TACD

TRANS ATLANTIC CONSUMER DIALOGUE

DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

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TRANSPARENCY OF PHARMACEUTICAL ECONOMICS

1. TACD recommends the US and the EU governments undertake the following measures:

   i. Any application for data exclusivity should include a disclosure of the costs of data collection.

   ii. The EU and the US should require firms that market pharmaceutical drugs in the US or the EU market to disclose, for each product,
      A. annual global (and national) revenues,
      B. costs of clinical trials, disaggregated by timing and nature of trial (Phase I, II, III, IV, etc), the number of patents and the duration of the trial,
      C. when the product involves licenses from third parties, the royalty payments and terms, and
      D. the role of the government in the development of the drug, including the awarding of grants, cooperative research and development agreements, licenses, tax credits and other subsidies.

   iii. Governments should publish data detailing the government's own costs of conducting clinical trials, which can be used as a benchmark for the cost of clinical trials.

   iv. The government should publish reports detailing public expenditures on the purchase of products developed initially with public funds.

2. TACD recommends that consumers and policy makers obtain better information about pharmaceutical economics. One of the most vexing issues in pharmaceutical policy making is the paucity of data to justify pharmaceutical industry assertions regarding drug development costs, profit margins or other relevant economic data. Governments have been negligent in collecting independent data on pharmaceutical economics. Accurate data on the economics of the pharmaceutical industry are needed to evaluate a wide range of government policies, including, for example:

   i. patent extensions,
   ii. pricing,
   iii. market exclusivity for health registration data,
   iv. orphan drug market exclusivity,
   v. compulsory licensing,
   vi. government technology transfer policies,
   vii. scope of patents, and
   viii. taxes.

There is a substantial public interest in having more detailed disclosures of private sector R&D investments, to address such questions as what is the percentage of R&D investments spent on development of new and innovative products, as opposed to "me too" therapies? How much of the private sector R&D budget is spent on non-essential medicines? What is the private sector allocation of spending between pre-clinical development, clinical trials, and post approval R&D? How much R&D is spent on tropical illnesses and other diseases that affect the poor? How much did the drug benefit from public subsidies?