

MOHAMMED HASSAR (*)

Orphan Drugs and Third World Countries (**)

Considerable attention has been given in recent years to the development of what is called "orphan products". Orphan products are drugs or devices with demonstrated or potential effectiveness which remain unavailable to the public because of a lack of commercial interest on the part of drug manufacturers since little or no profit would be derived from their sale.

In fact, the term "orphan products" comprises several groups of drugs:

1. Drugs and devices for patients with uncommon or rare diseases;
2. Drugs with potentially widespread use but that cannot be patented or the patent of which is nearing expiration;
3. Drugs for Third World countries. These can be new drugs (for tropical diseases, for example) or some old drugs that are still in demand in these countries but that might be discontinued in developing countries because they are not needed any more or their toxicity outweighs their benefit (like chloramphenicol).

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In this paper, we will deal with the drugs for Third World countries. But should this group of products be included under the heading of "orphan drugs"? Are they really orphan or are they searching for "unworthy or perhaps not yet mature parents"? Several aspects should be considered when dealing with this question. Let us consider the protagonists, they are numerous.

Third World Countries

The concept of Third World countries is misleading because these countries vary greatly in their wealth, research capacities and political regimes. However,

(*) Clinical Pharmacology - Faculté Médecine, Rabat, Morocco.

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most of them have endemic diseases and population growth that hamper development.

The major complaint of these countries is that they do not have the finances to tackle adequately the major diseases afflicting their people. If this is true for only a very limited number of countries, it is not the case for most other countries where it is the political will to bring about reforms that are needed. Long-term eradication of diseases is like a war. It necessitates careful and long-term planning, otherwise it is only a patchwork.

Developed Countries

These countries are the leading industrial countries. They enjoy a very high standard of life. They also control most of the international trade.

The citizens of these countries should understand that unless they help Third World countries in their fight against underdevelopment they might no longer enjoy their current way of life. Governments of these countries should also be less cynical in their dealing with Third World countries, shifting exports from arms to other more pacific goods. Otherwise those are only promises of opposition parties before elections.

Pharmaceutical Industry

The pharmaceutical industry has been very successful in the last forty years and it can be commended for that. Its business is to develop and market new drugs. It has the infrastructure and the talent needed to do so. Since research is expensive and time-consuming, the industry depends on profits, and any erosion of those profits will necessarily reduce its capacity to find new drugs. The industry has also been accused of not providing "public service". Compared to the fifties, it is true that the industry has done less. However, in several cases the industry has demonstrated its willingness and capacity to respond to the challenge (e.g., the Wellcome-WHO agreement).

Multinational Organizations

They can have an important role and serve as a bridge between Third World countries and the pharmaceutical industry. Unfortunately, they are too bureaucratic. In fact, they cannot deal directly with the scientists, without going through the official government channels. To free the correspondence from the hands of this modern Minotaur, a new Theseus is needed. The multinational organizations are also plagued by political pressures. Overall, some have done nice work despite all the pitfalls, while others are under heavy criticism.

Academic and Government-Sponsored Research Groups

They can have ideas, concepts and useful starting points for drug development, but they lack the capacities for producing new drugs. They can serve as a converging point for all the parties involved.

Regulatory Agencies

They are caught in the middle between several parties. They make sure that only safe and effective drugs are sold to the public. This makes it very difficult to be imaginative or flexible, but when there is a need, the regulatory agencies have made the necessary changes, like the recently approved new US legislation on orphan drugs (Jan. 83).

The Public

Certainly, the public has a role to play in the development of new drugs. It can be asked to share the cost prior to the development or after, by buying the drug. Also, subsidies are paid with tax moneys.

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All the protagonists have both converging and conflicting interests. Solutions should be found, otherwise there will be only losers. The pharmaceutical industry and the developed countries should participate and get involved in both the discovery and development of new drugs for TWC diseases. They just cannot shrug their shoulders and walk away. Third World countries, on the other hand, should share the cost of this development so that they will be more responsible and less wasteful. This will also be achieved by better management and suitable training of people. International organizations should work in close collaboration with all the parties, but they should try to be more efficient and improve their "MPGS" as the auto industry did. The times of illimited funds are over. This is also true for academic and government-sponsored research groups. Regulatory agencies must show more imagination without losing sight of their mission. Finally, the public has to decide what it wants. You cannot have "*le canon et le beurre*" as they say in French, the cannon and the butter.

DISCUSSIONS

C. GALEFFI (*)

Another point of view for the orphan drug issue is that related to the desertion of their manufacture by firms from developed countries on account of changed historical and epidemiological conditions. Thus, drugs regarded as essential by recent WHO documents for typical underdevelopment diseases (for instance, primaquine) are still available on the market because they are produced by developing countries but their quality does not meet the requirements of modern pharmacopoeias. Therefore it is difficult to find adequate chemical reference samples and the corresponding monographs lose their priority and drop out from pharmacopoeia. So, on one side there is the lack of an up-to-date quality criterion for essential drugs for wide morbidity diseases, and on the other side there is the marketing and the utilization of drugs endowed with a low grade also for the non-adoption of good manufacture practice.

The problem of orphan drugs of adequate grade is thus arising.

The transculturation occurring in developing countries for the simultaneous presence of traditional and modern medicine (the latter in embryonic form) develops into a very differential attitude of the people toward drugs. Thus besides a complete rejection due to mistrust and also disappointment, there is the race for taking possession of the drugs, especially if they are free of charge, under the protestation of the slightest illnesses. So healthy people use up the local availability of drugs, hamper the local health service, keep out and let die those who are seriously ill.

The problem thus involves the suitable distribution and the local availability, especially for the drugs in the endemic disease areas, but above all, the proper use of the drugs and the assured intake by the patients.

E. NYANDAT (**)

1. There should be a provision to control the sale of low quality drugs to the developing countries.

2. Selling of drugs on the street seems to increase in developing countries, therefore there should be educational clinics set up by WHO to inform the users and sellers of the hazard.

3. It has been a habit of young scientists that after completing their training in developed countries, they don't want to return to their original countries to apply their expertise in the field.

4. There should be a trial of crude extracts from any plant (e.g., pyrethrum), without chemical mixture, as an insecticide because spraying environments with insecticide has health hazards for humans and animals.

(*) Istituto Superiore di Sanità, Laboratorio Chimica del Farmaco.

(**) I.C.I.P.E., Nairobi, Kenya.