

International

India sets precedent for overcoming drug price barriers

In a landmark case, the Indian Patent Office last month (12 March) issued the first-ever compulsory licence to a generic drug manufacturer, effectively ending German pharmaceutical Bayer's monopoly in India on the drug sorafenib tosylate, used to treat kidney and liver cancer.

The Patent Office acted on the basis that not only had Bayer failed to price the drug at an accessible and affordable level, it was also unable to ensure that the medicine was available in sufficient and sustainable quantities in India. 'We've been following this case closely because newer drugs to treat HIV are patented in India, and as a result are priced out of reach,' said Dr Tido von Schoen-Angerer, Director of the Médecins sans Frontières (MSF) Access Campaign. 'But this decision marks a precedent that offers hope: it shows that new drugs under patent can also be produced by generic makers at a fraction of the price, while royalties are paid to the patent holder. This compensates patent holders while at the same time ensuring that competition can bring down prices.' Competition from the generic version will bring the price of the drug down dramatically in India, from over R39 600 per month to close to R1 260 per month – a price reduction of nearly 97%. 'This decision serves as a warning that when drug companies are price gouging and limiting availability, there is a consequence: the Patent Office can and will end monopoly powers to ensure access to important medicines,' said Michelle Childs, Director of Policy/Advocacy at the MSF Access Campaign. 'If this precedent is applied to other drugs and expanded to include exports, it would have a direct impact on affordability of medicines used by MSF and give a real boost to accessing the drugs that are critically needed in countries where we work. 'Under the World Trade Organization's TRIPS Agreement which governs trade and intellectual property rules, compulsory licences are a legally recognised means to overcome barriers in accessing affordable medicines. The Indian decision in fact mirrors similar

moves made in other countries, including the USA.

In February 2011, the US Patent Office decided not to prevent a 'generic' medical device used for skin grafts from being sold, but rather insisted that its manufacturer pay royalties to the patent holder. 'Behind this action is the idea that the public has a right to access innovative health products and they should not be blocked from benefiting from new products by excessive prices,' said Michelle Childs. 'If more compulsory licences are granted in this vein, the answer to the question of how to ensure affordable access to new medicines could radically shift.'

'Today's system is one where new medicines are patented, and drug companies aggressively defend their monopolies, at the expense of patients who can't afford the high prices charged. Instead, we could move to a more equitable system where new medicines have multiple producers, who each pay royalties to the patent holder, helping them not only to recoup their development costs but ensuring that people in developing countries have access. This move marks the first time India's patent law has been used to allow generic production when a drug is unaffordable. More generic companies should now come forward to apply for compulsory licences, including on HIV medicines, if they can't get appropriate voluntary licences,' said Dr Tido von Schoen-Angerer.

Africa

Tanzanian doctors suspend strike

Tanzanian doctors have suspended a nationwide strike after the country's president met union representatives to defuse a row with government, the doctors' association recently reported. The more than 1 000-strong Medical Association of Tanzania (MAT) is demanding better pay and conditions and the sacking of Health Minister Hadji Mponda and his deputy, whom they accuse of being 'enemies of doctors and the health sector as a whole'.

Hundreds of doctors went on strike, ignoring a court order to return to work,

forcing public hospitals across the country to turn away patients and suspend normal services.

'We would like to announce to the Tanzanian public that we are returning to work ... while the president addresses our demands,' MAT said in a statement. Tanzanian doctors earn a starting salary of 957 900 shillings (R42 000) a month, compared to members of parliament who earn about three times as much plus allowances. East African governments face mounting pressure from public sector workers and others over the rising cost of living. Earlier this month Kenya said it would sack 25 000 striking public health workers. Tanzanian President Jakaya Kikwete met union officials for 7 hours, a union spokesman said. 'The government has been urging doctors to return to work and save lives ... We are happy to see that doctors have now finally heeded this call,' Kikwete said in a televised national address. Previous talks with senior government officials, including the prime minister, ended in stalemate. MAT said doctors also wanted more equipment and medicines to be made available in hospitals. Teachers and some other public sector workers are also threatening industrial action. Tanzania's inflation rate hovered near 20% at the end of last year. The government hopes to bring it down to single digits by June this year.

Newer and more effective drugs for HIV/AIDS

New drugs are in the pipeline for the better treatment and management of HIV/AIDS, a meeting held in Cape Town to discuss how best to improve healthcare in Africa heard. While efforts to reduce the burden of disease in Africa over the last 10 years had improved, malaria, tuberculosis (TB) and HIV/AIDS are still critical issues facing African countries.

Sir Richard Feachem, Director of the USA-based Global Health Group, said newer and better drugs were in the pipeline. 'Better means down to one pill a day and, secondly, the drug is killing the virus more effectively and, thirdly, less side-effects. In

the past we have had problems with the side-effects of HIV drugs. We still do, but much less because the quality of drugs has improved,' he said. In the case of malaria, new diagnostics are now used to provide rapid and accurate tests for those in remote areas. Unni Karunakara, from Médecins sans Frontières (MSF), said this was a 'breakthrough' for Africa. 'Before, we had to rely on microscopes, whereby people had to go to the health centers - and that's if they even had one and someone who can draw blood. And, previously, people with malaria were treated symptomatically and many did not have malaria. So, now we are accurate. We are treating people with the disease. That is a huge improvement,' Karunakara said. Yet malaria still remains a huge problem on the continent. 'It kills about 800 000 children every year. Children who do not die of it are weakened by malaria. This is because they are out of school a lot due to episodes of malaria. Their cognitive development is impaired because of frequent attacks. So, malaria produces generations who have not benefitted from schooling to the degree they might have.' But, with insufficient funding curbing the burden of disease is difficult, particularly as foreign funding for health care in Africa was drying up.

'Foreign companies are deterred from investing. If they think that their new investment will be in a highly malarious area, they go somewhere else. Malaria costs Africa many billions of dollars every year and getting rid of it will be a huge boost not only for human welfare, but for the economy of Africa,' said Feachem. With international funding cuts, domestic funds were just insufficient to carry the burden of disease single-handedly. 'Many African countries have reduced their domestic expenditure on HIV and malaria because so much international money has come in that they have used the domestic money for some other priority. This is now causing a crunch because the international money is declining and the domestic money is not sufficient.'

'I think every African government needs to prioritise; and members of parliament and

ministers of finance to begin to systematically increase the domestic expenditures on health to reduce the dependence on international money, particularly in this era of international money declining,' added Feachem. Karunakara said that financial cut-backs could jeopardise years of hard work.

'We have come a long way on putting more people on treatment and there is progress within all of the chronic diseases ... The deaths of malaria having gone down and curing many more cases of TB and many more on treatment. But, now we are in a situation where money is a problem and this is a worrying moment because we have a momentum to keep up if we want to conquer the epidemic. This is not the moment to pull back; international donors must continue their funding and keep the progress we have made,' he said.

South Africa Premium rise is only option – Medshield

A staggering 61.93% premium increase on one of Medshield's medical aid options has left members having to pay out more for medical expenses every month. But the scheme says the hike was necessary for its self-sustainability. Medshield upped monthly premiums on one of the income-based options from R1 392.25 to R2 254.50 for a single member. The member, an 80-year-old pensioner who has been on this option for 6 years, is receiving chronic medication as he suffers from a chronic heart condition. The scheme covers about 50% of his medical expenditure a month and the remainder is up to him. 'I spend about R1 000 a month from my own pocket. I'm living off a small pension and now if I have to pay 61.9% more, how am I going to afford to buy my medicine? What I can't handle is more financial problems than I already have,' he said. But Medshield said the income-based options had proven difficult to sustain and therefore the scheme decided to discontinue the low-income bands of two of its offered options in line with section 33 of the Medical Schemes Act. The act states that all medical scheme

options should be self-supporting in terms of membership and financial performance. Medshield's executive principal officer, Duduza Khosana, said: 'The ability to manage risk effectively is important to the longevity of a medical scheme, and should be in the interest of all the members belonging to that scheme. This process plays a key role in ensuring that medical schemes maintain healthy solvency levels and have a favourable claims-paying ability.' She said the scheme made all efforts to keep contribution raises aligned to inflation, but healthcare cost increases universally outstripped inflation. Health inflation was running at 10.8% this year and consumer inflation at 6%. According to its budgetary projections, for Medshield to break even in 2012, an increase of 18.5% was needed. However, a weighted increase of only 12.1% was implemented. Medshield said most of its members received single-digit contribution increases. Council for Medical Schemes (CMS) chief executive Monwabisi Gantsho said data in its possession and published on the CMS website indicated that Medshield was granted an overall contribution increase of 12% for 2012. 'We are not aware of an increase of this magnitude and we will inquire at the scheme itself,' he said. Gantsho said it was inconceivable how a scheme would implement a contribution increase of 61.9% unless it had been done without consulting the CMS, in which case it became a compliance matter. Heidi Kruger, the spokeswoman for the Board of Healthcare Funders, said Medshield had found that members on the lowest salary band claimed much more than they contributed. Thus, it was unfair on other members and made the entire option unsustainable. Kruger said the increase did highlight the issue of the registrar's insistence that schemes must pay in full for prescribed minimum benefit conditions.

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