Orphan medicinal products

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Pharmaceutical research and development is not profitable for those approximately 5000 diseases that affect relatively few people and are thus considered as rare. Few companies are willing to make the investment and go through the administrative procedures required if the product will only be supplied to a small number of patients - hence the name "orphan drugs". The Committee adopted a report by Christian CABROL (UFE, F) on a Commission proposal for a Regulation to establish a Community procedure for designating orphan medicinal products and to introduce incentives for research, development and marketing (codecision procedure, first reading). This initiative follows the idea of the very successful U.S. "Orphan Drug Act" from 1983. In the community, the fourth Framework Programme for Research is already covering research on orphan drugs. The proposal's aim is to give incentives to the pharmaceutical companies concerned e.g. by an accelerated procedure for obtaining Community marketing authorisation and exemption for the applicant from paying all or part of the fee due on lodging the file. There will also be market exclusivity for ten years. National incentives should be allowed. Among the amendments adopted by the committee were the following: - A proposal for the setting up of an Orphan Medicinal Product Innovation Promotion Fund. It should be financed by the proceeds from the sale of orphan drugs after the expiry of the 10-year period exclusivity. - An addition to the definition of "orphan medicinal products" saying that it is unlikely that, without incentives, the marketing of the medicinal product in the community would generate sufficient return to justify the necessary investment.