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

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The French welfare state is a mixed system combining elements of various organizational models: with insurance funds and strong state intervention, relying mainly on wage related contributions and general taxation. Due to the funds deficits, an increasing state intervention occurred, particularly since the issue of cost-containment has figured prominently on the political agenda. This evolution took its origins in the reform of 1996 which introduced two important changes: the creation of a new income tax in the funding of the social security system (CSG) and a more active role for parliament in determining policy directions and expenditure targets (ONDAM) in each branch of the system. The regulation of drug expenditures is part of this whole process and is managed within the Haute Autorité de santé (HAS) - or French National Authority for Health – which is the body in charge of Health Technology Assessment in France since August 2004. The Transparency Committee within the HAS is in charge of the clinical evaluation of drugs for reimbursement. This body was created after the European Directive 89/102/CEE of 21 December 1988, known as the “transparency directive” that imposed a regulatory framework for price setting in European countries. A system of positive list prevails for drug reimbursement. The Transparency Committee proposes a listing of a new compound. A drug can be listed if its clinical value (SMR) is deemed “sufficient with regard to a list of criteria like efficacy and safety; severity of the disease; existence of alternative treatments, etc.. A scoring of Added clinical value (ASMR) is also determined which is then used as a basis for price negotiation for retail drugs with another body (CEPS or Economic Committee of Health Products). The ASMR scoring has 5 levels: major innovation, important improvement, significant improvement, minor improvement; and no improvement on the basis of a comparison to the other products already listed considered as comparables. Prices and distribution margins for non-reimbursable specialties are completely unregulated. For recognized innovative specialties, an international price is proposed by the company and co-opted by CEPS. Finally, the price of hospital drugs is completely uncontrolled until 2003 and is determined by negotiation between pharmaceutical companies and hospitals through tenders. With the introduction of activity-based (DRG) funding in hospitals, new rules have also been established for reassigned drugs and for expensive drugs. Aside from this central framework, a series of other measures concern the development of generics, the re-evaluation of drugs during their lifecycle in terms of rebates and delisting, the monitoring of drug use appropriateness, etc.

The whole regulation process for pharmaceuticals in France gives a limited role to economic evaluation but the situation is gradually changing.