

# Cost containment in the pharmaceutical sector

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This paper aims at presenting today challenges regarding cost containment in the French pharmaceutical sector. Some recent and future changes are described and commented.

## 1. Challenges in France

### 1.1 Pharmaceutical policy

The key actors of the pharmaceutical system for pricing and reimbursement in France are:

- The High Authority for Health (“Haute Autorité de Santé” - HAS) is in charge of assessing actual benefit and improvement of actual benefit provided.
- The Economic Committee for Health Care Products (CEPS) is in charge of price-volume negotiations. It sets the prices of reimbursable pharmaceuticals, as well as the prices of some hospital products.
- The National Union of Health Insurance Funds (“Union Nationale des Caisses d’Assurance Maladie” - UNCAM) sets the reimbursement rates for reimbursable pharmaceuticals.

Before reimbursement, there is an assessment of clinical and therapeutic benefits of new medicines. The assessment is performed by the HAS and includes:

- the Actual Benefit (“Service Médical Rendu” - SMR) which is assessed based on the severity of the disorder, the clinical effectiveness of the medicine and the impact on public health. The SMR is used by UNCAM to set the reimbursement rate.
- the comparison to existing treatment options and identification of added value will drive the Improvement of Actual Benefit (“Amélioration du Service Médical Rendu” - ASMR). The price is set by the CEPS according to the ASMR: high improvement leads to a price similar to prices used in other European countries (United Kingdom, Germany, Spain, and Italy). The price is negotiated between the CEPS and the pharmaceutical manufacturer.

There are four reimbursement categories: no reimbursement (in case of insufficient actual benefit), 35%, 65%, 100% (for expensive drugs that cannot be replaced). Patients with a chronic disease get 100% reimbursement for drugs in relation with their chronic disease.

## 1.2 Pharmaceutical budget

The French pharmaceutical budget is characterised by high volumes and a structural use of recent products. The sales of pharmaceuticals to community pharmacies by wholesalers or manufacturers reached 18,6 billion € in 2007 which is an increase of +3.6% compared to 2006. The increase in 2006 was lower. This increase can be analysed in three different parts:

- Price effect: -2.2% because of price drops of generics and some specific patented products.
- Volume effect: -0.5% because of products which are no longer reimbursed. Pharmaceuticals represented 335 € / inhabitant in 2006.
- Structural effect: +6.4%. This effect represents the change in consumption towards more recent and expensive products.

## 1.3 Focus drugs used in hospitals

Some expensive drugs are not included in the hospital budget which depends on the activity. They are fully reimbursed to the hospital in addition to drugs reimbursed in the activity based budget. This list of drugs represented 2,3 billion € in 2007 which is an increase of 10% compared to 2006. It leads to some difficulties for the hospital expenses.

Among these drugs, orphan drugs represent an increasing expense for the social security budget in France. These drugs addressing rare disease concentrate major issues of today cost containment. In France, global sales increased from 291 M€ in 2006 to 350 M€ in 2007 for a reduced number of patient and some annual treatment costs reaching hundred thousand of euros.

New orphan drugs will reach market authorisation in the coming years: end 2007, more than 500 molecules had been designated as orphan. Some of the issues are addressed in the pricing and reimbursement group of the pharmaceutical forum.

## 2. Recent changes

The pharmaceutical plan 2005-2007 aiming at reduction of expenses reached the objectives but some new ways need to be found for the coming years.

### 2.1 Volume regulation

Some tools have been recently implemented:

- Pharmaco economic assessment by the Haute "Autorité de Santé" (After the first assessment and after the price is set).
- Individual contracts between a prescriber and the social security fund allowing a fee provided objectives are fulfilled.

- Recommendation to give the price of products in prescription softwares.
- Extension of formal approval of the prescription before reimbursement (« Mise sous entente préalable »).

Risk sharing agreements have been used in France for a long time mainly based on price – volume agreements. Recently some agreements are based on a future relative effectiveness evaluation because there is a lack of current data. These agreements are quite difficult to implement because they lead to distortion in pricing (drugs with a low relative effectiveness evaluation may get a high facial price) and the agreement is quite difficult to end when the drug is evaluated again.

## 2.2 Price regulation

The discussion paper of Joan Rovira and Jaime Espin mentions that direct product price regulation is losing its traditional role in Europe, which is potentially true for innovative products. But this regulation still exists and varies from one country to another for most of the products coming to the market that are not innovative products.

## 2.3 Generics

The use of generics is strongly related to the prescription of generics or at least off patent molecules (pharmacists are allowed and financially encouraged to substitute). Tools described in chapter 2.1, especially individual contracts, might be used to develop generics in France. Some tools have been recently implemented such as the end of advanced payment if generics are refused by the patient.

## 2.4 Global budget regulation

Global cap is used in France through a mechanism which leads to the payback of a part of global sales which is above a growth rate fixed each year by the parliament specifically for pharmaceuticals. Actually this global payback is replaced by individual paybacks through individual agreements between a manufacturer and the CEPS.

## 2.5 Key issues proposed for debate

Although pricing and reimbursement is a national competence, all Member States face the same challenges regarding the budget sustainability. Much value can be found in exchanging experiences between the authorities. This is why France supports the informal network of competent authorities for pricing and reimbursement established by the Slovenian EU presidency.

Some issues to be debated during the peer review:

- Global cap: do other countries have experienced a global cap on the budget leading to high pay backs and working as an automatic stabilisator?
- Orphan drugs (Is price control based on the cost of production used?)
- Tenders for generics: what is the feedback of recent experience?
- Parallel trade: what about the control asked by companies on products which are exported through wholesalers?