European Pharmacopoeia

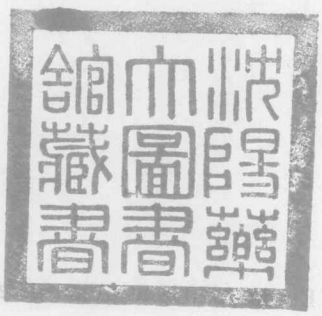
3rd Edition

1997

EUROPEAN PHARMACOPOEIA

Third Edition

Published in accordance with the
Convention on the Elaboration of a European Pharmacopoeia
(European Treaty Series No. 50)



Council of Europe
Strasbourg

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I. PREFACE

This is the Third Edition of one of the world's youngest pharmacopoeias, perhaps the youngest of all. It is a little more than thirty years since the Convention on which our work is based was signed by the eight founding members. Each of the first two editions was published over a period of about fifteen years: the first represented a formative period during which were developed the principles on which this international co-operative project was to be based; during the period of expansion represented by the second edition the number of monographs has quadrupled, reaching almost 1200.

In 1994, the European Pharmacopoeia Commission decided that the time had come to consolidate the work achieved, to implement a limited number of technical revision changes and to present the European Pharmacopoeia in a form that would be more convenient for users than the loose-leaf format that had served well during a period of expansion but was beginning to outlive its purpose. In view of the resources available and the strong desire to commit as much of them as possible to continued expansion, this decision was made only when there was assurance that such consolidation could be carried out without interfering with other work.

The Third Edition will be published over a much shorter period than its predecessors. Since the basis of the edition has been consolidation rather than extensive technical revision, the Commission has already initiated plans for a more extensive revision programme whose results will be incorporated into the Fourth Edition in four or five years' time. For the Third Edition, the Commission decided to concentrate on a limited number of revision topics: priority has been given to replacement of tests using experimental animals and to elimination wherever possible of toxic reagents from test methods. The reduction in the need for experimental animals is impressive with wide introduction of the test for bacterial endotoxins instead of the pyrogens test in rabbits in many monographs, especially antibiotics, the elimination of the test for abnormal toxicity in many monographs on antibiotics and vaccines and the introduction of physico-chemical assay methods for a number of biological products.

Users will note that the opportunity has been taken to reorganise parts of the Pharmacopoeia in such a way as to make them more easy to use. The former annexes, which had a special status, have been moved so that they are placed at the end of the monographs or general chapters that they concern; their different status is explained at the head of each text. The General Notices, which define interpretation rules for the texts of the Pharmacopoeia, have been thoroughly revised and reorganised: they should be consulted by all users. Some informative statements formerly included in the General Notices have been moved to an Introduction which gives amongst other things general information on policy matters of the Commission.

The period covered by the Second Edition was marked by innovation as well as expansion: the Biological Standardisation Programme, a joint activity with the Commission of the European Communities was initiated in 1991 and many reference preparations established under the programme are now in use; the Scheme for Certification of Suitability of Monographs was launched and is now functioning routinely; the European Pharmacopoeia was made available in CD-ROM form with an innovative operating system that enables users to exploit fully the resources. All of these will continue during the Third Edition. The most recent innovation has been the creation of the European network of official medicines control laboratories. This has entailed administrative restructuring with the creation within the Council of Europe of the European Department for the Quality of Medicines having two distinct branches, one dealing with the pharmacopoeia, the other with the network. The network will bring the Pharmacopoeia closer to one of its groups of users and we hope will bring benefits for all concerned.

As a result of the publication of the medical devices directive of the European Union, the inclusion of

sutures and dressings in the Pharmacopoeia has been reconsidered. A memorandum of understanding drawn up with CEN now defines the responsibilities of each body for standardisation of medical devices. The monographs on sutures will be maintained in the Pharmacopoeia but most dressings have been deleted with the publication of the Third Edition.

One of the aims of our work has always been international harmonisation within Europe but the global nature of the pharmaceutical industry obliges us to look towards even wider horizons. In the past few years a considerable effort in international harmonisation of pharmacopoeial standards has been made in co-operation with the pharmacopoeias of Japan and the United States of America. The goal of harmonisation is to bring the policies, standards, monograph specifications, analytical methods and acceptance criteria of these pharmacopoeias into agreement. Where a single common standard cannot be achieved, harmonisation means agreement based upon objective comparability and a clear statement of any differences. The procedures are now well-established and readers of Pharmeuropa will be familiar with the regular section devoted to the various stages of the system. The different stages in the harmonisation process from the 'Proposal stage' (stage 1) where a first draft is prepared, to the 'Consensus stage' (stage 5) are explained more fully in Pharmeuropa 7.1 under the annual review of the activities of the Pharmacopeial Discussion Group (PDG). The general chapters and monographs included in the Third Edition that have completed all the stages of international harmonisation are listed under "IV. Contents of the Third Edition".

The increase in the number of monographs has led to a similar increase in the number of reference substances and there are now over seven hundred in the catalogue. These reference materials are supplied to countries throughout the world in steadily increasing quantities. Their establishment and monitoring represent a major responsibility for the Technical Secretariat.

In addition to the expansion of coverage of the European Pharmacopoeia in terms of the number of monographs, there has been a steady increase in the number of participating countries which has tripled from the number of founding members of 1964. We can expect this expansion to continue over the next few years until this becomes truly the pharmacopoeia of the whole of Europe. The Commission, composed of delegations from the member States, welcomes to its Sessions a number of observer delegations, some from European countries that have the opportunity to sign the Convention: Bulgaria, the Czech Republic, Hungary, Lithuania, Poland, Roumania. Other observers come from further afield: Australia, Canada, the People's Republic of China and Syria.

In 1991, arrangements were made for new premises in Strasbourg for the Technical Secretariat which had for many years been housed in a very picturesque wood-frame building with a interesting history but which was increasingly unsuited to current needs. The new premises have been tailored to the needs of the Secretariat and are able to accommodate the substantial increase in staff numbers. The Commission records its indebtedness to the governments of the Member States for the financial contributions that have made this possible.

The Commission is greatly indebted to those many people who do the detailed work needed to maintain and expand the Pharmacopoeia. The many experts and specialists contribute an enormous amount of expertise and experience, on a voluntary basis. Colleagues in national pharmacopoeial authorities, control laboratories, the universities and industry all make their contribution. We gratefully acknowledge all that these people bring to our work.

On behalf of the Commission and myself, I thank very warmly all the members of the Technical Secretariat, the Director and her Deputy, scientists in the offices and laboratories, translators, secretaries and administrative staff, for their special contribution to the success of the Pharmacopoeia.

Lastly, I thank members of the European Pharmacopoeia Commission for their individual efforts which contribute largely to the success of the European Pharmacopoeia and for their inspiring support and goodwill that has been shown to me.

Prof. Dr D Schnädelbach

Chairman of the European Pharmacopoeia Commission

II. INTRODUCTION

The European Pharmacopoeia is published in accordance with the terms of the *Convention on the elaboration of a European Pharmacopoeia* (European Treaty Series No. 50) as amended by the Protocol to the Convention (European Treaty Series No. 134) under the auspices of the Council of Europe, signed by the Governments of Austria, Belgium, Bosnia-Herzegovina, Croatia, Cyprus, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, "the Former Yugoslav Republic of Macedonia", Turkey, the United Kingdom of Great Britain and Northern Ireland, and by the European Community.

The preparation of the Pharmacopoeia is the responsibility of two principal bodies:

1. *The Public Health Committee*, whose composition and functions are set out in Articles 3 and 4 of the Convention as amended by the Protocol:

   Article 3.

   "For the purposes of the present Convention, the Public Health Committee shall be composed of delegations appointed by the Contracting Parties".

   Article 4.

   "1) The Public Health Committee shall exercise a general oversight over the activities of the Commission and for this purpose the Commission shall submit a report on each of its sessions to the Public Health Committee.

   2) All decisions taken by the Commission, other than those of a technical or procedural character, shall be subject to the approval of the Public Health Committee. If the Public Health Committee does not approve a decision or approves it only partially, the Committee shall refer it back to the Commission for further consideration.

   3) The Public Health Committee, having regard to the recommendations of the Commission under Article 6 *(d)*, shall fix the time limits within which decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the contracting Parties".

2. *The European Pharmacopoeia Commission* is appointed in accordance with Article 5 of the abovementioned Convention. It is composed of delegations appointed by the Contracting Parties. Each delegation consists of not more than three members chosen for their competence in matters within the functions of the Commission.

   The functions of the commission established by Article 6 of the Convention as amended by the Protocol are:

   Article 6.

   "Subject to the provision of Article 4 of the present Convention, the functions of the Commission shall be:

   (a) to determine the general principles applicable to the elaboration of the European Pharmacopoeia;

   (b) to decide upon methods of analysis for that purpose;

   (c) to arrange for the preparation of and to adopt monographs to be included in the European Pharmacopoeia and;

   (d) to recommend the fixing of the time limits within which its decisions of a technical character relating

to the European Pharmacopoeia shall be implemented within the territories of the Contracting Parties."

In accordance with the terms of the Convention, the Contracting Parties undertake to take the necessary measures to ensure that the monographs of the European Pharmacopoeia shall become the official standards applicable within their respective territories.

PURPOSE OF THE EUROPEAN PHARMACOPOEIA

The purpose of the European Pharmacopoeia is to promote public health by the provision of recognised common standards for use by health-care professionals and others concerned with the quality of medicines. Such standards are to be of appropriate quality as a basis for the safe use of medicines by patients and consumers. Their existence:

- facilitates the free movement of medicinal products in Europe;
- ensures the quality of medicinal products exported from Europe.

European Pharmacopoeia monographs and other texts are designed to be appropriate to the needs of:

- regulatory authorities;
- those engaged in the control of quality;
- manufacturers of starting materials and medicinal products.

The European Pharmacopoeia is widely used internationally and it is the intention of the Pharmacopoeia Commission to work more closely with users of the Pharmacopoeia in order to better satisfy their needs and facilitate their cooperation. To this end improved procedures will be sought for obtaining advice on priorities for elaborating new monographs and enhancing the quality of the Pharmacopoeia.

TECHNICAL SECRETARIAT AND LABORATORY

The European Pharmacopoeia Commission has a Technical Secretariat with scientific and administrative staff, situated in Strasbourg. The European Pharmacopoeia Laboratory is situated within the Secretariat and, amongst other duties, is in charge of the establishment and monitoring of all reference materials needed for the monographs of the Pharmacopoeia.

GENERAL PRINCIPLES

General rules for interpretation of the texts of the Pharmacopoeia are given in the General Notices. The following information should also be noted.

The general principles applied in the elaboration of the European Pharmacopoeia are laid down in the *Technical Guide for the Elaboration of Monographs* available as a special issue of *Pharmeuropa*.

It is recognised that general chapters are used elsewhere than in the monographs of the Pharmacopoeia; in these circumstances users are recommended to consult the Technical Guide which gives extensive information on the application of many of the methods.

Patents. The description in the Pharmacopoeia of articles subject to protection by patent does not confer or imply any right to the use of such patents by any person or persons other than the proprietors of the patents concerned.

Use of animals. The Commission is committed to the reduction of animal usage, wherever possible, in pharmacopoeia testing and encourages those associated with its work to seek alternative procedures. An alternative or modified method is adopted by the Commission once it has been clearly demonstrated that it offers satisfactory control for pharmacopoeial purposes.

Hydrates. The degree of hydration is indicated in the titles of monographs only where more than one form is included in the Pharmacopoeia or where more than one form is currently available in commerce.

Chiral substances. The present policy of the Commission is to include a test for optical rotation for all chiral substances, either to confirm the racemic nature or to determine the specific optical rotation where a particular enantioner is required by the monograph. In older monographs published in the Second Edition and not technically revised since the present policy was established, for racemates and racemic mixtures a test to confirm the racemic nature has not usually been included unless the optically active form is also described or is readily available in commerce.

Polymorphism. Where a substance may show polymorphism, this is usually stated under Characters. In general, no particular crystalline form is required in monographs; exceptionally, in a few monographs, the crystalline form required is specified, for example, via an infrared absorption spectrophotometric identification test where the spectrum is required to be recorded using

the substance in the solid state without recrystallisation, the chemical reference substance provided being of the required crystalline form. However, for substances other than these exceptional cases, depending on the use of a given substance in a dosage form, it may be necessary for a manufacturer to ensure that a particular crystalline form is used. The information given under Characters is intended to alert users to the need to evaluate this aspect during the development of a dosage form.

Specificity of assays. For the elaboration of monographs on chemical substances, the approach preferred by the Commission is to provide control of impurities via a well designed Tests section rather than by the inclusion of an assay that is specific for the active principle. It is therefore the full set of requirements of a monograph that is designed to ensure that the product is of suitable quality.

Impurities. Many monographs, particularly those recently published, now have appended a list of known or potential impurities shown to be controlled by the tests. Known impurities (also referred to as 'actual impurities') are those that have been observed in batches of the substance; potential impurities are those that although they might be expected, from knowledge of the manufacturing process, to occur have not in fact been observed in batches during elaboration of the monograph. This list is intended to facilitate use of the monograph, especially during the licensing process for medicines (see *Impurities in new drug substances*, ICH tripartite note for guidance, May 1995). A series of potential impurities for a substance obtained by a given manufacturing process may be compared with the list to establish whether the monograph provides sufficient control. It is the intention of the Commission to include such lists wherever possible in new monographs and to add them to existing monographs during revision.

Medical devices. All editions of the Pharmacopoeia have contained monographs on articles that are regarded as medical devices, notably surgical sutures and dressings. For member States of the European Union, a unified framework for standardisation of medical devices is now provided by a directive. Following an agreement between the various parties involved, the Commission has decided that the monographs on dressings will be deleted once standards have been developed as foreseen by the directive. Specifications included in the section on containers will be adapted or, in some instances, deleted, to take account of future standards developed within the framework of the directive. The monographs on surgical sutures are to remain in the Pharmacopoeia but they have been modified to conform to the requirements of the directive and are now to be seen as standards of the type foreseen there. This adaptation of the monographs has involved deletion of some monographs on specific types of sutures in favour of a more general approach.

CERTIFICATION PROCEDURE

A procedure for the certification of suitability of monographs of the Pharmacopoeia with respect to control of the purity of a product from a given source has been established [see Public Health Committee (Partial Agreement) Resolution AP-CSP (93) 5]. Certificates may be granted with respect to published monographs or those available as definitive texts (see below). Details of the operation of this scheme are available from the Secretariat.

PUBLICATIONS

The **European Pharmacopoeia** is available in English and French versions in the form of a book with an annual supplement, and as an annually updated CD-ROM.

Pharmeuropa, the European Pharmacopoeia Forum, is published several times each year as an aid in the elaboration of monographs and as a vehicle for information on pharmacopoeial and related matters. It is available on subscription from the Technical Secretariat.

Definitive texts. Texts adopted by the Commission in any given year are published in the first half of the following year. In the period between adoption and publication, they are available from the Technical Secretariat as definitive texts in a 'Prepublication' brochure.

Implementation. The date on which monographs are to be implemented is fixed by the Public Health Committee following a recommendation by the Commission. This date is usually about six months after publication. Where a monograph is to be implemented at a date earlier than the next publication date of the Pharmacopoeia or a supplement, a Resolution of the Public Health Committee gives the full text to be implemented. The text is also published in *Pharmeuropa* for information.

Revision programme. Monographs and other texts of the Pharmacopoeia are revised as necessary following a decision of the Commission. The current revision programme is published in *Pharmeuropa*.

III. EUROPEAN PHARMACOPOEIA COMMISSION

COMPOSITION OF THE COMMISSION, IT'S GROUPS OF EXPERTS AND OF THE SECRETARIAT AS OF 31ST MARCH 1996.

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Croatia	L. STEFANINI ORESIC
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Greece	S. PHILIANOS A. TSOKA
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Italy	A. CASSONE M. CIGNITTI A. FARINA
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Group No 10C – Organic Chemistry - Synthetic Products

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Specialists:	
I	A. DE PASQUALE

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NL	J.H. ZWAVING
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Specialists:	
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F	S. BESSET
F	B. BRANCQ
I	G. DUGO
N	H. BREIVIK
D	H.D. KÄSEBORN
F	C. LEGE
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Experts:	
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CH	C. WASTIEL
D	R. SUCHI
DK	B. PEDERSEN
E	M. ROCA
F	L. MERLIN
GB	R.D. PICKETT
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N	P.O. BREMER
NL	M. KROON
Specialists:	
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F	B. MAZIERE
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IV. CONTENTS OF THE THIRD EDITION

For the information of the reader, lists are given below of: new monographs and general chapters added to the Pharmacopoeia with the publication of the Third Edition; monographs and general chapters that have been technically revised since the publication of the last fascicule of the Second Edition; monographs that were suppressed during the course of the Second Edition or that will be suppressed with the implementation of the Third Edition; list of monographs that have been revised or elaborated in collaboration with the Pharmacopoeias of the United States and Japan.

There has been a general change to the system of alternative identification schemes that was introduced in the Second Edition which is to be regarded as a technical change. The two identifications no longer have the same status and the second identification is subsidiary, as defined in the General Notices. The monographs having undergone such revision are not included in the list of technically revised monographs given below.

The monographs on dosage forms have been rearranged and are published apart from the other monographs. During this rearrangement, some dosage forms previously the subject of an individual monograph have been placed as sub-monographs in a more general category. Although such monographs may appear to have been suppressed, in reality this is not the case since specifications for the dosage forms in question are still included. Similarly the former annexes to the Pharmacopoeia have been re-arranged editorially and now appear with the monographs or general chapters concerned.

NEW TEXTS INCLUDED IN THE THIRD EDITION

Monographs

General Monographs on Dosage Forms

General Chapters