Procedure file

Basic information		
RSP - Resolutions on topical subjects	2003/2514(RSP)	Procedure completed
Resolution on authorisation of generic medicines at WTO level		
Subject 4.20.04 Pharmaceutical products and industry 6.20.01 Agreements and relations in the context Organization (WTO)	t of the World Trade	
		•

Key players		
European Parliament		

Key events	Key	events
------------	-----	--------

12/02/2003	Decision by Parliament	<u>T5-0052/2003</u>	Summary
12/02/2003	End of procedure in Parliament		
19/02/2004	Final act published in Official Journal		

Technical information		
Procedure reference	2003/2514(RSP)	
Procedure type	RSP - Resolutions on topical subjects	
Procedure subtype	Resolution on statement	
Legal basis	Rules of Procedure EP 132-p2	
Stage reached in procedure	Procedure completed	

Documentation gateway				
Motion for a resolution	B5-0103/2003	10/02/2003	EP	
Motion for a resolution	<u>B5-0110/2003</u>	10/02/2003	EP	
Motion for a resolution	B5-0123/2003	10/02/2003	EP	
Motion for a resolution	B5-0127/2003	10/02/2003	EP	
Motion for a resolution	<u>B5-0130/2003</u>	10/02/2003	EP	
Joint motion for resolution	RC-B5-0103/2003	10/02/2003		
Text adopted by Parliament, topical subjects	T <u>5-0052/2003</u> OJ C 043 19.02.2004, p. 0071-0245 E	12/02/2003	EP	Summary

Resolution on authorisation of generic medicines at WTO level

The European Parliament adopted a resolution on the authorisation of generic medicines at WTO level. To recall, the Declaration on the TRIPS Agreement and Public Health agreed by WTO members at Doha reaffirmed the right of countries to grant compulsory licences under certain circumstances. It also recognised that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing. The Commission suggested a multilateral solution and 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. Parliament welcomed the efforts of the Commission, but emphasised 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 the mechanisms referred to in paragraph 30 of the Declaration. The European Parliament deplored the American position, which favours a unilateral solution and a narrow list of medicines for which WTO intellectual property rules would be waived. The Americans have 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. Parliament called on WTO members to find an efficient solution as a matter of urgency, in order to avoid a deadlock that could derail the whole Doha development round. They should also honour the intention 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. The imposition of new constraints as part of the solution would violate the spirit of the Declaration and be justifiably seen by developing countries as evidence of bad faith. Parliament went on to state the importance of efficient measures to avoid trade diversion into the European Union of medicines, generic or otherwise, destined for developing countries. It asked 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. The competent European authorities should 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. Parliament went on to call for a re-evaluation of the specific issue of access to affordable medicines within the TRIPS Agreement to be carried out 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 relevant Declaration. Finally, the Commission was asked 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.?