Appendix 36
MEDICAL PREPARATIONS ( LICENSING, ADVERTISEMENT AND SALE) REGULATIONS, 1984.

The Minister for Health, in exercise of the powers conferred on him by sections 5 of the Health Act, 1947 (No. 28 of 1947) as amended by section 39 of the Health Act, 1953 (No. 26 of 1953) and by section 36 of the Misuse of Drugs Act, 1977 (No. 12 of 1977) hereby makes the following Regulations:

1. These Regulations may be cited as the Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984.

2. (1) Subject to sub-article (2) these Regulations shall come into operation on the 1st day of October, 1984.

(2) Article 4 of these Regulations shall come into operation, in the case of each category of medical preparation specified in the first column of the Second Schedule, with effect from the commencement date specified in the third column of that Schedule in respect of each sub-category of such preparation specified in the second column thereof.

(3) A person who on the 1st day of October, 1984, in circumstances to which article 4 applies, is responsible for the sale of any medical preparation or for procuring the manufacture for sale of any medical preparation specified in sub-category (2) of category 2 of the Second Schedule shall by the 1st day of December, 1984 notify the Minister in respect of such preparation, giving the name of the preparation, its dosage form and its active constituents in qualitative and quantitative terms.

3. (1) In these Regulations—

"the Act" means the Health Act, 1947;

"import" includes procure the importation, and cognate words shall be construed accordingly;

"the Minister" means the Minister for Health;

"manufacture" includes processing, compounding, formulating, assembling, filling, packaging, labelling and importing from countries other than Member States of the European Economic Communities;

"pharmacist" means a registered pharmaceutical chemist or a registered dispensing chemist and druggist;

"registered dentist" means a person registered in the register established under the Dentists Act, 1928 (No. 25 of 1928);

"registered dispensing chemist and druggist" means a person registered in the register of dispensing chemists and druggists established under the Pharmacy Act, 1951 (No. 30 of 1951);

"registered medical practitioner" means a person registered in the register established under the Medical Practitioners Act, 1978 (No. 4 of 1978);

"registered pharmaceutical chemist" means a person registered in the register of pharmaceutical chemists for Ireland established under the Pharmacy Act (Ireland), 1875;

"sell" includes distribute or offer or keep for sale or distribution or procure the sale or distribution, and cognate words shall be construed accordingly.

(2) In these Regulations any reference to an article or Schedule shall be construed as a reference to an article contained in these Regulations or as the case may be, to a Schedule thereto, any reference in an article to a sub-article shall be construed as a reference to a sub-article of that article and any reference in a Schedule to a paragraph shall be construed as a reference to a paragraph of that Schedule.

4. (1) A person shall not, in the course of a business carried on by him and in the circumstances to which this article applies—
   
   (a) sell any medical preparation, or
   
   (b) procure the manufacture for sale of any medical preparation,

except in accordance with a licence granted or renewed by the Minister under these Regulations, hereinafter referred to as a "product authorisation".

(2) This article shall apply in each of the following circumstances:—

   (a) where the person selling the preparation or procuring the manufacture for sale of the preparation has imported the preparation;
   
   (b) where the person selling the preparation or procuring the manufacture for sale of the preparation is responsible for the composition of the preparation and has not imported the preparation.

(3) For the purposes of sub-article (2) (b) a person shall be taken to be responsible for the composition of a medical preparation where he either:

   (a) manufactures the preparation to his own order or specification, or
   
   (b) procures, to his own order or specification, the manufacture of the preparation by another person.

(4) Subject to article 5 a person shall not import a medical preparation except in accordance with a product authorisation.

5. The provisions of article 4 shall not apply as respects:—

   (a) the sale of a medical preparation by a person lawfully keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons under the Pharmacy Acts, 1875 to 1977 where such sale is carried out and the preparation is extemporaneously compounded by or under the supervision of a pharmacist for such particular sale;
   
   (b) the importation or sale of a medical preparation by or to the order of a registered medical practitioner or registered dentist for the treatment of a patient under his care;
   
   (c) the importation of a medical preparation by any person for his own personal use, not being an importation resulting directly from a mail order advertisement directed to members of the public;
   
   (d) the importation or sale of a medical preparation solely for the purpose of its being exported.

6. (1) The Minister may grant or renew a product authorisation to any person who applies for such authorisation in accordance with article 7.

(2) A product authorisation shall be subject to the general conditions specified in the First Schedule to the Regulations and to such special conditions as may be specified in the authorisation.

(3) Unless sooner revoked by the Minister a product authorisation shall remain in force for a period of five years and may be renewed on application by the holder.

7. (1) An application for a product authorisation shall be made to the Minister and shall be in such form and be accompanied by the appropriate charge provided for under article 10 and by such information, documents, samples and other materials, as the Minister may require.

(2) An application for a product authorisation for a medical preparation in sub-category (2) of category 2 of the Second Schedule shall be made to the Minister at least twelve months before the commencement date applicable to medical preparations listed in the said sub-category.
(3) In the examination and determination of an application for a product authorisation the Minister shall take into consideration such criteria as appear to him to be relevant in the case of the application and, in particular, the information supplied by the applicant in relation to—

(a) the safety and efficacy of the medical preparation to which the application relates and the purpose for which the medical preparation is intended by the applicant to be administered, and

(b) the quality of the medical preparation.

8. Where the applicant for a product authorisation is not the manufacturer of the medical preparation or where the medical preparation is to be imported into the State, the Minister may require the applicant to furnish a written undertaking in a form approved by the Minister and signed by or on behalf of the manufacturer of the preparation that in the event of the product authorisation being granted or renewed the manufacturer will comply with such conditions as may be specified in such undertaking and, in particular, that he will:

(a) permit the inspection by or on behalf of the Minister of the premises where the preparation is to be manufactured and of the operations to be carried out in the course of manufacture;

(b) comply with any conditions relating to the manufacture of the preparation subject to which the authorisation is granted or renewed;

(c) comply with any requirements imposed by or under the law of the country in which the preparation is to be manufactured.

9. (1) The Minister may refuse an application for a product authorisation where:

(a) the applicant fails to submit information, documents, samples or other materials in accordance with article 7 (1), or

(b) the Minister is satisfied, following examination of such information, documents, samples or other materials that:

(i) the information contained in or furnished in connection with the application is found to be incorrect in any material respect, or

(ii) the preparation is harmful under normal conditions of use, or

(iii) the therapeutic efficacy of the preparation is lacking or is insufficiently substantiated by the applicant, or

(iv) the qualitative or quantitative composition of the preparation to which the application relates is not as declared by the applicant.

(2) The Minister may revoke a product authorisation with the written consent of the holder thereof, or where he is satisfied that:

(a) the preparation to which the authorisation relates is harmful under normal conditions of use, or

(b) the therapeutic efficacy of such preparation is lacking, or

(c) the qualitative or quantitative composition of such preparation is not in accordance with the information declared by the holder, or

(d) the controls on the preparation, or on any of its constituents, in the course of its manufacture as indicated in or in connection with the application or in compliance with any conditions subject to which the authorisation was granted or renewed have
not been carried out, or

(e) the requirements of the Medical Preparations (Licensing of Manufacture) Regulations, 1974 and 1975 have not been complied with, or

(f) the information contained in or furnished in connection with the application for the authorisation is incorrect in any material respect, or

(g) any condition subject to which the authorisation was granted or renewed has not been complied with.

10. A charge shall be paid to the Minister in respect of an application made to him pursuant to article 7, in accordance with such scale as the Minister, with the consent of the Minister for Finance, may from time to time determine.

11. (1) An authorisation granted or renewed pursuant to the European Communities (Proprietary Medicinal Products) Regulations, 1975 (S.I. No. 301 of 1975) and in force immediately before the commencement of these Regulations shall continue in force until it expires or is sooner revoked and shall have effect as if it were a product authorisation granted or renewed under these Regulations.

(2) An application made pursuant to the said Regulations which had not been determined prior to the making of these Regulations shall be treated as if it were an application for a product authorisation under these Regulations.

12. These Regulations shall not apply as respects:

(a) any medical preparation which is a homoeopathic preparation, or

(b) any substance or preparation which is intended solely for use as an ingredient in the manufacture of a medical preparation, or

(c) any medical preparation, consisting of a dried, crushed or cominuted herb or combination of herbs which is to be sold:

(i) under a designation which specifies the herb or herbs and the process of production only and does not apply any other name to the preparation, and

(ii) without any recommendation as to the use of the preparation as a medical preparation.

13. The Medical Preparations (Advertisement and Sale) Regulations, 1958 (S.I. No. 135 of 1958) are hereby amended by—

(1) The substitution of the following article for article 6 thereof:

"6. (1) Subject to sub-articles (2), (3), (4) and (5) of this article, a person shall not, in the course of a business carried on by him, sell a medical preparation unless there is legibly written in a conspicuous position on the container in which the preparation is sold and on every box or other covering of whatever nature enclosing the container:

(a) the name of the preparation being either the appropriate non-proprietary name or a proprietary designation,

(b) a description of the pharmaceutical form of the preparation,

(c) the quantity of the preparation in the container expressed in terms of mass, volume or capacity or number of dosage units,

(d) a statement of the appropriate quantitative particulars of the preparation,

(e) the manufacturer's batch reference number.

(f) (i) the reference number of any product authorisation granted or renewed pursuant to
the Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 (S.I. No. 210 of 1984) which relates to the preparation, and

(ii) the name and address of the holder of any such authorisation,

(g) the method of administration,

(h) the expiry date of the preparation where the duration of its shelf-life is less than three years,

(i) any special requirements for the handling and storage of the preparation,

(j) any other statements or particulars required to be stated by the provisions of any product authorisation granted or renewed pursuant to the Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 (S.I. No. 210 of 1984) which relates to the preparation.

(2) With effect from the 1st day of May, 1990 the expiry date referred to in paragraph (h) of sub-article (1) shall be stated regardless of the duration of the shelf life of the preparation.

(3) It shall be sufficient compliance with paragraphs (h) and (c) of sub-article (1) if the particulars specified in those paragraphs are written only on the box or other covering of whatever nature enclosing the container.

(4) (a) In the case of a preparation sold in a container which is an ampoule enclosed in a package it shall be sufficient compliance with sub-article (1) insofar as that sub-article relates to a container if only the particulars specified in paragraphs (a), (d) and (h) of that sub-article together with the route of administration are written on the container,

(b) In the case of a preparation sold in a small single dose container (other than an ampoule) on which it is impossible to give the particulars mentioned in paragraph (a) of this sub-article it shall be sufficient compliance with sub-article (1) if the particulars required by the said sub-article (1) are written only on the package enclosing the container.

(5) The particulars specified in paragraphs (g), (h) and (i) of sub-article (1) shall appear in the Irish or the English language.

(6) In this article:

'appropriate non-proprietary name' in relation to a medical preparation or active ingredient means—

(a) where such preparation or ingredient is described in a monograph in any pharmacopoeia for the time being in force in the State, any name or abbreviation of such name at the head of that monograph or, in the case of the European Pharmacopoeia, an approved synonym, or, where such name consists of two or more words, any name derived from a suitable inversion of such words which is provided for by such pharmacopoeia, or

(b) where such preparation or ingredient is not so described but has an international non-proprietary name, such international non-proprietary name, or

(c) where such preparation or ingredient is not so described and does not have an international non-proprietary name, the accepted scientific name or any other name descriptive of the true nature of the preparation or ingredient;

'appropriate quantitative particulars' in relation to a medical preparation means the quantity of each active ingredient identified by its appropriate non-proprietary name in each dosage unit or, where there is no such unit, in the container of the preparation, expressed in terms of mass, volume,
capacity, or units of activity, or percentage by mass, or volume of the total quantity.

'International non-proprietary name' means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name.

(7) Sub-article (1) shall not apply to a medical preparation which is:

(a) prepared or dispensed by or in accordance with a prescription issued by a registered medical practitioner or registered dentist, or

(b) sold or supplied by a registered medical practitioner or registered dentist for or to a patient under his care, or

(c) sold or supplied by a person lawfully keeping open shop for the dispensing or compounding of medical prescriptions or for the sale of poisons in accordance with the Pharmacy Acts, 1875 to 1977 where such sale or supply is carried out by or under the supervision of a pharmacist:

(i) in accordance with a specification furnished by the person to whom the preparation is to be sold, or

(ii) in circumstances where the person under whose supervision the preparation is sold or supplied exercises his own judgement as to the treatment required."

(2) The addition of the following article 7:

"7. These Regulations shall be enforced and executed by officers of the Minister.".

14. (1) These Regulations shall be enforced and executed by officers of the Minister.

(2) Subject to sub-article (3) any such officer, with a written authorisation of the Minister, may, at all reasonable times, for the purpose of ascertaining whether or not there is or has been a contravention of these Regulations:

(a) enter premises of any class or description,

(b) inspect any substance or article which is stored or offered or kept for sale or distribution at such premises,

(c) require the production of, and inspect and if he thinks fit take copies of any entry in any book, record or other document at such premises, and

(d) take (without payment) samples of any substances or articles stored or offered or kept for sale or distribution at such premises for test, examination or analysis.

(3) Sub-article (2) shall not apply as respects any of the following premises:

(a) such part of any premises (not being a shop) as is used by a registered medical practitioner or registered dentist for carrying on his practice, or

(b) a premises used only as a private dwelling.

15. (1) In any proceedings for an offence under section 65 of the Act in relation to these Regulations a certificate signed by:

(a) the State Chemist, or

(b) a public analyst appointed under section 10 of the Sale of Food and Drugs Act, 1875, stating the result of any test, examination or analysis of a sample shall, with regard to that sample, be evidence for all purposes of such result.

(2) The certificate referred to in sub-article (1) shall be in the form set out in the Third Schedule.
FIRST SCHEDULE

General conditions applicable to product authorisations

1. The authorisation holder shall report to the Minister any change in his name and address and in any address at which there is carried on a business to which the authorisation relates.

2. The authorisation holder shall ensure that any preparation to which the authorisation relates is manufactured only in accordance with the methods set out in, or furnished in connection with, his application for the product authorisation and that the specifications of the constituents and of the finished preparation are in accordance with the information contained in, or furnished in connection with the said application except insofar as may otherwise be approved by the Minister.

3. The authorisation holder shall not issue, or cause another person to issue, or consent to the issue of any advertisement or recommendation, relating to any preparation to which the authorisation relates, which contains particulars as to the uses, nature or effects of such preparation or warnings or precautions in use concerning such preparation, unless the terms of the advertisement or recommendation, insofar as they relate to such particulars, warnings, or precautions in use correspond to or differ only to an extent that is not material from those specified in the authorisation.

4. The authorisation holder shall inform the Minister of any material change that has been made, or is proposed to be made in the particulars contained in or furnished in connection with his application, in relation to any preparation to which the authorisation relates, that is to say:

   (a) in the composition of the preparation, or of any of its constituents,

   (b) in the specification of the preparation or of any of its constituents,

   (c) in the method of manufacture of the preparation or of any of its constituents,

   (d) in the methods and procedures described in the application for ensuring compliance with such specifications,

   (e) in the arrangements described in the application for storage of the preparation,

   (f) in the recommended uses, routes of administration or dosage schedules, or

   (g) in the method of retail sale, supply or sales promotion.

5. The authorisation holder shall inform the Minister of any additional information received by him which may alter the validity of data provided in support of the application, or may further the understanding of the substance and its effects or may alter the directions for use of the medical preparation which is the subject of the authorisation.

6. The authorisation holder shall keep a record of reports of adverse effects associated with the use of the preparation to which the authorisation relates. The record shall be available for inspection by a person authorised by the Minister who may take copies thereof. The authorisation holder shall furnish to the Minister a copy of any such report of which he has a record or of which he is aware.

7. The authorisation holder shall keep available for inspection by a person authorised by the Minister durable records of his arrangements:

   (a) for obtaining materials for the purpose of the manufacture by him or on his behalf of any preparation to which the authorisation relates, and

   (b) for procuring the manufacture, importation, storage, sale or supply of any such preparation, and

   (c) for the tests to be carried out on any such preparation or on the materials used for its manufacture and shall permit the person so authorised to take copies of, or to make extracts from, such records. The records shall be retained for a period of five years from the date on which the relevant batch of the preparation was released for sale or was imported by or on behalf of the authorisation holder.
8. The authorisation holder shall keep such documents as will facilitate the withdrawal or recall from sale or supply of any preparation to which the authorisation relates.

9. (1) The authorisation holder, on being informed by the Minister that any preparation to which the authorisation relates has been found:

(a) to be harmful under normal conditions of use, or

(b) to be lacking in therapeutic efficacy, or

(c) not to be in accordance with the information contained in or furnished in connection with the application for such authorisation, or furnished in compliance with any of the conditions set out in this Schedule, as regards the qualitative or quantitative composition of the preparation, or

(d) not to be in accordance with any conditions, other than those set out in this Schedule, which are specified in the product authorisation,

shall, if so directed by the Minister, withhold from sale all batches of the preparation or such batch as may be specified by the Minister, and so far as may reasonably be practicable immediately recall all supplies of the preparation or of such batch of the preparation as has already been issued.

(2) The authorisation holder shall comply with the conditions set out in sub-paragraph (1) where the controls on the preparation to which the authorisation relates, or on any of its constituents, in the course of its manufacture as indicated in or in connection with his application for the product authorisation or in compliance with the conditions set out in this Schedule, have not been carried out.

10. The authorisation holder shall notify the Minister of any decision to withdraw from sale or supply any preparation to which the authorisation relates and shall state the reason for that decision.

11. The authorisation holder shall on request by the Minister:

(i) furnish to him from such batch or batches as he may specify a sample of any preparation to which the authorisation relates for the purpose of test, examination or analysis, or

(ii) furnish to him full particulars of the tests which have been applied to such batch or batches of such preparation as he may specify and the result of such tests.

12. The authorisation holder shall, if requested by the Minister withhold from sale any batch or batches in respect of which a sample is, or particulars are requested to be furnished under sub-paragraphs (i) and (ii) of paragraph 11 until a certificate authorising the sale of the batch or batches has been issued to him by the Minister.

13. The authorisation holder shall ensure:

(a) that the preparation to which the authorisation relates is not sold unless it has been manufactured in the premises in respect of which any undertaking has been given pursuant to article 8.

(b) that such preparation has been manufactured in such premises and in such circumstances as to comply with any conditions specified in such undertaking.

14. The authorisation holder shall in the event of the authorisation being revoked surrender it to the Minister.

SECOND SCHEDULE.
<table>
<thead>
<tr>
<th>Category of Medical Preparation</th>
<th>Sub-category of Medical Preparation</th>
<th>Commencement Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Preparations which were not on the market prior to 1 October, 1974</td>
<td>1 October, 1984</td>
</tr>
<tr>
<td>2</td>
<td>Preparations of the following classes which were on the market prior to 1 October, 1984:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(a) Anti-Infectives.</td>
<td>1 October, 1984</td>
</tr>
<tr>
<td></td>
<td>(b) Hypnotics, sedatives, tranquillisers and anti-depressants.</td>
<td>1 December, 1985</td>
</tr>
<tr>
<td></td>
<td>(c) Corticosteroids, hormones, diuretics and drugs affecting the cardiovascular system.</td>
<td>1 April, 1986</td>
</tr>
<tr>
<td></td>
<td>(d) Analgesics, miscellaneous central and autonomic nervous system drugs (including anaesthetics).</td>
<td>1 April, 1987</td>
</tr>
<tr>
<td></td>
<td>(e) Metabolic and haematinic drugs, products locally acting on skin or mucous.</td>
<td>1 April, 1988</td>
</tr>
<tr>
<td></td>
<td>(f) Miscellaneous including products locally acting on gastrointestinal or respiratory tract.</td>
<td>1 September, 1988</td>
</tr>
</tbody>
</table>

THIRD SCHEDULE.

MEDICAL PREPARATIONS (LICENSING, ADVERTISEMENT AND SALE) REGULATIONS, 1984.

(S.I. No. 210 of 1984)

Certificate stating results of test, examination or analysis

This Certificate is issued by me, the undersigned, for the purpose of article 15 of the Medical Preparations (Licensing, Advertisement and Sale) Regulations, 1984 being (1) _______________ I hereby certify that I received on the _______________ day of _______________ 19 _______________ from (2) _______________ of _______________ a sample of (3) _______________ for test, examination and analysis: which was undamaged, duly sealed and marked (4) _______________. I further certify that the said sample
has been tested, examined and analysed by me or under my direction and that the results are as follows:— (5)

Signature .................................................. Date ..................................................

Address ..................................................

(1) Here insert official title of analyst.
(2) Here insert the name of the sampling officer or agent who submitted the sample for analysis.
(3) Here insert the name or description of the substance or product.
(4) Here insert the distinguishing mark on the sample and the date of sampling shown thereon.
(5) Here insert the relevant results as appropriate.

GIVEN under the Official Seal of the Minister for Health this 3rd day of August, 1984.

DARRY DESMOND,
Minister for Health.

The Minister for Finance consents to article 10 of these Regulations.

Dated this 3rd day of August, 1984.

GARRET FITZGERALD,
Minister for Finance

EXPLANATORY NOTE.

The purpose of these Regulations is to control the marketing of medicines for human use. The control is effected by means of a common licensing scheme which applies to all human medicines, both proprietary and non-proprietary. In addition the Regulations provide for certain labelling requirements for medicines this provision is given effect by way of amendment to the Medical Preparations (Advertisement and Sale) Regulations, 1958 which apply to medicines generally.

The Regulations come into force on 1st October, 1984. The application of the licensing scheme to non-proprietary medicines will commence on 1st October, 1984 in the case of all new preparations and on a phased basis for those non-proprieties already on the market.
THE NATIONAL DRUGS ADVISORY BOARD (ESTABLISHMENT) ORDER, 1966.

The Minister for Health in exercise of the powers conferred on him by sections 3 to 6 of the Health (Corporate Bodies) Act, 1961 (No. 27 of 1961), hereby orders as follows:

1. This Order may be cited as the National Drugs Advisory Board (Establishment) Order, 1966.

2. A body to be known as An Bord Comhairleach Náisiúnta Druganna or, in the English language, the National Drugs Advisory Board, is hereby established.

3. In this Order—

"the Board" means the National Drugs Advisory Board established by this Order;

"the Chairman" means the Chairman for the time being of the Board;

"the Minister" means the Minister for Health;

"Drug" means any prophylactic, diagnostic or therapeutic substance or mixture of substances which may be used for the prevention, diagnosis or treatment of human disease or defect or for the modification of physiological function in man.

4. The functions of the Board are as follows:

(a) to organise and administer a service for obtaining and assessing information as regards the safety of new and reformulated drugs and, in particular, their toxicity and other adverse effects,

(b) to organise and administer a service for obtaining and assessing reports on the adverse effects of drugs in use in the State,

(c) to advise the Minister and others concerned as to the precautions or restrictions, if any, subject to which drugs may be marketed or continued in use in the State,

(d) if requested by the Minister, to consider and report to him on the arrangements to be made for the quality control of drugs, for the registration and inspection of the premises of drug manufacturers, importers and wholesalers, and for the sampling and testing of drugs,

(e) if requested by the Minister, to advise on the certification for export purposes of drugs manufactured or processed in the State,

(f) if requested by the Minister and subject to such conditions as he may approve, to arrange for the collection and dissemination of information in respect of drugs, their pharmacological classification and therapeutic efficacy and in respect of economies in prescribing,

(g) if requested by the Minister, to make recommendations regarding standards for the composition, purity and strength of drugs and for the methods of testing drugs,

(h) to consider and report to the Minister on such general or particular matters in regard to drugs as he may refer to the Board for advice.

5. The Board shall consist of twelve members appointed by the Minister.

6. The term of office of a member of the Board shall be such period not exceeding four years as may be specified by the Minister when appointing him and he shall hold office for the period for which he is appointed unless he sooner dies, resigns by letter addressed to the Minister or ceases to be a member in accordance with article 7 of this Order.

7. A member shall cease to be a member of the Board on his being requested by the Minister to
resign.

8. The Minister shall appoint from amongst the members of the Board a Chairman who shall hold office until he ceases to be a member of the Board or until the Minister appoints another person to be Chairman.

9. The quorum of the Board shall be four.

10. The Board shall hold such and so many meetings as may be necessary for the performance of its functions.

11. The proceedings of the Board shall not be invalidated by any vacancy or vacancies among its members or by any defect in the appointment of the Board or any member thereof.

12. (1) The Chairman may, at any time, call a meeting of the Board.

(2) If the Chairman refuses to call a meeting of the Board after a requisition for that purpose, signed by three members of the Board, has been presented to him, any three members of the Board, may forthwith, on that refusal, call a meeting of the Board, and, if the Chairman (without so refusing) does not, within seven days after the presentation of the requisition, call a meeting of the Board, any three members of the Board may, on the expiration of these seven days, call a meeting of the Board.

13. At a meeting of the Board—

(a) the Chairman shall, if he is present, be chairman of the meeting.

(b) if and so long as the Chairman is not present, the members of the Board who are present shall choose one of their number to be chairman of the meeting.

14. Minutes of the proceedings of each meeting of the Board shall be entered in a book kept for that purpose and shall be signed by the Chairman of the meeting or of the next ensuing meeting.

15. (1) The names of the members present at a meeting of the Board shall be recorded in the minutes of the proceedings of the Board.

(2) The names of the members voting on any question arising at a meeting of the Board shall be recorded in the minutes of the proceedings of the meeting and the record shall show which members vote for and which against the question.

16. (1) A person shall not receive any remuneration for acting as a member of the Board.

(2) Members of the Board may be paid travelling and subsistence allowances in accordance with such scale as may from time to time be approved by the Minister.

17. (1) All acts of the Board and all questions coming or arising before the Board may be done and decided by the majority of such members of the Board as are present and vote at a meeting of the Board.

(2) In case of equality of votes on any question arising at a meeting of the Board, the chairman of the meeting shall have a second or casting vote.

18. (1) In order to facilitate the discharge of the functions of the Board, the Board may establish committees.

(2) The Board may appoint to any committee such members of the Board as are willing to act on the committee and, if the Board so think fit, other persons who have special knowledge and experience related to the purpose of the committee.

(3) The Board shall notify the Minister of the establishment of any committee, of the purpose of the committee and of the names of the members thereof.

(4) If considered appropriate by the Minister, he may appoint additional persons to be members of any committee.

19. The seal of the Board shall be authenticated by the signature of the Chairman or some other member of the Board duly authorised by the Board to act in that behalf and the signature of an officer of the Board duly authorised by the Board to act in that behalf.

20. (1) The Board shall cause to be kept proper accounts of all income and expenditure of the Board, and of the sources of such income and the subject matter of such expenditure, and of the property, credits and liabilities of the Board.

(2) The financial year of the Board shall be the period of twelve months ending on the 31st day of December in any year and for the purposes of this provision the period commencing on the date of this Order and ending on the 31st December, 1966, shall be deemed to be a financial year.

(3) A statement of accounts of the Board for each financial year shall, as soon as may be after the end of such financial year, be prepared and after such preparation be audited by and be subject to a report by an auditor appointed for the purpose by the Minister after consultation with the Board.

(4) The expenses generally of such audit shall be paid by the Board as soon as may be after each audit.

(5) A copy of the accounts and the auditor's certificate and report thereon shall be presented to the members of the Board and to the Minister.

(6) The Board and the officers thereof shall, whenever so requested by the Minister, permit any person appointed by him to examine the books and accounts of the Board in respect of any financial year or other period and shall pay such fee therefore as may be fixed by the Minister.

21. (1) The Board shall in each year, not later than such day as the Minister shall direct, make a report to the Minister of its activities during the preceding year.

(2) The Board shall submit to the Minister such information regarding the performance of its functions as the Minister may from time to time require.

22. (1) The Board may appoint such and so many officers and employ such and so many servants as the Board may, from time to time, think proper and in appointing any officer or employing any servant the Board shall comply with any directions given by the Minister relating to the procedure to be followed.

(2) Every officer of the Board holding office in a permanent capacity shall cease to hold his office on attaining the age of sixty-five years.

(3) The Board shall determine the remuneration and conditions of service of each officer and each servant.

(4) The Board shall, from time to time, assign such duties as they consider appropriate to each officer and servant of the Board and each such officer and servant shall perform the duties so assigned to him.

(5) The Minister may, whenever and so often as he thinks fit, declare that any of the powers conferred on the Board by this article shall be exercisable only with the consent of the Minister, and whenever any such declaration is in force, the said powers may, in relation to any office or employment to which the declaration applies, be exercised only with such consent.

23. A person who for the time being holds any office under or is in the employment of the Board shall be disqualified from being a member of the Board.
24. The Local Government (Superannuation) Act, 1956 (No. 10 of 1956) shall apply to the Board as if it were a local authority.

25. (1) For the purpose of the performance of its functions, the Board may, with the consent of the Minister, borrow money and purchase or take on lease any land.

(2) The Board may, with the consent of the Minister, sell, exchange, let or otherwise dispose of any land vested in it.

26. (1) The Board may accept gifts of money, land and other property upon such trusts and conditions, if any, as may be specified by the donor.

(2) The Board may not accept a gift if the conditions attached by the donor to its acceptance are not consistent with the functions of the Board.

GIVEN under the Official Seal of the Minister for Health this twelfth day of July, 1966.

DONOGH O'MALLEY,
Minister for Health.

EXPLANATORY NOTE.

The effect of this Order is to establish under the Health (Corporate Bodies) Act, 1961, a body, to be known as the National Drugs Advisory Board, which will organise and administer a service for obtaining, assessing and disseminating information as regards the safety of new and reformulated drugs and of drugs already in use, and will advise the Minister for Health on matters relating to the safety and quality of drugs.
March 21, 1983

FROM: Director, Office of Biologics, National Center for Drugs and Biologics

SUBJECT: Recommendations to Decrease the Risk of Transmitting Acquired Immune Deficiency Syndrome (AIDS) from Plasma Donors

TO: All Establishments Collecting Source Plasma (Human)

The acquired immune deficiency syndrome (AIDS) has caused serious concern because of the limitations for recipients of plasma derivatives if this disease is proven to be transmissible by blood or blood products. The major organizations involved in plasma collection have reached a consensus as to appropriate steps which should be taken to decrease the potential of blood or plasma donation by individuals who might be at increased risk of transmitting AIDS. Consistent with the recommendations of the American Blood Bank Association, the American Red Cross, the American Association of Blood Banks, the Council of Community Blood Centers, and the Public Health Service Interagency Committee, (copy enclosed) the Office of Biologics is advising that the following steps should be taken by all establishments collecting Source Plasma (Human):

1. Educational programs should be instituted to inform persons at increased risk of AIDS that until the AIDS problem is resolved or definitive cure becomes available, they should refrain from routine plasma donation because of the potential risk to recipients of certain plasma derivatives. As presently defined, persons at increased risk include those with symptoms and signs suggestive of AIDS, symptomatically asymptomatic or blastic viral with multiple partners, infected persons in the United States, persons of recent donors of intravenous drugs and sexual partners of individuals at increased risk of AIDS. Each source Plasma donor should receive information about AIDS including the need for individuals at increased risk to voluntarily exclude themselves from routine plasma programs.

2. If plasma is collected from a donor belonging to any of the groups at increased risk, a label should be affixed to each unit to restrict its use in accordance with 21 CFR 650.120(b)(4). The recommended label statements are "CAUTION: For use in Manufacturing Antihemophilic Factor or Other Products Only". Using negative plasma is already subject to special labeling and shipping restrictions and these programs are not affected by this memorandum.

*Such intravenous drug abusers are already excluded by existing regulations.

- 491 -
3. Introduction of personnel responsible for donor screening should be conducted with special attention to identifying the early signs and symptoms of AIDS in donors. The donor medical history should include specific questions designed to detect possible AIDS symptoms or exposure to patients with AIDS. Standard Operating Procedures (SOP) should be revised to include questions which elicit a history of night sweats, unexplained fever, unexplained weight loss, or signs of lymphadenopathy or Kopox's sarcoma.

4. Donors should be examined for lymphadenopathy. The initial and annual physical should provide an opportunity for an examination by the physician for generalized lymphadenopathy. A more limited examination should be performed by an adequately trained individual on each donor on the day of plasma collection and a record made of the results of the examination.

5. An accurate record of each source plasma donor's weight prior to each donation should be made to permit early identification of any unexplained weight loss. Any significant, unexplained decrease in weight should be considered cause for referral of the donor to a physician for complete evaluation prior to any further plasma collection. Any plasma in storage, which was previously collected from such a donor, should be quarantined until the physician's evaluation is completed.

6. The SOP should inform the staff that any products collected from a donor known or suspected to have AIDS should be considered potentially highly infectious and must be immediately quarantined and disposed of expeditiously and appropriately unless designated for investigative use related to AIDS. If not destroyed, such products must be labeled, stored, and shipped in accordance with the standard procedures for handling infectious materials. Appropriate disposal procedures include autoclaving or controlled incineration; overwrap is required to prevent staff in case of breakage.

Approved procedures developed by one of the major organizations such as the American Association of Blood Banks and the Council of Community Blood Centers may be referenced in the licensed establishment's SOP without individual submission to the Office of Biologics. Alternatively, licensed establishments which develop their own procedures should submit them to the Office of Biologics for approval concurrent with implementation. Revised labeling for plasma collected from high risk donor groups and identified for further manufacture of plasma derivatives should be submitted to the Office of Biologics (cow-852).

This procedure is intended to be an interim measure to protect recipients of blood and blood products until specific laboratory tests are available.

John C. Petricciani, M.D.
John C. Petricciani, M.D.

Attachment
MR/HM

13th September 1984

Mrs Marie W Tatt
Registration Manager
Miles Laboratories Limited
Post Office Box 37
Sooke Court
Sooke P.O.
Slough SL2 4LY
England

Re: KOATE - Dried Factor VIII Fraction PA 79/15/1-4

Dear Mrs Tatt

With reference to your application for the above product, authorization, in advance of dealing with the detailed Chemistry and Pharmacy matters outstanding following your replies of 3rd May last, I must inform you that:

(1) As the Factor VIII preparations currently on the Irish market are all heat-treated for prevention of hepatitis transmission, the National Drugs Advisory Board would be unwilling to accept any Factor VIII products which were not similarly treated;

(2) Moreover, haematologists have indicated that they would be unhappy about using Factor VIII concentrates whose original plasma was collected within the areas associated with Acquired Immune Deficiency Syndrome. A written guarantee and evidence that Cutter does not collect source plasma for this product from any of the risk areas would be required to satisfy this point.

As these matters are fundamental to the continued consideration of this product, we would appreciate an early reply.

Yours Sincerely,

Mary Rafter (nee Smith)
Pharmacist
Appendix 40
NATIONAL HAEMOPHILIA TREATMENT CENTRE
LÁRIONAD CÓIREÁLA HAÉMFILE NA HÉIREANN

ADULTS
ST. JAMES’ HOSPITAL.
P.O. Box 84.
Telephones (01) 787 261.

CHILDREN UNDER 16 YEARS
THE NATIONAL CHILDREN’S HOSPITAL.
Harcourt Street, Dublin 2.
Telephones (01) 873 208.

9th October, 1984

Dr. A. Scott,
National Drugs Advisory Board,
63/64, Adelaide Rd.,
Dublin 6.

Dear Dr. Scott,

An agent of a company supplying commercial consumption factor VIII concentrate mentioned to me the possibility that the NHF may require that heat treated products only be imported into the country. I felt as Medical Director of the National Haemophilia Treatment Centre I should comment on the subject of the importation of commercial factor VIII concentrates as the situation stands at present. I have taken the liberty of sending a copy of this letter to Dr. Paul Cotter as she and I are responsible for the treatment of most of the haemophiliacs in the Republic.

Haemophiliacs are in danger of developing hepatitis and AIDS by infusion of FVIII concentrates. Hepatitis may occur from infection with the hepatitis B virus, the non-A, non-B hepatitis virus and to a much lesser extent with cytomegalovirus, the Epstein-Barr virus etc. All imported products and those supplied by the Blood Transfusion Service Board are from subjects which have been screened for the hepatitis B. There is no screening method for non-A, non-B hepatitis.

Despite screening for hepatitis B haemophiliacs continue to develop hepatitis B using either imported or indigenous products. There has been a slight decline in frequency over the last five years possibly due to less infection from indigenous products.

Certain factors have to be borne in mind however. One is the degree of immunity built up in the haemophilic population and another the amount of concentrate used from different sources.

There is reason to believe that virtually all haemophiliacs develop non-A, non-B hepatitis once they have received any type of concentrated FVIII. Particularly at risk are those who have not received previous concentrate. Mild haemophiliacs therefore are likely to develop hepatitis with their first treatment. Recently heat-treated FVIII products have been or are being made available to Centres mainly on a trial basis by various commercial firms. The following is a list of methods used and the state of assessment.

Factor VIII concentrate

Producer         Method         State of assessment
Armour           'Dry' heating  Being treated
Hyland           'Dry' heating  Test complete – results available
Cutter           'Wet' heating  Not treated

Alpha            'Wet' heating  Claims 20% reduction in non-A, non-B hepatitis.

Immunco          Low pressure steam  Results to be treated with caution.

NY Blood Centre  Lipid solvents  Being tested by controlled clinical trial

Experimental
The results of the Hyland (Travenol) trial on 'virgin' haemophiliacs reveal that 12 out of 17 patients developed post transfusion hepatitis, 11 of which were considered to be non-A, non-B and one CHV. The evidence to date suggests that so far as non-A, non-B hepatitis is concerned the effects of heat treatment is at best partially beneficial. Of course different methods and new trials may point to a different conclusion.

What can be said for AIDS? It does seem the condition is more prevalent in the U.S. There are 69 haemophilic cases in the U.S. compared with 2 in the U.K. There is evidence that some condition is due to one organism it has spread from the U.S. possibly via Haiti. There is a strong body of opinion that the infecting organism is HTLV-3. All types of blood products, not only VIII concentrate, have been vectors of AIDS; packed cells, fresh frozen plasma, platelet concentrates. Thus AIDS is to be found in patients with Thalassaemia and sickle anaemia. It is known that wives and other sexual partners of haemophiliacs have become infected.

It is thought that there are AIDS related conditions. These include general unwellness, persistent lymphadenopathy and thrombocytopenia. The reasons for this assumption of relationship is based on progression of a number of these patients to full blown AIDS and HTLV-3 serology. We have a number of haemophiliacs who have clinical manifestations which could be regarded as an 'AIDS related condition'. We have no known case of definite AIDS. It is now known that AIDS can be transmitted by a normal bisexual husband to his wife. It is therefore quite possible that the wife of a 'normal' haemophiliac may develop AIDS.

There is some very preliminary information that heat treatment of VIII concentrate may destroy the HTLV-3 virus. This is very much in the experimental phase.

I will be meeting among others Dr. Paula Cotter later this year to discuss the purchase of VIII concentrate for 1985. I had in mind recommending purchase of usual concentrate for this year in view of the lack of clear-cut evidence of real advantages relating to heat treated products. I decided however to ask the views of the Medical Director of three of the largest centres in the U.K. and the director of a children's haemophilia centre; Dr. Charles Alm, Oxford; Dr. Peter Kornoff, the Royal Free Hospital; Dr. Geoff Savidge, St. Thomas' Hospital, and Dr. Frank Hill, the Children's Hospital, Birmingham. None intend to purchase heat treated concentrate at the present time on a routine basis. Dr. Savidge intends to use heat treated products for 'virgin' haemophiliacs. Dr. Kornoff expressed the view that if extra funds become available he would prefer to use them for more purified products rather than heat treated products.

My advice remains the same for the near future. We should continue to purchase routine VIII concentrate for 1985 assuming the producers have met the criteria laid down to prevent the dissemination of hepatitis B and AIDS. There are of course other questions which could be raised about the use of imported and indigenous products but these would also require lengthy and detailed consideration.

I trust the above is helpful.

Yours sincerely,