EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2012)

Opinion

Title **DG SANCO - Impact Assessment for a draft implementing regulation on measures for improving the recognition of prescriptions issued in another Member State (Article 11 of Directive 2011/24/EU)**

(draft version of 4 April 2012)

(A) Context

Directive 2011/24/EU on patients' rights in cross-border healthcare entered into force in April 2011 and its transposition by Member States is foreseen by 25 October 2013. The Directive provides rules for facilitating access to safe and high-quality cross-border healthcare and for the reimbursement of such healthcare costs. It also promotes cooperation in key areas for cross-border healthcare between Member States, including 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 impact assessment accompanies a proposal for measures implementing Article 11 of the Directive aimed at improving the recognition of cross-border prescriptions.

(B) Overall assessment

The report needs to be strengthened in several respects. First, it should provide a brief description of the current practice for dispensing prescriptions across borders and should better explain the problems related to authentication of prescriptions/prescribers, lack of information, product identification or comprehensibility to patients. It should then show how the problems would evolve in the absence of any further EU action, while taking into account the development of electronic prescriber databases at Member State level and the roll-out of non-handwritten prescriptions. Second, the content of the options and their difference from the status quo should be better explained. In doing so, the report should present alternative combinations of the "core set" of data that have been discussed with Member States and should clarify the added value of electronic registers. Third, the report should better describe how the options would be implemented in practice and on this basis better assess their main impacts. The report should also indicate the likelihood that Member States will opt for two parallel regimes, "cross-border only" and "domestic" prescriptions. Fourth, options should be more clearly compared against the criteria of effectiveness, efficiency and coherence. Furthermore, the report should indicate the likely distribution of impacts among Member States and prescribers. Finally, the report should clarify the foreseen monitoring and evaluation arrangements and should better reflect the divergent views of stakeholders throughout the main text.

(C) Main recommendations for improvements

(1) Strengthen the problem definition and baseline scenario. The report should recall the scope of the Directive explaining that the EU has an obligation to act. It should then briefly describe how the dispensing of cross-border prescriptions works in practice and should explain in detail the existing challenges related to the authentication of prescriptions/prescribers, availability of information, identification of medicinal products (or medical devices) and comprehensibility of the information to patients. Given that the demonstration of the problems is largely based on survey results generated by hypothetical examples, the report should better explain its methods and limitations. On that basis it should better describe the likely evolution of the issues at stake, while taking into account the development of electronic prescriber databases at Member State level and the roll-out of non-handwritten prescriptions (both fully printed prescriptions and e-Prescriptions).

(2) Improve the description of options. The report should better describe the content of the options and explain how they differ from the status quo. In doing so, it should clearly indicate: (i) which combinations of the "core set" of data could be realistically considered and have been discussed with Member States' authorities and (ii) the purpose of the electronic registers and what their added value is compared to the (alternative combinations of) "core set" of data (both at national and EU level). Finally, the report should clarify why national electronic registers are presented among the policy options despite being already considered as part of the baseline.

(3) Better assess the impacts. In order to fully appreciate the impact on patients and their mobility, on prescribers, on dispensers as well as on national authorities, the report should explain how the implementation of policy options would work in practice. On this basis, it should significantly strengthen the qualitative analysis of the main impacts and better explain the rationale behind the main assumptions. For example, it should better justify: (i) not considering start-up costs, (ii) solving all missing data issues or (iii) setting the average cost of visiting a local General Practitioner at EUR 34. The report should indicate the likelihood that Member States will opt for two separate regimes and should discuss in detail whether there is a risk that the existence of "cross-border only" prescriptions would have a negative impact on the mutual recognition of "domestic" prescriptions used in a cross-border setting. Finally, the divergent views of stakeholders should be better reflected in the analysis of impacts.

(4) Improve the comparison of options. The report should more clearly compare the policy options against the criteria of effectiveness, efficiency and coherence. It should further discuss any trade-offs within the policy options and clearly spell out the likely distribution of impacts, for example among Members States (e.g. depending on their existing data requirements and prevalence of cross-border healthcare) or prescribers (e.g. using handwritten vs. non-handwritten prescriptions). The report should also present the impact of the preferred option in absolute terms, i.e. how many cross-border prescriptions are likely to be dispensed in addition to the status quo, and should analyse the overall impact of the EU intervention in the worst case scenario.

(5) Outline clearer monitoring and evaluation arrangements. The report should clarify if there is a need to monitor objectives corresponding to product identification and the comprehensibility to patients and to what extent complaints could be used as a monitoring indicator. It should explain how the results of the repeated survey would be used in concrete terms (e.g. what "sufficiently conclusive" findings mean and what would happen if these findings were negative or insufficiently conclusive) and if there is a link

to the foreseen evaluation of the Directive itself.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

The report should more clearly explain the issues at stake in less technical language for the non-expert reader. The problem tree should indicate which of the identified problem drivers are not to be tackled by the proposal. Stakeholder views should be integrated more systematically throughout the report and better referenced (e.g. including views of industry involved in manufacturing and wholesale dealing of medicinal products and/or medical devices, public healthcare payers such as social security funds and feedback collected via targeted consultations).

(E) IAB scrutiny process	
Reference number	2013/SANCO/004
External expertise used	No
Date of IAB meeting	2 May 2012