EUROPEAN PARLIAMENT

1999 *2004*

Session document

11 February 2003

B5-0103/2003 }
B5-0110/2003 }
B5-0123/2003 }
B5-0127/2003 }
B5-0130/2003 }

RC1

JOINT MOTION FOR A RESOLUTION

pursuant to Rule 37(4) of the Rules of Procedure by

– Anders Wijkman, Mario Mantovani and Françoise Grossetête, on behalf of the PPE-DE Group
– Eryl Margaret McNally, on behalf of the PSE Group
– Nicholas Clegg and Astrid Thors, on behalf of the ELDR Group
– Didier Rod, Paul A.A.J.G. Lannoye, Nelly Maes, Alexander de Roo and Bart Staes, on behalf of the Verts/ALE Group
– Joaquim Miranda, Pedro Marset Campos, Luigi Vinci and Yasmine Boudjenah, on behalf of the GUE/NGL Group

replacing the motions by the following groups:

– Verts/ALE (B5-0103/2003),
– PPE-DE (B5-0110/2003),
– GUE/NGL (B5-0123/2003),
– PSE (B5-0127/2003),
– ELDR (B5-0130/2003),

on authorisation of generic medicines at WTO level

European Parliament resolution on authorisation of generic medicines at WTO level

The European Parliament,

– having regard to having regard to the WTO Ministerial declaration on the TRIPS agreement and public health, adopted on 14 November 2001 in Doha,

– having regard to its previous reports and resolutions on the WTO, major communicable diseases, openness and democracy in international trade, and eradication of poverty (A5-0062/1999, A5-0263/2001, A5-0331/2001, A5-0230/2002, A5-0394/2002, B5-0691/2001, B5-0692/2001 and B5-0693/2001),

– having regard to the proposal for a Council decision on Community participation in a research and development programme aimed at developing new clinical interventions to combat HIV/AIDS, malaria and tuberculosis,

A. whereas, in the Doha Ministerial Declaration of December 2001 (Article 17) the WTO member states stressed 'the importance they attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines' and, in this connection, adopted a separate binding Declaration,

B. whereas the EU's existing pharmaceuticals legislation should be fully taken into account when defining our policy on access to generic medicines,

C. whereas many of the poorest developing countries face severe health crises and are in urgent need of improved access to affordable essential medicines for treatment of diseases, and whereas these countries are heavily dependent on imports of medicines as local manufacturing is scarce,

D. whereas there is a proposal for a Council regulation to avoid trade diversion into the European Union of certain key medicines (COM(2002) 0592),

E. whereas the 'Declaration on the TRIPS Agreement and Public Health', paragraph 4, recognising the gravity of the public health problems facing many developing and least-developed countries, affirms that 'the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health', that it 'can and should be interpreted and implemented in a manner supportive of WTO members' rights to protect human health and, in particular, to promote access to medicines for all' and reaffirms 'the right of WTO members to use to the full the provisions in the TRIPS Agreement which provide flexibility for this purpose',

F. whereas paragraph 5(b) of the Doha 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,

G. whereas in paragraph 6 of the Declaration, the WTO member states 'recognise that WTO members with insufficient or no manufacturing capacities 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 of the member authorising such use, and therefore 'instruct the Council for TRIPS to find an expeditious solution to this problem',

H. whereas an EU proposal based on the Doha declaration of 2001 and the compromise proposed by the TRIPS Council Chairman was presented to the WTO members by Commissioner Lamy by letter dated 7 January 2003, suggesting a multilateral solution and giving an advisory assessing role to the World Health Organisation for other public health problems than those included in a list of 22 major infectious diseases,

1. Points out that combating major diseases in developing countries is a key area of poverty reduction;

2. Points to the fact that there exists today a discrepancy within TRIPS between countries possessing manufacturing capacity for generic medicines and those without such capacity, insofar as the former can decide unilaterally when to make use of a compulsory license, something that the latter cannot;

3. Welcomes the efforts of the Commission to secure the implementation of paragraph 6 of the Doha Declaration on TRIPS and public health by suggesting a multilateral solution and giving an advisory role to the World Health Organisation, but underlines at the same time that the list of diseases concerned must be interpreted with flexibility so as not to represent a further restriction on developing countries' use of compulsory licensing or Article 30 mechanisms;

4. Deplores the American position, which favours a unilateral solution and a narrow list of medicines for which WTO intellectual property rules would be waived, and which has blocked the adoption by the WTO TRIPS Council of a solution to the problem of access to medicines for developing countries before the end of 2002, as agreed in Doha;

5. Stresses the importance of efficient protection of intellectual property for the knowledge-based society;

6. Stresses that the rules on intellectual property rights must ensure that the results of medical research can benefit the developing countries in the form of new, easily accessible and affordable medicines;

7. Stresses that only multilateral agreements ensure the legal certainty needed by both developing countries and economic operators;

8. Considers it important that efficient dispositions are taken to avoid trade diversion into the European Union of medicines, generic or otherwise, destined for developing countries, and asks the Commission to ensure that the necessary safeguards against abuse are not so onerous as to undermine the objective of ensuring affordable and timely access to life-saving medicines in developing countries with insufficient manufacturing capacity;

9. Recalls that forthcoming EU legislation permits the manufacture of generic medicines if the medicinal product is intended for export to a third country which has issued a compulsory licence for that product, or where a patent is not in force, and if there is a request to that effect from the competent public health authorities of that third country, and notes that the manufacture and export of generic medicines by any WTO member in these circumstances is consistent with the TRIPS agreement and the Doha Declaration on TRIPS and public health;

10. Demands that the competent European authorities establish a permanent register of the medicines, generic and others, destined for developing countries, under commercial agreements, with the aim of increasing the efficiency of control;

11. Calls on WTO members to find a solution as a matter of urgency to paragraph 6 of the Doha Declaration, in order to avoid a deadlock that could derail the whole Doha development round, and to honour the intention of paragraph 6 of the Doha Declaration to ensure that WTO members without adequate manufacturing capacity benefit in full from the provisions of that declaration, on the same terms as WTO members who do have such capacity; and reminds them that to impose new constraints as part of the solution to the paragraph 6 problem would violate the spirit of the Doha Declaration and be justifiably seen by developing countries as evidence of bad faith;

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. Calls for a re-evaluation of the specific issue of access to affordable medicines within the TRIPS agreement to be made jointly by the WTO and the WHO within three years of the implementation of the agreement, in order to ensure that the rules are in keeping with the spirit of the Doha Declaration;

14. Asks the Commission 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;

15. Calls for the definition of ‘sufficient manufacturing capacity’ to be clarified and to be primarily based on an economically effective capacity;

16. Recalls that, to make these programmes and actions successful and effective for the population of developing countries, a clear commitment from the governments of these countries should be made regarding the setting-up of infrastructures (such as telecommunications, transport and research), and also regarding the fight against corruption;

17. Instructs its President to forward this resolution to the Council, the Commission, the WTO, the WHO, the UN Secretary-General, the governments of the ACP countries and the US Government.