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## **Editorial**

## The drug situation in lesser developed countries

The vast majority of the approximately 200 countries and territories in the world do not have a domestic pharmaceutical manufacturing industry. Perhaps around 50-70 have the capability of compounding final oral solid dosage forms from imported API (Active Pharmaceutical Ingredients) in what is generally referred to as a basic generic drug industry. Originator, branded new drug discoveries come from a group of about 10-12 countries that usually include the United States, the U.K., Switzerland, France, Germany, Japan, Belgium, Sweden, Denmark and a few others. These new, innovative drugs are often expensive and sometimes beyond the reach of patients in the lesser developed countries, (LDCs). They are also often beyond the level of affordability of governments in these LDCs. So, what can be done?

The World Health Organization (WHO) has suggested that some of these countries try one or both of two possible strategies. One is to generate a domestic generic drug manufacturing industry to save money by negating the need for the importation of costly drug products. They also suggest that the country can earn foreign exchange by exporting some of its production to nearby countries lacking a domestic production capability. On the surface, this sounds like a good strategy, but required is very large and often beyond the means of a single LDC. Secondly, there needs to be a pool of trained, experienced scientists and professionals who would operate the plant, a requirement not fulfilled in many places. Also if country A and its neighbour country B both decided to develop a modest generic drug industry, each is thinking of exporting to the other country. We know that such a plan may fail if both countries decide to produce the same, most needed generic drugs. Also, it is a reasonable bet that the quality, consistency and bioavailability of generic drugs made by the huge generic companies in Germany, China and India may be superior to the locally made generic products. In addition, there are economies of scale enabling the huge multinational generic producers to undercut the price of LDC-produced

It is pretty clear what a purchasing agent would do if faced with the question of buying a LDC-produced generic or one from an established European manufacturer at a lower price. The situation might not be as dismal as it appears. Groups of neighbouring countries could pool their resources and jointly develop a generic drug industry that creates jobs in all of the participating countries with formulation in one place, production elsewhere and marketing, etc. located at a third, different site. There would have to be an understanding that the relevant ministries of health would purchase the products produced by this joint venture, multipartner enterprise.

WHO has also advised some sub-Saharan and other countries to produce drugs from locally available plants and flowers, advising that there may be worthwhile pharmaceutically active substances in the stems, roots, bark, flowers or seeds of naturally occurring vegetation in that country. Again, on the surface, this seems like an interesting and possibly useful scheme. However, like the local generic production suggestion, production of natural product pharmaceuticals requires a very large capital investment, availability of skilled and experienced personnel, an infrastructure to handle quality control, standardization, packaging, distribution and marketing tasks. In addition, modern pharmaceutical companies worldwide when they discover an active substance in a plant or other vegetation attempt to isolate the active principal and they synthesize it in the laboratory. This enables them to sell a pure, standardized product that does not vary based on climate or weather conditions, plant infections and drought.

Perhaps the best near-term solution is for groups of countries to send tenders out to multinational companies jointly asking for bids on very large quantities of needed drugs. It is assumed that an order for drugs from five countries will obtain a lower price than available from five separate, individual orders. It is importation that modern epidemiological and management tools are employed in order to accurately as possible project the coming need for each drug, to avoid the costly waste from holding expired drugs in

inventory or from being out of stock and having to order rush, small quantities of a drug where the supply has been depleted. A group purchasing arrangement might also provide one additional benefit: that being that the member countries might borrow or lend to each other as supply realities dictate. A surplus in one country may be a shortage elsewhere.

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