INNOVATION, PATENTS AND PRICE OF PHARMACEUTICAL PRODUCTS

I am going to follow prof. Onida's suggestions, who asked me to answer the provocations from the previous speakers rather than giving the report I prepared — a report mainly aimed at illustrating the price policy in Italy.

Unfortunately, I have lost Mr. Giarda's provocation. Nevertheless, I can imagine it, given the institutional position he holds at the Treasury. On the other hand, I have caught two statements by the representatives of industry. The first one states that pricing is a major, even deciding element for research. In the second one I have caught a very critical hint towards the price regulation policy.

It has been told that prices are free in those countries where the development of the pharmaceutical industry is stronger and the research possibilities are much more promising than in Italy. And among these countries Germany has been mentioned. Then the problems of the diffusion of generics and the National Drug Plan have been touched on.

The answer to these opinions is very simple. Price is a useful tool to boost research, but it is not the only one. There are other very effective tools, which the Public Administration can make use of. In particular, there is the tool of registration; the so-called «Social Drug Policy» (positive or negative lists, co-payment, etc.); prescriptions control; and then patenting, which is the major tool aiming at protecting the invention.

I would like to set out clearly that price in itself is not an incentive to research. More widely, it is an incentive to the development of industry as a whole. Nevertheless, research depends on the degree of development of production. And therefore a policy of high prices should act as a spur even for research. I say «should», because in Italy more remunerative prices have been used to finance promotion rather than to boost the development of research. It is true that in the short run promotion is useful for each single firm, but in the long run innovation, that is the capacity of finding and commercializing new active principles, is the most important factor.

Speaking of price policy we should not neglect the clashing goals it is expected to reach: on the one hand, the development of industry and on the other hand, public expenditure control. A well-balanced policy should apply highly remunerative prices and in the meantime take measures aimed at limiting the domestic consumption. It is a whole of co-ordinated policies aimed at common goals, which in Italy it is not so easy to implement since it is well known that the

different tools depend on different Ministries (especially Ministry of Health and Ministry of Industry).

An example of how tools different from price can affect industry is offered by Germany. Here prices are free (not regulated, as in Italy), but the so-called «reference price» was introduced two years ago for the reimbursement by the Social Security System in force. Such reference price is the price of a generic having characteristics which are similar to the patented drug mentioned in the prescription. If the consumer asks the chemist for the prescripted drug, he is compelled to pay the price difference between the prescripted drug and the reference product. Obviously, this system has caused a widespread reduction of patented drugs prices.

The above mentioned case of Germany stresses the role that the introduction of generics can play while trying to limit public expenditure even in Italy. As early as in 1984 the Budget Act (Legge Finanziaria) provided for the inclusion of generics in the Italian positive list. Nevertheless, this rule has had a poor application up to now, mainly because of the strong opposition of industry.

Again about price policy, it is worthwhile stressing a fact which is particularly occurring in Italy: that is, the extreme difficulty in updating the price of products that have been on sale since long time and are still therapeutically valid. After years, this has brought about a reduction of the real price of such products together with a constant shift of prescriptions towards the most recent drugs having higher prices. The huge number of outstanding applications for updating old products prices is a negative factor which will contribute to freeze prices once again, with a consequent further shift of prescriptions towards new drugs.

As to the Common European Market, I do not think it will be politically possible to harmonize the methods for determining drug prices inside the EEC. Yet, the opening of national markets, that is the suppression of barriers to the exchange of pharmaceutical products inside the EEC, will automatically bring about a reduction of price differentials in different countries. For this reason, the price equalization inside the Common Market will not be a result of the harmonization of price policies in the different countries, but a straight consequence of suppressing barriers to the free circulation of such products.

At last, as regards the National Drug Plan (*i.e.* a plan aiming at financing pharmaceutical research via public lump-sum transfers), it is necessary to choose between public financing and setting up an environment able to boost the development of production and research activities. The latter alternative is undoubtedly to be preferred, since direct financing by the State is to be used only for basic research as well as for research aiming at finding «orphan» drugs, that is drugs curing rare diseases with no chance of being remunerative on the market. And if direct financing by the State must be, it should be proportioned to research results rather than to research costs.

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