familiarity with possible changes in prescription forms. It does not seem probable an evaluation could already be published by 2015. However, given applicable timelines, it would make sense to integrate the finding from the field study in the second compliance report due by 2018. This is not a necessity as the field study can be undertaken independently, but would enrich and streamline the 2018 report on the overall operation of the Directive 2011/24/EU.

If findings from the dispensing rate evaluation are sufficiently conclusive (i.e. a statistically significant improvement is measured), there will be no need to further repeat it.

7.3.2 Patient understanding

A study assessing effects on patient understanding, measured as set forth in the preceding sections, should be set up soon enough, i.e. ideally a soon as the proposed item list is finalised and before it is firmly established in everyday practice. This timing would allow to avoid patients growing familiar with the updated content of new prescriptions, which could skew the findings from any comparative measurement. Alternatively, a study could be set up at a later moment in time, recruiting individuals less likely to be familiar with EU-specific prescription form items (e.g. younger people, non EU residents).

If findings from the patient understanding evaluation are sufficiently conclusive (i.e. a statistically significant improvement is measured), there will be no need to further repeat it.

8. **Annexes**

8.1 Economic Evaluation

Abstract

Background

This evaluation addresses measures for the improved recognition by dispensers of medical prescriptions issued in an EU Member State (MS) other than the MS of the dispenser. The measures aim to ensure:

- the validity of a prescriber, to easily be verified in all member states;
- the correct identification of prescribed medicinal products or medical devices,
- the comprehensibility of the information to patients concerning the prescription.

The comparator "no policy action" (**option 1**) is compared to 3 policy intervention scenarios:

- the adoption of a non-exhaustive list of common elements in prescriptions (**option 2**)
- option 2 with added national prescriber databases accessible to dispensers (**option 3**)
- option 2 with an added EU-level prescriber database accessible to dispensers (**option 4**)

Methods

A probabilistic (Monte Carlo) cost minimisation analysis was made in Microsoft Excel® comparing the cost to patients and/or public payers as a result of non-dispensing of cross-border prescriptions under the 4 options. The main data sources are:

- Matrix 2012 study for comparator dispensing probabilities and doctor cost,
- SANCO 2012 public consultation for the effectiveness of prescriber authentication tools,
- NIVEL 2011 study for the percentage of handwritten prescriptions,
- CIBG 2011, Dutch Ministry of Health, for the cost of an EU-level database,
- Eurostat and OECD for various data: number of doctors, population data, etc.

The main model assumptions are:

- The non-dispensing of a prescribed product will incur the cost of a doctor's visit,
- For options 2-4 it is assumed that there is no non-dispensing due to "missing data" and lower non-dispensing due to "authentication issues"

To test model robustness, 1.000 simulations and further univariate scenarios were calculated.

Results

Option 2 minimises costs between EUR 7,7 and 10,2 per cross-border prescription. This corresponds to an increase in dispensing by some 20 percent points (from around 50% at baseline). An estimated EUR 8 million can be saved annually under option 2 with an added 200,000 cross-border prescriptions dispensed. The probabilistic analysis confirms option 2 as cost-minimising (88% of simulations). This finding was also robust in all univariate scenarios.

Discussion

In case a MS opts to have a separate cross-border prescription form, the general principle of mutual recognition of prescriptions shall continue to apply for "regular" prescriptions presented to a foreign dispenser. As such, this scenario at best will be equivalent to a (suboptimal) **combination of option 1 and option 2** (combination of respectively "regular" prescriptions and cross-border prescriptions used in cross-border settings): an improvement, but not delivering the full potential cost savings of option 2. As regards option 3, Member States already compile data on authorised prescribers. Further, Directive 2011/24/EU will reinforce patient rights to such information by electronic means. Hence, it appears logical to use this information with a view to cross-border dispensing of prescriptions. This would be through means of publicly accessible websites, shown to be the most cost-effective approach. However, dispensers express doubts on the usefulness of such information given likely issues with language, terminology, etc. for **option 3**. In line with the low volume of cross-border prescriptions, the set-up of a central EU-register of prescribers is not justified (**option 4**).

8.1.1 Introduction

The present document describes the economic evaluation conducted as part of the Impact Assessment on "Implementing measures for improving the recognition of prescriptions issued in another Member State under Article 11 paragraph 2 of the Directive on the Application of Patients' Rights in Cross-Border Healthcare (Directive 2011/24/EU)".

In the roadmap for this Impact Assessment[43] it is announced that 4 options are under consideration. The table below summarises the various options and the extent to which they are likely to address the three specific objectives set forth in the Roadmap and reiterated below:

1. to ensure that the validity of a prescriber from one member state can easily be verified in all member states;
2. to ensure the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, in respect of patient safety concerns in relation to possible product substitution;
3. to ensure the comprehensibility of the information to patients concerning the prescription.

Note that the objective of "Patient Understanding" is considered supplementary, i.e. in the sense that the information needed to ensure the product identification (objective 2) will be made as comprehensible to patients as possible. As such, the direct impact from patient understanding on (health) outcomes will not be formally assessed. However, input from a patient targeted consultation will be taken into specific consideration in finalising detailed policy options.

Table 18: Options/Objectives Matrix (crossed to measure relevance of option to objective)

	Option	Prescriber Authentication	Product Identification	Patient Understanding
1	No Policy Change ("status quo")			
2	Non-exhaustive List of Elements to be included in (Cross-border) Prescriptions	XX	XXX	XX
3	Option 2 combined with Member State Prescriber Databases	XXX		
4	Option 2 combined with central EU Prescriber Database	XXX		

8.1.2 Methods

The economic evaluation is reported in terms of the average cost (in euro, 2012 value) per cross-border prescription under the diverse options. A cross-border prescription is defined as a prescription written out in a different EU Member State than the Member State in which it is presented by the patient for dispensing.

The economic evaluation is under the form of a cost minimisation analysis. Possible health effects (patient harm) from non-dispensing of cross-border prescriptions were explored by Matrix 2012. It was found that the evidence base for modelling negative health outcomes was weak (regarding mainly case study reports) and estimations indicate that related health effects would be modest on any account. Also, it can be argued that the worse the expected patient health impact, the more the patient will ensure it does not occur (e.g. a diabetes patient

[43] See http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_004_mutual_recognition_of_prescriptions_en.pdf

requiring insulin). Consequently, no cost-effectiveness analysis (rendering outcomes in terms of money per avoided negative health effect, quality-adjusted life years, etc. was conducted.

8.1.2.1 Model Structure

A probabilistic decision model was designed. The model captures the direct financial effects on patients and public payers from the non-dispensing of a cross-border medical prescription. Note that effects are considered additional effects as differences with the same patient receiving treatment "at home". The model outcomes apply to the average cross-border prescription patient case. In a further step assumptions are applied to extrapolate effects to the full population of cross-border prescription patients in any given year in the European Union.

8.1.2.1.1 Tree Diagram

In Figure 4 the pathway a given cross-border prescription follows is displayed as it applies to option 1, the baseline comparator scenario:

- In case the prescribed product (or a generic equivalent) is dispensed no (additional) effects are assumed, i.e. the patient is treated as if (s)he were "at home."
- In case no product is dispensed, it is assumed this will entail a negative financial effect directly for the patient and/or indirectly for the reimbursing public payer:
    - Either the patient abandons to obtain the prescribed product, in which case the cost of the initial doctor consultation is a sunk cost with no outcome (i.e. patient is not delivered any product).
    - Or the patient chooses to pay for a local doctor consultation in order to obtain a new prescription and have the product dispensed, in which case the duplicate cost for an additional consultation applies.

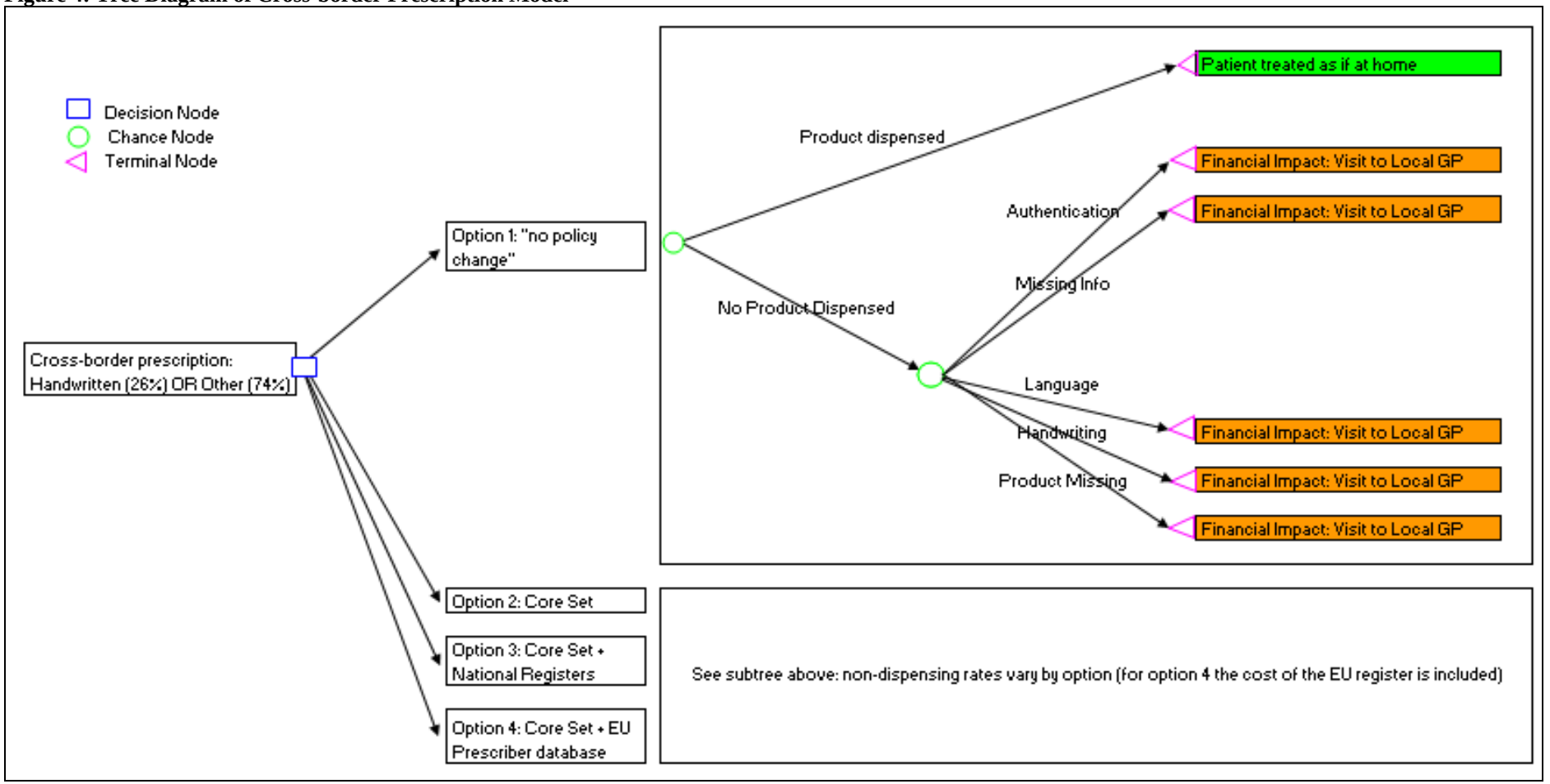
  Consequently it is assumed that the cost of a non-dispensed prescription is equivalent to the cost of one doctor consultation.

In the policy intervention scenarios it is expected that the non-dispensing rate of products will be lower as both product identification and prescriber authentication are improved (i.e. the dispensing of cross-border prescriptions will be improved as a result of an improved recognition by dispensers). Comparing effects from the three intervention scenarios will thus help to

1. validate whether an improvement in outcomes (higher dispensing rates and avoided costs) is achieved,
2. assess the comparative effect sizes across options and consequently support the policy decision for a given option.

Note that for options 3 and 4 the cost of establishing and running electronic prescriber registers will have to weighed against expected increases in prescription recognition from improved prescriber authentication.

Figure 4: Tree Diagram of Cross-border Prescription Model



8.1.2.1.2 Main Assumptions

The main assumptions underlying the presented model are:

- As regards Costs:
    - In case of dispensing, no (additional) costs are modelled. It is assumed that on average differences between more/less expensive countries and products will even out. Most prescriptions will attract reimbursement from the home Member State's public health payer. In keeping with Directive 2011/24/EU (foreseen transposition date by 25 October 2013), this reimbursement will be based on actual upfront payment made by the patient and will be capped at the reimbursement level applicable in the home Member State. Consequently, it appears unlikely cost arbitrage will take place whereby cross-border prescriptions are predominantly dispensed in low cost member states as financial incentives for patients, especially given the cost of travelling, seem limited (at the very maximum the patient co-payment that would be due in the home system would be balanced out).
    - In case of non-dispensing the financial impact on the patient (and ultimately public healthcare payers) will be limited to the cost of a doctor visit:
        - Only direct(ly) attributable effects are considered (e.g. no account is taken of effects on fellow travellers, etc.)
        - Only monetary effects are modelled (e.g. no cost is attributed to time lost by patient).
    - Under options 2, 3 and 4 no extra costs for the introduction of a list of elements in prescriptions are assumed (e.g. current paper forms are likely to run out in the future and would require reprints on any account). Note that the point" Member State experiences (if any) in changing national prescription forms." Was put on the agenda of the Cross-border Healthcare Expert Group "Recognition of Prescriptions – implementing acts" on 14 February 2012. The point, however, was not taken up by any of the present experts. Also, comments were received for one Member State where recently changes to national prescription forms were introduced (the UK). It was remarked that, in the case of paper prescription forms, sufficient transition time should be foreseen (stock clearance). Also, the issue of updating software packages was quoted as a possible source of costs. This point is developed further in the discussion section.
    - Under option 3 no (additional) costs for online prescriber registers at the level of Member States are assumed. Based on findings from the HPRO card project it appears most Member States already have some form of electronic health professional register that is available online (HPRO 2010). Further to this, the NIVEL 2011 study reported that from a total of 21 surveyed Member States, "Nineteen Member States have a registration or up to date list of qualified healthcare professionals with authorisation to prescribe. Seven Member States do not provide this information to dispensing healthcare professionals in other countries. In the other 12 Member States websites are the most common form to verify whether or not a professional is registered." In the annexes to this report a non-exhaustive list of existing online prescriber registers is presented. Note that

Article 6 (3) of the Directive 2011/24 states that "In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice". Moreover, in Article 6 (5) it is stated that "the information referred to in this Article shall be easily accessible and shall be made available by electronic means." Consequently:

- Member States will be required to make a data collection effort if they have not done so already and
- Arguably the most cost-effective way of providing foreign patients with such information by electronic means is through a publicly accessible website as compared to replying to individual phone calls, emails, etc.

The related cost is therefore assumed no to be attributable to option 3 as to be part of the baseline situation following the transposition of Directive 2011/24/EU by 25 October 2013. In the annexes to this report a brief cost-effectiveness analysis verifying this assumption is presented.

- Under option 4 an additional cost is assumed for the maintaining of a central prescriber database at the EU level. This cost is derived from an activity-based breakdown in the 2011 financial statement of the Dutch Ministry of Health (CIBG 2011). The corresponding activity, "BIG register", is that of maintaining a register[44] containing data on some 400 000 health professionals to which a website is attached that can be consulted by a wider audience. The cost is extrapolated to the EU-level by assuming it is proportional to the number of health professionals most likely[45] to be included: some 1 600 000 doctors and 300 000 dentists for the EU. A grey search did not yield any comparable reference costs for other Member States. Member of the epSOS[46] board were also contacted with the request to transmit relevant reference costs. One Member State expert submitted (qualitative) comments[47].

- As regards the non-dispensing rates varied by the options (i.e. the "effectiveness of each option"):
  - Based on Matrix 2012 five factors are assumed to drive non-dispensing:
    - Authentication issues (in particular authentication of the prescriber),
    - Information items missing on the prescription form based on the legislation of the dispenser's Member State,
    - Lack of understanding of foreign language,
    - Difficulty to interpret handwritten prescriptions,
    - Unavailability of the prescribed product (or a generic equivalent if the case applies).

[44] See http://www.bigregister.nl/zoeken/zoekenopnaamenspecialisme/default.aspx

[45] See NIVEL 2011: for 21 surveyed Member States it was found that physicians are allowed to prescribe in all MS, dentists have prescribing authorisation in a large majority of MS (n=19). Midwives and nurses have authorisation to prescribe in a minority of Member States and pharmacists in none of the MS that participated.

[46] epSOS – Smart Open Services for European Patients: epSOS is the main European electronic Health interoperability project co-funded by the European Commission and the partners, see http://www.epsos.eu/

[47] Following expenditure posts were identified: development for inputting the central database, user support, server hosting, (content) update of database, IT maintenance, user interface, adapting of software (physicians and pharmacists) to enable links to servers; certified access for physicians/pharmacists.

- It is assumed options 2-4 impact the two first drivers of non-dispensing through a harmonised minimum data set in prescriptions and through improving prescriber authentication by dispensers:
    - Non-dispensing due to missing information items is reduced to 0% for options 2-4 that all include the adoption of a core set of items.
    - Non-dispensing due to authentication issues is considerably, but not completely, reduced to a degree varying by the diverse options.

In light of the above, it should be understood that the model simulates varying degrees of non-dispensing for each option. This variation in the degree of non-dispensing will result in a variation of cost-impact (through avoided doctor consultations and the cost of a central EU register) for the various options. Note that issues related to the unavailability of a given product strictly speaking concern prescriptions that have been successfully recognised, but which cannot be dispensed for the overriding reason of non-availability of the prescribed product. Note also that non-dispensing as a result of difficulties to understand handwriting will also occur for "regular" prescriptions.

Further from the above it is clear that the assumed cost perspective is that of the patient and/or public payer depending on whether and to which extent patient pre-paid costs are reimbursed by public payers. Costs are limited to direct monetary effects. Model results will refer to business-as-usual in the long run. This implies start-up costs related to changing prescription forms, IT applications are not accounted for. From It became clear there are no cost estimations readily at hand. It was indicated that leaving Member States sufficient lead time to make stepwise adaptations (to phase in new prescription forms and to allow for the amortisation of commercial software packages) is likely to limit implementation costs at play. Also, it should be mentioned that long-term cost-saving "spill-over" effects could be expected from harmonising the content of prescription forms. This may help standardise software packages across the EU, hence increase competition among suppliers of those packages and ultimately generate cost-savings for the purchasers of those packages. Given all the aforementioned elements, it was decided to only model business-as-usual costs, but in a conservative way (not allowing for further savings from assumed spill-overs).

8.1.2.2 Data Inputs

The sections below present and discuss the various data inputs to the model. In general, these concern:

- Probabilities applying to the (non-)dispensing of cross-border prescriptions.
- Costs: the cost of a doctor visit as well as the cost of electronic prescriber registers per cross-border prescription.

8.1.2.2.1 Probabilities

8.1.2.2.1.1 The Matrix 2012 survey data

The main source for the non-dispensing probabilities for a given cross-border prescription is the Matrix 2012 study which includes a survey among some 1 000 pharmacists in 7 EU Member States (DE, FR, UK, PL, NL, GR, DK). Pharmacists were requested to score hypothetical cross-border prescriptions (based on actual prescription forms) between 0 "definitely dispensed" and 3 "definitely not dispensed".

Based on these scores (see) an average non-dispensing probability per cross-border prescriptions was derived (with an average scores of 0 equalling a 0% non-dispensing probability and an average score of 3 equalling a 100% non-dispensing probability) as presented in Table 20.

Following a correlation analysis, it was decided to lump the first two and last two non-dispensing factors together, taking the highest of each score (see Table 20) for the estimation of probabilities. For both pairs of factors an intra-rater correlation of 80% and higher was found. These probabilities (or more precisely reasons for non-dispensing) are shown in Table 21 and Table 22. The probabilities were calculated assuming they were proportional to the average scores in the Matrix 2012 survey for related non-dispensing factors. These probabilities are the starting point of our analysis and populate the model pathway for option 1.

Table 19: Matrix 2012 average scores (full sample of score prescriptions)

Scored Non-dispensing Factor	# Scores	Average Score (3=100%)
Verifying the authenticity of the prescription	7.340	61,07%
Verifying the prescribing doctor	7.280	65,28%
Language in which the prescription is written	7.292	54,02%
Prescription written by hand	7.247	59,26%
Not all the information you need is written on the prescription	7.087	53,18%
Access to the correct drug/device	7.176	45,64%
Access to alternative drug or device if the one on the prescription is unavailable	6.830	41,88%

Table 20: Matrix 2012 derived non-dispensing probabilities for cross-border probabilities

Type of Product	Non-dispensing Probability based on Matrix survey	# Scored Prescriptions
All sampled products	54,7% (95% CI[48]: 54,2%-55,2%)	7.440
Common[49] products	50,0% (95% CI: 49,2%-50,7%)	3.733
Less Common[50] products	59,4% (95% CI: 58,7%-60,2%)	3.707

Table 21: Break-down by assumed reason in case of non-dispensing common products

Common Products: reasons for non-dispensing		# Scores
Authentication	25,33%	3.686
Missing Info	20,09%	3.569
Language	20,29%	3.653
Handwritten	22,79%	3.638
Missing Product	11,50%	3.596

Table 22: Break-down by assumed reason in case of non-dispensing common products

Less Common Products: reasons for non-dispensing		# Scores
Authentication	21,96%	3.654
Missing Info	18,37%	3.518
Language	18,75%	3.639
Handwritten	20,11%	3.609
Missing Product	20,81%	3.580

[48] Confidence interval based on percentile values obtained through bootstrap simulation (1,000 iterations of sample average with resampling).

[49] By "common products" are meant products commonly used and available in all 7 Member States; (Matrix 2012).

[50] By "less common products" are meant products available in 3 or fewer Member States and/or less frequently used (Matrix 2012).

8.1.2.2.1.2 NIVEL 2011 data

The percentage of (cross-border) prescriptions assumed to be handwritten is based on the NIVEL 2011 study that included a survey among Member State (designated) experts presenting them with the below question:

"Can you give an estimate of the percentage of prescriptions that is currently processed using the following types of prescription forms?"

Replies to the above question are shown in Table 23 and where used to calculate a population-weighted estimate of the percentage of handwritten (cross-border) prescriptions in the EU (of some 26%[51]) as shown in Table 24.

Table 23: NIVEL 2011 survey replies on percentage of handwritten prescriptions

Countries	Handwritten paper prescriptions (% of all prescriptions)	Population (2011)
Austria	10%	8.404.252
Belgium	20%	10.951.665
Bulgaria	80%	7.504.868
Czech Republic	50%	10.532.770
Denmark	7%	5.560.628
Estonia	0%	1.340.194
Finland	20%	5.375.276
France	50%	65.048.412
Germany	1%	81.751.602
Hungary	2%	9.985.722
Italy	20%	60.626.442
Ireland	15%	4.480.858
Lithuania	0%	3.244.601
Malta	85%	417.617
Netherlands	1%	16.655.799
Poland	90%	38.200.037
Portugal	30%	10.636.979
Republic of Latvia	90%	2.229.641
Slovenia	60%	2.050.189
Spain	1%	46.152.926
Sweden	0%	9.415.570
	SUM	***400.566.048***
	% OF EU POPULATION	***80%***

Table 24: Work-up of estimated share of handwritten prescriptions

Handwritten prescriptions (%)	Value	Source
Average	25,9%	Population-weighted extrapolation based on NIVEL 2011
Min	20,7%	Based on assumption that all MS not in NIVEL 2011 sample (some 100 million residents) only use handwritten prescriptions
Max	32,5%	Based on assumption that all MS not in NIVEL 2011 (some 100 million residents) sample only use non-handwritten prescriptions
Median	26,4%	Based on assuming a triangular distribution, in which case mean = (min + max + median)/3

[51] Estimations were confirmed by the PGEU (personal email, 23 March 2012)

8.1.2.2.1.3 SANCO 2012 Public Consultation data

Whereas non-dispensing due to "missing data" is assumed to be reduced to 0% for options 2-4 and non-dispensing due to "handwriting" is assumed to vary along with the estimated percentage of prescriptions that are handwritten (26%) based on NIVEL 2011, non-dispensing due to authentication is assumed to vary for options 2-4 proportionally to scores obtained from the SANCO 2012 public consultation related to the below question:

"How can Prescriber Authentication Best be Guaranteed (score 1-9)?"

As the assessment and related decision to dispense a product for a cross-border prescription lies mainly with pharmacists, it was chosen to use replies by dispensers/pharmacists to the SANCO 2012 public consultation as a reference. Twelve individual dispensers/pharmacists replied, whereas 4 organised stakeholders replied (see Table 25). As the Pharmaceutical Group of the European Union (PGEU) has the widest coverage[52], PGEU scores are assumed to be most representative. However, as shown in Figure 5, there is some variance in the PGEU scores and the average scores from all four stakeholder organisation. Robustness for changes in assumed authentication effectiveness under the various options will be explored in the probabilistic model by taking the min-max range shown in Figure 5 into account.

Further, PGEU was requested by mail to provide additional information, in particular further explanations on the use of national databases (option 3). 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."

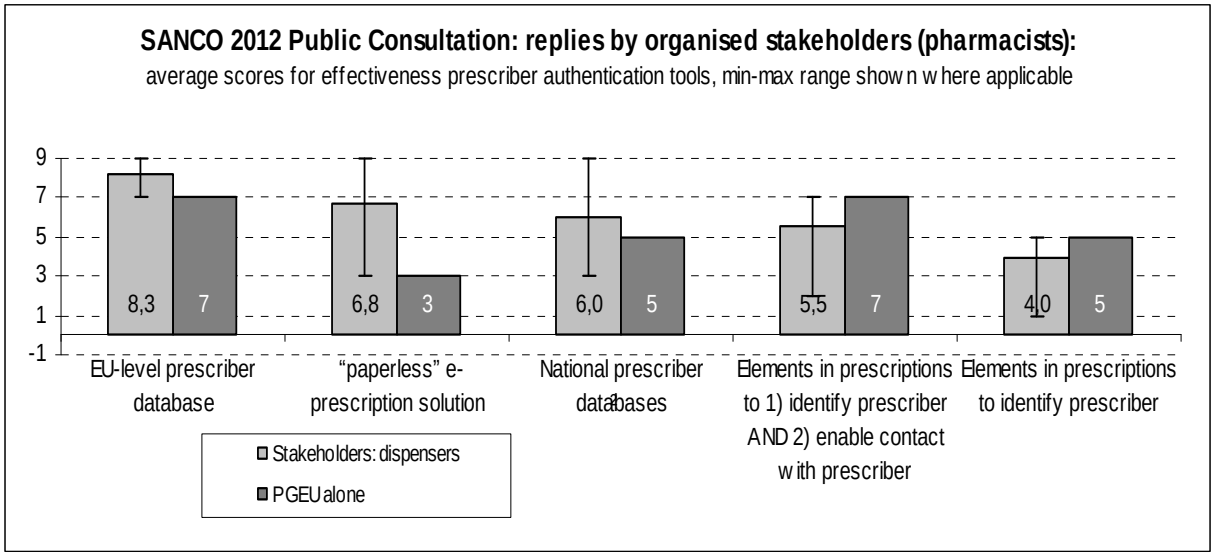
Table 25: Organised Stakeholders (pharmacists, all agreed to full data disclosure)

Name	Registration number in the Transparency Register.[53]	Geographical area
Pharmaceutical Group of the European Union (PGEU)	00086317186-42	EU wide
Sirpa Peura The association of Finnish Pharmacies	65416077600-17	Finland
Consejo General de Colegios Oficiales de Farmacéuticos de España (General Council of Spanish Pharmacists)	86233805607-24	Spain
Royal Pharmaceutical Society of Great Britain	26683956563-83	United Kingdom

[52] PGEU has members, national associations and professional bodies of community pharmacists, in 31 European countries including EU Member States, EU candidate countries and EEA members, see http://www.pgeu.org/en/pgeu/members.html

[53] See http://europa.eu/transparency-register/index_en.htm

Figure 5: Organised stakeholder (pharmacists) scores for prescriber authentication tools



Finally, PGEU scores and the derived authentication effectiveness are presented in Table 26. It is assumed that non-dispensing rate for options 2-4 compared to option 1 drop proportionally to the authentication effectiveness scores shown below.

Applying probabilities for successful authentication as in Table 26 departs from the implicit assumption that current cross-border prescriptions do not contain sufficient elements to identify the prescriber. However, as reported by NIVEL 2011 most Member States include[54] surname, family name ad work address of the prescriber in current prescription forms. The impact of this assumption on model results will be explored in the sensitivity analysis.

Table 26: SANCO 2012: work-up of authentication effectiveness by option

Authentication tool	Score (PGEU)	Authentication effectiveness (9 = 100%)	Matching option
Elements in prescriptions to identify prescriber	5	56%	*NA*
Elements in prescriptions to 1) identify prescriber AND 2) enable contact with prescriber	7	78%	2
National prescriber databases	5	56%	3
EU-level prescriber database	7	78%	4
"paperless" e-prescription solution	3	33%	*NA*

[54] Note, however, that the implementing acts under consideration are nevertheless expected to improve on this by partially harmonising prescriber identification through a non-exhaustive list "identifiable" as such.

8.1.2.2.2 Overview of all non-dispensing probabilities

In Table 27 and Table 28 an overview is offered for all probabilities applied in the model. The following main assumptions apply:

- The starting point are the Matrix 2012 derived probabilities for non-dispensing of a handwritten cross-border prescription.
- The probabilities for non-dispensing due to "missing data" were put to 0% for options 2-4 in both tables. It is assumed that the non-exhaustive list of elements addresses issues related to data requirements for prescription forms under rules in the Member State of the dispenser.
- A downward correction for the probability of non-dispensing due to authentication issues for options 2-4 in both tables. This correction is proportional to the scores the PGEU attributed to various authentication tools in the public consultation.

Finally, in Table 28 (probabilities for non-handwritten prescriptions) the probability of non-dispensing as a result of handwriting was set to 0%.

Table 27: Non-dispensing probabilities for handwritten cross-border prescriptions

Probabilities for Common Products

Variable	Value	Source
Non-dispensing rate option 1	**50,0%**	MATRIX 2012
Authentication	25,3%	based on MATRIX 2012
Information Missing	20,1%	
Handwriting	20,3%	
Language	22,8%	
Product Unavailable	11,5%	
Non-dispensing rate option 2	**30,1%**	MATRIX 2012
Authentication	9,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	33,7%	
Language	37,9%	
Product Unavailable	19,1%	
Non-dispensing rate option 3	**32,9%**	MATRIX 2012
Authentication	17,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	30,8%	
Language	34,6%	
Product Unavailable	17,5%	
Non-dispensing rate option 4	**30,1%**	MATRIX 2012
Authentication	9,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	33,7%	
Language	37,9%	
Product Unavailable	19,1%	

Probabilities for Less Common Products

Variable	Value	Source
Non-dispensing rate option 1	**59,4%**	MATRIX 2012
Authentication	22,0%	based on MATRIX 2012
Information Missing	18,4%	
Handwriting	18,8%	
Language	20,1%	
Product Unavailable	20,8%	
Non-dispensing rate option 2	**38,3%**	MATRIX 2012
Authentication	7,6%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	29,0%	
Language	31,2%	
Product Unavailable	32,2%	
Non-dispensing rate option 3	**41,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	27,0%	
Language	29,0%	
Product Unavailable	30,0%	
Non-dispensing rate option 4	**38,3%**	MATRIX 2012
Authentication	7,6%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation
Information Missing	0,0%	
Handwriting	29,0%	
Language	31,2%	
Product Unavailable	32,2%	

Table 28: Non-dispensing probabilities for non-handwritten cross-border prescriptions

Probabilities for Common Products			Probabilities for Less Common Products		
Variable	**Value**	**Source**	**Variable**	**Value**	**Source**
Non-dispensing rate option 1	**39,8%**	MATRIX 2012	Non-dispensing rate option 1	**48,3%**	MATRIX 2012
Authentication	31,8%	based on MATRIX 2012 and hypothesis for not handwritten	Authentication	27,0%	based on MATRIX 2012 and hypothesis for not handwritten
Information Missing	25,2%		Information Missing	22,6%	
Handwriting	0,0%		Handwriting	0,0%	
Language	28,6%		Language	24,8%	
Product Unavailable	14,4%		Product Unavailable	25,6%	
Non-dispensing rate option 2	**20,0%**	MATRIX 2012	Non-dispensing rate option 2	**27,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	10,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	57,1%		Language	43,9%	
Product Unavailable	28,8%		Product Unavailable	45,4%	
Non-dispensing rate option 3	**22,8%**	MATRIX 2012	Non-dispensing rate option 3	**30,1%**	MATRIX 2012
Authentication	24,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	19,3%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	50,0%		Language	39,7%	
Product Unavailable	25,3%		Product Unavailable	41,1%	
Non-dispensing rate option 4	**20,0%**	MATRIX 2012	Non-dispensing rate option 4	**27,2%**	MATRIX 2012
Authentication	14,1%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten	Authentication	10,7%	based on 1) assumption of all info included in item set and 2) MATRIX 2012 and 3) SANCO 2012 Public Consultation and 4) Hypothesis for not handwritten
Information Missing	0,0%		Information Missing	0,0%	
Handwriting	0,0%		Handwriting	0,0%	
Language	57,1%		Language	43,9%	
Product Unavailable	28,8%		Product Unavailable	45,4%	

8.1.2.2.3 Costs

The cost inputs for the model are presented in Table 29. It should be noted that

- the cost of the central EU prescriber register is subject to considerable uncertainty:
    - The grey search and Member State consultation (SANCO 2011, cf infra) yielded only one useful reference cost (CIBG 2011) applying to a register containing date for 400 000 health professionals.
    - Next, a cost estimate was derived by extrapolating the CIBG 2011 proportional to the number of health professionals the database was expected to contain (assumed to concern 1 600 000 practising doctors and 300 000 practising dentists) as reported by Eurostat data for 2009).
    - Finally, based on the Matrix 2012 study and the Matrix 2012 estimate of the annual number of cross-border prescriptions in the EU a cost for the central EU register per cross-border prescription was estimated. Note that Matrix 2012 estimated the number of cross-border prescriptions per annum in the EU to be in the range of 1.14 to 8 million. As the 7 Member States on which this range is based were selected for a high likelihood to attract cross-border patients, the lower[55] bound of the range is used for the reference case simulations. The sensitivity analysis will further assess model robustness for changes in the assumed number of cross-border prescriptions.
- the estimated cost of a GP is based on the Matrix 2012 study. This study presents the calculations extensively and explicitly corrects for the sake of cross-EU validity: "There is no systematic EU-wide evidence on the cost of an average GP visit. Whilst a widely-used figure within the UK is £36 for a 12 minute consultation this is likely to be above the EU average, i.e. not implementable as a reliable EU estimate." The found estimate was then corrected downward to EUR 34 based on the difference between the salary of UK GPs and an EU average. This EU average was based on 7 other EU Member States, using the number of GPs as weights: Austria, Czech Republic, Finland, Luxembourg, Germany, France, the Netherlands.

[55] This minimum value of 1.1 million is about half the estimated modal value of 2.33 million. This corresponds to the difference observed for Member States out of scope versus Member States in scope on the selection parameters used in terms of observed statistics for recreational tourism and health-related tourism reported in the Matrix 2012 study. In terms of criteria such as nights spent by tourists, etc. Member States out of scope represent less than half of the activity observed in Member States within scope. This is confirmation that the minimum value of the estimated range should be used.

Table 29: Cost Inputs

Cost	Value (2012 EUR)	Source
Cost of visiting local GP	34	MATRIX 2012: calculations made based on OECD data on GP salaries for 8 EU MS
Cost of option 4: central EU-level prescriber register (online accessible)	8 000 000	Based on published cost for the Dutch BIG-register, extrapolation made for number of registered health professionals to cover all doctors and dentists in the EU
Cost of option 4 per cross-border prescription	7.0	Calculation based on above and MATRIX 2012 estimations of annual number of 1,14 million intra-EU cross-border prescriptions

Note also that a specific survey on the topic of electronic prescriber registers was conducted among Member State designated experts (see Annex 1 for full question set). Only 8 Member State designated experts replied to this survey, with questions meant to probe the resource impact of electronic prescriber registers answered by even less Member States. The below table shows Sweden estimating needed human resources for running such a register at 3 FTE. Extrapolated proportional to population this would imply 160 FTE staff are needed to run an EU-level register.

The marked uncertainty around the cost of a central EU-level register will be explored in the probabilistic analysis by applying a uniform distribution over a range based on the findings from the SANCO 2011 survey on the number of server per registered health professional reported by Sweden and the UK, which vary by a factor of almost 5.

The uncertainty around the estimated GP cost is explored in the probabilistic analysis. The variability of this input parameter was based on the standard deviation found in the Matrix data, implying a high variability was assumed (coefficient of variation = SD/Mean = +/- 33%). Further, a univariate sensitivity analysis is included assuming a GP cost of EUR 28 rather EUR 34 based on the calculated difference in GDP per capita for these 7 EU Member States as compared to the overall EU average GDP per capita.

Table 30: SANCO 2011 survey on electronic prescriber registers in Member States

MS	Are all doctors in your country listed?	Please specify how many are listed.	Please estimate the personnel needed to run and update the register (number of FTE -full-time equivalent-allocated) ?	Please estimate the technical resources (e.g. server capacity) needed to maintain the register?
ES	Yes	The registry includes professional from the National Health System and the private practice. Currently, less of 10% of the total number of physicians. In the future: 50-99%.	-	-
DK	Yes	33.103		1
SE	No	Only licensed physicians are included in the registry. Excluded are non-licensed physicians which could be exemplified as not yet licensed physicians with a degree in medicine during their training, and also non-licensed physicians with short time special appointments for example physicians from other countries who have not yet been licensed to practice medicine in Sweden.	3	2
BE	Yes	50.000	25	20
IT	No	More than 150.000 physicians		Information not available
UK	Yes	There are currently 246, 237 doctors on our register (accurate as of 16 August 2011).	It is difficult to give a precise number. Most GMC staff in our Registration and Fitness to Practise Directorates assist in uploading and updating information on the register. This is supported by our IS staff. Doctors may also update their own records via a password-protected area of our website called GMC Online.	Around 20 servers are used to maintain the register.

8.1.3 Results

8.1.3.1 Deterministic Results

In
Table 31, Table 32 and Table 33 the outcomes from the deterministic model are presented:

- Option 2 minimises costs in all cases at a cost between EUR 7.7 and 10.2 per cross-border prescription. This corresponds for instance to a drop in non-dispensing probability for a handwritten cross-border prescription from around 50% to 30% when a commonly available product was prescribed.
- As can be expected costs are higher across the board for:
    - handwritten prescriptions due to higher non-dispensing rates.
    - less common products due to higher non-dispensing rates as a result from non-availability of the prescribed products

The saving per prescription from adopting option 2 compared to option 1 equates to some EUR 8 per cross-border prescription. Multiplied with the Matrix 2012 estimate of some 1.14 million cross-border prescriptions annually in the EU this implies savings of around EUR 8 million per year should be expected under option 2. In all, between 230 000 and 240 000 more cross-border prescriptions will be dispensed under option 2.

Difficulties in understanding a handwritten prescription may also occur outside of cross-border settings (often interacting with lacking familiarity of foreign languages). However, the cost ranking of options is unchanged when only considering the outcomes for non-handwritten prescriptions in the tables below. The overall savings compared to the status quo are slightly lower nevertheless.

Table 31: Deterministic model results

Calculated Cost per Cross-border Prescription: Common Products

TYPE OF PRESCRIPTION (26% HANDWRITTEN)	VARIABLE	OPTIONS			
		Option 1: status quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Handwritten Prescription	Probability of non-dispensing	50,0%	30,1%	32,9%	30,1%
	Cost of visiting local GP (EUR 2012)	17,0	10,2	11,2	10,2
	Cost of EU prescriber register (EUR 2012)				7,0
Other Prescription	Probability of non-dispensing	39,8%	20,0%	22,8%	20,0%
	Cost of visiting local GP (EUR 2012)	13,5	6,8	7,7	6,8
	Cost of EU prescriber register (EUR 2012)	0,0	0,0	0,0	7,0
All Types	Probability of non-dispensing	42,5%	22,6%	25,4%	22,6%
	Cost of visiting local GP (EUR 2012)	14,4	7,7	8,6	7,7
	Cost of EU prescriber register (EUR 2012)				7,0
Total Cost per Cross-border Prescription (EUR 2012)		**14,4**	**7,7**	**8,6**	**14,7**

Calculated Cost per Cross-border Prescription: Less common Products

TYPE OF PRESCRIPTION (26% HANDWRITTEN)	VARIABLE	OPTIONS			
		Option 1: status quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Handwritten Prescription	Probability of non-dispensing	59,4%	38,3%	41,2%	38,3%
	Cost of visiting local GP (EUR 2012)	20,2	13,0	14,0	13,0
	Cost of EU prescriber register (EUR 2012)				7,0
Other Prescription	Probability of non-dispensing	48,3%	27,2%	30,1%	27,2%
	Cost of visiting local GP (EUR 2012)	16,4	9,3	10,2	9,3
	Cost of EU prescriber register (EUR 2012)				7,0
All Types	Probability of non-dispensing	51,2%	30,1%	33,0%	30,1%
	Cost of visiting local GP (EUR 2012)	17,4	10,2	11,2	10,2
	Cost of EU prescriber register (EUR 2012)				7,0
Total Cost per Cross-border Prescription (EUR 2012)		**17,4**	**10,2**	**11,2**	**17,2**

Table 32: Estimated cost savings

Scenarios (1,145 million cross-border prescriptions)	Option 1: Status Quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Common products	17.000.000	9.000.000	10.000.000	17.000.000
Uncommon products	20.000.000	12.000.000	13.000.000	20.000.000
Common products	**ESAVINGS COMPARED TO STATUS QUO**	**8.000.000**	**7.000.000**	**0**
Uncommon products		**8.000.000**	**7.000.000**	**0**

Table 33: Estimated extra dispensed cross-border prescriptions

Scenarios (1,145 million cross-border prescriptions presented)	Option 1: Status Quo	Option 2: Core Set	Option 3: Core Set + National Registers	Option 4: Core Set + EU register
Common products	660.000	890.000	850.000	890.000
Uncommon products	560.000	800.000	770.000	800.000
Common products	**EXTRA DISPENSED PRESCRIPTIONS COMPARED TO STATUS QUO**	**230.000**	**190.000**	**230.000**
Uncommon products		**240.000**	**210.000**	**240.000**

8.1.3.2 Probabilistic Results

8.1.3.2.1 Distributions and uncertainty parameters/ranges

Parameter uncertainty is captured through the choice of distribution for input variables in our model:

- Beta distributions were used for variables that are unimodal and bounded between 0-1, such as probabilities,
- Triangular distribution were used for variables that are unimodal distribution and bounded within a known min-max range,
- Gamma distributions are used for zero-bounded skewed variables, such as costs,
- The uniform distribution was included were little is known about empirical parameter variability.

This way all variables in the calculation were included in the probabilistic model. Uncertainty from variables was accounted for by setting distribution parameters in keeping with:

- sample sizes for the MATRIX 2012,
- minimum/maximum and median values[56] based on NIVEL 2011 and SANCO 2012 surveys,
- reported standard deviation for the doctor cost data,
- wide uncertainty for the cost of a central EU register (cost variation of a factor 4 assumed based on SANCO 2011 Member State survey)

Using Excel® 2003 and VBA® 1000 simulations were ran in a Monte Carlo simulation model, drawing numbers at random from presented distributions. These simulations were ran using the "common product" scenario as a base case as this was thought to be most representative.

Table 34: distributions used in the probabilistic model

Variable	Distribution	Parameters based on
Non-dispensing rates	Beta	Reported number of scored prescriptions and number of scores in MATRIX 2012
Handwritten Prescription	Triangular	Based on NIVEL 2011: percentage for 21 MS (80% EU population) and assumption that remaining 6 MS respectively have 0%/100% handwritten prescriptions for min/max,
Authentication Effectiveness	Triangular	Reported average scores for organised stakeholders (dispensers) with PGEU score = mean and min/max taken from 4 stakeholders for each score, application of formula (after algebraic transformation): median = 3*average-min)max
Cost of GP	Gamma	Standard Deviation in reported GP salaries per MS from MATRIX 2012
Cost of EU register	Uniform	Uniform over range based on MS replies to SANCO 2011 survey

[56] Using formula for triangular distribution: mean = 3*(min + mode +max) for variables following a triangular distribution.

8.1.3.2.2 Results

Results from 1.000 simulations are depicted in the table and figures below:

3. Option 2 is confirmed as the preferred, cost-minimising, option and shows up 883 times as the cheapest option (option 3 is the cheapest option for the remainder of cases).
4. Option 4 is the least desirable option, showing up as the most expensive option 560 times (option 1 is the most expensive option the remainder of the time).

We conclude that the findings from deterministic model are robust for simulated changes in all input variables, ranking options by cost-savings expected:

1) Non-exhaustive list of elements (option 2)
2) (Elements in) List combined with national databases (option 3)
3) Status quo (option 1)
4) (Elements in) List combined with EU-level database (option 4)

Further it should be noted that options 1 and 4 are clustered (respectively 44% and 56% probability of being the least preferred option) as are options 2 and 3 to a lesser extent (respectively 88% and 12% probability of being the most preferred option).

Table 35: Probabilistic results (observations not clustered by simulation)

	Costs (EUR 2012) based on 1000 simulations			
	Option 1	**Option 2**	**Option 3**	**Option 4**
Max	37,6	21,0	23,3	30,9
p75	24,8	13,5	15,5	21,4
Median	13,5	7,2	8,1	14,7
p25	6,5	3,4	3,7	7,8
Min	3,7	1,9	2,0	5,2
Mean	14,2	7,6	8,5	14,7

Figure 6: Probabilistic results as boxplots (observations not clustered by simulation)

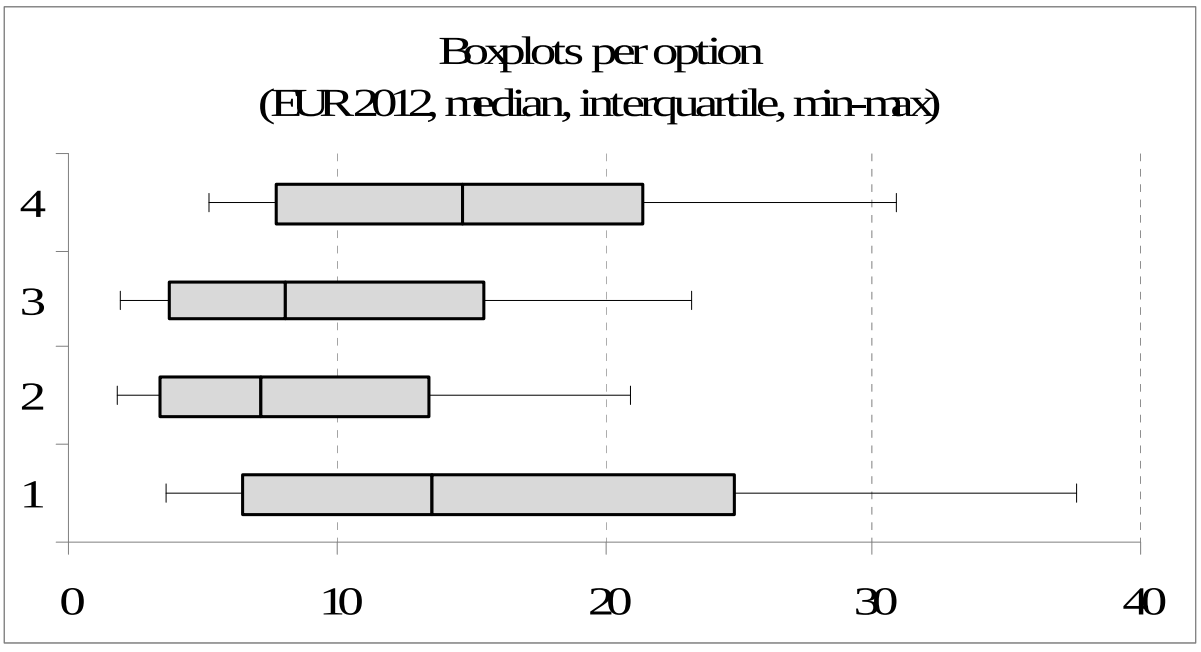


Figure 7: Probabilistic results as a scatterplot

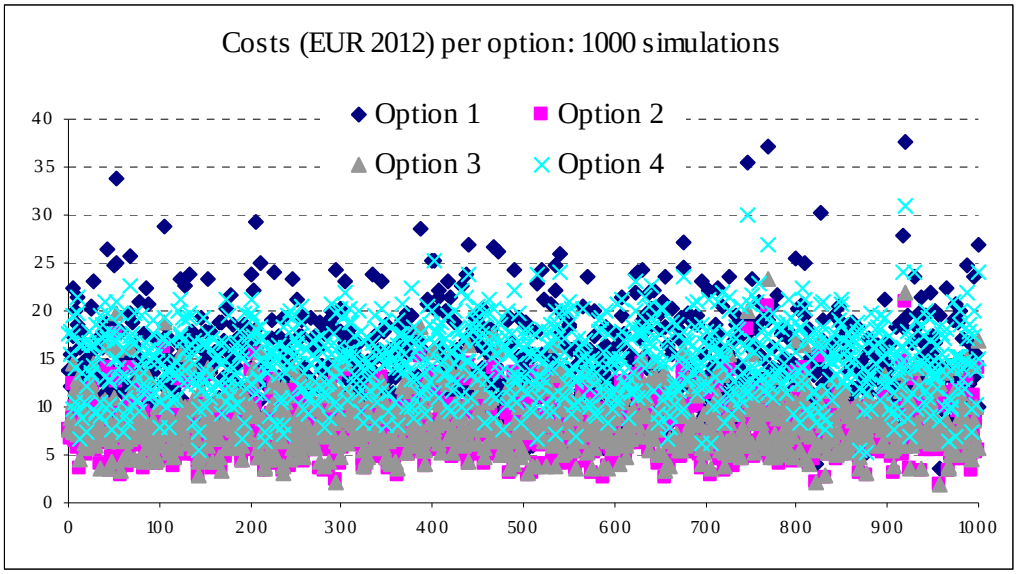
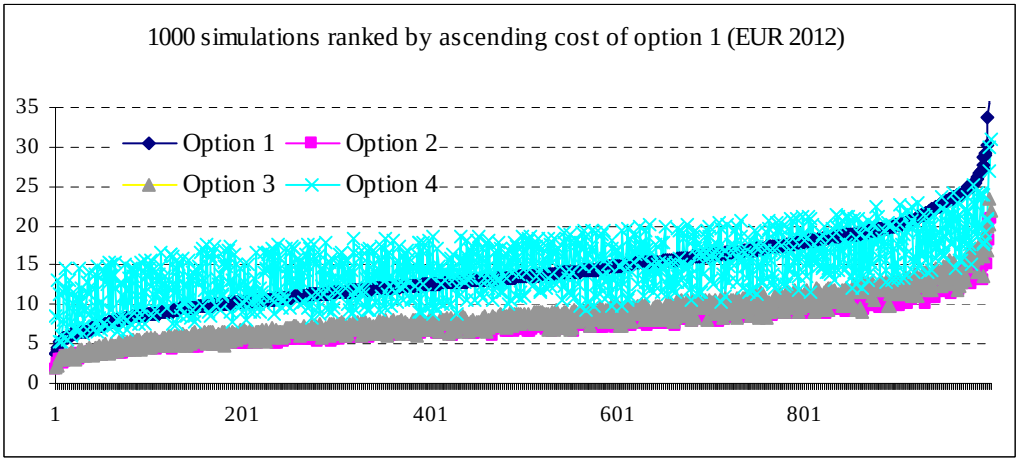


Figure 8: Probabilistic results as a scatterplot with simulations ranked by cost of option 1



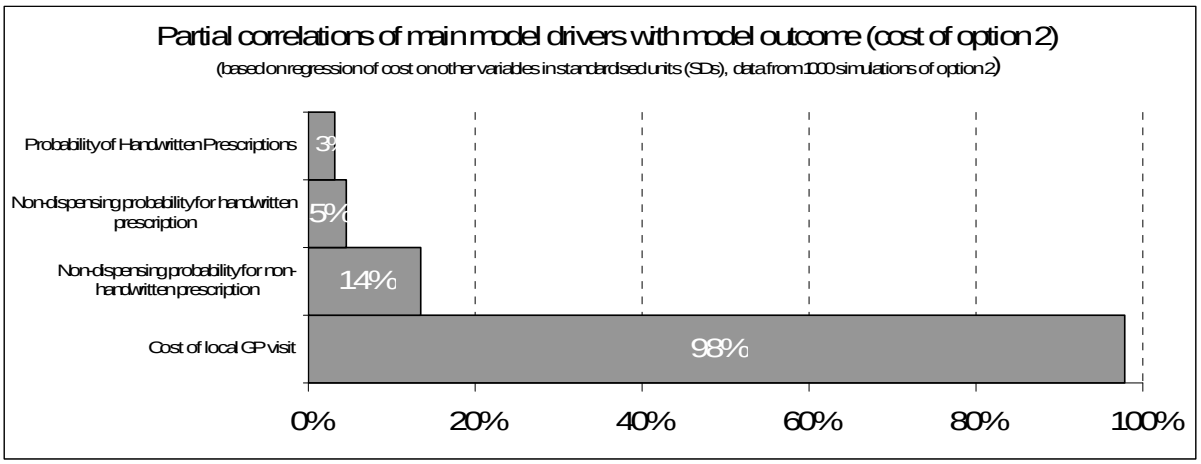
8.1.3.3 Sensitivity Analyses

8.1.3.3.1 Probabilistic Sensitivity Analysis

Using the output from 1 000 simulations, a linear regression[57] analysis was done to explore the association between the cost outcomes from option 2 (common products) and input variables. The result below in Figure 9 shows the 4 main drivers, defined as significant regressors for which the coefficients are shown in the below diagram:

- As the only cost input in option 2 concerns the cost of a doctor consultation, it should not come as a surprise that this variable is the main driver of the model result, which is a cost outcome.
- The importance of overall non-dispensing rates as model drivers should not surprise either.
- The impact the percentage of handwritten prescriptions (through non-dispensing from difficulties in reading handwriting) is an interesting finding. As such the fact whether a prescription is handwritten or not will not be influenced by the implementing acts at play. However, one could arguably expect the percentage of handwritten prescriptions to (further) diminish in the future. This would lower the cost impact for all options, including the status quo option.

Figure 9: Tornado diagram



[57] Measurement units were standardised (average divided by standard deviations) for all variables in regression.

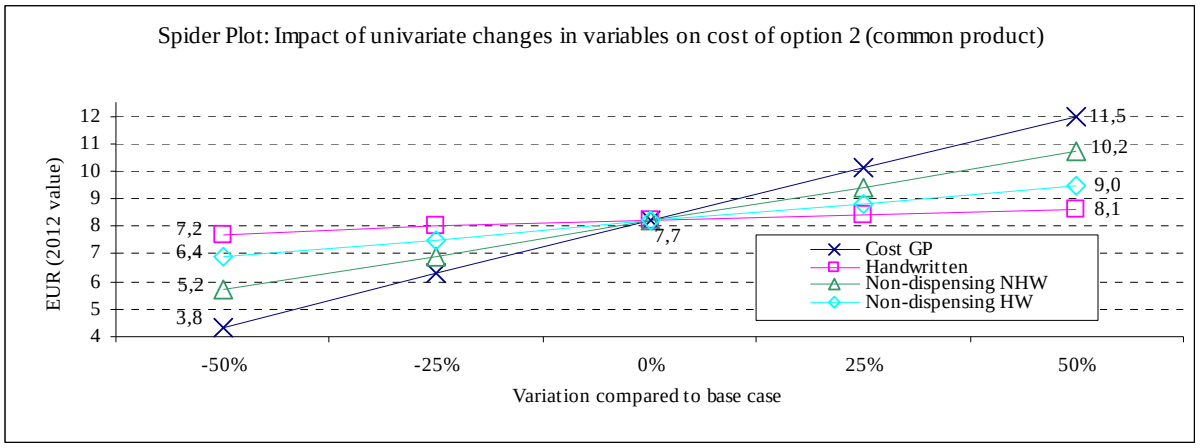
8.1.3.3.2 Univariate sensitivity analyses

8.1.3.3.2.1 Absolute impact of main model drivers

The absolute impact (in terms of EUR 2012) of varying the 4 identified drivers above is explored in Figure 10. This graph should be read as follows: respectively increasing/decreasing the assumed cost of a doctor consultation by 50% brings the cost of option 2 down to 3,8 euro / up to 11,5 euro (or elasticity of around 1). The steeper the line, the higher the elasticity and the higher the impact of variations in the related variable on the model outcomes.

It can be concluded that changes in the assumed cost of a doctor visit have an (almost) proportional impact on calculated costs per option. However, this variable drives the cost of all 4 options and consequently changes in this input variable would not alter the cost ranking of options.

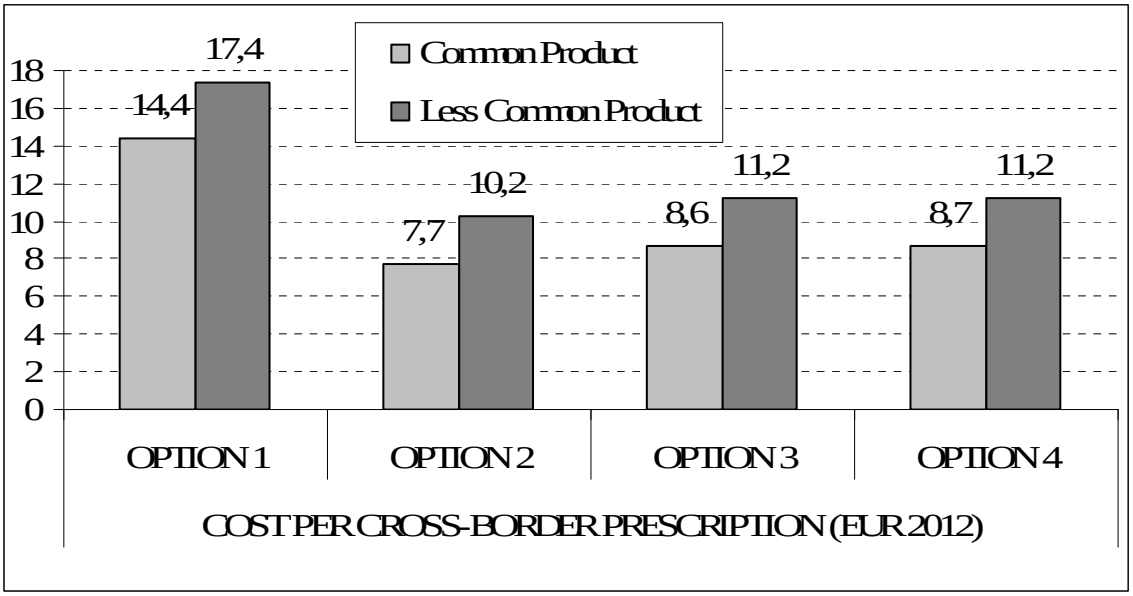
Figure 10: Spider plot



8.1.3.3.2.2 Univariate Scenarios

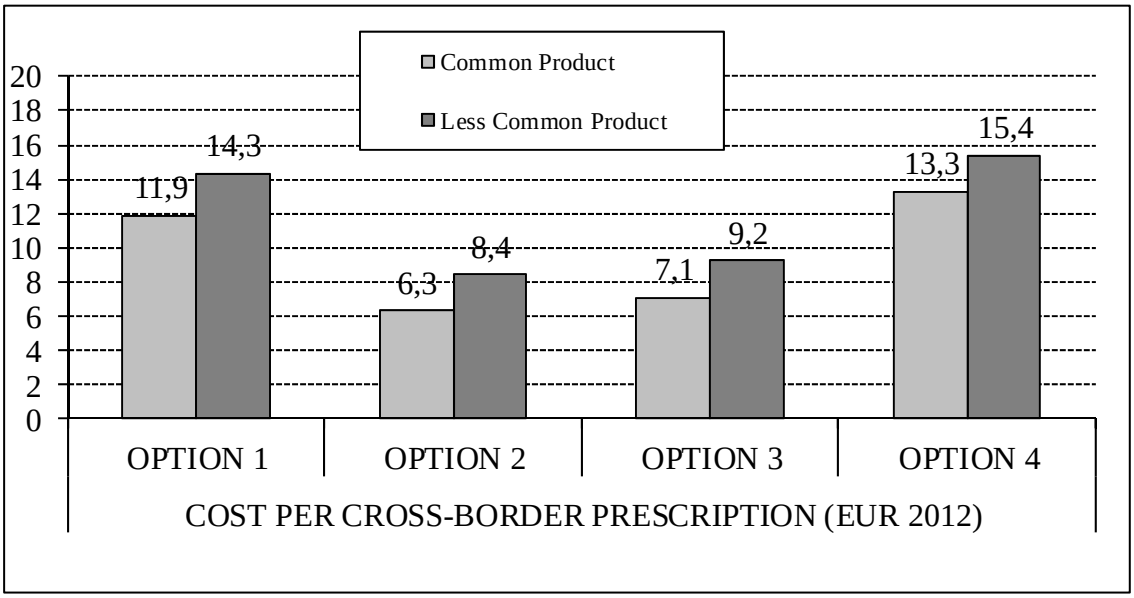
A further robustness test is presented in Figure 11 Assuming that the number of cross-border prescriptions increase from 1.14 million to 8 million, the upper bound of the range estimated by Matrix 2010 is tantamount to assuming the cost of the central EU register per cross-border prescription drops by a factor of around seven. This brings the cost for option 4 down considerably to a level comparable of option 3. Nevertheless, in this deterministic scenario option 2 remains the cheapest option and model findings seem robust, even when anticipating a steep increase in cross-border patients. As the authentication effectiveness of option 2 and option 4 is assumed to be equal, given the model's set-up, option 4 will always be marginally less cost-saving than option 2, even when assuming ex absurdo that all prescriptions would become cross-border prescriptions.

Figure 11: Univariate Sensitivity scenario: number of cross-border prescriptions increases to 8 million



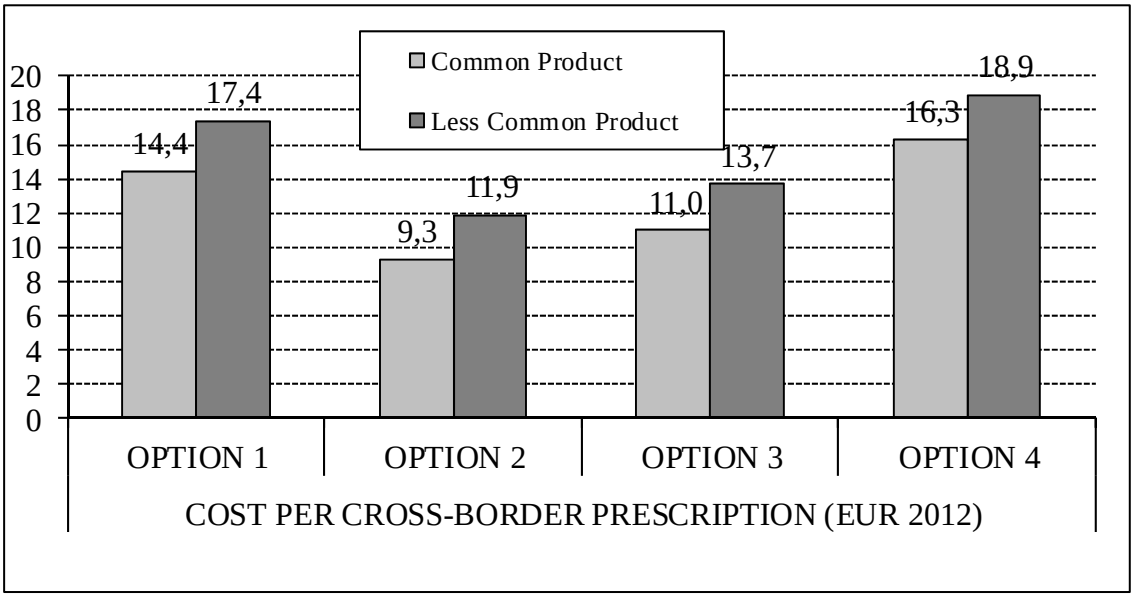
Next, a scenario is built assuming a GP cost of EUR 28 instead of EUR 34. This assumption is based on the observed difference in the GDP per capita between the 7 Member States the EUR 34 estimate is based on (Matrix 2012 study) and the overall EU GDP per capita. Respectively, the GDP per capita for 2010 amounted to EUR 30,100 and EUR 24,400 (2010 EUR value). Hence, a proportional drop of around 20% from EUR 34 to EUR 28 is used. The related model outcomes (see Figure 12) indicate that the cost ranking of options remains unchanged (as local GP cost is factored in for all options). However, associated overall savings (option 2 compared to status quo option 1) drop as the avoided unit cost of visiting a local GP is lowered.

Figure 12: Univariate Sensitivity scenario: GP cost of EUR 28 assumed



A further scenario is shown in Figure 13. If the authentication tool "prescriber identification through elements in prescriptions (but no contact details)" in Table 26 is assumed to already correspond to the current reality in Member States, then the effectiveness of options 2-4 used in the model should be calculated as the relative improvement compared to the corresponding authentication effectiveness of 56% (instead of an implicitly assumed 0%). Using this conservative[58] approach to authentication effectiveness under options 2-4, we see that options 2-4 become more expensive compared to the comparator, but that, nevertheless, option 2 is confirmed as the dominant, most cost-saving option.

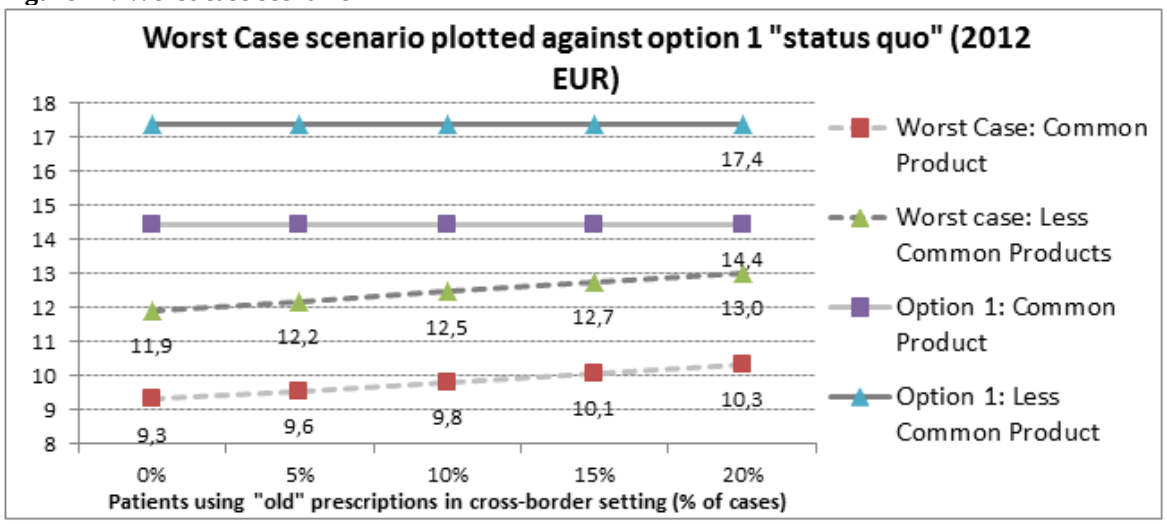
Figure 13: Univariate Sensitivity scenario: authentication effectiveness relative to status quo



[58] "Conservative" as the implementing acts entail a partial standardisation across EU Member States. Further, the list of non-exhaustive elements under assessment shall be identifiable as such. Both elements logically imply an improvement to the status quo, even if this already includes prescriber identification elements.

Finally, when combining the above scenario (see Figure 13) with the assumption that not all Member States will incorporate the non-exhaustive list of elements into all existing prescriptions, a "worst case scenario" can be constructed (see Figure 14). This scenario entails a certain percentage of prescriptions issued in a given Member State that do not contain the non-exhaustive list and that are nevertheless presented in a cross-border setting. Consequently, for this proportion of prescriptions the increased dispensing rate is assumed not to apply. The result is a drop in the expected cost savings under option 2 as shown below. The shown range of 0%-20% is illustrative. It appears unlikely, however, that this percentage should exceed the assumed range as this would imply both a majority of Member States no incorporating the non-exhaustive list in their existing prescriptions as well as a considerable share of cross-border patients not using the "cross-border prescription".

Figure 14: Worst case scenario



8.1.4 Discussion and Conclusions

8.1.4.1 Overall evaluation

The outcome of the economic evaluation is that, in terms of the increased recognition of cross-border prescriptions and the related cost-savings to be expected the assessed options are ranked in order of preference as below:

5. Non-exhaustive list of elements (option 2)
6. Non-exhaustive list combined with national databases (option 3)
7. Status quo (option 1)
8. Non-exhaustive list combined with EU-level database (option 4)

The robustness of this ranking was extensively tested and confirmed through a probabilistic analysis as well as a series of univariate scenarios.

Should certain Member States opt to restrict the use of the non-exhaustive list to those prescriptions of which it is assumed beforehand they will be used in a cross-border context (i.e. healthcare planned to be cross-border healthcare), this will imply that:

1. there will be a separate "cross-border prescription form[59]",
2. certain patients may still choose to present a "regular" prescription form to a cross-border dispenser.

In the latter case, the recognition of the prescription should not be less than currently (status quo) is the case as the general principle of mutual recognition of medical prescriptions (which predates the Directive 2011/24/EU) will still apply. It consequently follows that the situation in which if certain Member States opt for "separate cross-border forms" is the equivalent of combining option 1 (for cross-border patients presenting a "regular" prescription form") and option the preferred policy option, in this case option 2. As such, this will always be a suboptimal outcome, not fully realising the potential cost-savings option 2 offers.

Overall, it needs to be stressed that, given issues such as the medium of the prescription, the ability of the dispenser to understand the language in which the prescription is drafted, varying availability of products across EU Member States, it is clear that a 100% dispensing rate for cross-border prescriptions will never be achieved. The implementing acts assessed in this report are expected to at best increase the dispensing rate with some 20 percentage points (from 50% to 70% in case of a non-handwritten product for a product that is commonly available throughout the EU).

[59] See also expert input to NIVEL 2011: "the development of separate "cross border prescription forms" does not seem to be reasonable as it might not be foreseeable at the time of prescription neither for the doctor nor for the patient whether the prescription will be used in the home country or another country."

8.1.4.2 Limitations of the model

The main limitations concern:

- The wide overall uncertainty to which input variables are subject. For this reason a probabilistic model was built and additional univariate scenarios considered. The deterministic outcome of the model (raking with option 2 as preferred option) was found to be robust in all tests.
- The fact only business-as-usual costs are assumed. This implies no start-up costs are considered. This is counterbalanced by the fact that:
    - No dynamic beneficial spill-over effects are assumed either (improved intra-regional recognition of prescriptions within a given Member State, lower purchasing cost of prescription-related software packages through partial harmonisation of prescriptions across the EU,…).
    - There is a trade-off between the transition time left to Member States and start-up cost in line with the time it takes to clear stocks of already printed prescriptions, write off software packages, etc.
    - Specifically for the cost of an EU-wide prescriber register, it must be stressed that the reference data used (CIBG 2011) are based on financial data reflecting classical accounting valuation (such as amortisation of capital investment on a yearly basis) and are thus assumed to cover the full life-cycle cost of the investment. Consequently, possible start-up costs not captured in the accounts should be limited and furthermore difficult to quantify (such as staff learning curve effects).
- The implicit assumption that Member States will incorporate the non-exhaustive list of elements in their "regular" prescriptions that also serve for "domestic" care. If the uptake of the non-exhaustive list is limited to those prescriptions intended to be used for cross-border dispensing (in other words for (planned) care that us planned to be cross-border) the below issues should be considered:
    - The possibility of added costs (for printing prescription forms, etc.) due to lower economies-of-scale given smaller volume of cross-border patients.
    - The fact that, in case of care that is not planned to be cross-border, a patient may still want to have a product dispensed with a prescription that does not contain the non-exhaustive list. In the latter case, in principle the recognition of the prescription should remain at the current "status quo" level, but pharmacists may in the future be less inclined to dispense a product to foreign patients not carrying the harmonised prescription form.

8.1.4.3 Policy implications

Main policy implementations are as follows:

- Given the current low volume of cross-border prescriptions the set-up of a central EU-register of prescribers is not justified. Monitoring of the future evolution of the volume of cross-border healthcare would be needed to warrant any further consideration of such an initiative.
- As Member States currently compile data on authorised prescribers and as the Directive 2011/24/EU will further reinforce patient rights to obtain information from Member States on which health professionals are authorised to practice, it appears logical to assess how this information can be used also with a view to cross-border

dispensing of prescriptions. However, as raised by the PGEU there are some doubts on the extent to which information not necessarily available in a language understandable to the dispenser, referring to local terminologies could be made accessible to cross-border dispensers.

- The transition time that will be foreseen for measures to be put into place merits special attention.
- In case Member States opt to have a separate cross-border prescription form it should be made clear that the principle of recognition of prescriptions (which predates Directive 2011/24/EU) shall continue to apply to the same extent as currently is the case for cross-border prescriptions not containing the non-exhaustive list agreed on at EU level.

8.1.5 References

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8.1.6 Annexes to Economic Evaluation

Annex 1: Non-exhaustive list of existing health professional registers, with electronic access for pharmacists.

Member State	Electronic register	Source
AT	Online register: doctors	HPRO 2010
BE	registers can be consulted electronically by pharmacists. Access is given to information about doctors'	SANCO 2011 Survey
CZ	Online register: doctors, dentists and pharmacists	HPRO 2010
DK	registers can be consulted electronically by pharmacists. Access is given to information about doctors'	SANCO 2011 Survey
EE	Online register: doctors and pharmacists	HPRO 2010
FR	Online register: all regulated professions	HPRO 2010
LT	Online register: all regulated professions	HPRO 2010
NL	Online register: all health professionals (BIG register)	Online search: http://www.bigregister.nl/
IE	Online register: nurses and midwives	HPRO 2010
PL	Online register: doctors and dentists	HPRO 2010
PG	Online register: dentists	HPRO 2010
ES	Online register: doctors	HPRO 2010
SE	registers can be consulted electronically by pharmacists. Access is given to information about doctors'	SANCO 2011 Survey
UK	Online register: doctors and pharmacists	HPRO 2010

Annex 2: "no added costs for national registers" hypothesis (option 3).

Article 6 (3) of the Directive 2011/24 states that "In order to enable patients to make use of their rights in relation to cross-border healthcare, national contact points in the Member State of treatment shall provide them with information concerning healthcare providers, including, on request, information on a specific provider's right to provide services or any restrictions on its practice". Moreover, in Article 6 (5) it is stated that "the information referred to in this Article shall be easily accessible and shall be made available by electronic means."

This implies that Member States, insofar they not done so already, will need to compile data on healthcare providers, including on prescribers and their right to prescribe. As such, costs related to this data collection are not specifically attributable to option 3. The question remains whether the use of a publicly accessible website (which de facto could be consulted by cross-border dispensers) would be the most likely approach by MS to make information "available by electronic means". An alternative would be to have administrative staff consult an internal database and transmit information by email on ad hoc request by patients.

The table below presents an estimate for the number of patient contacts with healthcare providers (hospital staff in general, doctors, dentists) in the EU. These estimates are based on OECD Health 2011 data and extrapolated -proportionally to population sizes- to present an EU-wide estimate. It is found that around 4 billion patient contacts took place in 2008.

Applying the assumptions that

- 1% of healthcare concerns cross-border healthcare (proportional to the estimate of 1% of public health budgets contained in Impact Assessment accompanying the Directive on the application of patients' rights in cross-border healthcare(SEC(2008) 2164)),
- 60% of cross-border healthcare concerns planned healthcare for which patients might require information of healthcare providers in advance (based on the estimate found by Hermesse et al 1997:" A breakdown into the different types of access to health care abroad revealed the financial importance of preauthorized care (El12), as it was responsible for nearly 60% of the total cost of cross-border care")

implies that around 25 million patient-provider contacts for planned cross-border healthcare are expected annually in the EU.

The overall cost of maintaining a register and publicly accessible webpage for all doctors and dentists in the EU was estimated at EUR 8 million (see calculations for option 3). This implies a cost of minimally around EUR 0.30 per expected patient-provider contact (assuming that each planned cross-border contact a patient will have a prior information request).

Spending the same budget (EUR 8 million) by use of staff and ad hoc replies per email at an hourly cost of EUR 28 (based on Eurostat hourly labour cost data[60] and including 25% overhead costs[61]), would mean as little as 40 seconds of staff time could be spent per patient information request.

Even when assuming the use of online databases would avoid only 10% of prior information request by patients, this would still mean less than 7 minutes could be spent on these information requests by replying individually to each patient. This appears to be unlikely.

[60] Labour cost data for NACE Rev 2 " Public administration and defence; compulsory social security; education; human health and social work activities; arts, entertainment and recreation; other service activities"

61 Based on the "International Standard Cost Model Manual".

Furthermore, patients may have several follow-up questions starting with a general question (Is there a list of cardiologists in a given area?) and following up with more detailed questions (Is this particular cardiologist attached to that particular hospital?).

Consequently, it appears unlikely that Member States would use an approach that does not include publicly accessible registers of healthcare providers to comply with Article 6 of the Directive 2011/24/EU as this approach arguably is the most cost-effective.

Number of patient contacts in the EU per year: data for 2008

	All contacts	Per EU resident	Source
INPATIENT CARE (number of hospital discharges)	90.000.000	0,2	OECD Health 2011, data on hospital discharges for EU MS covering 86% of EU population
OUTPATIENT CARE (number of consultations)	4.080.000.000	8,2	*NA*
Doctors	3.450.000.000	6,9	OECD Health 2011, data on consultations per capita for EU MS covering 66% of EU population
Dentists	630.000.000	1,3	OECD Health 2011, data on consultations per capita for EU MS covering 62% of EU population
TOTAL	**4.170.000.000**	**8,4**	*NA*

Annex 3: SANCO 2011 survey among Member State designated experts on prescriber registers: question set

2. Registers of physicians
2.1 Is there an electronic register of physicians available in your country? -single choice reply- (compulsory)
2.2 Please provide the name and a short description of this electronic register. -open reply- (compulsory)
We have a project to develop an electronic registry of health professionals at the state level. The information provided is in relation to this project.
2.3 What type of electronic register is it? -multiple choices reply- (compulsory)
2.4 Can the regional register be accessed from other regions? -single choice reply- (compulsory)
2.5 Are all physicians in your country listed? -single choice reply- (compulsory)
2.5.1 Please specify how many are listed. -open reply- (compulsory)
2.6 Is the electronic register specifically developed for: -multiple choices reply- (compulsory)
2.7 The electronic register is managed by: -multiple choices reply- (compulsory)
2.8 What measures are established to protect personal data contained in the register from unauthorized access (e.g. PKI, RBAC, XSAP,…)? -open reply- (compulsory)
2.9 Which information is stored in the register? (please tick all that apply) -multiple choices reply- (compulsory)
2.9.1 Please specify -open reply- (compulsory)
2.10 Does this electronic register have a directory structure? -single choice reply- (compulsory)
2.11 Is this information structured according to a recognized standard? -single choice reply- (compulsory)
2.11.1 Please specify. -single choice reply- (compulsory)
2.11.1.1 Please specify. -open reply- (compulsory)
2.12 What standards and protocols for directory deployment are used? -multiple choices reply- (compulsory)
2.12.1 Please specify. -open reply- (compulsory)
2.13 What protocols are applied to provide access to the register? -multiple choices reply- (compulsory)
2.13.1 Please specify. -open reply- (compulsory)
2.14 Is access to this electronic register possible through: -multiple choices reply- (compulsory)
2.15 Please estimate the personnel needed to run and update the register (number of FTE -full-time equivalent-allocated) ? -open reply- (optional)
2.16 Please estimate the technical resources (e.g. server capacity) needed to maintain the register? -open reply- (compulsory)
2.17 How frequently is the register updated? -single choice reply- (compulsory)
2.17.1 Please specify. -open reply- (compulsory)
2.18 Is your country currently undertaking the establishment of a new electronic register of physicians or healthcare professionals in general in the context of a wider eHealth Project? -single choice reply- (compulsory)
2.18.1 When will this new electronic register be fully implemented? -open reply- (compulsory)
3. Pharmacists' access to the register of physicians
3.1 Can pharmacists identify physicians before dispensing a prescription (by any means, e.g. telephone)? -single choice reply- (compulsory)
3.2 Can physicians' registers be consulted electronically by pharmacists? -single choice reply- (compulsory)
4. Additional comments.
4.1 Please provide any other information you would like to add to clarify the information provided, including references of publications, etc. -open reply- (optional)

Annex 4: SANCO 2011 CBHC Directive Member State Survey: questions related to Article 11 (recognition of prescriptions)

	Is there any specific guidance ensuring that prescriptions issued in another Member State are effectively recognised in your country (e.g. regulations, guidelines for pharmacists)?	Are certain restrictions provided for the recognition of prescriptions and under which conditions?	Which are the main obstacles, if any, currently hampering the recognition by dispensers (e.g. pharmacists) in your country of prescriptions issued in another EU Member State?	Do you have any data sources reporting on the dispensing of prescriptions issued in another Member State in your country?	Entity/ies responsible for implementation of Article 11 of Directive 2011/24/EU?
AT	no	no	Language; availability of the prescribed drug; doubts if the prescription was issued by a person legally entitled to (in Austria only doctors, dentists and midwifes may prescribe drugs)	no	mainly Ministry of Health
BE	The Royal Decree of 10 August 2005 fixing the modalities for the prescription for human use requires that certain minimum information is on the prescription in order to enable correct dispensing of medicinal products or other products reimbursed (name and address prescriber, name or common name product, signature prescriber etc…).	No other restrictions are foreseen than the requirements for the prescription.	No information available.	We have data on the dispensing of pharmaceutical products (who give way to partial of total reimbursement by the compulsory health care insurance) on the basis of a prescription issued in another member state.	The Federal Agency for Medicines and Health Products, the National Institute for Health and disability Insurance and the eHealth-platform.
BG	The procedures for prescribing and dispensing medicinal products are governed by Regulation No 4/2009 on the procedures for prescribing and dispensing medicinal products (SG 21/2009).	The above Regulation currently contains no express provisions governing prescriptions issued in other Member States, therefore there are no such restrictions.	The Healthcare Facilities Act (ZLZ) and Regulation No 4/2009 require medicinal products to be prescribed by practicing medical doctors, defined by the Act as doctors registered either individually or as members of specialised medical practices or as working in an in- or outpatient healthcare facility. The medicinal products prescribed must have been approved for use in Bulgaria. When prescribing medicinal products, healthcare professionals can use either their international non-proprietary names (INN) or their trade names. If they use the trade name, the pharmacist must dispense the exact product prescribed. If they use the INN, the pharmacist can substitute it with a corresponding product, including a generic one. The pharmacist must also check whether the prescription is complete, which includes checking for the doctor's signature and personal stamp or stamp of his healthcare facility. This is done both to check the content of the prescription and to see whether the doctor in question is authorised to issue prescriptions.	At the moment the Bulgarian authorities have no information concerning the recognition of prescriptions from other Member States.	To implement Article 11 of Directive 2011/24/EU, the National Assembly will adopt the necessary statutory amendments and the Minister of Health will make the necessary amendments to the implementing provisions.
CY	No, only prescriptions from doctors registered in Cyprus can be recognised by pharmacist	N/A	National Legislation in force	N/A	Pharmaceutical Services- Ministry of Health of Cyprus
DE	Relevant regulations are laid down in the Prescription of Medicines Order. These regulations are to enter into force on 1 January 2012.	Restrictions on the recognition of prescriptions from other EU Member States in the context of the amendments to the Prescription of Medicines Order are only as provided for by Directive 2011/24/EU.	Apart from the language problem, dispensers may see the legality of the prescription as a possible obstacle.	No.	Federal Ministry of Health
DK	Yes, the Order on prescriptions.	Pharmacies may refuse to dispense a prescription if there are any doubts about its authenticity.	Recognition of prescriptions was introduced on 1 April 2011. It is therefore too soon to evaluate any problems etc.	The Danish Medicines Agency collects data.	Ministry of the Interior and Health.
EE	0	Narcotic and psychotic drugs are not dispensed based on the EU prescription. If the EU prescription displays corrections, or drugs that are not suitable to be taken concurrently are prescribed with the EU prescription, or the prescribed drugs are unsuitable for the holder of the prescription due to age or doses, then the drugs are not dispensed	1.Differing validity period for the prescriptions (60 days in Estonia, up to a year elsewhere)	Since 2010 second quarter the pharmacies report to the State Agency of Medicines the number and cost of the prescriptions issued in another Member state. If the State Agency of Medicines deems necessary, it has the right to ask for additional information on the issuing of medicines from the pharmacy. Pharmacies are required to store the prescriptions issued in another member state separately from all other prescriptions.	Government (Ministry of Social Affairs)

	Is there any specific guidance ensuring that prescriptions issued in another Member State are effectively recognised in your country (e.g. regulations, guidelines for pharmacists)?	Are certain restrictions provided for the recognition of prescriptions and under which conditions?	Which are the main obstacles, if any, currently hampering the recognition by dispensers (e.g. pharmacists) in your country of prescriptions issued in another EU Member State?	Do you have any data sources reporting on the dispensing of prescriptions issued in another Member State in your country?	Entity/ies responsible for implementation of Article 11 of Directive 2011/24/EU?
FL	Yes. Medicines Decree, section 29 (803/2009):	According to the Finnish Medicines Agency, Finnish pharmacies may dispense prescriptions issued in another Member State if the dispensing pharmacist can be assured of the validity of the prescription and he/she can ensure the proper and safe use of the medicinal product in this individual situation. If the prescription is unclear or the dispensing pharmacist is unable to assure the validity of the prescription, the patient must be directed to see a licensed physician.	There is no access to national databases of other EU Member States and there is no international database of licensed physicians in all EU Member States (including also the information of possible restriction on prescribing).	The Finnish Medicines Agency has the annual data of prescriptions issued in other Nordic countries and dispensed in Finnish pharmacies.	MSAH, Fimea, pharmacies.
GR	No, electronic prescribing and interoperability with other Member States within the context of cross-border cooperation and the dispensing of prescriptions have yet to be implemented.	YES	There is no common method for prescribing medicinal products or a uniform list of compulsory prescription medicines with other Member States.	No	The Ministry of Health and the Ministry of Labour and Social Security, and the social security institutions. Pharmacies are responsible for recognising the prescriptions and dispensing the medications. Their official supervision is performed by the Office of the National Chief Medical Officer and the county-based public health administrative body.
HU	No specific guidance exists.	Based on the applicable legislation (Section 20 of Decree 44/2004 (IV. 28.) ESzCsM) a prescription medication ordered by a person not listed in the operation register but entitled to order medications in a state may be dispensed if the prescription meets the following criteria:	If the content described under question no. 46 is not shown or not legibly shown on the prescription.	No	
IE	The Medicinal Products (Prescription and Control of Supply) Regulations 2003 SI no 540 of 2003 (as amended) addresses this issue. In this a prescription is defined as:	Prescriptions must be in ink and be signed and dated by the prescriber.	The prescription writing rules set out in national legislation and described in (46) above must be complied with (a minor omission is allowed).	No	Department of Health
IT	currently none	The pharmacist must reject requests for medicines made with prescriptions not in accordance with Italian law.	Having regard that the pharmacist can consider only the prescriptions written by doctors or veterinarians or graduates in dentistry legally entitled, the main obstacle of the dispenser is the difficulty to recognizing the professional who prescribed the medicine	currently none	Ministry of Health
LT	No	Yes	The main obstacles in recognition of the prescription issued in another Member State are:	No	Ministry of Health of the Republic of Lithuania
LV	No	There is no regulation currently in place that would enforce the recognition of prescriptions issued in another Member State.	-"- "-	No	Currently is under evaluation.
MT	No, current legislation specifies that pharmacists in Malta can dispense prescriptions of medical and dental practitioners registered with the Professional Regulatory Councils under the Health Care Professions Act in Malta. This legislation will be rectified to allow recognition of practitioners in other Member States provided that there are the means for verification of the professional status of the prescriber in the respective Member State.	Currently only prescriptions from professionals registered in Malta are recognised. This legislation will be rectified to allow recognition of practitioners in other Member States provided that there are the means for verification of the professional status of the prescriber in the respective Member State.	The current legislation restricts recognition of prescriptions. Current legislation under the Health Care Professions Act in Malta specifies that pharmacists in Malta can dispense prescriptions of medical and dental practitioners registered with the Professional Regulatory Councils. . This legislation will be rectified to allow recognition of practitioners in other Member States provided that there are the means for verification of the professional status of the prescriber in the respective Member State.	No	The Licensing Authority as designated by the Medicines Act, 2003.
PL	Such prescriptions are dispensed on the basis of an ordinance issued by the Minister of Health.	A pharmaceutical product can be dispensed by a pharmacy, based on a foreign prescription, without reimbursement (full price paid by the patient).	A problem can occur when a prescription is issued for a drug which is not registered in Poland or the EU. That's why it is better to write on the prescription the name of the active substance instead of the commercial name.	No	Ministry of Health
RO	Yes	Yes	The current main obstacles to the recognition by dispensers in Romania of prescriptions issued in another Member State of the EU relate to:	Yes	Ministry of Health

	Is there any specific guidance ensuring that prescriptions issued in another Member State are effectively recognised in your country (e.g. regulations, guidelines for pharmacists)?	Are certain restrictions provided for the recognition of prescriptions and under which conditions?	Which are the main obstacles, if any, currently hampering the recognition by dispensers (e.g. pharmacists) in your country of prescriptions issued in another EU Member State?	Do you have any data sources reporting on the dispensing of prescriptions issued in another Member State in your country?	Entity/ies responsible for implementation of Article 11 of Directive 2011/24/EU?
SK	No	No	Identification of validity of prescriptions	No	MoH
SL	There is no specific guidance; for the dispensing of medicinal products for which a prescription is required, the conditions laid down in the Rules on the classification, prescribing and dispensing of medicinal products for human use (Official Gazette of the Republic of Slovenia No 86/2008) must be met; these Rules lay down the composition of a prescription: the information to be contained in the administrative section and the technical section of the prescription and the set of information on the prescribed medicinal product (Articles 23 and 24).	No.	Prescriptions from other EU Member States are encountered mostly by pharmacies located near the borders with Italy, Austria and Hungary.	ZZZS reimburses insured persons for the costs of the purchase of medicinal products that are prescribed on a prescription and that are entered on a positive or intermediate list of medicinal products whenever they can purchase these medicinal products abroad and the products are not available on the Slovenian market for various reasons — this right of insured persons is set out in a generally applicable legal act of the ZZZS entitled Rules governing compulsory health insurance. In cases of urgent medical treatment, when an authorised medicinal product is not available on the market in Slovenia, insured persons buy this urgently needed medicinal product abroad and claim a reimbursement of costs on the basis of the medical record — this right, as well, is defined in the Rules governing compulsory health insurance (in exceptional cases, the ZZZS may grant an insured person a technical medical device, medicinal product or foodstuff intended for particular nutritional uses or provide him/her with a full or partial reimbursement of costs to which he/she is not entitled under the Rules). On the basis of the above, medicinal products that are prescribed in accordance with the Rules on the classification, prescribing and dispensing of medicinal products for human use are also recognised in the other Member States of the EU, and our citizens have no difficulty in purchasing in other EU Member States medicinal products that have been prescribed in Slovenia.	The entity/ies which will be responsible for the implementation of Article 11 of Directive 2011/24/EU have not yet been designated.
UK	Yes – set out in the Prescription Only Medicine (Human Use) Order 1997 as amended. The Royal Pharmaceutical Society also issues guidelines for pharmacists.	Controlled drugs in Schedules 1 to 3 of the Misuse of Drugs Regulations, unlicensed medicines and those which do not have a Marketing Authorisation recognised in the UK are excluded from the arrangements.	1. Worries by the supplying pharmacists that the prescription is not genuine – it is currently very difficult to perform any sort of 'due diligence' and checking registration status of the prescriber is not possible with EEA prescribers. The UK has transparent, online and telephone based registration checking tools for healthcare professionals and we do not believe that this exists in Europe extensively and certainly not online. Conforming registration via the competent authority over the telephone is fraught with practical difficulties – language and the fact that many European competent authorities do not have a register at all.	No	Medicines and Healthcare products Regulatory Agency (MHRA – DH). The legislation here is UK wide.

8.2 Web-links to background documents

Impact Assessment roadmap document "Implementing measures for improving the recognition of prescriptions issued in another Member State under Article 11 paragraph 2 of the Directive on the Application of Patients' Rights in Cross-Border Healthcare", available from (last accessed on 26 July 2012):
http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_004_mutual_recognition_of_prescriptions_en.pdf

"NIVEL 2011", Study SANCO/2010/C5/2010 for the identification and development of a non-exhaustive list of elements to be included in prescriptions, available from (last accessed on 11 December 2012):
http://ec.europa.eu/health/cross_border_care/docs/nivel_cross-border_prescriptions_en.pdf

"MATRIX 2012", Study EAHC/2010/Health/01/Lot1: Health Reports for the Mutual Recognition of Medical Prescriptions: State of Play, available from (last accessed on 11 December 2012):
http://ec.europa.eu/health/cross_border_care/docs/matrix_mutual_recognition_prescriptions_en.pdf

Public consultation on measures for improving the recognition of prescriptions issued in another Member State, General description, available from (last accessed on 26 July 2012):
http://ec.europa.eu/health/cross_border_care/consultations/cons_prescriptions_en.htm,

Public consultation report, available from (last accessed on 26 July 2012):
http://ec.europa.eu/health/cross_border_care/docs/cons_prescr_report_en.pdf

8.3 Compliance with Commission consultation standards

The below table shows how the public consultation on measures to improve the recognition of prescriptions in another Member States was conducted in compliance with "The Commission's minimum standards on public consultation[62]".

Compliance with Commission consultation standards

A Provide consultation documents that are clear, concise and include
The consultation was accompanied by an explanatory page presenting background, consultation period, policy field, objective of the consultation and contact details. This included reference to the consultation document: the IA roadmap discussing policy options. Also, reference was made to a data privacy statement explaining the applicable data confidentiality procedures.
B Consult all relevant target groups
All target groups identified in the IA roadmap document where included. Further, a category "others" was added to allow self-identified target groups to respond.
C Ensure sufficient publicity and choose tools adapted to the target group(s)
The public consultation was publicised on the Commission's single access point for consultation, 'Your Voice in Europe'. The Interactive Policy Making (IPM) tool was used to design and run the structured questionnaire.
D Leave sufficient time for participation
The public consultation was open for contributions between 28 October 2011 and 8 January 2012 in respect of the minimum consultation period of at least eight weeks for open public consultations as applicable before 1 January 2012.
E Provide — collective or individual — acknowledgement of responses and feedback
Most respondents contributed via the web-based survey, receiving confirmation of their contribution this way. Contributors sending input via email received a confirmation mail within 5 working days. An analytic report of the public consultation was published on the DG SANCO website. All respondents were informed of this via their indicated email contact address.

[62] See http://ec.europa.eu/governance/impact/commission_guidelines/docs/ia_guidelines_annexes_en.pdf

8.4 Ex ante evaluation check of option 4

The IA roadmap states the IA also serves as "ex ante assessment for option IV in keeping with Article 21 of the financial regulation[63]. The table below summarizes how various elements in the required ex ante evaluation have been addressed in the IA and related documents.

Article 21 of the financial regulation applied to option 4

Ex ante evaluation criterion	Corresponding elements in IA documents (as retrieved from IA roadmap, IA and the Economic evaluation)	IA Ref
(a) the need to be met in the short or long term;	Improved recognition of medical prescriptions issued in another Member State	IA
(b) the objectives to be achieved;	To ensure that cross-border healthcare is as safe and efficient as possible. Remove barriers to free movement of patients and health products	IA
(c) the results expected and the indicators needed to measure them;	Lower costs for patients and public health payers as a result of higher dispensing rates (from current 50%) by improved prescriber authentication and les "missing data" issues in prescriptions. The indicators needed are described under (h) below.	Economic evaluation
(d) the added value of Community involvement;	The proposed initiative is intended to implement Article 11 para. 2 of the Directive 2011/24/EU. Uniform conditions are needed to do so (Article 291 para. 2 TFEU). Moreover, the principle of the mutual recognition of prescriptions predates Directive 2011/24/EU. it derives directly from EU rules on freedom to provide services (Article 59 TFEU). Data indicators needed are the same as those described under (h) below	IA
(e) the risks, including fraud, linked with the proposals and the alternative options available;	The main risk involved is the wide uncertainty in applicable costs. This is reflected in the economic evaluation, where it is estimated that option 4 would even increase costs compared to the status quo in 56% of simulated cases. **Option 4 is ranked last** in terms of expected cost-savings, even worse than taking no policy action..	Economic evaluation
(f) the lessons learned from similar experiences in the past;	A fully integrated (i.e. "paperless") ePrescription IT environment as operational in Denmark, covering 85% of Danish prescriptions, i.e. 44 million prescriptions, had an investment cost at start-up of EUR 20,5 million. The fully integrated ePrescription IT environment Apoteket, covering over 80% of Swedish prescriptions, has a running cost of around EUR 1 per prescription. The combination of both findings points to high and variable costs at play.	Roadmap
(g) the volume of appropriations, human resources and other administrative expenditure to be allocated with due regard for the cost-effectiveness principle;	Based on 1) published cost for the Dutch BIG-register and 2) extrapolation made for number of registered health professionals to cover all doctors and dentists in the EU, the overall cost for the EU budget is estimated at an annual "business as usual cost" of 2012 EUR 8 million.	Economic evaluation
(h) the monitoring system to be set up."	The Matrix 2012 study was set up to measure the effective recognition of cross-border prescriptions via a survey presenting pharmacists with hypothetical cross-border prescriptions based on the content of currently used prescription forms. In other words, the Matrix 2012 provided a "zero-measurement". Consequently, the intended approach to evaluate the effectiveness of the proposed initiative is to repeat the 2012 study. This evaluation should take place as soon as the proposed initiative has been fully implemented. Most likely this will mean an evaluation will be presented at the latest 5 years after the introduction of the proposed initiative. **Indicators to measure**: The non-dispensing rates for cross-border prescribed medical product should be measured for common and less common products, as well as for handwritten and other prescriptions. Non-dispensing rates should be broken down by reasons for non-dispensing due to issues with • Authentication, in particular of the cross-border prescriber • Missing information • Handwriting • Understanding the language on the prescription • Product availability Progress is assessed by measuring changes in frequency of the first two reasons.	IA

[63] See http://ec.europa.eu/budget/biblio/documents/regulations/regulations_en.cfm