

Generic pharmaceutical drugs: Import them, till when?

In 2009, the Brazilian medicine market was estimated in R\$25 billions (US\$14 billions), which corresponds to the 10th position in the world ranking and approximately to 12% of the world market.

It represents a considerable slice of the world market and it is the first in Latin America.

Medicines can be classified in pharmaceuticals, biopharmaceuticals and generics.

Generally speaking, the first ones includes the phytochemicals and other kinds, the main difference between pharmaceuticals (considered as a medicine active substance) and the biopharmaceuticals (originated from biotech processes) being their monopoly-protected marketing, by means of the patent granted by the State to the companies/institutions that discovered or invented them.

Generics sales represent about 8% of the Brazilian medicine market.

They are molecules the patents of which have expired (*ca.* 20 years after their discovery/invention) and consequently can be produced, distributed and sold by any lab or pharmaceutical company, either public or private, provided that they follow the regulations established by the National Health Surveillance Agency (ANVISA).

The Generics Act (9787/99) has established the generic pharmaceuticals trade in Brazil and determined that their final prices should be about 40% less than that of the patent-protected medicines.

In spite of the benefits brought by the 9787/99 Act, which made it easier for the Brazilian people to manage to buy medicines, the Brazilian pharmaceutical companies that deal with the generics segment are restricted to formulating and packaging the active substances (the pharmaceuticals) they import from distant manufacturing markets, mainly India, Korea or China, bleeding the country currencies and remaking a modern version of the "Trade route to India"

Considering that generics have a synthetic origin and that, in Brazil, we have academic competence on Organic Synthesis in the several Graduate Programs, considered highly-qualified by the Brazilian Federal Agency for Support and Evaluation of Graduate Education (CAPES), part of such expertise can be used to study known synthesis routes, described in the literature on generics patents.

Besides that, we can also introduce relevant innovations in those routes or develop new, original and unprecedented ones from economically and environmentally more attractive inputs.

Finally we can still anticipate original routes for future generic pharmaceutical drugs that come to lose their

patent protection, which will enable us to produce them locally and even become one of the great pharmaceutical manufacturers.

The world top-selling medicine, which, in 2009, reached the amount of US\$13 billions, will have its patent expired in June, 2011, which represents a great commercial opportunity in the generics segment.

Several bottlenecks involving the pharmaceuticals production, either generic or not, are still to be overcome in Brazil.

It is worth noting the extreme necessity, not to say the complete lack of certified basic scale-up labs, qualified to adapt synthetic routes successfully developed on university lab benches, where one works at most on a centigram level.

The promotion of the competence integration, by articulating the research on synthetic routes for generic medicines or new pharmaceutical drugs, at bench level, in more than one academic-university labs, identified by their specific competence on determined synthesis routes, including the preparation of the necessary basic inputs, will also depend on the basic scale-up labs that may innovate in their management model.

To succeed, such labs should be managed by multi-institutional committees working in turn and have the participation of members of companies interested in specific projects, members of the funding agencies, members of the participant science and technology institutions and of the participating researchers.

Among the patent-protected molecules in Brazil, only one is the result of research carried out in the country. This is insignificant for a consumer market as important as the Brazilian one.

Besides reducing the dependence on imported generic pharmaceuticals, the investment in generics synthesis is a very good beginning for the development of new pharmaceutical drugs.

It is necessary that such actions be encouraged because only this way we will inhibit our vocation for mere medicine-consumer market. Better late than never!

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