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MOTION FOR A RESOLUTION

further to the Commission statement

pursuant to Rule 37(2) of the Rules of Procedure

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on behalf of the Verts/ALE Group

on access to medicines and paragraph 6 of the Doha Declaration on TRIPs and Public Health

B5-0103/2003

European Parliament resolution on access to medicines and paragraph 6 of the Doha Declaration on TRIPs and Public Health

The European Parliament,

– having regard to the Doha WTO Ministerial Declaration on the TRIPs Agreement and Public Health, adopted on 14 November 2001, and in particular paragraph 6 thereof,

– having regard to its previous resolutions and those of the ACP-EU Assembly on AIDS, the WTO, and access to medicines for AIDS patients in the Third World (notably ACP-EU 3305/01/fin., ACP-EU 3315/01/fin., A5-0331/2001, B5-0691, B5-0692 and B5-0693/2001),

– having regard to the communication from the Commission to the Council and the European Parliament, the Programme for Action on accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction, and the European Parliament resolution of 4 October 2001,

– having regard to the Wijkman report on the proposed Parliament and Council regulation on aid for poverty diseases in developing countries (HIV/AIDS, malaria and tuberculosis) (A5-0394/2002),

– having regard to the European Parliament legislative resolution on the proposal for a European Parliament and Council directive amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (COM(2001) 404 - C5-0592/2001 - 2001/0253 (COD)), which recognises in amendment 196 that 'manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence for that product, or when a patent is not in force and if there is a request to that effect by the competent public health authorities of that third country',

A. whereas the agreement on the Doha Declaration on TRIPs and Public Health was a significant achievement and was seen as a key indicator of the seriousness with which developed countries take the concerns of developing and least developed countries on public health issues, access to essential medicines for all and the need to put people before patents,

B. whereas the significance of the Declaration should be seen in the context of the fact that poor countries undergoing structural adjustment programmes have been forced to reduce their spending on public health services to comply with macro-economic conditionalities laid down by international financial institutions for loan grants,

C. whereas paragraph 4 of the Declaration states that '… the TRIPs agreement does not and should not prevent members from taking measures to protect public health'. The same paragraph states 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',

D. whereas paragraph 5(b) of the Declaration reaffirms the right of countries to grant compulsory licences and the freedom to determine grounds upon which such licences are granted, and whereas paragraph 6(c) reaffirms that each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency,

E. whereas WTO members which have sufficient domestic manufacturing capacity are not limited in any way as to the use of the compulsory license and do not need to refer to the WTO to use their rights under TRIPs, but, as recognised by paragraph 6, members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement, since Article 31(f) of the TRIPs agreement limits compulsory licensing predominantly to supplying the domestic market,

F. whereas the WTO TRIPs Council was therefore mandated to find an expeditious solution to this problem – while ensuring that production for export to a country that has issued a compulsory license, but does not have manufacturing capacity, can take place from a country that provides pharmaceutical patents – and to report to the General Council before the end of 2002,

G. whereas this mandate clearly intended that those countries which lack such capacity should not be put at a disadvantage by discriminatory restrictions and that the solution sought should be workable, automatic and economically viable,

H. whereas the deadline was not met, primarily owing to the insistence of some pharmaceutical companies and the United States government that there needed to be further restrictive definitions of public health crises, together with a specified list of diseases to which the provisions applied,

I. whereas earlier proposals by the Commission on behalf of the EU were also unsatisfactory and the Commission has now proposed that the advice of the World Health Organisation could be sought in the event of a dispute, but that such advice would be non-binding,

J. whereas the TRIPs Council is to reconsider the matter at its forthcoming session,

1. Reaffirms that access to health care is enshrined in the Universal Declaration of Human Rights, and as such should be respected;

2. Considers that the language of the Doha Declaration is clear and unambiguous and the question of what does or does not constitute grounds for the issue of compulsory licences does not require further interpretation, either by means of an 'approved list' or of any external approval mechanism. Any allegations of abuse of the provisions of TRIPs should be dealt with through the relevant disputes procedure;

3. Welcomes the efforts of the Commission to find an equitable solution to the problem

stated in paragraph 6 of the Doha Declaration, but believes that the ongoing negotiations should not result in discrimination between WTO members with differing capacities to respond to public health problems,

4. Insists that the Commission must therefore respect the clarifications provided in the Doha Declaration and reject any position that would result in limitations regarding the scope of diseases or the countries that could make use of an effective solution to the problem defined in paragraph 6;

5. Considers that the most effective solution is a limited exception under Article 30 of the TRIPs agreement whereby WTO members may permit third parties to make, sell, and export patented medicines and other health technologies to address public health needs. This would allow production for export activities to be defined under national law as an exception to the rights of patent holders; there would be no need to require a compulsory license for export-oriented production of this kind;

6. Regrets, therefore, the EU position based on amending Article 31, since this implies a dual system of 'compulsory licensing' (in both the producer and the importing country), which makes administering the system far more complicated for developing countries;

7. Insists that neither the countries with insufficient manufacturing capacities nor the countries that will utilise the mechanism to produce for export should be subject to any conditions, notification procedures or any other procedural mechanism more onerous than the ones already provided for under WTO rules;

8. Recognises that the WTO is not the most appropriate body to arbitrate or make rules on questions of public health or access to essential medicines and that, in this regard, the TRIPs Agreement has to be subservient to other values and authorities, as is implicit in the Doha Declaration;

9. Agrees with the Commission that the World Health Organisation (WHO) could play an important role, but warns that the autonomy and authority of the WHO should not be compromised; in this context encourages the Commission to consider the WHO proposal for a solution to paragraph 6, presented to the TRIPs Council on 17 September 2002;

10. Considers, therefore, that the Commission's proposal for the WHO to draw up a list of diseases concerned is not acceptable since it would represent a further restriction on developing countries' use of compulsory licensing or Article 30 mechanisms, while developed countries are not subject to any such limitations;

11. Considers that when conflicts arise, as they certainly will in this case, between intellectual property rights and public policy questions, they should always be resolved for the benefit of people and not patents. Further, underlines that there is a timetable laid down in the TRIPs Agreement for overall review of its workings, which has not been met, and notes that this process is also stalled in Geneva;

12. Asks the Commission and the Member States to support a broader discussion under the auspices of the WHO on how the TRIPs agreement affects the availability of affordable

generic medicines;

13. Asks the Commission also to investigate alternative strategies for addressing the issue of the lack of product development for neglected diseases and to support the WHO in including this issue on its agenda;

14. Instructs its President to forward this resolution to the Council, the Commission, the Member States, the WTO, the WHO and the UN Secretary-General.