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A Conversation with Eloan Pinheiro

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Dr. Eloan Pinheiro has played an important role in expanding access to treatments for AIDS. After beginning her career as a research chemist for a multinational pharmaceutical company, she later became the Executive Director of Fundacão Oswaldo Cruz/Farmanguinhos, in Rio de Janeiro, Brazil. Dr. Pinheiro was chiefly responsible for the development and manufacturing of inexpensive generic versions of AIDS medicines in Brazil. After her retirement from Farmanguinhos, Dr. Pinheiro worked for the World Health Organization on the scale-up of AIDS treatment in developing countries. In May 2008, Dr. Pinheiro spoke with the editors of KES.

KES: Dr. Pinheiro, when did you first become interested in the manufacture of medicines for the treatment of AIDS?

Dr. Pinheiro: In 1996, a Brazilian Presidential decree established the principle of governmental responsibility for providing all HIV–infected citizens with medication essential to the combat of the AIDS epidemic, without taking money from the citizens' pockets. This fact, along with increasing pressure from a pool of non-governmental organizations, pushed the Ministry of Health (MoH) and the National Program of DST/AIDS (STDs and AIDS) to request from Farmanguinhos the production of all ARVs off of patent. The other reason was that the MoH, unduly burdened by the high cost of imported medicines, strengthened its proposition to Farmanguinhos: analyzing brand-name drugs and developing their generic forms.

As director of Farmanguinhos, I accepted the challenge because the mission and vision of Farmanguinhos was focused on its social role. Since then, I have believed that the price of any drug cannot determine whether one lives or dies.

KES: For those who don't know, what is Farmanguinhos?

Dr. Pinheiro: Farmanguinhos is a Technical Institute Unit of the Oswald Cruz Foundation (Fiocruz), which is responsible for the production and development of essential medicines. Fiocruz is a public foundation directly linked to the Ministry of Health. Consequently, Farmanguinhos is the government's official laboratory. Its main role is supplying medicines to the

strategic programs of the Ministry of Health and providing safe medicines to the Brazilian population free of charge.

KES: In 1996, Brazil had not yet granted product patents on AIDS drugs. But what were the other challenges in developing generic versions of AIDS drugs?

Dr. Pinheiro: Our patent law was implemented in May 1996, but the main reason for developing generic drugs, in my view, was that the majority of people from developing countries have to live with low salaries or even without any income. In such circumstances, purchasing medicines is a luxury, and if the government does not have an efficient public health system, many people die without treatment. To confront this problem, governments have to establish policies on research and development, policies to incentivize industrialization, legal procedures to permit the accelerated approval of generic drugs, and programs to make universal access to medicines and treatment possible.

In Brazil, such policies were implemented, and comprised: (i) governmental purchasing associated with price negotiation, (ii) a generic drug-manufacturing policy for non-patented medicines, and (iii) the introduction of a referential pricing rule for medicines (maximum price paid by the government for specific medicines). Farmanguinhos, as the public laboratory of the MoH, successfully executed its role.

These measures have strongly contributed to the reduction of prices for medicines in Brazil. The reduction of medicine prices was obtained not only for anti-retrovirals (ARVs), but also for other medicines on the market. The Brazilian Generics Law entered into force in February 1999 (Brazilian Generics Law, No. 9,787/99).

In addition, the generic medicines-manufacturing policy contributed to local capacity building, increased market competition, and strengthened Brazilian technical competence aimed at acquiring the know-how to produce Active Pharmaceutical Substances and ARV formulations.

These were some provisions which were implemented in order to execute a strategy with the goals of ensuring access to medicines in developing countries and strengthening local production and development.

It is because of this increase in generic production that bigger price reductions for ARVs are possible now (see Figures 1 and 2).

KES: Brazil issued its first compulsory license on an AIDS drug in 2007. Until then, Brazil had not made or imported any generic AIDS drugs that

were invented and patented after 1996, the year Brazil extended product patents to pharmaceutical drugs. Why did Brazil stop using generic AIDS drugs for so long, and why was there so much caution in using the compulsory license mechanism?

Dr. Pinheiro: When Brazil signed the TRIPS agreement in 1994, we knew that it would bring a lot of problems, firstly, because Brazil exports shoes, citrus fruits, soybeans, etc., to the U.S., and, in addition, these economic sectors have strong representatives in the Brazil Congress to defend their interests. Secondly, the implementation of the TRIPS flexibility, which was permitted by the Doha Declaration (2001), has been proved neither easy nor automatic in developing countries due to the political and economic pressures and retaliations from developed countries, particularly from the USA. Moreover, the lack of clear procedures for requesting and managing compulsory licenses brings uncertainty as to how active pharmaceutical ingredients can be purchased on the international market at an affordable price.

From 1996 until 2000 the National Program provided HAART with off-patent drugs. The unique exception was the drugs nelfinavir, which was purchased from Roche. In this case, the Brazilian government tried hard to decrease the price, negotiating with the owner. To strengthen their position in the negotiation with Roche, even, the MoH requested that Farmanguinhos develop, on a pilot scale, the 250 mg dosage of nelfinavir and the 200 mg efavirenz, importing a small amount from Indian Companies producers of generic versions.

That strategy elicited a strong reaction. Indeed, the USA threatened Brazil using its "Special 301 Report", threatening to impose trade sanctions against Brazilian exportation of items such as orange juice, shoes, soybean and others. Obviously, the USA gained Brazilian allies in the export sector.

Despite the government's attempt to issue a compulsory license, the measure was not accomplished because of the above-mentioned economic pressures. Notwithstanding, the MoH has gotten a significant price reduction on those drugs.

Nowadays, the question is the high price of new, patented drugs which come to the market every year. Indeed, the Brazilian government has to both maintain a sustainable AIDS program and deal with patented medicines, despite their high prices.

Currently, the MoH and the Ministry of Science and Technology give financial support for the development of innovative drugs derived from both older and newer drugs, regardless of their patent status.

This action definitely will improve the national capability to quickly respond whenever a compulsory license is needed.

KES: You eventually left Farmanguinhos to join the staff of the World Health Organization (WHO) in Geneva. What were you doing at the WHO, and what is your opinion of the work of the WHO regarding AIDS and access to medicine?

Dr. Pinheiro: In July 2004, I was invited to work at the WHO to organize, within the Department of HIV/AIDS, the Clearing House, which had as objectives the collection, consolidation and dissemination of strategic information regarding affordability, accessibility and availability of HIV drugs. The main tasks I was in charge of were compiling data on the market prices of medicines and Active Pharmaceutical Ingredients (API), as well as identifying their producers. I was responsible for collecting data about the status of medicines on the market, including registration, prequalification and patent status. My other duty was to analyze the actual infrastructure in low- and middle-income countries, aiming to build in local production for medicines. My expertise in formulation and pharmaceutical production notwithstanding, I could unfortunately never accomplish such a very important task to help people living with AIDS, in Africa, Asia, wherever.

The objective of my work was to bring transparency to the ARVs market, helping the MoH and its partners in their advocacy to increase access to those drugs.

In my view, the WHO is an important organization, which is recognized worldwide and it is necessary to drive policies more actively. Unfortunately, there are sectors in the WHO that are very conservative and that don't believe in building local capacity in developing countries for the production of medicines. On the other hand, I realize that the WHO suffers from the significant influence of members who contribute more money to support the WHO infrastructure. This fact tilts the balance of power in favor of developed countries, strengthening their proposals. The actions and strategies of developing countries carry less weight. Consequently, developing countries and least-developed countries, which comprise the majority of WHO Member States, face additional difficulties in attending to their poor population in need of medicines.

I couldn't organize a patent database to provide information to these countries because the most important target for the WHO was to establish the differential pricing policy for ARVs medicines. Indeed, in my opinion, to solve the access problems surrounding these medicines, it is essential to

improve local production capability in order to produce them within quality standards. However, to achieve this goal, it is necessary to truly focus on it.

The aforementioned factors are transforming the WHO into a bureaucratic organization and, consequently, the WHO is making much less progress in favor of the worldwide poor population. In other words, the WHO could do much more to benefit poor people by seeking a balanced position between their members.

From my viewpoint, the spotlight on the status of a patent is a very important issue, because this tool provides means to the governmental and private industry institutions to take decisions on drug production and procurement.

I believe that the mission of the WHO should be to do everything necessary to decrease the inequities in health between countries.