



Position Paper

Ensure Market Access for Innovative Medicines

Exec. Summary

- In many countries market access to innovative medicines for patients is often delayed.
- There is a global trend that clinical guidelines and Health Technology Assessments (HTA) developed by authorities or payers are used as a mechanism to restrict the access of patients to innovative medicines.
- However, immediate access to innovative medicines for patients can save their lives and significantly reduce their suffering.
- Patients should get instantaneous access to innovative medicines so that they can live longer and better lives: They should get the medicines when they need them.

Issue

In many countries market access to innovative medicines is often delayed or denied because of complex regulatory and reimbursement procedures. In practically all countries with price regulation, new medicines are not launched as long as reimbursement and pricing decisions are pending. There is a global trend that clinical guidelines and Health Technology Assessments (HTA) produced by health authorities or payers are often used as a mechanism to restrict access of patients to innovative medicines.

Background

Existing pricing and reimbursement procedures can mean that patients' access to innovative medicines might be significantly delayed. The usage of Health Technology Assessments (HTA) by authorities or providers can offer insight when evaluating the efficiency of innovative medicines. However, to make a real difference to improving patient care and physician decision-making, this process needs to be both scientifically robust and transparent. The value of HTA should lie in appraising both the direct benefits of new medicines to patients and society; not as a measure for cost-containment or to delay access to innovative medicines for patients.

Our Position

Patients should get immediate access to innovative medicines so that they can live longer and improve their living conditions. For the well-being of the patients we recommend the following concrete approach:

- Patients should have instantaneous access to life-saving innovative medicines. Therefore, the grant of marketing authorization should allow pharmaceutical companies to immediately launch a product in the market.
- Clinical development and regulatory procedures should be optimized: the processes should reflect a fair risk/benefit ratio balancing the need to ensure the safest medicines with that of providing patients with fast access to life-saving and life-enhancing medicines.



- A dialogue between companies and regulatory and public authorities should start at an early stage of drug development in order to increase predictability and coherence about evidence and data required by payers in order to support reimbursements and to ensure that patients will receive innovative medicines as fast as possible.
- It is in the patients' interest that when evaluating reimbursement levels, public authorities should focus on the overall value of innovation, beyond the mere cost of products to consider their overall socio-economic benefits (beyond a silo-budget mentality).
- Health Technology Assessments (HTA) should not be misused to restrict access for patients to innovative medicines: They should be scientifically robust and transparent.