PRICE REGULATION IN THE PHARMACEUTICAL INDUSTRY IN ITALY

I will make only a few comments on the role played by expenditure on pharmaceutical products in the increase of total expenditures of the National Health Service and provide some suggestions on how to improve the regulation process of drug pricing.

From 1980 to 1990, expenditure for pharmaceutical products has grown at the average annual rate of 17.1% whereas total health expenditure of the public sectors has grown at 15.5% per year, with an increase of the consumer price index of about 10%. The quantity of pharmaceutical products consumed has remained unchanged, thus the increasing trend in expenditure has been set almost entirely by the increased average price of drugs. The industrial average price of drugs has increased from Lit 1,470 per packet in 1980 to Lit 6,409 in 1989. As a result, the relative price of drugs has increased about 7% per year. Considering that the price of pharmaceutical products is strictly regulated by government agencies, it is interesting to enquire the reasons for this dramatic increase in the ten years period.

According to evaluation of the Commission on Public Expenditure the increase in the relative price of drugs (+7% per year) is due for a 2% to the development of truly innovative products. For the remaining 5% it is attributable to:

a) price increases granted by the regulatory bodies to «new products», even though the therapeutical content of these new products has not been significantly different from the content of existing drugs;

b) systematic change in doctor's prescription habits that have progressively substituted new and more expensive products for existing drugs.

The regulatory policy toward the pricing of «new products» with no innovative therapeutical content has been designed primarily for objective of industrial policy since the beginning of the 80's. Industrial policy aimed at increasing the national drug prices in the domestic market in order *a*) to reach the price level prevailing in other European countries, *b*) to help the domestic pharmaceutical industry and *c*) to provide incentives for investments from abroad. The ultimate aims were to raise employment in the research field, to improve the trade balance of the sector, and to decrease the cost of foreign royalties in the balance of payments.

It is a general view that such objectives have not been realized. In fact, one observes that:

1) employment in research activities in Italy has remained nearly stationary;

2) the trade balance deficit has worsened, turning from about 2% of total trade in 1980 to 25% in 1989;

3) the technological gap, as measured by the amount of the royalties paid for foreign patents, has increased;

4) the national industry has progressively lost its share of the domestic market, down from 60% in 1980 to 40% in 1989.

As a consequence of the systematic introduction of «new products» at new prices, drugs with equal therapeutical properties are currently supplied at prices that differ up to 30%; drugs with similar therapeutical content show price differences ranging from 1 to 3. Years of price regulations seem to have produced a bizzarre and inefficient structure of drug prices.

In recent months, regulations have been modified and made more efficient. Hopefully the changes will represent an improvement upon the present situation to the advantage of the National Health System.

In closing, one may wonder whether it would be better to revise the role played by the Public Administration in the matter of control of drug pricing. Presently the public agencies in change of pharmaceutical products regulate too much of the production and marketing activities. They:

1) decide which new products can be paid by the NHS;

2) set the prices of such products;

3) determine the share of the price to be paid by consumers;

4) govern competition in the distribution phase through licencing of selling outlets;

5) regulate the yearly increases of existing products to meet inflation and expenditure targets, and

6) occasionally revise the list of pharmaceutical products admitted to NHS prescriptions.

The procedure seems over-extended and the public interest is lost in the midst of too much regulation.

On the other hand, the NHS agencies:

1) do not inform doctors on the contents of new drugs, as the pharmaceutical industry is being entrusted with this fundamental public activity;

2) do not inform consumers;

3) do not control doctors' prescriptions.

The systems of control is thus excessive for some aspects and insufficient for others. If a suggestion may be given, it is that regulations should be modified to follow the Dutch guidelines: free pricing of products on the one hand and, on the other, definition of fixed subsidy by the NHS for classes of drugs containing homogeneous products. The market will set the prices, the NHS will fix the fraction of the price that will be paid by public funds.

PIERO GIARDA