EU options for improving access to medicines

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The European Parliament adopted by 568 votes to 30, with 52 abstentions, a resolution on the EU options for improving access to medicines.

Parliament 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.

Pharmaceutical market, competition and pricing: Parliament highlighted the importance of both public and private R&D efforts in discovering new treatments. However, it stressed that the high level of public funds used for R&D is not reflected in the pricing which impedes a fair public return on public investment.

Members 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.

Deploring the litigation cases aiming to delay generic entry, Members pointed out that biosimilar medicines enable increased competition and that their market entry should not be delayed.

Members stressed the importance of assessing the real therapeutic, evidence-based added value of new medicines. The price of a medicine should cover the cost of the development and production of that medicine and should be in line with the therapeutic added value it brings to patients.

Main recommendations: Parliament 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;
- set up a framework to reinforce the competitiveness and use of generic and biosimilar medicines, guaranteeing their faster entry onto the market and monitoring unfair practices;
- 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.

The resolution also called for the:

- fostering of R&D driven by patients unmet needs, such as by researching new antimicrobials, given that drug-resistant diseases could cause 10 million deaths annually worldwide up to 2050;
- promotion of research in areas such as rare diseases and paediatric diseases;
- adoption of strategic plans to ensure access to life-saving medicines (for instance the coordination of a plan to eradicate hepatitis C in the EU);
- establishment of 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;
- evaluation of the implementation of the regulatory framework for orphan medicines;
- promotion of 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.

Intellectual property: 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.