EUROPEAN PHARMACOPOEIA

VOLUME III

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PREFACE

It is now ten years since I had the honour of presiding at the inaugural Session of the European Pharmacopoeia Commission, during which the first Chairman was elected. At the end of my term of office, in looking back over these ten years I see with great satisfaction the extent of the work of the Commission, which with calmness and determination has overcome so many difficulties which lay in its path.

I must, above all, pay tribute to Professor G.B. MARINI-BETTOLO and Professor Carl STAINIER, my predecessors in the office I have held for three years. Their scientific ability and the patience and good will they have shown have brought us safely through the first delicate stages of our work. Differences in legislation and traditions as well as human personalities have necessarily had to be faced, but thanks to my predecessors an atmosphere of confidence was rapidly created which enabled the common task to be achieved in a spirit of harmony.

To list all the achievements of the last three years would take too long. They are represented, in fact, by the contents of the present Volume and I do not wish to yield to the temptation to draw attention to the inclusion of this or that text which may have taken more time or encountered more difficulties than another. I shall underline only what seems to be new or to have special importance from a European or International stand-point.

— Radiopharmaceutical preparations comprising a general introduction and eight monographs, have been grouped in a special chapter separate from the normal alphabetical arrangement because of the special nature of this subject. Hitherto few pharmacopoeias other than the European Pharmacopoeia have dealt with this intricate problem; consequently the publication of these texts is of very great interest in all pharmaceutical and medical circles.

— Vaccines and Sera for veterinary use, though not yet included in the third volume, will be published within a few months. The Group of Experts concerned with these texts began work in 1970 and has held seventeen meetings. The monographs produced constitute one of our most interesting achievements, since they are the first to establish international unification in this field.

— A general monograph on Parenteralia, included in this Volume, marks the adoption of a long debated principle. About twelve monographs of this type are in course of preparation, several of which, and particularly that on Tablets, are almost completed. These general monographs on galenical pharmaceutical products will be applicable to all preparations in this category. However, it is important to note that the general monographs on immunosera and vaccines for human and veterinary use and the general chapter on radiopharmaceutical preparations apply only to those preparations which are the subject of monographs in the European Pharmacopoeia, in order to take account of the various sources and different special characters of these classes of medicaments.

— In preparing a monograph on Vitamin A and Vitamin A Concentrates, the experts concerned have carried out many collaborative experiments in order to arrive at valid methods of control.

— Finally, it should be noted that fifteen recognised analytical methods have been added; some of these, such as atomic absorption, are introduced into the Pharmacopoeia for the first time.

The publication of this third volume and the forthcoming Supplement mark the completion of the first edition of the European Pharmacopoeia.

The preparation of a second edition will begin immediately and will include monographs already in the course of elaboration together with corrections and amendments proposed by the delegations. During this stage of the work it is not intended to call in question the work already accomplished, but the revision, which has already begun will, over the next few years, bring the texts up to date. The new member States will be able to participate in this process.

During my term of office I have had the pleasure of seeing the last two of the signatory States ratify the CONVENTION ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA, thus permitting Denmark and Ireland, who already have Observer status, to become, at an early date, Parties to the Convention. Since the consequence of this ratification is to open the possibility of accession to all the member States of the Council of Europe, I would like to express the hope that other countries will join and thus achieve our aim of a common Pharmacopoeia for the whole of Western Europe.

It will fall to the task of my successor to facilitate the accession and to integrate the representatives of these countries into a body which has now gone through its initial trial period: the Commission and its Groups of Experts are now well accustomed to their rules of procedure and methods of work.

In concluding my comments I wish to pay tribute to the very considerable work carried out by the Commission and its Groups of Experts, work which is far more extensive than the completion of the present volume. I also wish to thank the numerous experts who in one way or another have assisted us and have so generously contributed their effort and their time. The Technical Secretariat also has carried out its responsibilities with efficiency and discretion, an often thankless task, without which no useful results could have been achieved.

Once more, with the present volume of the Pharmacopoeia, a new stone is added to the building, whose importance for the construction and the prestige of a united Europe will be appreciated far beyond the frontiers of our several States.

LÉON ROBERT
Chairman of the Commission 1971-1974

THE EUROPEAN PHARMACOPOEIA COMMISSION

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1971 — 1974

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GROUPS OF EXPERTS

In accordance with Rule 6 of the Rules of Procedure approved by the Public Health Committee and adopted by the Commission, Groups of Experts are appointed by the Commission, being chosen for their personal competence from the proposals of the delegations.

Group No. 1

Biological Methods and Statistical Analysis

F. HARTLEY, *Chairman*	(United Kingdom)
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Chemical Methods

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A. MARIANI	(Italy)
P. de MOERLOOSE	(Belgium)
M. PESEZ	(France)

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Group No. 3

Nomenclature and Drafting

P. LALANNE, *Chairman*	(France)
L. ANKER	(Switzerland)
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R. MOREAU	(France)
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Physical and Physico-Chemical Methods

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E. STÜRMER	(Switzerland)
L. TENTORI	(Italy)
E. VAIREL	(France)

Sub-Group: Insulin Preparations

The following Experts in collaboration with the members of Group No. 6 participated in the elaboration of the monographs on insulin.

J. MACABIES	(France)
A.C.C. NEWMAN	(United Kingdom)
J.W. de VRIES	(The Netherlands)

Group No. 7

Antibiotics

H. VANDERHAEGHE, *Chairman*	(Belgium)
E. COTTA-RAMUSINO	(Italy)
M. DUBOST	(France)
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Group No. 9

Inorganic Chemistry

A. CALÒ, *Chairman*	(Italy)
L. DRYON	(Belgium)
J. FLAHAUT	(France)
J.A. FRESEN	(The Netherlands)
D. GIEGLING	(Germany)
E.F. HERSANT	(United Kingdom)
H. MÜHLEMANN	(Switzerland)
J. RONDELET	(Belgium)
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Group No. 10

Organic Chemistry - Synthetic Products

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L. ANKER	(Switzerland)
J. BOSLY	(Belgium)

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Group No. 11

Organic Chemistry - Natural Products

M.-M. JANOT, *Chairman*	(France)
J. ALLEN†	(United Kingdom)
P. CORDIER*	(France)
W. DECKERS	(Germany)
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Sub-Group: Vitamin A

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G.F. PHILLIPS	(United Kingdom)
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† Died 1973.

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K. KREBS, *Chairman***	(Germany)
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A. LE HIR	(France)
K. MÜNZEL	(Switzerland)
J. POLDERMAN	(The Netherlands)
G. ROSS	(Germany)

Group No. 13

Pharmacognosy

F.H.L. van Os, *Chairman*	(The Netherlands)
P. DUQUÉNOIS	(France)
J.W. FAIRBAIRN	(United Kingdom)
L. FAUCONNET*	(Switzerland)
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J. LEMLI	(Belgium)
A. MIRIMANOFF*, *Former Chairman*	(Switzerland)
E. STAHL	(Germany)
E. STEINEGGER	(Switzerland)
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Sub-Group: Fatty Oils

The following Experts in collaboration with the members of Group No. 13 participated in the elaboration of the monographs on fatty oils and the general methods applied to them.

K. MÜNZEL	(Switzerland)
W. HEERS	(Germany)
R. LARDÉ	(France)
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* Retired 1972.
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Group No. 14

Radioactive Compounds

R. PAUL, *Chairman*	(France)
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P. DUMONT	(Belgium)
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Group No. 15

Vaccines and Sera

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Sub-Group: Blood and Blood Products

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G. GHYSELS	(Belgium)
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* Retired 1973.

CONTENTS

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