POSER OVER MEDICINE SUPPLIES
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Patients worldwide suffering from various ailments have benefited from cheap generic Indian drugs. But will Indian companies be able to supply new drugs in the future?

INDIA may be more famous for the Taj Mahal, its religious ceremonies, Bollywood films and one of the highest economic growth rates in recent years.

But more than all these, India has had positive worldwide impact through its large supplies of low-cost, good quality generic medicines. Millions of lives have been saved or prolonged by this.

Many people go to India to buy life-saving generic medicines from pharmacies and bring them back in suitcases to give to relatives who cannot afford the expensive original products.

A decade ago, an Indian company called Cipla produced HIV-AIDS generic drugs that could treat a patient for US$300 (RM930) a year, far cheaper than the branded product's cost of US$10,000 (RM31,000) a patient a year. Today, the Indian drug cost has been cut further to below US$80 (RM248).

This has enabled millions more AIDS patients to be treated. India supplies 70% of the HIV-AIDS drugs obtained by Unicef, the Global Fund and Clinton Foundation for developing countries.

And 75%-80% of medicines (not only for AIDS) distributed by the International Dispensary Association to developing countries come from India. No wonder India has been termed the pharmacy of the developing world.

Last week, the Indian Drug Manufacturers' Association (IDMA), which has 700 drug companies as members, celebrated its 50th anniversary. There was much to celebrate, including the industry's high growth, wide range of medicines, and its contribution to good affordable drugs.

But there are also many factors that may hinder the continuation of the companies' role as chief supplier of medicines for developing countries.

A main factor of the industry's success has been the government's move in 1970 to exclude pharmaceutical drugs from product patents.

This paved the way for local companies to produce generic versions of the expensive foreign drugs, and within a few decades they had taken over 80% of the local market, while also supplying cheap medicines abroad.

The situation took a negative turn when the intellectual property agreement known as TRIPS was established in 1995 together with the World Trade Organisation. It disallowed countries from excluding medicines from patentability.

However, TRIPS allowed countries to determine the criteria for an invention that can be granted a patent, and the ability of the government to grant a compulsory licence to local companies to produce the patented products if their requests to patent owners to give a voluntary licence do not succeed.

To implement its TRIPS obligations, India passed changes to its patent law in 2005 so drugs could now be patented.

However, the new law also contained flexibilities such as strict criteria for patentability (trivial changes to a patent-expired product would not qualify for a new patent), allowance for public opposition to a patent application before a decision is made, and compulsory licensing.

India has one of the best patent laws in the world that still gives some space to its producers to make generic drugs.

But it is also true that the old policy space has been eroded because many new drugs since 2005 have been patented by multinational companies which are selling them at exorbitant prices.

Indian companies can no longer make their own generic versions of these new medicines unless they successfully apply to the government for compulsory licences, and that is quite cumbersome; or unless they obtain a licence from the patent-owning multinational, and that usually comes with stringent conditions, especially for export.

Another worry is that India is negotiating a free trade agreement with the European Union. Such agreements usually contain provisions such as data exclusivity and extension of the patent term, which prevents or hinders generic production.

Finally, six Indian companies have recently been bought up by large foreign firms. If this trend continues, the Indian drug market may be dominated by multinationals again.

It is uncertain whether they will continue to supply the developing world with cheap generic medicines when this may be in conflict with their own branded products.

International health organisations such as Unaids, Unitaid and Doctors Without Borders have raised their serious concerns that these recent trends may threaten India’s role as the chief supplier of affordable medicines to Africa and other developing countries.

“Millions will die if India cannot produce the new HIV-AIDS medicines in future, it is a matter of life and death,” said Michel Sidibe, Unaids executive director, during a visit to India last year.

Thus, a strategy is needed that involves the government and the drug companies, that ensures the local drug industry continues to thrive, that it produces not only the existing medicines but also new medicines even if they are patented, and that they are supplied at cheap prices not only in India but to the developing world, too.

That was the sobering message that emerged at last week’s 50th anniversary conference of the Indian drug association, even in the midst of congratulations on the achievements of the past.