europeanpatients'forum

Review of the EU Transparency Directive (Council Directive 89/105/EEC)

EPF Position Statement

The European Patients' Forum (EPF) welcomes the Commission's legislative proposal to review the Directive 89/105/EEC, the "Transparency Directive". While we recognise that the Directive alone will not resolve all problems regarding access, and while we respecting the Member States' competence for decisions concerning pricing and reimbursement, EPF supports the Commission's proposals overall. They are an essential step forward towards ensuring that *the procedures* for decision-making at national level are as equitable, effective and transparent as possible. The overall aim of the revision should be to ensure equitable access to therapies for all patients across the EU. In addition the Directive should ensure that the principles of good governance, including transparency and stakeholder involvement, are applied in the decision-making processes in Member State.

EPF calls on all Member States to cooperate in order to modernise Directive 89 in a way that is centred on meeting the needs of patients.

Current delays in access are unacceptable from an equity perspective

The wide divergences across the Union in patients' access to treatment, including medicines, are in our view unjustifiable[1] and lead to health inequalities across the EU.[2] Access to healthcare is recognised as a main factor behind health inequalities,[3] while the European Parliament recognises patients with chronic diseases as a group whose needs should be taken into special consideration when addressing health inequalities.[4] Access to medicines, for patients, implies both availability *and* affordability of the treatment.[5] The current disparities are contrary to the principles set out in the Charter of Fundamental Rights, the EU's commitment to the principle of well-being[6], and to the fundamental European values of equity, solidarity and good quality in healthcare.[7]

---

[1] e.g. the European MS Barometer 2009, published in November 2010, available at www.emsp.org/index.php?option=com_content&view=article&id=121:ms-barometer-2009-results&catid=55:multiple-sclerosis-information-dividend&Itemid=152; The EURORDIS Survey on patients' access to orphan drugs: www.eurordis.org/content/new-eurordis-survey-patients%E2%80%99-access-orphan-drugs-europe; the Diabetes Policy Puzzle: is Europe making progress? 2nd edition. Available at www.idf.org/webdata/docs/EU-diabetes-policy-audit-2008.pdf

[2] For more information see EPF's position statements on health inequalities, available at our website: http://www.eu-patient.eu/Initatives-Policy/Policy/Health-inequalities/

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0567:FIN:EN:PDF

[4] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2011-0081

[5] A medicinal product or service is accessible when it is functionally available to every patient who needs it, namely: when it is possible to prescribe it, it is distributed along reachable channels, and its cost is affordable.

[6] Article 3, Treaty on European Union

[7] Council Conclusions on Common values and principles in European Union Health Systems (2006/C 146/01)

European Patients' Forum, rue Belliard 65, B-1040 Brussels
Phone : +32 (2) 280 23 34 Fax: +32 (2) 231 14 47
Email: info@eu-patient.eu Web: www.eu-patient.eu

Delays in access exacerbate the costs of chronic disease to health systems

Delays in treatment also have a long-term economic cost to society.[8] Chronic diseases, if not treated promptly, lead to deterioration of health and reduced life expectancy.[9] Non-adherence to medicines is a serious problem, costing the European Union an estimated €1.25 billion annually.[10] Patients' lack of access for financial reasons is a known factor in poor adherence.

Conversely, early diagnosis and prompt treatment lead to better health outcomes and quality of life by avoiding or delaying complications of illness and unnecessary interventions or hospitalisations. This contributes to the long-term sustainability of health systems as well as societal well-being. With proper treatment, persons with chronic diseases can continue to contribute fully to society by, for example, staying in employment for longer. Improving access to medicines should be seen as a crucial part of achieving the goals of "smart" and "inclusive" growth of the Europe 2020 Strategy.

What is missing from the Commission's proposal: stakeholder involvement and real transparency

Since the Transparency Directive was adopted, more than 20 years ago, the societal context in which it functions has undergone a profound transformation. Notably, there has been enormous progress in the engagement of civil society, including patients' and consumers' organisations, in all aspects of public policy. Moreover, the concept of "transparency" is now understood to apply much more widely than at the time the Directive was adopted. Citizens have a right to know what decisions are taken, by whom and with what criteria. We regret that the Commission has not taken the opportunity to modernise the proposal in this respect.

EPF considers that the overall aim of the Directive in this wider societal context should be strengthening good governance, accountable, timely and transparent decision-making in the EU Member States on medicine pricing and reimbursement decisions – questions which have a direct impact on patients and citizens. The revised legislation should include requirements for public transparency and appropriate stakeholder involvement in the way decisions on medicines are taken in Member States. In our view this is perfectly within the scope of the Directive.

The Commission proposals: key provisions

Below we state our views on some of the key provisions of the proposal, from the patients' perspective. We then identify some essential elements that are missing from the proposal, namely genuine transparency and stakeholder involvement.

[8] A Dutch study indicated that the impact of an average 7 months' delay in access resulted in 20,000 lost healthy life years (HLY) and costs to industry, patients and social health insurance of some €1 billion. Source: European Commission Stakeholder Conference, 15 December 2010, presentation of Pierre Hausemer, Principal Consultant, Matrix Knowledge.

[9] For example, the life expectancy of patients with diabetes is reduced by the vascular complications of the condition by as much as 15 years. Source: International Diabetes Federation.

[10] Medi-Voice project http://cordis.europa.eu/fetch?CALLER=FP6_PROJ&ACTION=D&DOC=3019&CAT=PROJ&QUERY=1170700793308&RCN=75025

The EPF statement is based on a consultation of our member organisations, with input from the Policy Advisory Group and the EPF Board.

Scope of the Directive – Articles 1, 11, 10, 12

The transparency requirements apply to all pricing and reimbursement measures adopted at national, regional and local level), including "demand-side measures" (measures to control or promote the prescription of specific medicines). Excluded from the scope are public procurement (which is subject to laws on public procurement) and voluntary contractual agreements with individual companies. Medical devices are excluded from the scope (Recital 7). Their inclusion was examined in the impact assessment, but discarded due to the specificities of this market.

EPF acknowledges that the commission has decided not to extend the scope of the Directive for reasons of practicality, given that the mechanisms for pricing and reimbursement of medicines and medical devices are very different in Member States and often undertaken by different bodies. However, we would like to stress the importance of close coordination between the respective bodies and processes in order to ensure timely access to personalised medicine therapies (involving combinations of a drug and device or diagnostic test) this is important as such innovative therapies will undoubtedly increase in the coming years.

Definition of Health Technology Assessment – Article 2

The proposal introduces a definition of health technology assessment as follows: "an assessment of the relative efficacy or of the short- and long-term effectiveness of the medicinal product compared to other health technologies in use for treating the associated condition."

EPF welcomes the inclusion of all necessary steps in the time limits in which decisions should be made, including conduct of HTA where applicable. Greater Harmonisation at EU level in the definition of HTA could potentially help Member States in their decisions and reduce the complexity of procedures. However, if a common definition is adopted, then EPF recommends that it should be in line with that already used in EU cooperation (EUNetHTA: "a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner."[11])

We also refer to Article 15 of Directive 2011/24/EU on patients' rights in cross-border healthcare, which will states that the EU network of bodies responsible for HTA in Member States shall be based on the principles of good governance. These principles should be applied also at national level to ensure that treatments are made available and accessible in a way that meets the medical and social needs of patients and is beneficial to the wider society. EPF calls for meaningful involvement of patients in Health Technology Assessments (HTAs) together with appropriate training and support for patient representatives.

11 http://www.eunethta.eu/upload/WP4/Final%20Deliverables/HTA%20Core%20Model%20for%20Medical%20and%20Surgical%20Interventions%201%200r.pdf

Time limits for pricing and reimbursement decisions – Article 3 and 7

The Commission proposes to shorten the time limits from the current 180 days, and to make them more proportionate. Generic medicines should be assessed within 15/30 days provided the reference product is already priced and included in the health insurance system; all other products within 60/120 days; except products subject to HTA (90/180 days). For price increases and derogations from reductions/freezes, the limit is set at 60 days (Articles 4 and 5).

EPF welcomes the shorter time lines proposed by the Commission. For generic products whose reference product is already priced and included in the health insurance system, it should be possible to make a pricing and reimbursement decision within a considerably shorter time period than for other products. For other products, a longer time would be needed but we stress that under no circumstances should the time lines be lengthened beyond the current maximum of 180 days, as this would be completely unacceptable to patients across Europe. Importantly, the agreed time lines should be enforceable.

The proposal splits the overall time lines into a time for pricing decision and a time for decision on reimbursement. This may be problematic as regards, for example, health technology assessment (HTA) and where this fits into the process in different Member States. It may be more useful to approach the time limits as *overall* times that include all necessary steps, including HTA where applicable. Such approach could provide more flexibility for different Member States procedures.

Regarding the "tacit approval" in the absence of a pricing decision by the set deadline (Article 3, para.6), we understand this provision as allowing the company to market the product at the price proposed, not that the Member State is obliged to fund the product at that price. However from the patient's perspective *access to patients is a function of both availability and affordability of a product*. A decision on reimbursement must therefore be part and parcel of the decision on pricing.

Information about pricing and transparency decisions, the procedures and criteria on which those decisions are taken, and the bodies or persons responsible, should be available in the public sphere. The criteria used should be objective and verifiable.

Sanctions for non-compliance – Article 8

The Commission proposes a remedies procedure relating to the inclusion of products within health insurance systems. Member States are obliged to designate a body to oversee the implementation of the requirements of the Directive: this body must be independent from the pricing and reimbursement body, and it would have the powers to adopt interim measures; award damages to the applicant; and impose penalty payments to the national authority. The decisions of this body would be binding on the Member State. However paragraph 2 of Article 8 also specifies that the designated body may decide not to take any measures, if their negative consequences could exceed the benefits.

EPF believes that effective sanctions are needed to ensure compliance, as the main problem with the current Directive is that the time lines for pricing and reimbursement decisions are not respected by Member States.

We are concerned that Article 8 (2) may undermine the enforcement of the timelines, unless it is strictly restricted to specific cases and does not impact negatively on patient access. To avoid such negative impact, the national designated bodies should be obliged to include representatives of consumers and patients. Stakeholder involvement is needed to ensure that the decisions taken by that body are in the interests of patients and wider society, without unintended negative impacts on access. Furthermore, for reasons of transparency, information on the body, its members, its mandate, etc. should be publicly available.

Notification procedure for draft national measures – stakeholder consultation – Articles 15 and 16

Article 16 mandates Member States to notify the Commission of proposed draft measures; the Commission has the opportunity to send its observations within three months. Article 15 mandates Member States to consult "interested parties" at national level when considering draft measures.

EPF welcomes these provisions. In our view, the rationale for Article 16 is to prevent situations where a Member State adopts a national measures that is afterwards found to be incompatible with EU legislation and could result in lengthy legal procedures, which would have a detrimental impact on patients. Improved dialogue between Member States should in our view be supported. However, the 3 months delay for the Commission to reply may be considered as excessive. The Commission should be able to comment in a shorter time frame.

Given that national measures on pricing and reimbursement have a direct impact on patients, patients clearly constitute an "interested party" and have a right to be consulted through their representative organisations.

Civil society organisations are often under-resourced and membership-based. EPF believes that a reasonable time period must be established under Article 15 in collaboration with patient and other civil society organisations, so that it allows them enough time to analyse the draft measures and prepare a response. The rules of consultations, and the results of all consultations, should be made publicly available without delay. EPF would stress that in this context, "business confidentiality" should be interpreted narrowly in favour of maximum transparency.

Clarity of the procedures – Articles 3, 4 and 7, Article 13

Member States should establish in details the particulars and documents to be submitted by the applicant and cannot request additional information not explicitly required under national legislation or administrative guidelines. There should be no re-assessment of the elements on which marketing authorisation is based, including quality, safety, efficacy or bioequivalence, in the framework of pricing and reimbursement procedures.

EPF welcomes provisions that bring clarity to assessment process. However, Article 13 should be rephrased so that it is clear Member States may *access* data from the marketing authorisation in their pricing and reimbursement assessment, but not to *call into question* that data. There is no justification to re-evaluate aspects which have already been evaluated by the body responsible for granting the marketing authorisation.

Monitoring of implementation and impact – Article 17

The proposal requires bi-annual reporting by Member States to the Commission on the application of time limits, including the number of applications received, time taken to issue a decision, and analysis of the main reasons for delays. The Commission will publish a first report on the implementation of the Directive after three years.

EPF believes it is essential to have the perspective of users of medicines – patients and consumers – on the real impact of the Directive on their lives to be included in regular evaluation of the Directive. The Commission should therefore regularly consult with stakeholder organisations in Member States representing patients and consumers, to gather their views concerning the impact of the Directive on access to medicines.

Conclusion

Overall, the European Patients' Forum welcomes the Commission's proposal for a revision of the Transparency Directive. We believe that, while the proposal still needs more work on its details, it has the potential to deliver improved access for patients. However, we also believe there is a need to go beyond legislative review and initiate joint efforts to find solutions to the serious problems of health inequalities facing all Member States.

There are currently wide discrepancies in the availability and affordability of many medicines across the EU, with some Member States, particularly the smaller or less attractive markets, facing problems in medicines availability. *EPF calls for reflection among all stakeholders on different models with potential to achieve more equitable and transparent pricing across the Union.*

Healthcare is more than medicine, and patients also face discrepancies in access to high-quality chronic disease management, preventive services and appropriate support services. These health inequalities are exacerbated by the current financial crisis. EPF calls for the member states, the commission and all stakeholders to m*ake the alleviation of health inequalities a priority based on the fundamental European values of universality, solidarity, equity and access to good quality care*.

Patients have a unique experiential knowledge that is currently under-utilised as a resource for improving the quality and effectiveness of the healthcare system. Patients can identify unmet needs and help define areas where investment will add real value. Patient centredness is increasingly recognised as a key aspect of high-quality healthcare; moreover, listening to patients and following their preferences is shown to result in better quality of care, better health outcomes, greater satisfaction *and* improved cost-effectiveness of healthcare.[12] *EPF therefore calls on Member States to involve patient organisations at the policy level in developing, implementing and evaluating strategies for improving the quality and patient-centeredness of healthcare systems*.

[12] For a detailed discussion, please see EPF's response to the European Commission's consultation on the reflection strategy on chronic diseases, http://www.eu-patient.eu/Press/News/EPF-response-to-chronic-diseases-consultation-stresses-patients-central-role-/ and our position papers on health inequalities: http://www.eu-patient.eu/Initatives-Policy/Policy/Health-inequalities/

EPF and our member organisations are committed to playing a constructive role in the revision of the Transparency Directive and will be pleased to provide further input in consultation with our European-wide network of member organisations.
For further information please contact:

Nicola Bedlington
EPF Director
nicola.bedlington@eu-patient.eu

Kaisa Immonen-Charalambous
EPF Senior Policy Adviser
kaisa.immonen.charalambous@eu-patient.eu

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 54 member organisations, which are chronic disease-specific patient organisations working at European level, and national coalitions of patients organisations. Collectively they reflect the voice of over 150 million patients living with various chronic diseases in the European Union. EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.