The drug market regulation in the context of the economic crisis in Germany

La Prestación Farmacéutica frente a la Crisis Económica en Europa
Universidad Carlos III, Getafe, Madrid

15 October 2010

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Germany is one of the last countries with a health care system of completely free pricing of pharmaceutical products followed by a more or less unrestricted access to reimbursement. Germany does not regulate ex-manufacturer prices of pharmaceuticals at market entry. On the other hand, maximum reimbursement amounts (known as reference prices) are set for products which can be clustered in groups of equivalent (generic) or comparable products. Maximum reimbursement amounts are in effect for a large part of the pharmaceutical market covered by statutory health insurance funds putting pressure on prices of clustered products. In addition, across-the board price reductions or freezes have occurred on several occasions, and rebates have been regularly imposed on manufacturers. These measures, along with incentives influencing physicians' prescriptions, have helped Germany to contain the growth of expenditures. However, German pharmaceutical prices have been found to be among the highest in the EU, both for patented and generic drugs, when considered at either the ex-manufacturer or the retail level.

The 2007 Health Care Reform Act introduced two important changes with the aim of ensuring value for money in pharmaceutical expenditures. First, statutory health funds are allowed and encouraged to contract with manufacturers to obtain lower prices in exchange for a "preferred status" for their drug on their formulary. Second, the Institute for Quality and Efficiency in Health Care (IQWIG) assess the benefits and costs of new drugs with the aim of capping reimbursement prices of new entrants if necessary to ensure that their use is not less efficient than existing therapies.

Mid of 2010 the new federal government announced that due to increasing expenditures for pharmaceutical products a fourth hurdle will be introduced at the beginning of 2011. Rapid assessments of the clinical evidence on the ground of "value dossiers" (benefit assessment) and price negotiations for all pharmaceuticals entering the German market within a period of up to one year after market approval will be implemented.