Brussels, 24 November 2010

STATEMENT

European Parliament endorses proposal on Information to the General Public on Prescription Medicines 'Information to patients'

EPF welcomes this as an important step forward towards a wider European-wide information and health literacy strategy, to achieve equitable access of all patients in the European Union to high-quality information on medicines and health issues.

EPF welcomes the vote in the European Parliament on 24 November, where a substantial majority endorsed the report of Mr Christofer Fjellner MEP. The report is a considerable improvement on the original Commission proposal, achieving above all a shift from a quite narrow focus on the rights of industry, to the right of patients to access high-quality, non-promotional information about the medicines they take. There is still some room for improvement in the current proposal to make it really work for patients, but overall it is a positive step.

Below we set out some of the key aspects of the proposal from the patients' perspective.

- *National information portals* for patients and citizens will be set up by the authorities of Member States in collaboration with stakeholders. The creation of such portals will enhance confidence and contribute towards equal access by all EU citizens to good quality information, complementing rather than replacing the patients' relationship with the health professional.
- Industry will be able to make available certain information through specific channels, strictly on a "pull" basis and subject to pre-approval from competent authorities. The ban on direct-to-consumer advertising of prescription medicines is maintained. *Companies will be obliged to make available the statutory documents* in the format that they have been approved by the competent authorities: i.e. the package leaflet, summary of product characteristics and public version of assessment report.
- In addition, they *may make available, under strict limitations and with pre-approval*, certain other types of information, such as environmental impact and adverse reactions, and will be able to respond to specific requests for information from members of the public. The proposal includes a number of measures to avoid indirect advertising and protect consumers from misleading or inappropriate information.
- The above voluntary information includes *information on clinical trials* relating to the product in question. EPF welcomes the inclusion of such information, but we are disappointed that this is not obligatory on companies. There is a great need for more transparent information on clinical trials, particularly the outcomes of all trials including 'failed' ones, which are a very

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valuable source of information to patients. EPF believes this is a vital issue that needs to be addressed.

- *Member States will be responsible for monitoring* of industry information and ensure only the permitted types of information are provided and only in the approved formats. Member States may continue their own pre-existing control mechanisms, such as the system currently in place in Sweden, though they may choose to further enhance such mechanisms.
- *Quality criteria and a code of conduct* will be adopted for the information provided by industry. EPF recommends that the Core Quality Principles developed by the Pharmaceutical Forum and endorsed by EU Member States should be adopted for all information to patients, whether its source be industry or public authorities, to ensure that the information is patient-centred.
- *The patient leaflet* will undergo a review by national authorities and EMA, together with patient organisations, to ensure it corresponds to patients' needs. In its current format the leaflet is notoriously difficult to read and understand. The revision will include a short paragraph setting out the benefit and risks of the product, as well as a short description of further information aiming at safe and effective use. The patient leaflet is an essential tool for medication safety and adherence to therapy, and EPF therefore strongly supports the proposed review.
- EPF is concerned that certain parts of the proposal as amended appear to *qualify the involvement of patients* by referring to "independent" patient organisations, without defining how their independence would be assessed, and by whom. It is entirely appropriate that individual experts involved in policy processes should be subject to a transparency requirement. This is the case for health professionals, who must disclose any conflicts of interest. Collective qualification, however, is more problematic and if defined too narrowly could have the unintended consequence of excluding groups of stakeholders from having a voice in the democratic process. As a model of good practice, EPF proposes the criteria used by the European Medicines Agency in its work with patients' and consumers' organisations.

One step forward within a wider process

EPF has argued consistently that the current proposal should be seen as one component in the wider context of an EU-wide "information to patients and health literacy" strategy. Echoing the explanatory statement of Mr Fjellner MEP, EPF calls upon all EU Institutions to work together with all stakeholders, including patient organisations, to formulate a coherent and ambitious, patient-centred strategy on information to patients.

EPF hopes the current political momentum will be maintained to achieve important change in this area that will benefit the patients and the health systems in the long run, and we commit to work with the Institutions in the next stage of the legislative process to further refine the proposal, in order to ensure tangible benefits for patients will be achieved.

Ends

Information for editors:

The European Patients' Forum (EPF) is a not-for-profit, independent umbrella organisation of patients' organisations in the EU. EPF currently has 44 member organisations and represents the collective rights of around 150 million patients across the Union living with a variety of chronic conditions. EPF advocates for high quality, patient-centred, equitable healthcare for all patients in the EU

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