Comité Economique des Produits de Santé

Summary of the activity report for 1999

CEPS

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In accordance with Article D.162-2-5 of the Social Security Code, the Economic Drug Committee (Comité Economique des Médicaments) presents an activity report to the government each year. The Committee has been renamed Economic Committee on Health Products (Comité Économique des Produits de Santé - CEPS) as prices of drugs and medical devices will now be the responsibility of the same Committee.

This report describes the main activities of the committee for the year 1999. It is divided into three parts:

Section 1: explains the regulation of drug expenditure.

Section 2: concerns the pricing negotiations.

Section 3: presents the organisation and role of the Committee.

Development of generics and premiums for innovation are the main long-term objectives of the CEPS.

1.1 The Regulation of the Drug Market

1.1.1 *Accord Sectoriel*

On 19 July 1999, the *CEPS* and the *SNIP* (the pharmaceutical industry association) signed an *accord sectoriel* (industrial agreement). This agreement was designed to:

- Assure mutual transparency and cooperation between the government and the industry.
- Engage structural reforms on certain issues including development of the generics market, self-medication, and re-evaluation of reimbursed drugs. These measures should facilitate the reimbursement of innovative drugs.
- Set up an overall financial regulation scheme, compatible with the *Objectif National des Dépenses d'Assurance Maladie* (*ONDAM*, target growth for healthcare spending).

1.1.2 Regulation by Pharmaco-Therapeutic Class (Drug Category)

Based on the European Pharmaceutical Market Research Association (*EPhMRA)* classification, reimbursable drugs are divided into groups of drugs that, from an economic point of view, belong to the same market. At the end of each year, the total sales of each group of drugs are

compared to the predetermined sales level (based on the *ONDAM*). If sales exceeded this threshold, the *CEPS* can cut drug prices.

1.1.3 Individual Company Agreements (*Conventions*)

The signing of the industrial agreement between the *CEPS* and *SNIP* prompted the signing of individual agreements with pharmaceutical companies for the following three years. During the first financial year, 148 pharmaceutical companies (out of the 178 constituting the total sales of reimbursable products) signed individual agreements with the *CEPS*. These cover 97% of reimbursed drugs.

The *CEPS* ensured that companies reduced their promotional spending, and that generic manufacturers expanded their range of products, as well as securing a larger share of the market.

Compliance with the agreements is strictly monitored by the *CEPS.*

1.1.4 The Importance of Innovation

The *accord sectoriel* reaffirmed the need to provide patients with innovative drugs as early as possible, especially in the treatment or prevention of serious diseases. Signatory parties agreed that this objective could only be envisaged under the constraint that resources are naturally limited, and provided that the price and quantity of these drugs did not handicap their marketing outside France.

The *CEPS* also indirectly encourages innovation by attaching importance to the generics market, the development of which will free up funds to help finance research and development.

1.1.5 Generic Medicines

Generics are bound to play an increasing role in the regulation of drug expenditure. As a result, the committee is committed to speeding up the processing of dossiers for generics. Generics manufacturers have no restrictions on promotional activity, and are not covered by the regulation described in the agreements.

1.1.6 Price Revisions

The increasing range of products, and the desire to reduce healthcare expenditure, led the committee to harmonise the prices of products

within certain therapeutic classes. Only vein tonics, vasodilators, calcium supplements, magnesium products and mucolytics were affected by the first revision. As a result, 110 products had their prices cut by convention, and 4 others, by order (decree) in the absence of agreement. With this measure, the government aims to make savings of Fr180 million within a year ($30 million).

Each convention sets an annual rate of change in turnover for sales of reimbursable products. Rebates that companies have to pay if they exceed this target, were lowered to compensate for the reduction in annual turnover related to these price cuts.

1.1.7 Control of Drug Expenditure

The Social Security Code specifies that:

Art. 162-17-3-II- "The Economic Committee of Health Products follows up drug expenditure in order to assess whether the change in expenditure is compatible with the *ONDAM*."

In 1999, the committee realised that expenditure was increasing considerably, exceeding the *ONDAM*. Therefore, the committee took the initiative to reduce the price of drugs within specific therapeutic classes, and negotiate a financial regulation scheme.

1.1.8 Tools

The monitoring of drug expenditure is a difficult task for the committee. The *ONDAM* focuses on compulsory reimbursement expenditure paid by the health insurance, whereas the measuring instrument for both the *CEPS* and pharmaceutical groups, are sales statistics for ambulatory products (*GERS: Groupement d'Etudes et de Recherches Statistiques*). Therefore, the *CEPS* and *SNIP* set up a working group whose objectives are as follows:

- Suggest a new way of monitoring expenditure, and explaining the gaps between the *ONDAM* expenditure and the total sales for ambulatory products *(GERS*).
- Propose a tool, accepted by both the pharmaceutical companies and the *CEPS*, which will enable the definition for each drug of the volume of sales for which no reimbursement is claimed. The idea is to encourage the development of reimbursed products in self-

medication, and thereby prevent companies from having to pay conventional rebates.

1.2 Pricing Negotiations

Drug price setting accounts for the main role of the *CEPS*. In 1999, the committee met 51 times (one day per week).

1.2.1 Facts and Figures

Registration Dossiers Presented to the Committee

1364 dossiers were presented to the *CEPS* between the 1st January and the 31st December 1999, *ie* more than 25 dossiers per week. Compared to the previous year, the number of dossiers increased by 27% (corresponding to a further 288 dossiers). 48% are first registrations, 39% are renewals of registration, and 13% are price modifications or extensions of indications.

Dossiers Concluded

In 1999, 1156 dossiers (from 131 manufacturers) were concluded. Either an agreement was achieved between the company and the *CEPS*, or the *CEPS* or the company refused to settle, or the company withdrew its dossier. As previously, these dossiers are mainly first registrations or renewals of registration. Amongst the 1156 dossiers, 371 were generics, 56 had a European marketing approval, and 22 had an *ASMR* (clinical merit rating) of 1 or 2.

Length of Procedure

Article R.163-7-1 specifies that for registration, decisions have to be taken and notified to the pharmaceutical company concerned within 180 days following receipt of the dossier.

From Presentation to Conclusion

The time between presentation of the dossier to the committee and publication in the *Journal Officiel* amounts to an average of 196 days. The shortest time spent on a dossier was 47 days, and the longest 570 days. 69% of dossiers were processed within six months.

Main Steps of the Procedure

a) Simultaneous presentation of the dossier to the *CEPS*, and the *Commission de Transparence* (*CT*, Transparency Committee) – *CT*'s opinion on the dossier (on average 51 days).

b) *CT*'s opinion – First session of the *CEPS* (69 days on average). This time will be reduced with the use of electronic transmission.

c) First session – Last session of the committee, *ie* negotiations between the committee and the pharmaceutical companies (average of 10 days).

d) Last session – Publication in the *Journal Officiel* (the average is over 2 months).

Different Processing Speeds According to the Dossier

The procedure for registration renewals (218 days) lasts, paradoxically, longer than for first registrations (180 days).

For products with a European marketing authorisation, and also for products that receive an *ASMR* rating 4 (corresponding to a minor progress in terms of efficacy and/or usefulness), the total procedure takes longer, respectively 231 and 305 days.

1.2.2 Negotiation Mechanisms

Article L.162-16-1 of the Social Security Code sets rules for the pricing of reimbursable drugs:

"The price of each of the products mentioned in the first paragraph of Article L. 162-17 is set by convention between the pharmaceutical group concerned and the Economic Committee on Health Products *(CEPS)* in accordance with Article L. 162-17-4 or, failing that, by decree of the Health Minister, following the committee's opinion. In order to set a price, the committee will take into account the clinical merit of the drug, the price of comparable products, expected and/or observed sales volume, and current and/or potential uses of the drug."

General Context

The committee, whose mission is to set the best price possible for the Social Security, faces the following constraints. It has to:

- consider both the global drug market and the *ONDAM*
- meet healthcare needs
- and treat companies (and drugs) equally.

Price Setting

Two scenarios are possible. Either the drug claiming reimbursement does not have any clinical improvement (without *ASMR*), and its registration has to bring savings to the Social Security; or it proves to be clinically better, and its registration will lead to increased costs.

The setting of an initial price is accompanied with revision clauses. This stems from the hypothesis that only time and use can confirm or invalidate a product's price.

Drugs without *ASMR* (level 5 and 6)

These drugs should bring savings to the Social Security. Savings on total treatment costs are evaluated and do not only take into account the daily drug price. These drugs should not generate any volume increase for the class. The *CEPS* is wary of new galenic forms developed to substitute existing out of patent drugs and then compete with generics.

Drugs with *ASMR* (levels 1 to 4)

These drugs are adding costs to the healthcare system. An *ASMR* does not mean a price increase, as the committee estimates that an increased market share could be a sufficient reward for innovation. There is no relation between the price scale and the *ASMR* rating. For innovations, the European price is considered by the *CEPS*, but it is not a mandatory basis for discussion.

Price Revisions

There are two clauses relating to price revision: clauses on cost per day, and clauses on volume.

Clauses on Cost per Day

These clauses are themselves divided into two categories: clauses on dosage forms, and clauses on posology. They are designed to assure that the real cost of use per patient remains in accordance with the one agreed with the company at the time of registration.

Clauses on Volume

Many volume agreements were discarded at the time of the signing of the conventions in 1999. However, the committee negotiated price/volume agreements in cases where the *ASMR* of an innovative product was only valid for certain of its indications, or for a limited number of patients; and it was likely that the product would be prescribed in all indications, instead of cheaper products, and without clinical advantage.

These clauses were also used at the time of registration of extremely innovative products, where their market share was unclear, in order to limit the financial risk for the Social Security.

Price Cuts

Price cuts can result from the implementation of an existing agreement on price revision, or be decided on the initiative of either the committee (at the time of registration renewal) or the company (in order to remain competitive - so far, only generics are affected, but the committee is hoping to extend this trend to patented drugs).

Price Increase

The committee accepted increases in price for products that are indispensable in terms of healthcare needs, but whose registered price no longer covers their manufacturing and marketing costs. Products suitable for this revision also include elderly products whose market share has progressively diminished, and orphan drugs.

1.3 The Organisation and Procedures of the Committee

The modification of the pricing criteria and of the length of dossier processing stated in Decree 99-554 on 2nd July 1999 had an impact on the organisation and procedures of the committee.

The committee set the following objectives:

- reduce the length of dossier processing
- increase transparency of its decisions
- improve dialogue with pharmaceuticals companies

The committee also expanded its number of permanent staff, and developed its equipment.

1.3.1 Procedures

Internal procedures were remodelled. The committee's aim was to clarify its decisions by favouring the written form over the oral. It also gave greater importance to pharmaceutical companies' opinions, and with *AFSSAPS*, formed a group of experts whose role is to define the relevance of health economics studies produced by companies in support of their price propositions.

Pricing negotiations are divided into three major steps:

1. The Dossier

When applying for registration, the pharmaceutical company provides the *CEPS* and the transparency commission with a dossier, which can be complemented at any time with useful arguments.

2. The Report

For each pricing dossier, studied by the *CEPS*, a report is produced by a *rapporteur*. The economic perspective of the product is the main focus of this report. The *rapporteur* cites the price decided by the pharmaceutical company and the arguments developed in order to support this proposition. If the *rapporteur* does not agree with the pricing proposition, he/she provides the *CEPS* with alternatives. The report follows a set pattern. It must especially highlight the financial implications for the health insurance of each hypothetical price proposed.

3. Decision and Notification

Following each session of the *CEPS*, the pharmaceutical company receives a letter stating the content of the decision and its motives.

1.3.2 Meetings with Pharmaceutical Companies

The *CEPS* accepts the requirement to hold hearings with representatives of pharmaceutical companies. Personal contact between companies and individual members of the *CEPS* is to be avoided.

1.3.3 Pharmaco-Economic Studies

Pharmaco-economic studies are sometimes included in the dossiers submitted by companies. Consideration of such studies supposes that

the validity of design and data have been predetermined. The *AFFSAPS* and the *CEPS* have set up an ad hoc committee of health economists, independent from the industry, with the objective of appraising such studies.

1.3.4 The Organisation

- The committee increased its number of staff.
- The president of the committee is now working full-time.
- The administrative division has ten permanent staff, compared to six in 1998.
- New *rapporteurs* were appointed, in accordance with Article D. 162-2-7 of the Social Security Code. There are now 16.
- The committee also initiated the implementation of a new information and management system.

1.4 Glossary

Accord sectoriel: industrial agreement signed on 19 July 2000, setting the pricing and reimbursement policy of the government until 31 December 2002.

Agence Française de Sécurité Sanitaire des Produits de Santé, (AFSSAPS): the Health Products Safety Agency.

Amélioration du Service Médical Rendu (ASMR): clinical improvement rating.

Comité Economique des Produits de Santé (CEPS): the former Comité du Médicament (Economic Committee on Health Products).

Commission de Transparence: Transparency Committee.

Groupement d'Etudes et de Recherches Statistiques (GERS): statistics institute.

Objectif National des Dépenses de l'Assurance Maladie (ONDAM): the target growth for expenditure on healthcare set by the government every year.

Syndicat National de l'Industrie Pharmaceutique (SNIP): the pharmaceutical industry association.