RIDER OF 7 OCTOBER 2010 BETWEEN CEPS AND LEEM

The Healthcare products pricing committee (CEPS) and the pharmaceutical companies now agree to take their relationship forward within the contractual framework set forth herebelow.

A- Article 1, 3rd paragraph - new text:

« They will continue to send the committee, both in hard copy and electronic format, commercial data, of which the companies shall retain ownership, including but not restricted to the statistics produced by the industry's statistics gathering association GERS[2] regarding sales to both community pharmacies and healthcare establishments. Furthermore, to enable CEPS to make the necessary forecasts, at the end of each quarter the committee shall be sent information on the quarterly declarations of sales by quantity (number of common dispensing units) and by value (turnover ex VAT per common dispensing unit) to healthcare establishments which the companies governed by this agreement undertake to make to GERS, in accordance with the agreement signed between GERS and CEPS. The quarterly sales declarations shall be made with regard to both medicines covered by pre-market approvals and medicines that already have marketing authorisation, including orphan medicines, and shall cover all companies whether or not they are members of GERS. »

B- Article 2 – new text:

« **Article 2: Monitoring spending covered by national health insurance**

The parties agree to monitor spending on medicines every three months in consultation with each other, in particular regarding the information mentioned in Article L.162-17-3, paragraph II of the Social Security Code (Code de la sécurité sociale). This consultation shall be organised within the framework of the abovementioned joint monitoring group set up under Article 1 hereabove. The parties shall consult on all medicines covered by compulsory national health insurance, both those distributed to community pharmacies and those included on the lists set out under Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code. »

C- I- Article 1, after last paragraph – new text:

« A Generics Monitoring Group shall also be formed, which shall be made up of members of CEPS and representatives of companies operating in the generics market: pharmaceutical companies, wholesaler-distributors and community pharmacists. LEEM shall ensure that companies selling generic drugs are specifically represented among the pharmaceutical industry representatives. The group shall meet to discuss the matters set out in Article 13 herebelow among others. »

II- Article 13 – new text:

« **Article 13: Development of generics and fixed accountability tariffs (*tarifs forfaitaires de responsabilité* – TFRs)**

The parties to this agreement agree that the development of the generics drugs market represents a valuable contribution to the funding of medical advances.

The generics monitoring group shall study the development of the generics market and carry out a critical analysis of how the market is functioning and the prevailing economic conditions for companies affected by the development of this market.

The group shall be consulted about all plans to set or to change a “fixed accountability tariff”, as shall the manufacturers of the proprietary products concerned.

The group shall also be consulted about all public plans to lower generics prices and about changes that the committee is considering introducing to its overall price setting procedure for the substitution list: allowance entitlements, price increase rules for original drugs and generics, etc.

The committee shall take into consideration the logistical pressures which the pharmaceutical companies will be put under by any changes to the fixed tariff levels. »

D- Article 4, 8th paragraph:

« When a “quantity clause” is inserted at the time the sale price, official rate or outpatient prescription fee is set, relating to the medicine’s target population or to the indication for which the medicine was given an ASMR rating, including medicines mentioned in Article 10 a), the clause may be revised in the light of new information emerging from the post-marketing studies required by the health regulatory bodies, including relevant epidemiological data and other data that could lead to revising the target population, after the Transparency Commission has been consulted on the matter and a dossier including a summary of the updated pharmacovigilance data has been studied. »

E- After article 10, new article:

« **Article 10 a: Access to orphan medicines**

To ensure that the patients concerned continue to have access generally to orphan medicines under conditions that are acceptable to the pharmaceutical companies and *l’assurance maladie* alike, and subject to the provisions of Article 4 hereabove, the committee may request a company selling an orphan medicine costing more than €50k per patient per year, under the terms of its agreement with the company, to undertake to supply the medicine to all patients eligible for the treatment without restriction in return for setting a price in keeping with standard international prices, up to a set turnover threshold. »

F- I- Article 5, 2nd paragraph is supplemented as follows:

« It also includes for information purposes a list of the company’s proprietary products that are registered on one or other of the lists provided in Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code (*Code de la sécurité sociale*), together with their published outpatient prescription prices or official rates and decisions made by CEPS under Article L. 162-22-7-1of the Social Security Code where applicable or any undertakings made, especially those made under Article 8 c) herebelow. »

II-– Article 9: new article:

« **Article 9: Quantity Clauses**

When the committee intends to apply the terms of Article L. 162-22-7-1 of the Social Security Code to a drug included on the list provided under Article L 162-16-6 or it is considering inserting a “quantity clause” for a medicine included on the list provided under Article L. 162-16-5, which would include provisions on clawback payments or price reductions, the committee shall inform the company selling the medicine of its intention; however the publication of the official rate or the outpatient prescription price shall not be delayed until this process has been completed. »

The committee shall make every effort to reach an understanding with the company and to formally set out this understanding in a rider to its agreement with the company.

If no agreement is reached, once the company has been given the opportunity to present its comments, the committee shall notify the company of its decision under Article L. 162-22-7-1 or if applicable of

the conditions under which it will announce that it is requesting a price reduction in the light of the quantities that have been sold. »

G- After article 13, new article:

« **Article 13 a: Price consistency**

In the event that a significant number of less expensive medicines, in particular generics, emerge within a pharmacotherapeutic group in which this is justified in view of the degree to which the medicines that constitute the group are sufficiently interchangeable from an economic point of view in terms of the nature and degree of the medical benefit they provide, the prices of the more expensive medicines, in particular of those still protected by patens, may be gradually brought into line so that in the long term there will be no significant gap between the prices of these medicines and those of the less costly ones. The desired price reductions may not be introduced until at least one year after these less expensive medicines have come onto the market and shall only apply to medicines that represent little or no medical progress in the majority of their indications. »

H- Article 1, 4th paragraph is supplemented as follows:

« For medicines that have been granted pre-market approval (whether in the context of a cohort programme or a named patient programme, before the file is examined the companies shall send a summary and analysis of the data from the study and information gathering protocol to both the Transparency Commission and CEPS, to provide them with a body of information, in particular on how the product should be used and the nature of the population receiving the treatment. »

I- Article 18, c) 1), 3rd paragraph is inserted:

« The above two paragraphs shall be applicable to reductions in the outpatient prescription prices or the official rates for medicines included on one or other of the lists under Articles L. 162-16-5 and L. 162-16-6 of the Social Security Code (*Code de la sécurité sociale*), provided that these reductions also relate to the sale prices used in practice and on condition that the reductions are not being introduced for the purpose of bringing the prices back into line with current prices in the main European Union Member States. »

J- Article 12, 2nd paragraph:

« If a company requests a price increase for one of its proprietary products that satisfies a medical need not catered for by any other less expensive medicine and the price increase is justified in view of the financial circumstances surrounding the production of the medicine, when evaluating the request account shall be taken of obligations arising from tests on traces of the medicine in water and of the specific cost of the collection and disposal of sharps waste from patients self medicating with the product. »

K- Article 4, 3rd paragraph is supplemented as follows:

« In the event that the Pound should fall strongly against the Euro within a short space of time, this shall not be allowed to have any short- or medium-term impact on the French equivalent of the new sale price in Euros of medicines sold in the United Kingdom, in respect of medicines whose prices were set prior to this depreciation. »

L- Article 11, last paragraph – new text:

« Penalty payments payable in the event of failure to carry out the studies within the agreed timescale, under the terms of Article L. 162-17-4-5, of the Social Security Code, shall be set according to the

procedure provided in Article 15 b) herebelow. »

M- Article 19, first paragraph – new text:

« This agreement, which replaces the 'community' framework agreement of 13 June 2003 as amended and the "hospital" framework agreement of 23 March 2004 as amended, shall be effective until 31 December 2012. »