EGYPTIAN INITIATIVE FOR PERSONAL RIGHTS

المبـــادرة المصـــرية للحقـــوق الشخصيـــة

Facts about the New Drug-Pricing Decree

The Decree Threatens Citizens' Right to Health

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The Egyptian Initiative for Personal Rights (EIPR) filed an urgent lawsuit (no. 64/ 2457) with the Court of Administrative Justice seeking the suspension of the Minister of Health decree that went into effect on 25 September 2009. The decree establishes a new pricing system for drugs in Egypt, which will inevitably entail a sharp increase in prices. The EIPR believes that by adopting this pricing system, the state is evading its responsibility to guarantee citizens the right to have access to medicines. At face value, the decree maintains the structure of a pricing system. However, in reality, it completely removes the state from the equation, thus leaving global market forces to determine the prices of medicines.

The EIPR hopes this brief guide will clarify matters and correct misconceptions about the new pricing system.

1. How will medicines be priced under the new decree?

Decree 373/ 2009 on the pricing of pharmaceutical drugs, issued by the Minister of Health on 8 September 2009, establishes two different pricing systems, one for brand-name drugs and another for generic drugs. A brand-name drug is one that contains a new or innovative active ingredient, regardless of whether it has been patented. On the other hand, a generic drug is therapeutically equivalent to a brand-name drug, but is cheaper.

Under the decree, the price of brand-name drugs will be set 10% lower than the cheapest consumer price of the drug in the countries in which it is currently available. Appended to the decree is a list of 36 countries that shall be consulted by the Ministry of Health in order to confirm the prices of the brand-name drugs therein.

The price of generic drugs will be set at a fixed percentage markdown of brand-name drugs. The decree establishes three categories of generic drugs based on the quality certifications obtained by the manufacturers. The first category, which will be priced 30% lower than the brand-name equivalent, includes those drugs made by a factory licensed by the Ministry of Health and certified by international agencies. The second category, to be priced 40% lower than the brand-name equivalent, includes those drugs made by factories licensed by the Ministry of Health alone. This category of drugs will exist only until 2020, at which time all such factories must have received quality certification by international agencies or face closure. The third category, to be priced 60% lower than the brand-name equivalent, includes those drugs made by companies that do not maintain their own factories. Rather, they have contracted out the license to manufacture the drug.

2. How does the new pricing system differ from the old one?

The new system is fundamentally different from the old system. Whereas under the old system, drugs were priced according to production costs, the new system has liberalized pricing, thus making prices dependent on market forces in other countries regardless of the economic, demographic or legal conditions in Egypt.

Under the old system (established by Decree 314/ 1991), the price of drugs manufactured locally, whether generic or brand-name, was based on the real production cost of the drug as well as a set profit margin for the manufacturer, distributor and pharmacist. The production cost of the drug includes the cost of raw materials, administrative and industrial overhead, and research. These costs are calculated based on documents and invoices submitted by the pharmaceutical companies and manufacturers. Using these guidelines, a pricing committee formed by the Minister of Health sets the consumer price of drugs after examining all relevant documents.

3. Does the recent decree mean that the price of drugs in Egypt will go up?

Without a doubt, the decree will lead to an unprecedented increase in the price of drugs in Egypt because it links the price of brand-name drugs with the prices in foreign markets and the prices of generic drugs to those of their brand-name equivalents. Prior to this decree, the consumer price of medicines in Egypt was the lowest in the Middle East. Linking prices in the Egyptian market with those in foreign markets will certainly bring about a hefty price increase.

The ramifications of this become clearer when we consider that 68% of pharmaceutical expenditure in Egypt is paid for by Egyptian citizens, according to the National Health Accounts, published in 2005. Moreover, according to a study conducted by the World Health Organization in 2004, the price of drugs in

Egypt is already high relative to its per capita income. This means that many Egyptians cannot afford to buy them.

4. What about the section in the decree that states that the lowest consumer price in 36 countries will be the basis of pricing, and that the price of brand-name drugs in Egypt will be 10% lower than that?

The decree does not necessitate that the drug be registered in all 36 countries. Pharmaceutical companies may simply choose Egypt to be one of the first countries in which they would register their new drugs. In turn, this will link the domestic prices to the prices in the wealthiest and most expensive countries.

The Ministry of Health considered neither Egypt's level of development in relation to the countries listed in the appendix of the decree, nor the current price level of drugs in Egypt compared to its per capita income. According to 2008 figures from the World Bank, which cover the member countries (185 nations), as well as all other economies (a total of 210 economies), every country on the Ministry's list has a higher Global National Income (GNI) per capita than Egypt, with the exception of India and Sudan. The average annual GNI per capita of the countries on the list is US $28,539, compared to US $1,800 in Egypt. This means that the cost of drugs will be based on prices in countries that have an average GNI per capita that is 16 times higher than Egypt's.

Given these facts, one must ask why the Ministry of Health linked the price of medicines manufactured in Egypt with the prices on foreign markets. What criteria did the Ministry use to select the 36 countries listed on the appendix to the decree? For example, why did the list disclude countries like Pakistan or Yemen, despite the Ministry of Health's claims that it "exerted great effort" to include them in the selection? For whose interest was this decree passed, if not for the interest of the Egyptian patient?

Our objections are not limited to the selection of these 36 countries per se. Even if the Ministry decided to accept price guidelines from countries not included on the list, what are the chances that the prices in these countries will be appropriate to the income level of the average Egyptian citizen, when Egypt is ranked 147 out of 210 economies in terms of GNI per capita?

5. What about the prices of generic drugs? Will they go up as well?

Under the new decree, the price of generics is based on the price of brand-name drugs. High prices for the brand-name drugs will necessarily entail higher prices for generic drugs, too. Even when the price of a brand-name drug is relatively reasonable, this may not necessarily ensure that the average Egyptian citizen will be able to afford its generic equivalent.

A study conducted by the Pharmacists Syndicate in Gharbiya in October 2009 found that the provisions in the new decree will lead to a 199% increase in the general price of generic drugs. Currently, the consumer price of generic drugs is sometimes 80-90 % cheaper than their brand-name equivalents. For example, one Plavix pill, administered to heart patients to prevent blood clots, is sold for LE 12, while the generic equivalent costs only LE 2. Hence, the generic drug is 83% cheaper than the brand-name drug. Assuming that the factory is licensed only by the Ministry of Health, the generic pill will cost LE 7.20 (40% less than Plavix), under the new decree. This is a 360% increase over the current price.

Nevertheless, this price increase is minor compared to the stark increases that are sure to come when the price of brand-name drugs is linked to the price on foreign markets. This will undoubtedly increase the price of generic drugs as well.

It should be noted that the decree proposes a unified price for all generic drugs. That is, it makes no distinction in prices between the first, second, third or tenth generic product to be registered. This means that even if 11 generic versions for the same brand-name drug are registered, (11 is the maximum limit set by the Ministry of Health decree on the registration of pharmaceuticals in June 2009) medicine prices will not decrease. Although the decree has left the pricing of drugs to the free global market forces, the Ministry of Health has made sure that competition between local producers of generic drugs will not benefit the Egyptian consumer or patient by lowering prices.

6. This decree applies to the pricing of new drugs. Does this mean it will have no effect on the prices of drugs that have already been registered?

Although the decree will apply only to new medicines, it will undoubtedly have an impact on the prices of drugs currently on the market. Under both the old and the new pricing systems, prices are periodically reviewed, every two years under the old system and every three years under the new one. Companies will not accept the old prices and will ask that the new pricing system be applied to their products when the pricing review takes place. Furthermore, the new decree stipulates that Decree 314/ 1991 will remain in effect only for the pricing of nutritional supplements; it made no mention of any type of pharmaceuticals. Hence, in a few years, the price of all drugs on the market may go up, including drugs that were registered and priced years ago.

7. But shouldn't the drug pricing system be reformed?

Of course, there are challenges facing the old pricing regime. Among them, is a huge discrepancy in prices and the high price of some basic drugs, which makes them inaccessible to many citizens. However, instead of meeting these challenges, the state has totally removed itself from pricing, shirking its responsibility to Egyptians. We cannot accept any reform initiative that is focused primarily on satisfying corporate greed. It is unacceptable for such initiatives to cause increases in consumer prices, leaving citizens at the mercy of global market forces. These reforms completely disregard the interests of Egyptian patients.

Egyptian patients were not among the interested parties that were consulted during the drafting of this decree, although they will be most affected by it. Using the language of commerce, they are still the consumers. The Deputy Minister of Health for Pharmaceutical Affairs boasted in the media that the ministry had consulted pharmaceutical companies while drafting the decree. However, he refused to meet with civil society organizations regarding the same decree. The EIPR requested an interview several times before the decree was issued, but to no avail.

8. What about the Ministry's claim that the decree will address the "crisis of corruption" which characterized the old system?

There are several criticisms that can be pointed at the old system, one of them being the ambiguity in the pricing system. The mechanisms and criteria by which drugs were priced were not entirely clear. Under the new decree, however, the pricing process will face a different set of difficulties. The Ministry of Health will not be able to review the consumer prices of drugs in certain countries included in the appendix, primarily because there is no set price for these drugs. In other words, some countries do not have a compulsory pricing system. In turn, the price of pharmaceuticals, like any other commodity, is determined on the basis of supply and demand in these countries. Thus, the price may vary from one day to the next and from one place to another in the same country. Even in countries that maintain a pricing system, the prices may not be freely published and available to all.

9. The decree will give companies incentives to improve the quality of the drugs they produce. Are we against quality?

The assumption that low prices mean low quality is false and dangerous because it harms the reputation of effective generic drugs simply because they are cheaper. In turn, it fosters demand for costly drugs based on the misconception that they are the only high quality drugs available.

The term "generic" refers to pharmaceutical preparations that have the same active ingredient and are therapeutically as effective as the brand-name drugs they are equivalent to. The MOH's approval of a particular generic drug means it is deemed as effective as the brand-name one. If the generic drug does not meet the effectiveness of the original, the manufacturer will be in breach of its obligations, and should be held liable. This necessitates continuous supervision

from the regulatory authority, namely the Ministry of Health, which should impose punitive measures on the breaching companies. It is absurd to ask people who need medications to pay extra in order to compensate companies for failing to maintain quality standards or for negligence by government regulatory agencies.

Unfortunately, the total reliance on international and foreign quality certifications is a clear admission by the Ministry of Health that it does not possess effective means to regulate the quality of drugs produced locally. Moreover, it does not intend to expand its capabilities in this field. Hence, the state is once more removing itself from the drug market and burdening the patient with the cost of quality certifications.

Bibliography

- Decree 373/2009 on the pricing of human pharmaceutical preparations. Issued by the Minister of Health, 8 September 2009.
- Decree 296/2009 on the reorganization of the rules and procedures for the registration of human pharmaceutical preparations. Issued by the Minister of Health, 28 June 2009.
- Decree 96/2004 on the establishment of a pricing committee for pharmaceutical medicines and nutritional supplements. Issued by the Minister of Health and Population, 21 April 2004.
- Decree 314/1991, on the pricing of medicines and pharmaceutical preparations, Issued by the Minister of Health, 26 September 1991.
- Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Appendix 1C of the Marrakesh Agreement Establishing the World Trade Organization. Signed in Marrakesh, Morocco, 15 April 1994.
- National Health Accounts in Egypt 2001-2002 November 2005.
- World Bank, Gross National Income Per Capita 2008, Atlas Method and PPP October2009, http://siteresources.worldbank.org/DATASTATISTICS/Resources/GNIPC.pdf
- World Bank. "Al-Bayanat Wa-l-ihsa'iyat: Tasneef Al-buldan", http://www.albankaldawli.org/dataandresearch/data.statistics.countryclass.html
- American Chamber of Commerce in Egypt. Pharmaceutical Sector Developments in Egypt, Business Studies Series, 2006, http://www.amcham.org.eg/BSAC/StudiesSeries/Report49.asp.
- World Health Organization and Health Action International, with the coordination of the Ministry of Health and Population and the Central Administration for Pharmaceutical Affairs. "Survey Report: The Prices People Have to Pay for Medicines in Egypt," July 2004, http://www.haiweb.org/medicineprices/related/200407_Egypt.pdf
- Pharmacists Syndicate in Gharbiya. "Al-athar Al-mutarattiba 'Ala Qarar Wazir Al-sahha No. 373", 2009 and "Al-ladhi bi-mujibihi Yatimm Raf' As'ar Al-adwiya Al-ganisa" (generics) Fi Misr, October 2009.
- Ministry of Health On-line Registered Priced Products Directory. http://www.mohp.gov.eg/Sec/Drugs/DrugsPrice.asp?x=3

- Health Action International On-line. http://www.haiweb.org/medicineprices
- Magdi al-Gallad and Tariq Amin. “D. Hatem Al-Gabali Wazir Al-sahha Fi Hiwar Shamil (1-2): Al-hajma Al-sharisa Li-influinza Al-khanazir fi Yanayir wa Fibrayir...Wa-l-Virus Qad Yatawattan fi Misr,”Al-MasryAl-Yom, 25 October 2009.
- Imad al-Sayyid, “Kamal Sabra. Al-shuqaq wa Al-badrumat Asbahat Makhazin Adwiya,” Al-Masry Al-Yom, 26 October 2009.
- Khalid Abu Bakr and Sharin ‘Abd Al-Raziq. “Al-Gabali: Al-fasad Huwwa Sabab Ilgha’ Nizam Al-tas’ir Al-qadim’ wa Sa- ataraja’ ‘An Al-qarar Al-jadid Idha Thabata Fashaluh,” Al-Shorouk, 4 November 2009.

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