

## STATEMENT TO TRIPS COUNCIL ON ACCESS TO MEDICINE, IN THE CONTEXT OF AVIAN FLU PANDEMIC AND OTHER EMERGENCIES

**Consumers International**  
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In the view of Consumers International, the provision for countries to opt out of importing generic drugs to address public health crises does not serve the interests of consumers anywhere. It creates a strong likelihood that the costs of producing stockpiled medicines will be high, particularly for active pharmaceutical ingredients, which are very sensitive to economies of scale and competition. It will also reduce the capacity to produce. It will clearly result in lower levels of stockpiles everywhere. This puts everyone north and south at risk of potentially preventable death and suffering should an avian flu pandemic occur.

As this week's WTO Council for TRIPS meets to review the effectiveness of the implementation of the 30 August 2003 decision, Consumers International urges WTO members to consider the simple question: 'Is the current system working?' In light of the current situation with respect to avian flu, Consumers International requests the TRIPS Council to immediately issue a clarification on how members who have opted-out of the 30 August 2003 decision may opt back in.

Furthermore, Consumers International asks the members of the WTO TRIPS Council to immediately begin a review of the intellectual property rules and practices that are in place by members to address public health problems, including but not limited to the case of a possible avian flu pandemic.

This review should include:

- a. an assessment of the medical threats to the public health that an avian flu pandemic, SARS or other emerging health threats present
- b. an assessment of the degree to which WTO members have prepared for such cases, including the stockpiling of medicines for an avian flu pandemic or other important threats
- c. the degree to which the actual management of intellectual property policies and practices are consistent with the 2001 Doha mandate that WTO members implement laws in a manner that is consistent with the protection of public health and access to medicine for all
- d. the degree to which the TRIPS Agreement and its implementation by WTO members should be modified in order to ensure that effective measures are taken to protect the public from such emergencies.

### **Explanatory note**

As noted in the excellent WTO FAQ on compulsory licensing [1] compulsory licensing of patents is consistent with the TRIPS agreement, and WTO members are free to choose the grounds for doing. Despite countless news reports to the contrary, compulsory licensing is not limited to cases of emergencies or even to public health. That said, it is timely and important to highlight public health emergencies as an important special case, and one that illustrates: 1) the vast gap between official rhetoric and performance in terms of essential protections for public health, and 2) flaws in the 'solution' to the problem of exporting medicines manufactured under a compulsory license that is being discussed this week in the WTO TRIPS Council.

Today the world is waking up to the seriousness of yet another serious global health problem - that of a possible avian flu pandemic. If you believe the reports by the public health experts, 'the probability that a pandemic will occur has increased.' This is how the WHO describes an influenza pandemic: [2]

'Influenza pandemics are remarkable events that can rapidly infect virtually all countries. Once international spread begins, pandemics are considered unstoppable, caused as they are by a virus that spreads very rapidly by coughing or sneezing. The fact that infected people can shed virus before symptoms appear adds to the risk of international spread via asymptomatic air travellers.

The severity of disease and the number of deaths caused by a pandemic virus vary greatly, and cannot be known prior to the emergence of the virus. During past pandemics, attack rates reached 25-35% of the total population. Under the best circumstances, assuming that the new virus causes mild disease, the world could still experience an estimated 2 million to 7.4 million deaths (projected from data obtained during the 1957 pandemic). Projections for a more virulent virus are much higher. The 1918 pandemic, which was exceptional, killed at least 40 million people. In the USA, the mortality rate during that pandemic was around 2.5%.

Pandemics can cause large surges in the numbers of people requiring or seeking medical or hospital treatment, temporarily overwhelming health services. High rates of worker absenteeism can also interrupt other essential services, such as law enforcement, transportation, and communications. Because populations will be fully susceptible to an H5N1-like virus, rates of illness could peak fairly rapidly within a given community. This means that local social and economic disruptions may be temporary. They may, however, be amplified in today's closely interrelated and interdependent systems of trade and commerce. Based on past experience, a second wave of global spread should be anticipated within a year.

As all countries are likely to experience emergency conditions during a pandemic, opportunities for inter-country assistance, as seen during natural disasters or localized disease outbreaks, may be curtailed once international spread has begun and governments focus on protecting domestic populations.'

The few reported human cases of avian flu have been deadly. The WHO maintains a running report of the 'Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO.' On 20 October 2005, WHO reported that 118 cases had been reported. Of the 118 persons who were infected, 61 died - over half the total.

According to WHO, despite the increasing risks, the world is not prepared for a pandemic.

Despite an advance warning that has lasted almost two years, the world is ill prepared to defend itself during a pandemic. WHO has urged all countries to develop preparedness plans, but only around 40 have done so. WHO has further urged countries with adequate resources to stockpile antiviral drugs nationally for use at the start of a pandemic. Around 30 countries are purchasing large quantities of these drugs, but the manufacturer has no capacity to fill these orders immediately. On present trends, most developing countries will have no access to vaccines and antiviral drugs throughout the duration of a pandemic.

A variety of efforts are underway to identify possible vaccines or medicines that can be used to reduce the damage from a pandemic. Health experts are calling for huge increases in public sector subsidies and directed research to come up with new treatments, and to stockpile certain medicines that could be used now. According to WHO:

'Two drugs (in the neuraminidase inhibitors class), oseltamivir (commercially known as Tamiflu) and zanamivir (commercially known as Relenza) can reduce the severity and duration of illness caused by seasonal influenza. The efficacy of the neuraminidase inhibitors depends on their administration within 48 hours after symptom onset. For cases of human infection with H5N1, the drugs may improve prospects of survival, if administered early, but clinical data are limited. The H5N1 virus is expected to be susceptible to the neuraminidase inhibitors. . . .

For the neuraminidase inhibitors, the main constraints - which are substantial - involve limited production capacity and a price that is prohibitively high for many countries. At present manufacturing capacity, which has recently quadrupled, it will take a decade to produce enough oseltamivir to treat 20% of the world's population. The manufacturing process for oseltamivir is complex and time-consuming, and is not easily transferred to other facilities'

So far, most fatal pneumonia seen in cases of H5N1 infection has resulted from the effects of the virus, and cannot be treated with antibiotics. Nonetheless, since influenza is often complicated by secondary bacterial infection of the lungs, antibiotics could be life saving in the case of late-onset pneumonia. WHO regards it as prudent for countries to ensure adequate supplies of antibiotics in advance.'

Given these sobering reports, what is actually being done? WHO has received a promise for a donation of some 3 million doses of oseltamivir from Roche. The United States has a target of providing vaccines for 20 million persons and antivirals for another 20 million, but only a fraction of this is actually available today.

How much is needed? Opinions vary. Dr Henry Miller of the Hoover Institute is calling for a US stockpile of 10 billion doses of oseltamivir, in order to provide 100 days of medicine for 100 million persons, to ride out the 'first wave' of a major pandemic.<sup>[3]</sup> This is more than three thousand times the proposed WHO stockpile, which is now the main resource for the more than 5.2 billion people living in developing countries. As noted above by WHO: 'On present trends, most developing countries will have no access to vaccines and antiviral drugs throughout the duration of a pandemic.'<sup>[4]</sup>

There are two causes for the small stockpiles - capacity and price. Roche and Gilead, the two firms that control the relevant patents on oseltamivir, have been unwilling or unable to expand production of the medicine, and have yet to freely license their patents to generic suppliers, because Roche is afraid that liberal licensing of the patents to generic suppliers will undermine its monopoly. WHO now estimates that it would take a decade for Roche to manufacture the desired oseltamivir stockpiles. There also has been very little demand from governments for stockpiles of oseltamivir, because of the high prices that Roche has charged - US\$6 per dose in some press reports.

Governments all over the world are now making announcements that they will consider compulsory licenses for the oseltamivir patents. These include members of the US Congress, as well as governments in Argentina, Korea, the Philippines and Thailand. Roche is now carrying out a public relations and damage control effort to salvage as much control over the patents as possible. Of course, the situation with Roche and oseltamivir is only part of the story. There is certainly a need for addressing increased generic supplies of zanamivir and other medicines, for example.

None of the governments who are talking about issuing compulsory licenses on these patents have actually done so, and none are likely at the point where they have any idea of how to set remuneration for purchases of generic products for stockpiled use. The WTO has admirably created a useful FAQ on compulsory licensing, in response to this unfolding crisis - something that that WIPO has not done. But none of the UN agencies have addressed some of the glaring problems that will have to be done if compulsory licensing is actually implemented to address the pandemic.

One particular problem concerns the nature of the 30 August 2003 decision regarding the implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health. While there were many problems with the 30 August 2003 Decision (see appendix below), the one point we will highlight today concerns the 'opt-out' provision that countries may elect as importers, and the mandatory 'opt-in' provisions for both importers and exporters.

First, the WTO TRIPS council should note and reflect upon the fact that no countries have notified the WTO that they intend to use the 30 August 2003 decision as either an importer or an exporter. Given the current situation, this raises profound questions about the way the global community perceives the 30 August 2003 decision. With populations at a growing risk of a public health emergency, and the clear evidence that stockpiles of medicine are far under-sourced, the lack of WTO notifications is damning evidence that the current system is not working.

Second, and harder to explain, is that fact that 23 countries opted- out as importers, and another ten were required to opt-out by the European Commission as a condition of joining the EU. As a consequence of this fact, hundreds of millions of people will be likely be unable to obtain generic medicines for stockpiles, because they will not have the domestic capacity to manufacture the needed medicines. These include virtually everyone from the United States to Latvia.

Countries that have opted-out as importers, even in cases of national emergency:

Australia, Austria, Belgium, Canada, Czech Republic, Cyprus, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Netherlands, New Zealand, Norway, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, United Kingdom and the United States.

The decision to opt-out of the 30 August 2003 decision, even for a national emergency, is either evidence that the decision is highly unworkable and irrelevant for these countries, or that trade officials want to allow their own populations to go without

life saving medicines in a time of emergency - a result clearly contrary of obligations of Paragraph 4 of the Doha Declaration on TRIPS and Public Health. It also the case that there have been no press reports about this deplorable situation - denying people in those countries with the information they need to influence democratic institutions.

The fact that the 33 countries are opting-out of the 30 August 2003 decision has the effect undermining the legitimacy of the 30 August 2003 decision, and is partly responsible for the reticence of developing countries to openly use this decision.

Consider a possible scenario of an avian flu pandemic appears within the next few years. Even if some countries have sufficient or even excessive stockpiles of generic medicines, they would not be able to share medicines across borders. Estonia, Poland, UK, Greece, Latvia, France, the Netherlands, New Zealand, Australia, the United States and other members of this group of opt-out countries will each be in a state of autarky, an ironic obligation to be imposed on them by an organisation officially devoted to liberalised trade. It also means that none of the opt-out countries will be customers of the generic suppliers in developing countries, except under voluntary licenses from patent owners, reducing economies of scale for the developing country generic industries. Thus, the possibility of building strong independent generic manufacturing capacity will be undermined. Of course, this is probably what some countries were seeking when they created the opt-opt possibility.

In the view of Consumers International, the opt-out provision does not serve the interests of consumers anywhere. It creates a strong likelihood that the costs of producing stockpiled medicines will be high, particularly for active pharmaceutical ingredients, which are very sensitive to economies of scale and competition. It will also reduce the capacity to produce. It will clearly result in lower levels of stockpiles everywhere. This puts everyone North and South at risk of potentially preventable death and suffering should an avian flu pandemic occur.

In addition, Consumers International urges TRIPS Council members to consider the implications of terms of exclusivity for the protection of pharmaceutical test data on access to medicines. Under Article 39.3 of the TRIPS Agreement, members are required to protect pharmaceutical test data used for marketing approval by regulatory authorities against unfair commercial use. However, in the implementation of Article 39.3, certain WTO members have chosen to grant exclusive rights to rely upon pharmaceutical test data which is used for the registration of medicines. This practice erects barriers to generic competition because it is expensive, time consuming and sometimes unethical to replicate the tests.

The term of such protection generally ranges between five and ten years in countries that have adopted this system. In the event of a public health crisis, such type of legislation would mean that countries would have to wait five to ten years depending on the period of exclusive rights before there could be generic competition. Consumers International believes that any country that creates exclusive rights in health registration data undermines the mandate of paragraph 4 the Doha Declaration which asserts that the TRIPS Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' Certainly, such an approach would put populations at risk in the case of an avian flu pandemic.

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#### Footnotes:

[1] Trips And Health: Frequently Asked Questions, Compulsory licensing of pharmaceuticals and TRIPS,

[http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

[2] Avian influenza frequently asked questions, updated 19 October 2005,

[http://www.who.int/csr/disease/avian\\_influenza/avian\\_faqs/en/index.html](http://www.who.int/csr/disease/avian_influenza/avian_faqs/en/index.html)

[3] 15/9/05, HHS Buys Vaccine and Antivirals in Preparation for a Potential Influeza Pandemic, News Release.

<http://www.hhs.gov/news/press/2005pres/20050915.html>

[4] Henry I Miller, MD, Preparing for the Pandemic, 10/17/05, <http://www.techcentralstation.com/101705B.html>

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#### About Consumers International

Consumers International (CI) supports, links and represents consumer groups and agencies all over the world. It has a membership of 234 organisations in 113 countries. It strives to promote a fairer society through defending the rights of all consumers, especially the poor, marginalised and disadvantaged, by supporting and strengthening member organisations and the consumer movement in general campaigning at the international level for policies which respect consumer concerns.

## **Consumers International Position on Implementation of Paragraph 6 of the Doha Declaration on TRIPS and Public Health**

Consumers International welcomed the Doha Declaration on the TRIPS Agreement and Public Health in 2001. The declaration affirmed the primacy of public health. It also confirmed the legitimacy and importance of the use of compulsory licensing of patents to protect public health and, most importantly, 'the freedom to determine the grounds on which such licences are granted.' However, there is continuing concern about countries that lack the capacity to efficiently manufacture medicines, and about the limitations on the export of generic medicines to such countries.

The Doha Declaration mandated the TRIPS Council to find practical solutions to these problems by December 2002. This deadline was not met. An imperfect compromise decision by the General Council on 30 August 2003, which was accompanied by a reading of a Chairman's statement on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health 'provided for an interim waiver of Article 31(f) of the TRIPS ( which mandates that production under compulsory licensing is to be predominately for the domestic market).'

This waiver is intended to allow countries with manufacturing capacity to make and export pharmaceutical products to other countries with public health needs, notwithstanding the restriction in Art 31 (f) to predominately domestic markets. The decision stated that the waiver will remain effective until an amendment has come into effect to replace it, and, that members should commence negotiations for an amendment that will provide a 'permanent solution' to this issue. Negotiations on transposing the waiver decision into an amendment to the TRIPS Agreement are still on going within the TRIPS Council despite the passing of two deadlines to reach such an agreement. The African Group has submitted two proposals for amendment at the recent TRIPS council, which received wide support from developing countries but are opposed by a number of developed countries. There is no agreement on the shape and format of the amendment.

The 30 August 2003 decision by the General Council was widely criticised by public health groups on the grounds that it was restrictive, complex, and protectionist. It allows wealthy countries to export to poor countries, while restricting imports from poor countries to rich countries. It does not explicitly recognise insufficient economies of scale or comparative advantage as a basis for determining eligibility for importing countries, even though the realisation of efficient scale economies and favourable comparative advantage is one of the main putative advantages of liberalised trade. Decisions regarding remuneration are made in exporting rather than importing countries. The procedures for compulsory licensing for export for public health reasons are far more complex and burdensome than are required for compulsory licensing for domestic use, or when compulsory licenses are issued as a remedy to anticompetitive practices under Article 31.k and 40 of the TRIPS.

### **Consumers International recommends:**

The Africa group proposal seeks to solve some of the problems with the 30 August 2003 decision by the General Council, and should be supported.

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