EU options for improving access to medicines

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The Committee on the Environment, Public Health and Food Safety adopted an own-initiative report by Soledad CABEZÓN RUIZ (S&D, ES) on the EU options for improving access to medicines.

Members recalled that public health systems are crucial to guaranteeing universal access to health care, a fundamental right of European citizens. Health systems in the EU face challenges such as an ageing population, the increasing burden of chronic illnesses, the high cost of development of new technologies, high and rising pharmaceutical expenses, and the effects of the economic crisis on healthcare spending. These challenges prompt the need for European cooperation and new policy measures at both EU and national level.

The report called for national and EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public healthcare systems, and to ensure future investment in pharmaceutical innovation.

Among other recommendations, Members called on the Commission and the Member States to:

- reinforce the negotiation capacities of Member States in order to ensure affordable access to medicines across the EU;
- develop closer collaboration in order to fight such market fragmentation and to work on shared criteria to instruct price and reimbursement decisions at national level;
- propose a new directive on transparency of price-setting procedures and reimbursement systems;
- implement Directive 2011/24/EU on the application of patients rights in cross-border healthcare in a fair way, avoiding limitations to the application of the rules on reimbursement of cross-border healthcare, including the reimbursement of medicine;
- foster R&D driven by patients unmet needs, such as by researching new antimicrobials, coordinating public resources for healthcare research in an effective and efficient manner, and promoting the social responsibility of the pharmaceutical sector;
- promote initiatives for guiding public and private-sector research towards bringing out innovative medicines for curing childhood illnesses;
- promote public and private-sector research into medicines for female patients;
- adopt strategic plans to ensure access to life-saving medicines; Members called in this regard, for the coordination of a plan to eradicate hepatitis C in the EU;
- establish framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases, such as cancer, that cannot yet be treated to a satisfactory degree;
- set up a framework to promote, guarantee and reinforce the competitiveness and use of generic and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices;
- evaluate the implementation of the regulatory framework for orphan medicines (especially as regards the concept of unmet medical need, how this concept is interpreted and what criteria need to be fulfilled in order to identify unmet medical need), to provide guidance on priority unmet medical need;
- promote ethical behaviour and transparency in the pharmaceutical sector, especially regarding clinical trials and the real cost of R&D, in the authorisation and assessment of innovation procedure;
- observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market in order to counter abuse and promote fair prices for patients;
- propose legislation on a European system for health technology assessment as soon as possible;
- increase cooperation between the Member States as regards price-setting procedures.

The Commission is called upon to analyse the overall impact of intellectual property on innovation on, and on patient access to, medicines, by means of a thorough and objective study, as requested by the Council in conclusions of 17 June 2016, and, in particular, to analyse in this study the impact of supplementary protection certificates (SPCs), data exclusivity and market exclusivity on the quality of innovation and competition.

Lastly, Members urged the Commission and the Member States to launch a high-level strategic dialogue with all the relevant stakeholders, together with representatives of the Parliament on current and future developments in the pharmaceutical system in the EU, with the aim of establishing short-, medium- and long-term holistic strategies for ensuring access to medicines and for the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to affordable prices and faster access to medicines for patients.