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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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

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1. INTRODUCTION

In April 2011, Directive 2011/24/EU on patients' rights in cross-border healthcare entered into force¹. This Directive lays down rules to facilitate access to safe and high-quality cross-border healthcare and on reimbursement of such healthcare. It steps up cooperation between Member States in key areas for cross-border healthcare, including on measures to improve the recognition of prescriptions issued in another Member State ('cross-border prescriptions').

This impact assessment (IA) focuses on these measures to improve the recognition of cross-border prescriptions. This occurs in 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. The measures assessed are contained in Article 11(2) of the Directive, where it is stated 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.'

Paragraph 4 of this Article states that, in adopting the above measures, the Commission "shall have regard to the proportionality of compliance costs as well likely benefits". For this reason, it organised an impact assessment (IA). This IA presents evidence for political decision makers on the advantages and disadvantages of policy options for implementing the above measures by assessing the main potential impacts that can be expected.

¹ See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF>.

2. PROBLEM DEFINITION

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 Union², the requirements for admission to the profession of doctor have been harmonised and must be recognised in other Member States. As a result, a prescription 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 Directive 2011/24/EU. Nevertheless, there is evidence that the real-life application of this principle to cross-border prescriptions to date is suboptimal.

Initial research on the recognition of cross-border prescriptions was carried out in a support study to the IA, 'Matrix 2012'. This included a survey completed by nearly 1000 pharmacists across seven Member States (Denmark, Germany, Greece, France, Netherlands, Poland and UK) sharing their views on dealing with foreign prescriptions for eight pathologies (asthma, chronic obstructive pulmonary disorder, depression, diabetes, epilepsy, hypertension, ischemic heart disease and osteoarthritis/rheumatoid arthritis). In all, the pharmacists scored 7440 hypothetical prescriptions.

The findings from Matrix 2012 suggest that 55% of patients face difficulties in getting prescribed products dispensed in another country. The key challenges are verification of the prescriber (such as a doctor), possibly exacerbated in handwritten prescriptions, unfamiliarity with the language and missing information. The availability of (substitute) products was mentioned as a problem less often. The latter is a problem driver that is not related to actual recognition of the prescription. Problem drivers related to language or handwriting are not tackled by the proposed measures either.

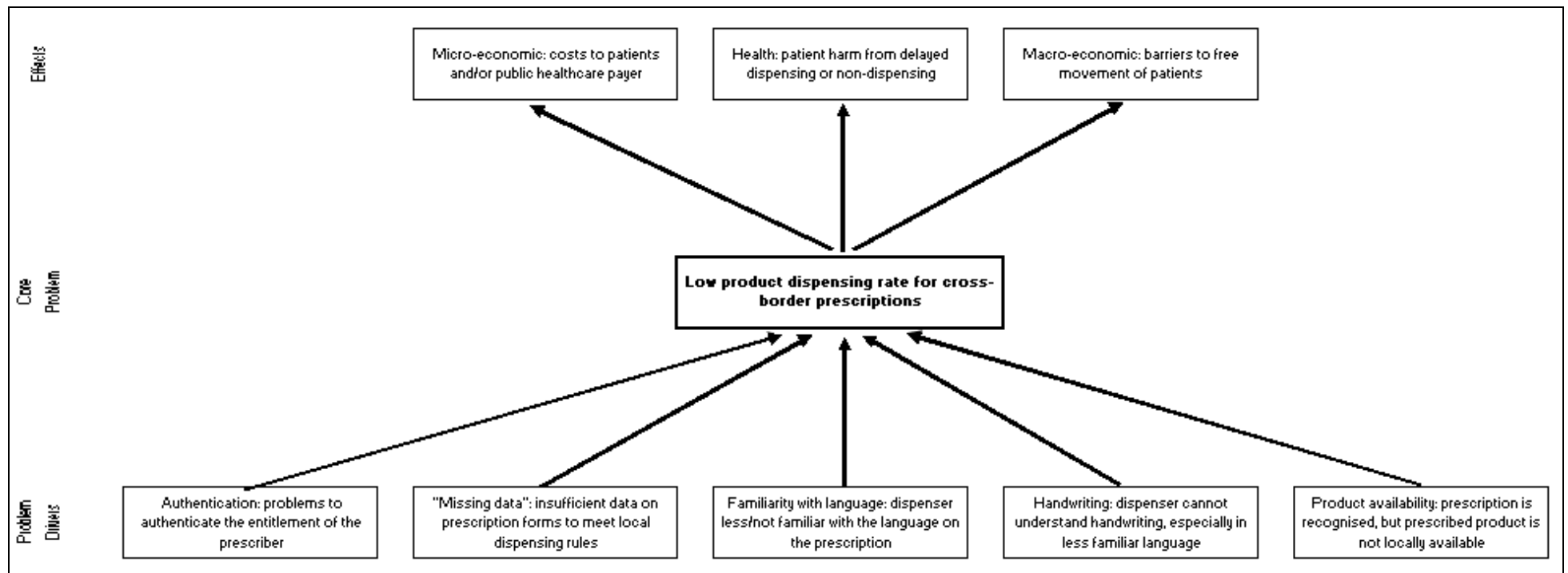
The main effects that can be anticipated as a result of a low dispensing rate of cross-border prescriptions are:

- negative health effects for patients not receiving a prescribed product or receiving it late (for instance after having obtained a prescription with a local prescriber),
- negative financial effects for patients and 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 overleaf illustrates this discussion of the problem, problem drivers and effects.

² European Court of Justice, judgments of 7 March 1989 (C-215/87 Schumacher) and 8 April 1992 (C-62/90 Commission v Germany).

Problem tree



3. RATIONALE FOR EU ACTION

There are two legal bases for EU action in this field, one explicitly in Directive 2011/24/EU and one implicitly in Article 56 TFEU on the liberalisation of services.

The proposed implementing act is intended to implement Article 11(2) of Directive 2011/24/EU. Uniform conditions are needed to do so (Article 291(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 the freedom to provide services (Article 56 TFEU).

4. OBJECTIVES

There are two general objectives:

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

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

- To remove barriers to the free movement of patients and health products.

The proposed implementing acts aim to improve the 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.

There are three specific objectives, to ensure:

- that a prescriber’s validity in one Member State can be easily verified in all Member States;
- the correct identification of medicinal products or medical devices prescribed in one Member State and dispensed in another, to address patient safety concerns over product substitution;
- comprehensible information to patients concerning their prescription.

5. POLICY OPTIONS

Four options are considered.

Option 1 is the ‘no policy change approach’. The baseline evolution given the current state of play is based on Matrix 2012. This option is the yardstick against which policy options 2, 3 and 4 are evaluated.

Option 2 is to adopt a non-exhaustive list of information on cross-border prescriptions that must be included in prescriptions and clearly identifiable in all prescription formats (a ‘core set’). This core set would be independent of the actual prescription medium (paper and/or electronic). It 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 identify the product (objective 2) will be made as comprehensible to patients as possible. Consequently, the measures described under Article 11(2)(a), (c) and (d) of Directive 2011/24/EU can be simultaneously addressed by defining a core set that allows for:

- the authentication of prescribers (in particular by including direct contact details such as name and phone number or email 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 information to be readily understood by patients.

Option 3 combines option 2 with the requirement to establish (or use an existing) prescriber database at Member State level and the obligation (direct or indirect) for dispensers to consult these databases.

Option 4 combines option 2 with the creation of a prescriber database at EU level and the obligation (direct or indirect) for dispensers to consult this database.

Options 3 and 4 work on the assumption that dispensers (such as pharmacists) need electronic prescriber registers to verify the legal entitlement of the prescribing health professional, and need to be able to consult registers across EU borders.

6. ANALYSIS OF IMPACTS

Option 1: ‘no policy change’

It is clear that patients suffer negative health effects when their medical products are not dispensed (or delayed). However, no firm evidence base was found for quantifying the effects. Not dispensing medical products also has a negative financial effect on patients and public healthcare payers. This effect is assumed to be the cost of a doctor visit for every non-dispensed prescription. This cost was estimated at EUR 34 on average in the EU (Matrix 2012).

Options 2, 3 and 4 aim to reduce these negative health- and cost effects by improving the dispensing rate of cross-border prescriptions.

Option 2: ‘non-exhaustive list’

It is assumed that dispensing rates would improve by some 20 percentage points under option 2 as:

- ‘missing data’ issues for dispensers are solved under option 2;

- ‘prescriber authentication’ improves, based on data in the IA public consultation.

The negative health effects will be avoided in proportion to the improved dispensing rate, creating an overall positive health impact under option 2. Proportional to the improved dispensing rate, on average, a positive cost impact (from avoided doctor consultation costs) of around EUR 7 is expected (20 % of the average doctor cost of EUR 34).

For dispensers, an overall improvement of their business practices is expected due to the proposed measures. Faster recognition of cross-border prescriptions will yield time savings for dispensers during business hours.

Option 3: ‘non-exhaustive list combined with national prescriber registers’

It is assumed that dispensing rates would improve by some 17 percentage points under option 3 as:

- ‘missing data’ issues for dispensers are solved under option 3;
- ‘prescriber authentication’ improves, based on data in the IA public consultation. The authentication effectiveness of option 3 is lower than for option 2 as dispensers expect the mandatory use of national prescriber registers to be time-consuming and confusing due to language/terminology issues.

The negative health effects will be avoided in proportion to the improved dispensing rate, creating an overall positive health impact under option 3. 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 average doctor cost of EUR 34).

No (additional) costs for prescriber registers accessible to dispensers at the level of Member States are assumed. Under Article 6(3) and (5) of Directive 2011/24, Member States will be required to collect data on prescribers, if they have not done so already, and make related data available by electronic means. The most cost-effective (and thus the expected) way of doing this is by using a publicly accessible website. The related cost is therefore not assumed to be part of option 3 as it is part of the baseline situation following transposition of Directive 2011/24/EU by 25 October 2013.

Option 4: ‘non-exhaustive list combined with EU-level prescriber register’

It is assumed that dispensing rates would improve by some 20 percentage points under option 4 as:

- ‘missing data’ issues for dispensers are solved under option 4;
- ‘prescriber authentication’ issues are improved based on the IA public consultation.

The negative health effects will be avoided in proportion to the improved dispensing rate, creating an overall positive health impact under option 4. 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).

There would be an additional cost for maintaining a central prescriber database at EU level. This cost is estimated using an activity-based breakdown in the 2011 financial statement of the Dutch Ministry of Health. The corresponding activity, ‘BIG register’, is to maintain a register containing data on some 400 000 health professionals, feeding into a website³ that can be consulted by a wider audience. The cost is extrapolated to EU level by assuming it is proportional to the number of health professionals most likely to be included: some 1 600 000

³ See <http://www.bigregister.nl/>.

doctors and 300 000 dentists in the EU. This leads to an estimated annual cost of the EU-level central register of EUR 8 million.

The table below shows the impact of the various options compared to the status quo, as a summary of the preceding sections.

Main impacts by option in qualitative terms (+/- 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.

7. COMPARISON OF OPTIONS

Preferred option

The options are ranked in terms of preference by expected cost-savings, as follows:

- (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 database (option 4)

The preferred option is option 2: a non-exhaustive list of information common to all prescriptions, without any further requirement to compile electronic prescriber registers accessible to cross-border dispensers. This option is expected to improve the dispensing of cross-border prescriptions 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 fewer patients will need 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 and an increase of well over 200 000 cross-border prescriptions being dispensed. Should the number of cross-border prescriptions increase in the future, the overall savings will increase in the same proportion.

‘Cross-border only’ forms

If a Member State opts to have a separate cross-border prescription form, the general principle of mutual recognition of prescriptions will continue to apply for ‘regular’ prescriptions presented to a foreign dispenser. The general principle of mutual recognition of prescriptions should apply undiminished for these prescriptions. 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. 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.

Options 3 and 4

Under option 3, dispensers express doubts as to the usefulness of national registers for cross-border dispensing, given likely issues with language, terminology, etc. As a result, option 3 is less cost-saving than the preferred option 2 given the (slightly) lower dispensing rate of prescriptions in option 3.

Under option 4, the low volume of cross-border prescriptions does not justify the compilation of a central EU register of prescribers, which was estimated to cost EUR 8 million. This may become a (more) cost-effective policy option in the future if the volume of cross-border healthcare increases considerably.

8. MONITORING AND EVALUATION

Prescriber authentication and medical product identification

The main indicator to assess the effectiveness of the proposed measures for improved prescriber authentication and medical product identification is the product non-dispensing rate for cross-border prescriptions, broken down by reasons for non-dispensing:

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

This rate could be compared to the Matrix 2012 measurement in order to make an ex-post impact evaluation. Progress will be assessed by measuring changes in the non-dispensing rate specifically for the first two reasons above.

The best approach to evaluate the effectiveness of the proposed measures is to launch a study similar to the Matrix 2012 study, using the same sample of Member States and hypothetical prescription cases. It is probably necessary to update the names of prescribed products on the prescriptions used for the study. If some Member States choose to introduce a separate ‘cross-border’ prescription form, this should also be taken into account in the study design.

The evaluation should take place as soon as the implementing acts are fully implemented and dispensers are sufficiently familiar with the new prescription forms. This is likely to mean conducting an evaluation at the latest five years after the measures are brought in. If the findings from the evaluation are sufficiently conclusive, there is no need to repeat it. The involvement of dispensers in the evaluation would be on a voluntary basis, as was the case in the 2012 study that managed to recruit almost 1 000 pharmacists.

Patient understanding

Patient understanding of information on the prescribed product should be measured by looking at more specific aspects, such as:

- Understanding the course of treatment: when/how/how long to follow the treatment and with what frequency?
- Understanding of any potential treatment-related adverse effects.

This measurement should distinguish between whether patient understanding is based on direct effects (only the prescription is used as an information source) or indirect effects (information on a prescription that allows patients to consult additional information sources). The measurement should follow a comparative design assessing understanding of the current and proposed prescription form by two groups of selected individuals.

Ideally, patient understanding should be measured as soon as the proposed item list is finalised and before it becomes firmly established as everyday practice. This would avoid the findings becoming skewed because patients had already grown familiar with the new form for prescriptions.

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