TACD

TRANS ATLANTIC CONSUMER DIALOGUE

DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

DOC NO. HEALTH-3-00

DATE ISSUED: FEBRUARY, 2000

DATA EXCLUSIVITY AND HEALTH REGISTRATION DATA

1. TACD opposes the harmonization of data exclusivity for pharmaceutical registration data to 10 years. The US and the EU both provide periods of "data exclusivity" in the regulatory approval of pharmaceutical drugs: in the US this is 5 years, in the EU it is 10 years. The EU period was originally designed to compensate for a lack of patent protection on pharmaceutical in some EU member countries, and the lack of patent protection on medicines from biotechnology. This rationale is no longer valid with the new World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPs) rules that require broad patent protection in all EU member countries.

2. TACD recommends that companies that seek data exclusivity protections be required to disclose the costs of investments. Data exclusivity provisions are part of a growing class of *sui generis* forms of protection that are designed to protect investment, rather than innovation. Because data exclusivity is not a reward for invention (which is already rewarded by patents) but rather a protection of investment, there should be greater transparency of the basis for the protection and a reasonable relationship between the investment and the protection.

3. TACD asks the EU and the US to report on trade disputes that are related to introduction of generic forms of Paclitaxel in the EU market. TACD should be provided with copies of all correspondence and memorandums that have been sent between the US and the EU or its member countries on the trade related aspects of Paclitaxel registration in the EU. The US and the EU should also report to the TACD who invented Paclitaxel, and who sponsored the clinical trials used for EU and US marketing approval.

4. TACD asks the European Commission's DG Entreprise to report on the barriers to entry for generic forms of Paclitaxel in the EU market.

5. TACD asks DG SANCO to report on the public health consequences of barriers to entry for generic forms of Paclitaxel in the EU market.