



POSITION PAPER

S&D ENVI RECOMMENDATIONS FOR BETTER ACCESS TO MEDICINES IN THE EUROPEAN UNION

A MORE SOCIALLY JUST EUROPE

Consumer rights

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INTRODUCTION

Insufficient access to essential medical products poses a serious threat to the well-being of a large section of the population in Europe. Ensuring that patients have access to essential and affordable medicines is one of the core objectives of the EU and the WHO. The Charter of Fundamental Rights recognises the right of citizens to preventative healthcare and the right to benefit from medical treatment. Unequal access to medicines is not a new phenomenon, but the recent economic crisis has only exacerbated the problem. The increasingly high cost of medicines and shrinking public health budgets jeopardise affordable access to essential medicines. Moreover, the growing need and rising costs of healthcare as a result of an ageing population will further aggravate the situation. Member States should assure that a sufficient portion of their budgets be dedicated to the health and wellbeing of their citizens.

Proper access means that medicines, even those for rare illnesses, should be made readily available and easily affordable in addition to being safe, effective, and of high quality. But various factors influence their availability, such as the selection of medicines on the market, the focus areas of pharmaceutical research, the supply systems, financing mechanisms, pricing, reimbursement and cost-containment policies of individual countries, as well as rigid patenting rules. All these factors should be properly analysed with the aim of finding ways of overcoming obstacles and reducing inequalities in access to medicines and treatments for patients. This is a priority for the S&D Group.

Everyone has a right to good healthcare, so it is vital that medicines are available in the EU to all citizens at a fair, equitable and affordable price.

The high prices of new treatments for diseases such as Hepatitis C recently prompted S&D MEPs to support member states in a call for EU-wide measures to enable patients to access affordable and innovative therapies.



In light of mounting concerns, the S&D ENVI Working Group organised a workshop bringing together experts and stakeholders from all sides to take a closer look at some of the key issues obstructing access to medicines in Europe. As a result of the discussions, we have drawn up a list of recommendations calling on the EU and its Members States to take action to tackle this problem on the various levels.

1 PRICING AND TRANSPARENCY

- Examine and compare the differences in prices of the same medicines in the MS when adjusted to purchasing power parity.
- Demand more transparency from industry when negotiating prices to ensure fair deals for all countries. Avoid confidentiality agreements, and tiered or differential pricing.
- Encourage joint procurement of vaccines and other medicinal products by Member States, which would strengthen their negotiating power driving down purchasing prices, thus providing lower costs for patients.
- Call for a new Transparency Directive following the withdrawal of Directive 89/105/EEC, that aims to ensure the transparency of measures established by EU countries to control the pricing and reimbursement of medicinal products.
- Call on drug developers to respect transparency in the production costs of medicines, in order to understand the proportion of R&D investment reflected in the purchase price, with a view to ensuring the right balance between a fair price for patients and a fair return on investment for industry.
- Ensure easy public access to data on all clinical trials carried out for new and existing medicines in line with the revised Clinical Trials Regulation.

2 GENERIC COMPETITION

- Promote measures to stimulate the uptake of generic medicines, which can effectively lower costs and reduce overall expenditure on medicines.
- Stimulate competition between generic medicines and established medicines where the patent has expired, which can incentivise innovation and reduce the costs of pharmaceuticals.
- Take measures to ensure that generic medicines are not being unfairly prevented from entering the market.

3 RESEARCH & DEVELOPMENT

- Increase public funding for research and innovation for the development of new medicines.
- Rethink patenting rules to find a way to incentivise and finance R&D, as investment by industry tends to focus on areas where a return can be expected.
- Encourage public and private research into innovative medicines for the treatment of paediatric diseases.
- Consider alternative incentive models such as prizes and conditional public funding.

- Introduce conditions such as affordable pricing and non-exclusive licencing if a large share of R&D needed to develop a new medicinal product is publicly funded.
- Gather statistics on the proportion of funding provided by public, industrial and philanthropic sources to pharmaceutical R&D.
- Examine ways to encourage private and public research to redress the gender inequality in medical R&D so that all citizens can benefit from more equitable access.
- Ensure that information on public funding of R&D is available.

4 INTELLECTUAL PROPERTY

- Examine how industry is using patents and licencing; establish whether patents hinder innovation as regards medicines for diseases where there is no profitable market, such as rare diseases.
- Consider establishing conditionality within the Horizon 2020; claim co-ownership of IP for projects funded by EU grants.
- Monitor whether patents are granted for genuine innovation; examine the practice of ‘evergreening’, where pharmaceutical companies get patents for inventions that are not actually new, but are ‘old science’ with minor modifications to existing products in order to keep their patents indefinitely.

- Carry out an in-depth study on the influence patenting systems have on research and development on new and innovative medicines.

5 EU COMPETENCES

- Defend the independence and transparency of EMA in the assessment and approval of medicines so as to ensure high quality, safety and efficiency.
- Promote EMA's initiative on the safe use of adaptive pathways where it is deemed appropriate, to reduce the time to bring a medicine to the market, ensuring that marketing authorisation will only be granted if there is a positive balance of benefits and risks for a defined patient population.
- Strengthen the provisions of Article 81 of Directive 2001/83/EC to address supply shortages of medicines.
- Monitor anticompetitive practices in Member States to protect consumers from artificially high drug prices.

6 ECONOMIC CRISIS

- Examine the influence of the economic crisis on access to affordable medicines for some segments of the population.
- Examine the effects of budget cuts and the subsequent re-distribution of spending on public healthcare systems and on preventative medicine, which could be detrimental to health in the medium to long-term.

7 EXCHANGE OF GOOD PRACTICES

- Promote information-sharing and cooperation between MS on pricing, reimbursement and procurement policies, and on the rational use of medicines.
- Support cooperation through the Health Technology Assessment networks to identify the safest and most clinically effective treatments.
- Develop a European framework, in line with Article 15 of Directive 2011/24/EU, to provide reliable, timely, transparent, comparable and transferable information on the relative efficacy of health technologies to support Member States' decisions.
- Examine changes needed throughout Europe to ensure that European information on relative efficacy is integrated in national decision-making, hence increasing quality and efficiency of assessments, and ultimately reducing access differentials throughout Europe in order to meet patients' needs.
- Promote eHealth solutions where possible.
- Invest in educational programmes to raise awareness of the responsible use of medicines.

8 TTIP AND OTHER TRADE NEGOTIATIONS

- Ensure that the TRIPS-plus provisions included in the IPR chapter of EU trade agreements do not undermine access to medicines.

- Ensure that the ISDS mechanism in TTIP and other trade agreements is replaced with a new system for resolving disputes between investors and states which is subject to democratic principles and scrutiny.

- Guarantee public access to information on the safety and effectiveness of medicines.