

fact that the agreement reached by 146 member states of the World Trade Organization (WTO) on 30 August applies to all medicines. But they warned that the new procedure could be time-consuming and bureaucratic, and that the drugs may still be too expensive for some countries.

The UN Secretary-General Kofi Annan, issued a statement to the WTO meeting in Cancun, Mexico, days after the deal was clinched in Geneva, saying there was a "moral imperative" for each WTO member state to implement the agreement without delay.

Dr Jonathan Quick, Director of Essential Drugs and Medicines at the World Health Organization in Geneva, said the deal solved only part of the problem to getting affordable drugs, for example to AIDS/HIV patients in the poorest African countries. There were other outstanding issues, such as distribution and a lack of qualified staff. "Now we have the deal," he said, "it's the starting point we have, and we're looking ahead. The point is to implement it, monitor it, see if it works and adjust it if it doesn't."

Campaigners fear that poor countries in Africa, Asia and Latin America, which were supposed to benefit from the deal, may face unnecessary red tape and have to waste precious time to fulfil requirements, such as proving they have no manufacturing capability of their own. Generic drug companies too fear they may be slowed down by red tape which could be a disincentive to take on such orders.

Campaigners criticize the agreement, saying it is unrealistic to require manufacturers to declare they are producing drugs for "humanitarian" not "business" reasons, but hope this will be treated as a formality. Other rules threaten to push up the costs of producing copies of patented drugs, as companies have to invest in research to copy the patent before they can go into production. Campaigners fear that rules requiring companies to make their packaging distinctive so that the copies can not be mistaken for the originals and be diverted to developed countries could increase costs too.

These special measures to ensure such drugs are not diverted were included on the insistence of the United States, so as not to undermine the pharmaceuticals market or remove

the incentive for the industry to invest in research on new drugs. Once importing countries and generics manufacturers have cleared all of these hurdles, prices could be prohibitively high for some of the world's poorest countries.

Jonathan Berger of the AIDS law project at the University of Witwatersrand in Johannesburg, South Africa, summed up the view of many campaigners: "It is way too much red tape, and that it is not a feasible solution. Having said that, it can be used, and the onus is on developing countries with manufacturing capacity to make sure that the appropriate legal framework is in place. That way they can act as quickly as possible to satisfy the needs of countries with no manufacturing capacity."

MSF also urged countries to make the most of trade "flexibilities" allowed by the agreement. Small African countries, for example, can group together and place a joint order with a generic drugs company to make this a viable business proposition.

Jonathan Quick said that WHO would do its best to help countries overcome any difficulties with the procedure: "We know there are some administrative issues that have to be dealt with, but we are prepared to work with countries to deal with those."

India and South Africa are among the countries expected to issue compulsory licences to export copies of patented drugs. Brazil, which also has a pharmaceuticals manufacturing capability, has said it is unlikely to export cheap copies of patented drugs under this system, as its drugs industry is heavily subsidized by the government to tackle public health crises at home.

Brazil may, however, use the WTO deal to force European and US drug companies to lower their prices for patented drugs. Other countries may also prefer patented drugs, which have been tried and tested, too. "The agreement gives countries an extra negotiating strength they didn't have before," said an EU diplomat.

Exemptions agreed under the deal on pharmaceutical patent protection for least-developed countries are valid until 2016. While 23 developed countries have said they would not make use of the system, 11 less wealthy

Drug prices may be too high despite WTO deal

A landmark deal that waives international trade rules may work if implemented in good faith, experts say. Poor countries with no manufacturing capability of their own will be allowed to import cheap copies of patented essential drugs under a complex procedure.

Campaigners for access to medicines including aid organizations, Oxfam and Médecins sans Frontières, welcomed the



WHO/S.Granger

Doctor prescribing medication in Mongolia

nations, including Israel, Mexico and Turkey, said they would, but only in emergencies.

The deal agreed by the Trade-Related Aspects of Intellectual Property (TRIPS) council of the WTO, covers all patented products or products made using patented processes in the pharmaceutical sector, including active ingredients and diagnostic kits. Under the agreement, the government of a least-developed country may ask another country such as India or South Africa with a generic drugs industry to issue a “compulsory licence” to produce a particular medicine or pharmaceutical product.

The country with the generic drugs industry notifies the TRIPS council as to which product it intends to export and to which country and in what quantity. It must specify the type of packaging to ensure these copies of patented products are easily identifiable. After the TRIPS council

has received this information, some WTO member states may ask questions and may even object under the terms of the TRIPS agreement.

Once the manufacturer gets the go-ahead, it can start to produce cheaper copies of the patented products and drugs, and export them to the country or group of countries that requested them. Dr Quick said it would be at least a year before needy people in a poor country that uses the system finally receive such drugs. ■

Fiona Fleck, *Geneva*