

Drug donations: treat or treatment?

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The global pharmaceutical market for cancer is growing rapidly but largely passes low- and middle-income countries by. Do drug donation and preferential pricing schemes reach patients in need, or are they a placebo?

According to marketing specialists IMS, the global pharmaceutical market grew by 7% in 2005 to US \$602 billion. Of this, 81% was spent in the ten biggest drug markets and just 19% in the countries where most people live.

Asia, Africa and the Pacific accounted between them for 8.2% of the global drug market while Latin America accounted for only 4.2%, despite record growth in both areas.

Cytostatic drugs were the fastest growing sector, with a growth of 18.6% over 2004, and a global value of \$28.5 billion. IMS reported that more than 2,300 products were in clinical development, including 96 oncology products in phase III clinical trials or pre-approval stage.

The fastest growing markets, experiencing double-digit growth, were China, Korea, Mexico, Russia and Turkey and, according to IMS, pharmaceutical manufacturers are working in these emerging economies “to address unmet healthcare needs”. However, the healthcare needs of the world’s poorest countries are not being addressed in this equation.

A report compiled by Oxfam, VSO and Save the Children (*Beyond Philanthropy: The pharmaceutical*

industry, corporate social responsibility and the developing world, 2002) challenged the pharmaceutical industry to improve its efforts to tackle the health crisis in developing countries. The report called for a tiered pricing system or more flexible interpretation of intellectual property rights to enable better access to medicines, rather than philanthropic ventures. “Recent price reduction offers represent a welcome step forward, but as ad-hoc commitments, they cannot achieve the predictability, sustainability and efficiency necessary to meet the needs of developing countries.”

PATENT LICENSING

Innovative cancer drugs are subject to patent licensing, which protect pharmaceutical companies that have spent millions on a drug’s development, allowing them 20 years after the drug is invented to recover their costs and make profits. (In practice, the companies get less time than this because they lose the time they were waiting for approval.) But patents keep prices high and put the drug out of reach for people and countries on low incomes. In 2005, when India passed a Patent (Amendment) Bill as a condition of joining the World Trade Organization

(WTO), it had to take hydra (a generic form of Glivec used to treat chronic myeloid leukaemia) off the Indian market, although this is still being disputed in the Indian courts.

Yogendra Kumar Sapru, chairman of the Indian Cancer Patients Aid Association, told *Tehelka* newspaper: “Under the new law, new medicines will be available only to the rich. If a patient develops resistance to the first generation of drugs, it will be impossible to avail new drugs at a cheaper cost.”

Some of the world’s least-developed countries have a WTO exemption from drug patents until 2016. Bangladesh, for one, is using this period to develop a rapidly growing generic drug industry worth \$500 million in 2005 and growing at 10% a year.

Making generic versions of innovative medicines available would appear to be a useful approach to solving drug access issues in countries with limited resources. However, generic drugs are not without their problems.

It is difficult to be sure about the quality and strength of some generic drugs. Often doctors have to prescribe twice the amount of a branded product. There is a clear need to ensure

quality, so that patients in developing countries do not end up with a sub-standard product.

In poor countries, cancer drugs are rarely paid from the public purse but by individual patients. Local charities spring up to help to defray these costs. The Kidwai Memorial Institute of Oncology in Bangalore in Southern India is one of many hospitals to set up its own Cancer Drug Foundation “to help thousands of poor and deserving cancer patients who need costly anti-cancer drugs for treatment.” In Cameroon, Paul Ndom, head of medical oncology at Yaoundé General Hospital, established the Solidarity Chemotherapy Association (SOCHIMIO), whose members can buy anti-cancer drugs at half the normal price.

PATIENT ASSISTANCE PROGRAMMES

The response of the pharmaceutical industry to criticism has been the development of Public Private Partnerships, which provide preferential pricing or no-cost drugs to low-income countries.

Novartis Oncology describes its GIPAP programme for Glivec (imatinib) as “one of the most generous and far-reaching international patient assistance programmes ever developed for a breakthrough cancer therapy”. By September 2006, 18,300 patients with chronic myeloid leukaemia (CML) or gastrointestinal stromal tumours (GIST) had received Glivec free of charge in 81 countries. Novartis ships the drug to treatment centres that demonstrate oncological

and haematological expertise and diagnostic and monitoring capabilities. Physicians must register with the not-for-profit Max Foundation to enrol patients who meet criteria set by Novartis. These stipulate that the patients must be properly diagnosed, the physician must be qualified to treat CML and be willing to follow guidelines, and the patient must not have the means or the insurance to pay for the drug.

These guidelines meet the WHO Guidelines for Drug Donations (http://whqlibdoc.who.int/hq/1999/WHO_EDM_PAR_99.4.pdf), which say that donations should:

- Benefit the recipient and be based on expressed need
- Be made with respect for the wishes and authority of the recipient
- Have no double-standards in quality
- Be based on effective communication between donor and recipient

The GIPAP scheme reaches significant numbers of patients, but has been criticised on a number of fronts.

First, it is donor driven, rather than being based on a needs assessment in receiving countries. It therefore distorts priorities, say critics, as doctors devote more attention to this cancer simply because they can access treatment.

The Indian Cancer Patients Aid Association has been critical, saying that the drug reaches few patients. Association chairman Sapru said: “Less than 2% of patients have availed the GIPAP programme.”

However, Axios International, which administers the GIPAP pro-

gramme for Novartis in more than 40 countries, says that low uptake cannot be blamed on Novartis. Chief Axios CEO Joseph Saba says: “In India, I would be surprised if it is more than 10% of patients, but not because Novartis is denying the drug. Very often we do not have access to these patients because they are not diagnosed and referred for inclusion in the programme.”

A SPECIALISED HOSPITAL

Axios has wide experience of drug donation schemes in HIV as well as cancer, and runs AccessToTreatment.org a portal – through which institutions in least-developed countries can access medical products from four companies (Abbott Laboratories, Boehringer Ingelheim International, Novartis, and Pfizer). By March 2006, 421 institutions in 92 countries had become involved in such programmes, benefiting more than 3 million patients.

Saba says: “At this stage, drug donations programmes are not so significant in relation to cancer in a broad sense. However, as more treatments to cure or stabilise cancer are discovered, the need for donations or other programmes to increase access becomes more urgent. Glivec was the first breakthrough drug; that is why we were very interested in collaborating with Novartis.”

Axios also designed and implemented the AstraZeneca breast cancer initiative to create a reference centre for breast cancer at the Tikur Anbessa Specialised Hospital in Addis Ababa,

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Ethiopia. AstraZeneca made a cash donation to strengthen local infrastructure, and provides Nolvadex (tamoxifen) and Arimidex (anastrozole) through a drug donation programme.

EMPHASIS ON MANAGEMENT

Karol Sikora acts as adviser to AstraZeneca and has been closely involved in their support for Tikur Anbessa. He says that the emphasis has been on setting up a management system that works in the country, rather than on providing drugs alone.

“Getting a plane and bringing thousands of tamoxifen tablets would, I think, really be of no value. One needs to have guidelines of management. The job is not about dumping drugs in a country but of making sure that the drug gets used effectively.”

As part of the three-year programme to raise the capacity of the team at the hospital, a feasibility workshop was held in Addis Ababa fol-

lowed by a workshop on pathology. Ethiopian doctors also began the process of sifting through international guidelines to sort out what was desirable and feasible in their setting. An institution-based cancer registry has been established. In 2007 the plan is to declare the University hospital as the reference centre.

Sikora says that strong project management put local people in control. “The most important thing is getting the local teams involved so that they feel it is their project. That is the problem with a lot of drug donation programmes. Companies want to get involved in the distribution, and they come with good meaning, but the local people feel that it is not their project.”

Drug donation and preferential pricing programmes bring undoubted benefits, but do not meet the needs for cancer treatment for the majority of people in developing countries. That is why, say campaigners, changing trade rules to limit patent life and

allow local licensing of generic drugs is essential. Médecins Sans Frontières (MSF) says: “We are talking about systematic long-term medicines provision for about 90% of the world’s population. You can’t deal with that on a donations basis. It is not realistic.”

However, Saba from Axios says: “Drug donations programmes do have a future as part of increasing access to medicines in developing countries. They provide an opportunity to improve the ability of local institutions to diagnose and treat patients, as well as strengthen their reporting and forecasting processes to ensure a continuous supply of medicines. They also establish a relationship between the company and the country, to learn better ways of making the drug available. It is an emerging process. At the end of the day, we are working to improve the availability of drugs for patients.”

THE NEED FOR OPIOIDS

Not all drugs are expensive. Opiates such as morphine and codeine are a key weapon in pain relief and hugely important in successful palliative care. They can be produced cheaply and without patent restrictions in all parts of the world.

Pain relief is not the only unmet pharmaceutical need affecting cancer patients in low- and middle-income countries. But it is a good start, and countries can do something about meeting this need, without having to resolve global trade problems.

GLOBAL PHARMACEUTICAL SALES BY REGION, 2005

World audited market	2005 Sales (US\$bn)	% Global sales	% Growth year-over-year (constant \$)
North America	\$ 265.7	47.0	5.2
Europe	\$ 169.5	30.0	7.1
Japan	\$ 60.3	10.7	6.8
Asia, Africa and Australia	\$ 46.4	8.2	11.0
Latin America	\$ 24.0	4.2	18.5
Total IMS audited*	\$ 565.9	100%	6.9%

* Source: IMS MIDAS, MAT Dec 2005