The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: **EUROPEAN ECONOMIC COMMUNITY**

2. Agency responsible: Commission of the European Communities

3. Notified under Article 2.5.2 [✓], 2.6.1 [✗], 7.3.2 [✓], 7.4.1 [✗], Other:

4. Products covered (CCCN where applicable, otherwise national tariff heading):
   Medicinal products for human and veterinary use (EX-CH.30)

5. Title: Regulatory Measures in Favour of High Technology Medicinal Products, Particularly those Derived from Biotechnology

6. Description of content: New procedures to co-ordinate measures adopted by the member States on the marketing of biotechnology and other high technology medicinal products; amendment of the requirements for the acute toxicity testing of human and veterinary medicines; introduction at Community level of the requirement that safety tests on human and veterinary medicines comply with good laboratory practices; guidelines on the conduct of certain tests and trials on human medicines; new procedures for amending the detailed testing requirements for human and veterinary medicines.

7. Objective and rationale: To facilitate the marketing of high technology medicinal products in the Community and to ensure that the detailed testing requirements for medicinal products reflect the current state of scientific and technological progress.


9. Proposed dates of adoption and entry into force: Adoption: Before 1 July 1985
   Entry into force: 1 January 1986

10. Final date for comments: 31 March 1985

11. Texts available from: National enquiry point [✓] or address of other body: