**Healthy trends**

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IT is heartening to see Pakistan take its place among global generic medicine manufacturers like Cipla (India) and Teva (Israel). Here is why it is important.

It is in the context of a new antiviral medicine developed and tested by Pfizer and found to be effective in treating Covid-19. The medicine`s (generic) name is nirmatrelvir, which when given in combination with a low dose of ritonavir-an existing antiviral medicine used to treat HIV infection was found to reduce the risk of hospitalisation/ death by 89 per cent, compared to placebo in patients, within three days of the onset of symptoms. The medicine was issued Emergency Use Authorisation by the US Food and Drug Administration (FDA) in December 2021.

The medicine is patent-protected by Pfizer under the trade name of Paxlovid. It is priced at $530 per treatment regimen. Obviously, this is unaffordable for governments and people in lowand middleincome countries. Since almost all new medicines are researched and developed in high-income countries, with heavy public and private investments, intellectual property rights, especially product and process patents, are closely guarded. Simply put, they provide monopoly rights to the producer to sell the product at a high price to recoup R&D costs and make huge profits. When the medicine is of significant public health importance to deal with a disease that is prevalent in rich and poor countries it poses a huge economic and ethical issue with regard to the availability of the same medicine to patients in LMICs.

In the wake of high-priced and thus inaccessible medicines for HIV infection for the people of Africa and strong civil society treatment-access campaigns, some important global institutions were born, one of which is the innovative Medicines Patent Pool, situated just across the road from the WHO headquarters in Geneva. In order to make available the same high-priced, patent-protected medicines of high public health importance in LMICs, and at the same time protect markets for these medicines in highincome countries, the MPP serves as a platform whereby the producers of the high-priced medicinestake a differentiated market approach, also called the tiered price approach, and sub-license the same medicine through the MPP to a limited number of reliable generic producers in LMICs. A stringent scrutiny process takes place to select these producers. Selection is a global testimony of the credibility of manufacturers. The originator company then shares, through a non-exclusive licence, the knowhow and transfer technology to these producers in LMICs to manufacture these medicines and make them available at affordable rates in the domestic market as well as to export to an agreed number of other LMICs. There are strict conditions to ensure that these manufacturers do not export to any country other than those on the agreed list. This happens after a careful market study. This system is a kind of a cushion to improve access to medicines of public health importance in LMICs, without losing the market in high-income countries where they continue to be sold at high prices.

To illustrate, by going back to nirmatrelvir, the US government has already bought 20 million treatment courses at the company price of $530 per course (10 tablet pack) which makes the total cost more than $11 billion. It has a voluntary licence agreement with the MPP, which in turn has sublicensed 35 generic manufacturers from LMICs.

This will help expand the medicine`s access in 95 LMICs that account for approximately 53pc of the world`s population. The heartening fact is that a Pakistani company has also qualified for the sublicensing along with 34 others from LMICs. All these companies were scrutinised for their capacity to produce medicines in `a manner consistent with World Health Organisation prequalification standards and/or the standards of an SRA` (Stringent Regulatory Authority, for example, the FDA, the UK`s Medicines and Healthcare products Regulatory Agency, and the like). In August 2021, Pakistan also obtained the first WHO prequalification for a product produced locally levofloxacin (an antibiotic) not surprisingly by the same local company.

Earlier, the same manufacturer was sub-licensed by the MPP to produce the first oral anti-viral medication for Covid-19, molnupiravir, a product of Merck(MSD). This sub-licensing also allowed export to 105 countries. Once the production of molnupiravir starts in Pakistan it will be made available at around $20 per pack whereas the MSD price for the same pack is $700.

In the wake of Covid-19, some important developments have taken place in Pakistan`s health technology space. In May 2020, Gilead, another pharmaceutical giant, signed an agreement with a Pakistani company to produce remdesivir and to potentially export to 127 other countries. Pakistan became a part of a multi-country Phase-III vaccine clinical trial for a single-dose Chinese vaccine for Covid-19, reportedly earning $10m. This was managed by the National Institute of Health in Islamabad. A few credible contract research organisations have also emerged in the last few years, which are involved in clinical research including clinical trials for Covid19 products. Pakistan is also now part of the WHO transfer of technology programme for mRNA technology-based vaccine manufacturing in the country.

These are positive trends and would also inevitably provide positive impact on regulatory pathways development. The Drug Regulatory Authority of Pakistan is also now steadily developing under a stable leadership although it still has a very long way to go. During Covid-19, Drap lived up to the challenges by protecting the public health as newer technologies started coming in and requiring urgent market authorisations. A harsh reality, however, continues to haunt: most pharmaceutical companies in Pakistan are not producing medicines in accordance with minimum international standards of good manufacturing practices.

The areas of vaccine, biosimilar products, diagnostics, medical devices and medical equipment, with the exception of the Sialkot hub producing world class surgical instruments, need to leapfrog and the government needs to provide support to private sector initiatives in these vital areas.  The writer is a former SAPM on health, professor of health systems at Shifa Tameer-i-Millat University and WHO adviser on U HC.

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