

Statement of the African Regional Workshop on Patents and Access to Medicines: Appropriate National and Regional Policy Responses

(Addis Ababa, 1- 4 March 2005)

The Workshop was organised by the Commission of the African Union (AUC), the United Nations Development Programme (UNDP), the World Health Organization (WHO) and the Third World Network (TWN).

INTRODUCTION

1. The African Regional Workshop on Patents and Access to Medicines: Appropriate National and Regional Policy Responses was held at the African Union headquarters in Addis Ababa from 1 to 4 March 2005. It was co-organised by the Commission of the African Union (AUC), the United Nations Development Programme (UNDP), the World Health Organization (WHO) and the Third World Network (TWN).
2. The Workshop was attended by 135 participants, including representatives from governments of 35 African Union member states, as well as representatives from non-governmental organizations, international agencies and experts and practitioners in the field of health, development and international law.
3. The Member States represented were Algeria, Benin, Burkina Faso, Burundi, Cape Verde, Central African Republic, Chad, Republic of Congo, Democratic Republic of Congo, Djibouti, Egypt, Equatorial Guinea, Ethiopia, Gabon, Ghana, Kenya, Madagascar, Malawi, Mali, Mauritius, Mozambique, Namibia, Nigeria, Saharawi Arab Democratic Republic, Senegal, Somalia, Sierra Leone, South Africa, Sudan, Swaziland, Tanzania, Tunisia, Uganda, Zambia and Zimbabwe.
4. The Intergovernmental and International Organizations that participated were the African Union Commission (AUC), World Health Organization (WHO), the United Nations Development Programme (UNDP), the South Centre, East African Community, International Organization on Migration (IOM).
5. NGOs represented were the Third World Network, Consumer Project on Technology, Health Action International Africa, Médecins Sans Frontières (MSF), Institute for Sustainable Development (ISD), Southern Environmental and Agricultural Policy Research Institute (SEAPRI), Trade law Centre for Southern Africa (TRALAC), Association de Lutte contre le Sida Maroc (ALCS), Students Stop AIDS Society (Kings College London), Caritas (Egypt), MMM Counseling Center (Ethiopia). The business sector was represented by Cosmos Ltd (Kenya), Varichem Pharmaceuticals (Zimbabwe), Bethlehem Pharmaceuticals (Ethiopia), East African Pharmaceutical Factory (Ethiopia), Ethiopian Pharmaceuticals Manufacturing Enterprise (Ethiopia) and the Indian Pharmaceutical Alliance (India).
6. The workshop was organized through several plenary sessions, working groups that considered country reports, and panel discussions, on a wide range of topics. Representatives of the participating Member States of the AU, NGOs and Experts attending the meeting adopted the following conclusions and recommendations.

GENERAL

7. Participants stressed that the issue of the effects of patents on access to medicines is very crucial for the African region which among all continents in the world is the poorest and its people are most affected by serious diseases, and therefore the need for access to affordable effective medicines is a must. Deaths attributable to HIV/AIDS alone in 2004, estimated at 2.5 million, are equivalent to ten times the devastation caused by the Tsunami of December 2004. It is urgent that all countries act individually and collectively to remove all obstacles to securing sustainable supplies of essential medicines for the people of the region.
8. Yet the complex web of intellectual property rights and patents is keeping HIV/AIDS and other essential medicines out of the hands of those who are most in need. The situation is critical since most of the people who do need such medicines are not getting them, as many of these medicines are expensive. The prices are high because important medicines are patented and the companies that hold the patents have a monopoly of

sales and control the prices. Besides they are rarely willing to issue voluntary licenses on reasonable terms to enable the production of generics. That has resulted in the inability of the majority of Africans to pay the high cost of medicines in the world market.

9. In many African countries there are patent laws that grant exclusive rights to patent holders, including for pharmaceutical products. Most African countries are members of the World Trade Organisation and thus they are obliged to implement the Agreement on Trade Related Intellectual Property Rights (TRIPS). As a result, most African countries have granted patent protection for pharmaceutical medicines, with the effect that the companies holding patents are able to charge high prices, which in turn adversely affects access to medicines, especially for the poor.

10. We recall that the Africa Heads of State and Government at their Extraordinary Summit in April 2002 at Abuja adopted the Abuja Declaration on HIV/AIDS and other related infectious diseases in Africa through which they committed themselves to many actions, including providing affordable medicines to cure those diseases.

11. We also recall the AU Assembly Decision: Assembly/AU/Dec.55(IV) adopted by Heads of States and Government in January 2005 in Abuja, which urged Member states “to take the lead in TRIPS negotiations and in implementing measures identified for promoting access to affordable generic drugs.” Given the commitment of our leaders and the flexibilities in TRIPS, it is time to translate the principles contained in the Doha Declaration into concrete gains at continental, regional and national levels to let our peoples benefit from.

USING FULLY THE FLEXIBILITIES IN TRIPS AND THE DOHA DECLARATION

12. However, there are many flexibilities in the TRIPS Agreement that allow governments to establish pro-health measures such as compulsory licensing, government use provisions and parallel importation and production of generic versions of medicines that have been patented. The African Group in the WTO played a pioneering and leadership role in negotiations for the landmark Doha Declaration on TRIPS and Public Health in 2001, which among other things stated that “The TRIPS agreement does not and should not prevent members from taking measures to protect public health”; “We reaffirm that the Agreement can and should be interpreted in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”; and

“We reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” **We therefore urge policy makers, international and regional organizations to take full advantage of the flexibilities provided in the Doha Declaration and Paragraph 6 decision, by enacting enabling trade and intellectual property legislation that will speed the importation and/or production of essential medicines.**

13. In this respect, the Doha Declaration has also allowed the postponement of the implementation of TRIPS obligations on pharmaceutical products to 1 January 2016 for LDCs. After that date, the WTO shall also grant further extension of the transition, upon duly motivated request by the LDCs. We encourage and urge governments in LDCs in the African region “to use, to the full” the flexibilities accorded to LDCs in TRIPS and the Doha Declaration in this regard.

14. The WTO General Council in August 2003 also adopted a decision aimed at facilitating developing countries with insufficient or no production capacity to produce pharmaceuticals, to have a sustainable supply of imported generic products, by waiving the requirement that the supply of medicines under compulsory licenses in countries that can produce them have to be predominantly for the domestic market. We note however that this decision imposes several conditions on importers and exporters who wish to make use of the waiver, which may hinder the smooth operation of the mechanism.

15. There is a relationship between patents, price and generic competition. In general, prices of generics are lower compared with the prices of branded products. But when there is competition between both products, the prices of branded products would decline. Countries that do not have access to generics pay higher prices. Therefore, we urge African countries to adopt and implement policies that promote generic competition in order to enhance access to medicines. Governments should also consider mechanisms for the regulation and control of medicine prices.

16. We also urge governments of developing countries in Africa to similarly use to the full, the flexibilities that they are provided, including measures such as compulsory licensing, government use measures and parallel importation, so as to ensure access to medicines.

17. It is crucial that African countries strengthen their capacity and knowledge about their rights and obligations in relation to patents and access to medicines, including understanding the implications of TRIPS and other agreements and proposals, and what are the ap-

appropriate policy measures and legal options available.

18. African governments are urged to review their patent laws and to amend them, where appropriate, to bring them in line with the best options and provisions possible. The patent laws should enable the country to provide compulsory licenses, government use orders and parallel importation in simple and effective ways. The governments in the region should then exercise their rights by taking these measures to ensure access to medicines.

19. We note that many publications and documents from WHO, UNDP and Third World Network (TWN) provide useful guidance on implementing the TRIPS flexibilities. We therefore recommend that these documents, including the Manual on Good Practices in Public Health Oriented Patent Policies and Laws and its supplementary papers (which were developed with the encouragement of the AU and published by TWN) be used as a key reference point for review of policies and laws.

20. We congratulate those African countries (and developing countries in other regions) that have already started to make use of safeguard measures such as “compulsory license” and “government use” orders that allow the supply of generic medicines in their countries. We are also encouraged by cases in some African countries where negotiations have led to voluntary licenses for the supply of generic drugs. We encourage other African countries to look at and learn from these experiences.

21. We call upon the African Union Commission to prepare a set of guidelines on appropriate national policy measures and national patent legal provisions for African countries, which enable them to make use to the full the flexibilities in TRIPS agreement and the Doha Declaration on TRIPS and Public Health that support public health and access to medicines for all. The Commission should also assist African countries to build their capacity to institute the appropriate policies and laws.

22. We call upon the WHO to expand its activities in providing technical assistance to African countries to review their laws and policies so that they can make full use of TRIPS flexibilities to promote public health, and to continue to assist African countries in implementing national medicine policies and in strengthening medicine regulatory capacities.

23. We urge UNDP to scale up capacity building support at national and regional levels to enable countries to apply the full flexibilities of the Doha Declaration

and Paragraph 6 to sustainably import or produce lowest cost, quality HIV/AIDS drugs. This includes support to countries in the legal and economic assessment of national drug manufacturing and related capacity.

24. We encourage African countries to increase their capacity in technical knowledge in understanding their rights and obligations in WTO and the use of TRIPS flexibilities in patent laws and health policies through collaboration with stakeholders and NGOs, in particular the Third World Network.

“PARA 6” MECHANISM FOR COUNTRIES WITH NO OR INADEQUATE MANUFACTURING CAPACITY

25. The temporary mechanism to address the “para 6 issue” to ensuring supply of medicines to countries with no or inadequate manufacturing capacity, known as the August 30 2003 decision, provides a waiver to TRIPS Article 31(f) for exporters. However this decision imposes several conditions on importers and exporters who wish to make use of the waiver, which may affect the ability for the mechanism to meet its goal. African countries should make use of this “temporary solution” mechanism where appropriate to test how effective it is in practice, and to take steps to improve the mechanism if needed.

26. We call for a more appropriate “permanent solution” that revises TRIPS and that removes the Article 31(f) constraint without placing new constraints so that the export and import of generic medicines can be smoothly facilitated. We support the position and efforts of the African Group in this respect.

27. African authorities should propose in the WTO a united common position to review the TRIPS Agreement aimed at expanding the policy flexibilities in TRIPS to promote public health. For example to consider that countries are enabled to exclude patents on pharmaceuticals and to determine the period of patents on pharmaceuticals without a TRIPS-prescribed minimum period. We note that before the TRIPS agreement came into being, many countries had excluded pharmaceutical products from patentability, for example in India Patent Act 1970.

TRIPS-PLUS PROVISIONS IN BILATERAL AND REGIONAL AGREEMENTS

28. The proliferation of bilateral and regional trade and economic agreements that contain TRIPS-plus provisions or proposed provisions on IPRs is a matter of serious concern, as these prevent the use of TRIPS

flexibilities. The related “TRIPS-plus” provisions of such agreements include restrictions in the use of compulsory license; extension of the period of patentability; the use of the national drug regulation authority as “patent police” to block approval of generic products on the ground that the products are patented; and “data exclusivity” (where drug regulatory authorities are prohibited from relying on test data submitted by originator companies for marketing approval for a period of time).

29. African countries should guard against proposals to introduce TRIPS-plus IPR provisions in bilateral and regional economic agreements, and should insist that they would not be included in these agreements.

30. We recommend that the AU Commission initiate efforts to enhance collaboration among the Ministries of Health, Trade and Industries and Patent offices, so as to build their capacity to monitor and analyse the implications of TRIPS-plus provisions in bilateral agreements, to be able better negotiate such agreements and to maintain TRIPS flexibilities. We also ask WHO, UNDP and TWN to support such efforts.

31. It should be ensured that African regional agreements such as the Bangui Agreement 1999 do not offset or prevent the full use of the TRIPS agreement and the Doha Declaration of TRIPS and Public Health. Governments should review these agreements and recommend how to reconcile any possible discrepancies between such agreements and the TRIPS/Doha flexibilities, in a manner that supports pro-public health policy measures.

POST-2005 SITUATION

32. We would like to express great concern about the impact of the expiry of the transition period on 1 January 2005, in particular with regard to the continued production and supply of generic medicines and active pharmaceutical ingredients in producing countries, such as India. The expiry of the transition period on 1 January 2005 requires countries that had not previously done so, to extend patent protection to pharmaceutical products and to grant patents to applications placed in the “mailbox”. The implementation of the new obligations should be in a manner that facilitates the continued and regular supply of good quality and affordable generic medicines. It is particularly important that the supply of medicines, active pharmaceutical ingredients and other pharmaceutical products to African countries is not disrupted.

33. We also urge countries that export and supply medicines and raw materials to African countries to take all the necessary measures to ensure that African countries continue to receive the needed supplies of these medicines.

34. In the examination of patent applications for pharmaceutical drugs, the views of those with pharmaceutical expertise (including in the relevant health departments) should be sought, in order to enable better decisions on the granting of medicines patents, including addressing the problem of “evergreening” of drug patents.

ISSUES RELATING TO DRUG REGULATION, PROCUREMENT AND FINANCING

35. We view the importance that African countries should take seriously the issues related to drug regulation and good practices in procurement of medicines. All medicines procured and distributed (whether by originator or generic producers) should meet the requirements of quality, safety and efficacy.

36. The WHO prequalification project, although intended as a service for UN procurement agencies, has become a useful quality criterion for developing countries in providing them with the choice of a range of quality medicines for priority diseases. The prequalification project has been important in securing access to affordable medicines. We ask therefore that the WHO prequalification project be further strengthened, in light of the continuing public health crisis. It is, however, important for countries to build their regulatory capacities. We therefore ask WHO to continue its work in providing technical assistance and capacity building of drug regulatory authorities to improve access to medicines of assured quality.

37. We are concerned that some trade partners are attempting to have African countries grant exclusive rights over test data to the originator drug company, through bilateral or regional trade and economic agreements, which would have adverse effects on supply of generic medicines and access to medicines. The drug regulatory authorities are being asked through bilateral or regional agreements to take on non-safety issues relating to IPRs, for example that drug regulators deny approval for generic drugs that are patented. Also, we note that the TRIPS Agreement does not require that exclusive rights be granted over the test data submitted for the approval of the originator medicines.

38. The drug regulatory authorities are being also asked through bilateral or regional agreements to take on

non-safety issues relating to IPRs, for example to deny approval for generic drugs that are patented. We recommend that governments ensure that drug regulatory authorities carry out activities within their area of competence (ensuring safety, efficacy and quality of medicines) and that are not asked to take on additional responsibilities such as enforcement of IPRs.

39. We recommend that governments give higher priority and where needed more budget resources to be allocated in order to build the capacity of drug regulatory authorities so that they can perform their tasks effectively

40. African Governments should also make full use of TRIPS flexibilities in relation to the data protection issue, i.e. that WTO members are not required to establish “data exclusivity” provisions and LDCs do not have to implement data protection provision until 2016. Further, countries that have already entered into bilateral agreements that include obligations for data exclusivity or protection could consider reviewing these obligations included through amendment of such provisions and also examining the possibility of “compensatory liability” for the use of data.

LOCAL DRUG PRODUCTION

41. Local production, where feasible, is an important component of a national medicine policy, by contributing to the establishment of a reliable supply system. The development of local production capacity will require an enabling policy and technological environment, including through support by government through provision of incentives and infrastructure as well as appropriate IPR and procurement policies.

42. The AU Commission in collaboration with its developmental partners should make progress on identification and promotion of **centers of excellence** for the production of medicines in the region, including for traditional medicines. We request the AU Commission, WHO and UNDP to conduct studies on an enabling regional policy framework on drug manufacturing in Africa.

43. African countries should encourage local drug manufacturers to cooperate among themselves at national and regional level to strengthen local and regional drug production. The local manufacturers should also be enabled to have access to the African Union Commission through their respective associations, so that they could express their views on the development of local production.

REGIONAL COOPERATION

44. There is a lot of scope for regional cooperation in Africa in improving access to medicines. The Doha Declaration and the August 30 2003 Decision has increased the space given to African countries to cooperate regionally. For example, regional economic groupings that have LDCs forming at least half of their membership are eligible to be treated as a “domestic market” in relation to the supply of generic medicines under compulsory licensing. This can facilitate regional cooperation in marketing, supply and trade so that African countries can take advantage of economies of scale.

45. It is recommended that the AU Commission initiate efforts to coordinate a regional approach, including studies on the feasibility and modalities of regional cooperation in the area of supply of and access to medicines. Measures for cooperation can include establishing a system for the collection and sharing of information on prices and supply of medicines; establishing regional or sub-regional groupings as “domestic markets” for the purposes of taking advantage of certain TRIPS flexibilities; regional arrangements for compulsory licensing (so that a license can be issued and used by countries within a region); regional technology, research and innovative cooperation arrangements, and the consideration of regional patent pools to expand access to medicines and regional cooperation to control anti-competitive practices. The WHO, UNDP and other agencies should assist the AU Commission where appropriate.

46. The best practices shared during the workshop demonstrated the critical need for establishing an active learning network among the participants of the workshop where issues and cutting edge precedents can be shared. Equally important is the establishment of active South-South cooperation among countries within the Africa region and between other regions as well to adapt emerging best practice for the importation or production of low cost, quality essential medicines. We request UNDP to increase support for South-South cooperation among groups of developing countries, to facilitate this exchange and transfer of best practices.

RECOMMENDATIONS FROM WORKING GROUPS OF THE WORKSHOP

47. Participants of the workshop also had extensive discussions in working groups which examined country reports as well as discussed general issues. The recommendations of the working groups are in Annex I and form an integral part of this Statement.

Recommendations of Working Groups of the African Regional Workshop on Patents and Access to Medicines: Appropriate National Policy Responses, Addis Ababa (1-4 March 2005)

Working groups comprising representatives of various countries in each group met during the workshop and prepared reports of their discussion. Below is a summary of the recommendations of the working groups.

GROUP A: Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Zambia, Zimbabwe

¹ There is a need to make all stakeholders aware of the important issues regarding the TRIPS agreement, particularly the flexibilities in it.

¹ There is a need to build the capacity of intellectual property offices so that applications for patents are carefully scrutinized and necessary consultations done

¹ There is a need to urgently review all relevant legislations pertaining to patents so that they do not negatively impact on access to essential medicines.

¹ There is a need to strengthen the national drug regulatory authorities so that the pharmaceutical sector of the countries is properly regulated

¹ There is a need to ensure that negotiations for bilateral trade agreements are undertaken together with proper consultations with all relevant stakeholders to avoid jeopardizing the flexibilities in the TRIPS Agreement

¹ Member countries must carefully assess their technical assistance needs so that they are able to make appropriate and specific requests for technical assistance.

¹ National governments should make available adequate resources to enable timely procurement of medicines so that supply and access is not compromised

¹ All government policies that have an impact on access to essential medicines should be reviewed so that they are consistent with the TRIPS Agreements and incorporates the flexibilities that are available to im-

prove access to essential medicines.

¹ National governments should consider the possibility of local or regional production of essential medicines so as to maximize available manufacturing potentials

¹ Each country should identify priority activities that will be undertaken to raise awareness about the use of safeguards in the TRIPS Agreement and to promote public health aspects in trade agreements.

¹ A learning network should be created to share information on the TRIPS Agreement, medicines prices and other relevant information that will assist Member countries to improve access to essential medicines.

¹ The recommendations from this workshop should be disseminated to the AU heads of governments and state, to all ministries responsible for trade, health and patents. The AU should take the lead in disseminating the information.

¹ There is a need to draft, disseminate and obtain consensus on a Program of Action for the implementation of recommendations that arise from this workshop.

GROUPS B AND C: Benin, Burkina Faso, Burundi, Central African Republic, Republic Of Congo, Democratic Republic Of Congo, Djibouti, Madagascar, Mali, Senegal, Tchad

¹ Governments and the WHO should work towards strengthening the capacity of the national drug regulatory authorities

1 Governments, the AU, sub-regional organizations, WHO and the UNDP should promote regional approaches for local production and group procurement of medicines including traditional medicine

1 Governments, the AU, WHO and civil society organizations should sensitize the relevant authorities on how to effectively implement the obligations and safeguards in the TRIPS Agreement.

1 Governments and the WHO should strengthen the systems of control of the quality of drugs

1 The WHO, WIPO, OAPI, AU, WTO, ARIPO, UNDP and sub-regional organizations should update and build the capacity of the relevant stakeholders on access to medicine as well as develop suitable guides relevant to the issue.

1 The AU, UNDP, WTO, WHO, TWN, OAPI and sub-regional organizations should organize more workshops for countries at national and sub-regional levels.

1 The AU should make available on the AU website regular updated information on the TRIPS Agreement and all other relevant agreements, in particular that have effects on access to medicines.

1 The AU, WHO and sub-regional organizations should analyze and emphasize the flexibilities in regional agreements on intellectual property, particularly in relation to access to medicine

GROUP D: Cape Verde, Equatorial Guinea, Ghana, Nigeria, Sierra Leone

1 All national laws in relation to access to medicines need to be fine-tuned to incorporate and make maximum use of safeguards in the TRIPS Agreement and the Doha Declaration.

1 There is a need for administrative guidelines for implementing these safeguards.

1 Technical assistance in designing financial sustainability plan needs to be provided

1 There is a need for an interactive website that covers issues raised at this workshop.

1 Governments need to provide incentives to local manufacturers to encourage and assist them to produce affordable medicines

1 The national patent offices should be automated.

1 There is a need for a model patent law, that is consistent with the TRIPS Agreement and that incorporates all the flexibilities.

1 Governments need to increase the budget for the procurement of medicines to deal with the increased disease burden.

1 The AU should coordinate all the follow up activities arising from this workshop.

GROUP E: Egypt, Soudan, Tunisia, Saharawi Republic

1 The creation of a network that facilitates exchange of information and experiences and raises awareness is recommended.

1 There is a need to build the capacity of human resources to facilitate the use of safeguards in the TRIPS Agreement

1 More national/regional workshops should be organized

1 Implementation of all the decisions of the African Union concerning health policy in HIV/AIDS, Malaria and Tuberculosis (Sudan) is encouraged.

1 Organizers and all international organizations should support the Saharawi people by building the capacity of their health system and by supporting financially the prevention policies especially on the HIV/AIDS, Malaria and Tuberculosis epidemics.

GROUP F: Ethiopia, Kenya, Tanzania, Uganda, Somalia

1 There is a need to create awareness among policy makers and the public by:

i) Holding meetings with MPs, government officials and other stakeholders;

ii) Publicizing the issues in media;

iii) Updating stakeholders through the exchange of information, sharing of experiences and where possible, attending the relevant WTO/WIPO meetings.

1 An assessment to identify the available and capable human resources should be conducted. There should be capacity building for existing resources.

1 There is a need to develop laws where none exist and to review and amend existing inadequate legislation so that the laws and policies are consistent with the TRIPS Agreement and its flexibilities. For this, technical assistance is needed.

1 A check list should be prepared to measure whether the relevant legislation allows access to medicines.

1 Relevant officials need to be sensitized on matters affecting access to medicines and related issues

1 Countries should develop common negotiating positions, for example in forthcoming meetings at the WTO TRIPS Council which will be attended by African countries present at the workshop and where the Africa Group proposal on the permanent solution to the problem faced by countries with insufficient or no manufacturing capacity (paragraph 6 of the Doha Declaration will be discussed.

1 There is a need to exchange and share experiences with other countries, to make use of contacts established in the workshop to consult and utilize information which each country has respectively

1 There is a need to establish linkages between local, sub-regional and regional levels. Existing initiatives should be utilized.

1 The use of alternative forms of medication such as traditional medicines should be encouraged.

1 There is a need to ensure continued supply of affordable and quality generic medicines

1 Local production should be encouraged. In this regard, Article 65(4) of the TRIPS Agreement should be amended to allow developing countries to delay for a further period of 10 years the application of the provi-

sions on patents to pharmaceutical products so that WTO members can strengthen the local capacity to produce generic versions of pharmaceutical drugs.

1 A checklist to determine whether legislation / policy has been implemented and regular review of implementation through Monitoring and Evaluation teams should be developed to create awareness of the lack of implementation. (The involvement of the civil society may be needed)

1 The TWN Manual on Good Practices in Public-Health-Sensitive Policy Measures and Patent Laws is a useful guide and as such the AU should recommend it as a tool for its Members to use

1 The AU Commission should assist Somalia to set up the relevant regulatory infrastructure. Members should share their experiences with and give their support to Somalia.

1 Support should be given to Ethiopia in its negotiations on accession to WTO especially as far as IP is concerned so that Ethiopia can make full use of the TRIPS flexibilities in its new IP law.

1 Countries should take advantage of the technical assistance and funding available, for example from WHO and UNDP

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