TRIPS & PUBLIC HEALTH

The 30 August WTO General Council Decision, WT/L/540, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health"

Paper by the Commonwealth Secretariat

BACKGROUND

1. Commonwealth Heads of Government at Aso Rock welcomed the 30 August 2003 WTO agreement on affordable drugs and called for its interpretation and implementation in a manner that makes appropriate drugs available at low cost to poor countries. Heads of Government recognised:

> "that diseases such as HIV/AIDS, malaria and tuberculosis are not only health problems but are also development issues. ... [and called] for reforms at the national level to create effective health delivery systems, as well as adequate external support to achieve this." (Aso Rock Declaration).

2. Commonwealth developing countries are among the highest HIV/population ratio worldwide: "the threat from HIV/AIDS is especially great in Sub-Saharan Africa, which has two-thirds of the world's 40 million persons living with HIV/AIDS, and in the Caribbean." (Aso Rock Declaration) Commonwealth developing countries with insufficient or no manufacturing capacities in the pharmaceutical sector – mainly small states and least developed countries (LDCs) – require technical assistance at both the national and regional level, if they are to benefit from the Decision.

3. The 30 August 2003 WTO General Council Decision, WT/L/540, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health" addresses the instruction of the WTO Ministerial Conference to find an expeditious solution to the problem of the difficulties that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement. WTO Ministers at Doha agreed "that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the 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."

4. The 30 August Decision is designed to be part of the wider national and international action to address problems associated with access to medicines. Many fear that the problems encountered in making drugs available to those who need them at affordable prices may be further exacerbated with the end of WTO transitional arrangements for the extension of product patent protection to pharmaceuticals in 2005 (LDCs are excepted until 2016). The TRIPS Agreement allowed countries that had not provided patent protection for pharmaceutical products at the time of its entry into force in 1995 a 10-year grace period, at the end of which (1 January 2005) they were required to introduce a national system for granting product patents.

5. Significantly, concerns have been expressed over the fact that with the expiry of the 2005 deadline, India is now obliged to provide a product patent protection and to review an estimated

7000[1] mailbox patent applications that production of generic versions of medicines in India will be adversely affected, and consequently, its supply to other developing countries. It is worth noting that Indian generic manufacturers are currently the main suppliers of affordable antiretroviral and other HIV-related medicines to many developing countries, and comprise the majority of generic firms on the WHO Prequalification List for antiretroviral products.[2]

6. WT/L/504 offers an important avenue for addressing Members' concerns. The effectiveness of the Decision in fulfilling its objectives will depend on how far in practice the concerned exporting and importing countries are able to implement these procedures effectively.

THE 30 AUGUST 2003 DECISION

7. The Decision elaborates a system that would permit countries with insufficient or no manufacturing capacities in the pharmaceutical sector to import cheaper generic versions made in other countries under compulsory licenses. The system also provides for rules that would enable countries belonging to regional economic groupings (of which at least half of the members are LDCs) to export products imported under the system to other countries in the region and, where the potential exists, gradually develop a pharmaceutical industry that could produce drugs that are needed for the treatment of diseases prevailing in the region. The provisions of the Decision apply to patented products and products manufactured through patented processes that are required for the treatment of all diseases affecting human beings. These terms include "active ingredients necessary for the manufacture of patented products" and the "diagnostic kits" needed for their use.

8. The Decision imposes complimentary obligations on importing and exporting countries. The obligations imposed on importing countries are in fact less onerous than those to be implemented by exporting countries.

9. The importing country is required to make a notification to the Council for TRIPS. The notification shall contain:

- a specification of the names and expected quantities of the products needed;
- a confirmation that the importing country (other than a least developed country), has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products; and
- a confirmation that – where a pharmaceutical product is patented in its territory – the country has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the 30 August Decision on the implementation of paragraph 6 of the Doha Declaration.

10. TRIPS obligations with respect to payment of remuneration to the patent holder by the importing country are waived in respect of those products for which remuneration is paid in the exporting country.

11. Exporting countries are required to implement the following procedures:

- Notification to the Council for TRIPS of the grant of the license, including the conditions attached to it. The notification shall include:
  - the name and address of the licensee,
  - the products for which the license has been granted,

---

1 Estimates from various sources vary between a range of 5000-9000 applications for pharmaceutical and agro-chemical products that are currently filed in the mailbox.

2 See the list of pre-qualified manufacturers and products in http://mednet3.who.int/prequal/ .

* the quantity for which it has been granted,
* the countries to which the products are to be supplied,
* the duration of the license,
* the address of the website where the information is posted.[3]

- The compulsory license issued by the exporting country shall contain the following conditions:

  * only the amount necessary to meet the needs of the importing country may be manufactured under the license; and
  * the entire quantity of this production shall be exported to the country which has notified its needs to the Council for TRIPS.

12. Adequate remuneration shall be paid in the exporting country, taking into account the economic value to the importing country of the use that has been authorised in the exporting country.

13. WTO Members opting to use the system as importing or exporting countries must have in place appropriate domestic regulations to allow for importation or exportation. Canada was the first WTO Member to introduce necessary legislative amendments to facilitate exportation to developing countries seeking to access medicines in the context of the 30 August Decision. Other Commonwealth countries, such as India, have more recently adopted the necessary implementing legislation and/or regulations.

SASD'S ECONOMIC AND LEGAL SECTION (ELS) PROGRAMME OF TECHNICAL ASSISTANCE

14. ELS is implementing a programme of technical assistance for Commonwealth developing countries. The overall project objective is to assist developing countries in establishing appropriate frameworks and effective procedures to implement WTO Decision WT/L/540. ELS initially commissioned nine (9) national case studies.[4] The case studies provide an assessment of the institutional framework and procedures that may have to be built up at the national level and examine the possibilities for regional solutions. The studies were presented at a highly successful workshop held in Geneva in October 2004 bringing together a number of significant actors in the field. The report on the Geneva workshop contains various recommendations on the steps that could be taken at national level and by regional organisations, for the implementation of the provisions in the WTO Decision on Access to Medicines, relating to the development of trade and production of pharmaceutical products in order to meet the requirements for the pharmaceutical products needed for treatment of diseases prevailing in the countries that are members of regional economic groupings.

15. The Workshop's recommendations address issues such as:

- co-operation between countries through pooling of import requirements of pharmaceutical products;

- development of inter-regional trade in imported products by member countries of regional economic groupings;

---

[3] The Decision imposes obligations on the licensed firm/licensee, before shipment begins, to post on a website information relating to the quantities being supplied to each destination and the distinguishing features of the products.

[4] Bangladesh, Barbados, India, Jamaica, Kenya, Mauritius, South Africa, Tanzania and Uganda.

- development of pharmaceutical products on a regional basis to meet public health requirements of the countries in the region;

- development of regional patent systems.

16. The group of Commonwealth developing countries in Geneva has proposed that the Commonwealth Secretariat in conjunction with the ACP Secretariat and the Agency for International Trade Information & Co-operation (AITIC), sponsor a workshop with the aim of examining the practical steps that could be taken to implement the workshop recommendations, *viz.* to develop trade and production in countries with insufficient manufacturing capacities, of pharmaceutical products needed for the treatment of diseases prevailing in the region (taking into account the relevant provisions in the Decision) and for ensuring quality and safety standards of such products. The delegation of Mauritius has offered to provide host facilities. The proposal highlights the need for workshop participants to be selected with a view to ensuring that the deliberations remain practically oriented and result in concrete proposals for investment, to develop production and trade. In this regard, separate discussions are also ongoing with other agencies, such as the German Development Agency (GTZ) which has expressed its commitment to a narrower programme of assistance focused on promoting the development of production capacity in LDCs through taking advantage of TRIPS flexibilities, particularly the 30 August Decision and the Doha Ministerial Declaration on the TRIPS Agreement and public health.

17. The importance of co-operation at the regional level with a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products is an important feature of the 30 August General Council Decision, particularly for smaller Commonwealth members and Africa.

18. ELS is collaborating with strategic partners such as DfID, WHO, WTO and UNCTAD, with a view to defining appropriate legislative systems to promote the effective management of the pharmaceutical cycle in the context of WT/L/504 – at national and/or regional levels. Examples of existing institutional structures for regional co-operation include the Commonwealth Regional Health Community Secretariat in Eastern and Southern Africa, the African Association of Central Medical Stores for Generic Essential Drugs (ACAME) for French-speaking West African countries and the Organisation of Eastern Caribbean States (OECS) in the Caribbean. ELS is engaging with strategic partners in discussions on, *inter alia*, co-ordination mechanisms for bulk procurement (as exists in the Pacific and Eastern Caribbean) as well as regional patenting systems whether based on mutual recognition or other formalised arrangements (such as the African Intellectual Property Organisation (OAPI) and the African Regional Intellectual Property Organisation (ARIPO)).

19. ELS has pursued consultations with a number of strategic partners, including DFID, WHO, the World Bank and UNCTAD. There was overwhelming endorsement of the contribution made by ELS' programme of assistance and agreement on moving forward with work at national and regional levels - the focus moving away from Geneva to capitals. The very positive response to the national case studies - which have been requested by numerous agencies as a reference - provided strong impetus for the commissioning of six regional studies: three in Africa, and one in each of the following regions – Asia, the Caribbean, and the Pacific.

20. The six regional studies build on the work already undertaken at the national level, extending the scope of coverage to facilitate a greater appreciation of the challenges posed to a larger sampling of vulnerable Commonwealth developing countries, with a view to designing appropriate national and/or regional solutions depending on the circumstances, in particular as regards:

- the steps that need to be taken at national, sub-regional and regional levels in order to facilitate trade in essential medicines (i.e. exports and re-exports of imported drugs) between regional partners facing similar health problems;

- the steps that need to be taken at national, sub-regional and regional levels to facilitate joint procurement arrangements for sourcing essential medicines for distribution within smaller jurisdictions, with a view to providing an integrated/co-ordinated response to countries facing similar health problems;

- the potential capacity for the development of production facilities by making judicious use of the right to grant compulsory licences, where this could be implemented on a competitive basis; and measures that could be taken to encourage the transfer of technology for the development of the manufacturing industry in countries with no or insufficient manufacturing capacities;

- measures that are necessary for furthering development of regional patents and co-operation in the area of compulsory licenses;

- modifications that may have to be made in the national patent laws to permit the development of trade on a regional basis, in products imported under a compulsory license and the development of a national industry to enter the regional market.

21. The six regional studies as well as the formerly commissioned nine national studies will comprise a part of the documentation (a package of research material) to be utilised in national and/or regional workshops bringing together key regional stakeholders and decision makers, with contributions of in-house expertise from, *inter alia*, WHO, ICTSD, DfID Health Resource Centre, UKPO, UNCTAD, the World Bank, and the Commonwealth Secretariat. DfID has committed £120,000 towards the organisation of such workshops. WHO, UNCTAD and the World Bank are committed to either providing and/or funding the necessary expertise. In addition to commissioning the regional studies, the Commonwealth Secretariat will provide in-house expertise as well as fund the participation of the regional experts retained to undertake the six case studies. An agreement in principle with our strategic partners has been secured in placing the focus on Commonwealth countries with a view to achieving economies of scope with work undertaken by partnering institutions in parallel.

CONCLUSION

22. The ELS programme of assistance focuses on the revision of national laws and establishment of appropriate national and regional frameworks. This focus derives from the fact that the 30 August 2003 Decision will have little positive impact on access to essential medicines at affordable prices without revisions to the existing legal framework: to the extent that national laws are not revised to implement the terms of the Decision, patent owners may invoke this and prevent a government from exporting or importing medicines under the more flexible regime provided for by the 30 August Decision.

23. The World Bank has produced a *Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*. The documentation includes draft notifications and draft patent act amendments to assist WTO Members in implementing the 30 August 2003 Decision. The World Bank guide expressly provides:

> "this Guide can only provide a starting point. The actual implementation of the Paragraph 6 Decision will take place within the contours of each country's existing legislative and

regulatory framework, practice and jurisprudence. The authorities of each country will have to work with their own legal experts to arrive at a solution that is right for their situation."

24. ELS is working with, *inter alia*, World Bank consultant and co-author of the World Bank Guide, Fred Abbot, with a view to assisting Commonwealth developing countries and regions with the effective implementation of the 30 August 2003 Decision in a manner that addresses their individual circumstances.

25. It is generally observed that the new post-2005 environment (wherein nearly all countries in the world have to implement the TRIPS Agreement) will require a re-thinking of medicines procurement strategies which address the impact of intellectual property protection (in particular patent protection). Our expectation is that with appropriate legislative frameworks in place, appropriate regional mechanisms operative, and desirable public/private sector partnerships established – there will be a greater sense of "pharmaceutical security" – so to speak – security in sources of supply, and where feasible, enhanced regional production, on a competitive basis, for the provision of high quality medicines at low prices for all.