EUROPEAN PHARMACOPOEIA

VOLUME II 1971

COUNCIL OF EUROPE

EUROPEAN PHARMACOPOEIA

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NOTICE

The official texts of the European Pharmacopoeia are in French and English and are published in the present volume and its French language counterpart.

No translation to other languages may be considered as official other than those appearing in the national pharmacopoeias of the signatory countries of the European Pharmacopoeia Convention or those which may from time to time be authorised by the European Pharmacopoeia Commission and published by authority of the Council of Europe.

All communications concerning the European Pharmacopoeia should be addressed to the Secretary to the European Pharmacopoeia Commission, *Council of Europe - Strasbourg - France.*

INTRODUCTION

The publication of this, the second volume of the European Pharmacopoeia, marks an important stage in the "progressive elaboration" of a pharmacopoeia common to the countries concerned, as envisaged in the Convention of July 1964 and desired by the eight signatory States.

This volume, like the first, is the result of the patient and energetic efforts of specialists in all our countries who have voluntarily contributed their expert knowledge and the services of their laboratories to the work of the Commission. Its importance lies in the number of monographs it contains and in their quality and variety.

During this stage the Commission has been confronted by a number of often fundamental and difficult administrative and legal problems concerning, for example, methods of biological assay, the use of reference substances and the procedure to be followed for revising monographs.

The style of presentation adopted in the first volume has been retained; however, attention is drawn to the detailed summary of contents included at the beginning of the book, and to the index which is cumulative for the two volumes.

A number of corrections to the texts of the first volume have been included as a separate chapter, except in the case of corrections to reagents: the latter will be found in the Reagents chapter.

The General Notices have been revised and extended and, for convenience, are printed in full in Volume II. They are applicable without distinction to both volumes.

In presenting the nomenclature and structural formulae of chemical substances, the rules of the International Union for Pure and Applied Chemistry have been followed wherever possible. Resonance formulae have not been shown. The stereochemistry of compounds has been shown when this affects their pharmacological activity or when it is justified in connection with the analytical identification of certain isomers.

The chapter on analytical methods has been enlarged, particularly by the introduction of amperometry, fluorimetry and gas chromatography and the application of infra-red spectrophotometry and of thin-layer chromatography in the identification and purity tests of the steroid hormones.

Of the monographs a large proportion has been devoted to antibiotics, steroid hormones and vaccines and immunosera.

When fiducial limits are prescribed, it is intended that a statistical analysis using recognised mathematical techniques shall be applied to the experimental results of the assays. The Commission has decided that it would be useful to publish, for information in the Annex, a section on the statistical interpretation of the results of biological assays, giving examples.

Surgical dressings and ligatures are the subject of a number of monographs which have presented particular problems. It is interesting to note the new system which has been introduced to indicate the diameters of surgical ligatures, using a decimal number which corresponds to the diameter expressed in tenths of a millimetre.

The completion of these monographs has called for a considerable amount of research on the part of the experts: this and the discussions which have taken place in the Commission have been characterised throughout by a real and unanimous desire to arrive at conclusions acceptable to all concerned.

The elaboration of a common Pharmacopoeia is now well advanced: it constitutes an irreversible phenomenon. The work is continuing and it is hoped that in the not too distant future the stage will be reached where the task will consist only of keeping it up to date.

It is with great satisfaction that I associate in my appreciation and thanks the members of the Commission, the members of the Groups of Experts and the officers of the Technical Secretariat, each of whom in his own special sphere has undertaken a heavy task, sometimes hazardous but always exhilarating, and has carried it out with conviction, care and patience, happy through the European Pharmacopoeia, to make his contribution to the building of a united Europe.

CARL STAINIER

Chairman of the Commission 1968-1971

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