

Executive Summary

This paper looks at two important regulatory and budgetary aspects linked to the issue of access to medicines in Europe. The first aspect concerns the approval process of a new medicine or treatment – the difference between the time it takes to approve a medicine for use by the European Medicines Agency (EMA) and the time when patients may be able to purchase this medicine in their respective countries. The second aspect deals with the time it takes national authorities to reach a decision about the reimbursement status of different medicines and treatments, once they have been authorised for market use.

Accordingly, the paper focus on two empirical questions: Are there significant differences in the time it takes after a medicine is approved for market by the EMA and the date when it actually becomes reimbursed and thus fully available to most Europeans? And what has been the effect of many EU countries' policies relating to the cost of pharmaceuticals on the actual availability of medicines and treatments to patients?

By looking at a sample of 40 medicines in two EU Member States, Denmark and Sweden, this paper has found that there exists a significant time delay between the approval of a medicine for market through the European Centralised Procedure of EMA and the time when that medicine becomes available to many European patients through reimbursement. For Sweden and Denmark the results of this sample are not encouraging. The averages range from a high of 331.1 and 397.8 days respectively for each country to a low of 199 and 261. Even at the lowest range this is still a time lag of close to nine months for Denmark and over six months for Sweden.

In addition, this paper has found that there are large variations between individual Member States regarding when a specific medicine or therapeutic class of medicines and treatments become reimbursable and thus accessible to the majority of patients. For instance, Swedes have to wait considerably less to receive reimbursement for Oncologics and Cancer-related treatments than their Danish counterparts. For the seven medicines sampled in this therapeutic class, Swedes had to wait an average of 159.6 days, whereas in Denmark a reimbursement decision took almost 200 days longer at 348.3 days. The opposite can be said for Antipsychotics and Antidepressants. For these medicines the Danish approval process took on average 241.1 days, whereas in Sweden the process reached almost a full year at 337 days. These discrepancies are so large that one can talk of a 'postcode lottery': a patient's national address within the EU determines when they can access a particular medicine or treatment, rather than when it was first approved by EMA.

By comparing the date of EU-wide market approval of a medicine or treatment through the European Medicines Agency (EMA) with the date on which the medicine is first reimbursed in an individual Member State this paper finds that that Europe still has a long way to go before having a "single pharmaceutical market".