The European Pharmacopoeia (Pharmacopoeia Europaea, Ph. Eur.) is a major regional pharmacopoeia which provides common quality standards throughout the pharmaceutical industry in Europe to control the quality of medicines, and the substances used to manufacture them. It is a published collection of monographs which describe both the individual and general quality standards for ingredients, dosage forms, and methods of analysis for medicines. These standards apply to medicines for both human and Convention on the Elaboration of a European Pharmacopoeia. The European Pharmacopoeia was created within the legal framework of the Convention on the Elaboration of a European Pharmacopoeia (CETS 050). Signatory parties are obligated to accept the standards set in the European Pharmacopoeia and if need be give them priority over already existing national standards. The institution responsible for the elaboration of the European Pharmacopoeia and its constant further development is the European Directorate for the Quality of Medicines & HealthCare (EDQM). The EDQM is composed of 240 specialists with backgrounds in pharmaceutics, biology, chemistry, bio-chemistry, medicine, medical technology and administration.

PROTOCOL TO THE CONVENTION ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA (ETS No. 134) (Strasbourg, 16.XI.1989)

Preamble The member States of the Council of Europe which are Parties to the Convention on the Elaboration of a European Pharmacopoeia of 22 July 1964 drawn up within the Council of Europe's Partial Agreement in the Social and Public Health Field, hereinafter called. “the Convention”, Having regard to the Convention and particularly to the provisions of Article 1 thereof; Considering that the European Economic Community has adopted rules particularly in the form of dire