September 2014

HAI Europe Recommendations

Keys to improving access to, and the rational use and good governance of, medicines in Europe

Medicines are a key component of patients' treatment. Yet, in Europe, the increasingly high cost of medicines and shrinking public health budgets combine to jeopardise affordable access to needed medicines.

The urgency of the situation requires effective policy intervention by the European Union (EU) and its Member States. The new mandate of the European institutions presents an opportunity to promote positive initiatives and explore new mechanisms and pharmaceutical policies that contribute to affordable access to medicines, their rational use and good governance.

HAI Europe calls upon the EU to embrace the following recommendations:

Generic competition can efficiently lower costs and reduce overall expenditure on medicines

- Increase scrutiny of anti-competition practices by pharmaceutical companies to block or delay generic competition of medicines
- Support legislation to facilitate Member States' uptake of generic drugs as a measure to decrease pharmaceutical expenditure
- Consider issuing compulsory licences to guarantee affordable access to high-priced life-saving drugs of assured safety and therapeutic added value

Needs-driven, open models of innovation can bring more affordable medicines for unmet medical needs

- Make full use of the opportunity that Horizon 2020 offers to explore the "de-linkage" of research and development (R&D) costs from the final price of medicines
- Ensure that publicly funded health R&D results in public goods and medical products that are suitable, more affordable and accessible (support innovation inducement prizes, socially responsible licensing, open source research)

Effective price control mechanisms and reimbursement policies can contribute to the affordability of medicines with therapeutic added value

- Enhance the exchange of Member States' best practices in procurement, price negotiations and health technology assessments to support equitable access to medicines with therapeutic added value
- Support price transparency by establishing a publicly accessible EU database where governments publish the actual price of medicines (publish discounts and rebates)

Full transparency of medicines safety and efficacy data allows prescribers and consumers to make informed decisions contributing to patients' safety

- Ensure that the transparency provisions of the Clinical Trials Regulation are implemented in ways that place public health over commercial interests
- Consider clinical trial data and pharmacovigilance data as a public good; not as trade secrets

Independence, transparency and accountability of decision-making processes and bodies reinforce public health and consumers' trust in medicines policy

- Implement robust conflict of interest policies in regulatory decision-making bodies, such as drug regulatory agencies, health technology assessment bodies, price and reimbursement committees and ethics committees, and ensure process transparency
- Support good prescription practices and disrupt financial links between the pharmaceutical industry and prescribers

For further information, visit www.haieurope.org, or email Health Action International Europe policy advisors, Aliénor Devalière (alienor@haiweb.org) or Ancel.la Santos Quintano (ancel.la@haieurope.org).