-7 MAY 1975

Department of Health and Social Security
Medicines Division
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LP 1

G J Roderick Esq
Secretary
The Lister Institute of Preventive Medicine
Elstree
Herts
WD6 3AX.

Your reference 1043.C
Our reference ML/0134/01
Date 5 May, 1975.

Dear Mr Roderick

Following the meeting on 16 April we had a word about the application of the Act to the Institute's activities, as the Department's agents, of the blood products laboratories at Elstree and Oxford.

The Institute's manufacturer's licence under the Medicines Act 1968 refers only to the preparation of sera, antitoxins, vaccines, toxins and antigens and not also to preparations of human blood. Since the Institute, in respect of such preparations, is carrying out activities that come within the purviews of the Medicines Act 1968 it is necessary that the activities and the premises in which they are carried out should be covered by a manufacturer's licence under the Act, even though in this connection the Institute is acting as the Department's agent.

The necessary authorisation can be sought either by an application for a variation of the Institute's existing licence to cover the additional operations or by an application for a separate licence relating specifically to these operations. I am therefore enclosing some notes on how to apply for a manufacturer's licence; the same kind of particulars are required for an applications for a variation of the existing licence.

Yours sincerely

GRO-C

R E Tringham

photocopy to Dr. Maycock.

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MEDICINES ACT 1968 and 1971

APPLICATION FOR PRODUCT LICENCE

Instructions for completing Form MLA 201

Applicants should submit one copy of page 1 and three copies of subsequent pages. A further copy of the subsequent pages should be filed as the top document at the beginning of each of the volumes of scientific evidence. Page 2 of MLA 201 is available in A3 size if required.

1. Page 1

1.1 Name of Product: If the marketing name is not yet settled give another (possibly temporary) name by which the product can be identified.

1.2 Name and Address: Licences may be held by individuals, or by legal persons such as limited companies. In the latter case, the company's full legal style, registration number and registered address should be stated here. If some other title (eg. a division of the company) is to be shown on the licence it should be shown against "trading style".

1.4 Role of Licence Holder: See paragraph 3.3 of the Guide to Licensing System (MAL 1) for definition of "the person responsible for the composition". Delete or amend as necessary.

1.5 Activities for which licence is required: Delete, amend or add as necessary.

1.6 If any earlier applications relating to this product have been made (either under the Medicines Act or under the earlier voluntary scheme) the dates of the applications and the Department of Health and Social Security reference numbers should be given.

1.7 Manufacture before the grant of the licence: If the applicant wishes the licence to authorise the sale or supply of stocks of the product manufactured for test purposes before the grant of the licence, this should be indicated here.

1.8 Scientific evidence: Give the number of pages in each volume of the supporting evidence.

1.9 Supplementary information: Give the number of pages attached as described in paragraph 3 below.

1.10 Relevant provisions: The applicant may ask for a licence for a period of less than five years and may ask that any of the provisions set out should not apply or apply in a modified form. If so application should be amended accordingly and the reason for the proposal indicated.

2. Page 2

This page provides for entries relating to the basic product particulars; normally these particulars will appear in precisely this form as part of the licence and cannot therefore be subsequently varied without the agreement of the licensing authority. Any details not strictly required for this purpose may be given as part of the supporting material. Unless, however, the applicant expressly requests otherwise the licensing authority will exercise discretion as to whether any of these further details are inserted in the licence particulars. In general, data sheets and labels will be required to be in accordance with information given on this page. If there is insufficient room on the form for any item, applicants may use plain paper. If so, the order and general layout of items should conform and each page should be signed and numbered. The following points should be noted in completing page 2:-

2.1 Name: If the marketing name is not yet settled this should be left blank and the name notified later as available.

2.2 Pharmaceutical form: Describe the pharmaceutical form, eg, tablets, capsules, injections and state whether the product is

(a) in a form for administration to human beings: or
(b) for use as an ingredient in preparing medicinal products.

2.3 Active constituents: Indicate the way in which the active ingredients will be presented on any leaflet, label or descriptive material. Each constituent should be described under

(a) its approved name or monograph name
or (b) where there is no approved name or monograph name, the non-proprietary designation or other descriptive appellation by which it can be readily identified.
or (c) the trade name, in other cases.

2.4 Uses:

State: Recommended clinical use, the proposed route(s) of administration and any directions for use to be included in labels or leaflets.

2.5 Recommended dosage and dosage schedule: State the recommended dosage for:-

(i) adults, and, if appropriate,
(ii) children and infants by age groups

distinguishing, where appropriate, between therapeutic and prophylactic doses, and between dosages recommended for different clinical uses.

2.6 Contra-indications, Warnings and Precautions: State particulars of contr-indications, warnings and precautions to be included in the data sheet, container label, package label, or any leaflets.

2.7 Method of Retail Sale and Supply: State whether it is proposed to make the product available -

(a) for general sale; or
(b) only through registered pharmacies -
  (i) for over the counter sale; or
  (ii) only as a prescription item; or
(c) through some other specified group of outlets, eg, herbalists, hospitals, clinics, laboratories, or by automatic machines.

3. Supplementary Particulars

The following information should be given on separate sheets numbered 3, 4, etc.

3.1 Physical characteristics: Describe the physical characteristics of the product. Depending on the nature of the product, the headings under which the description should be given may include the following -

(a) colour, odour, taste;
(b) specific gravity, viscosity, consistency;
(c) particle size, bulk density, crystal form;
(d) size, shape, superficial markings for identification purposes;
(e) hardness, disintegration and delayed release characteristics.

3.2 Manufacture: State;

(a) the manufacturing or assembly operations relating to the product (dosage form).
(b) the address of each place of such manufacture and assembly.
(c) the names and addresses of manufacturers or suppliers of the active constituents. This information will not normally be required for substances meeting BP specifications and bought on the open market.
(d) the arrangements made for storage of the product by the proposed licensee or on his behalf and the address of each place of such storage.

Only a brief outline of operations and arrangements is required.

3.3 Quality control: State in respect of manufacture of the finished product and in respect of the constituents used in manufacture or assembly -

(a) whether quality control will be exercised and to what extent - for example, for identity and/or assay.
(b) whether the decision that any batch of the product is of acceptable quality for sale or supply will be made by the proposed product licence holder: and, if not, who will make it.

3.4 Containers: State the type of containers to be used in marketing the product and any directions given for storage and transport.

3.5 Labelling: Give particulars of any details to appear on labels and leaflets in addition to any details already given on Page 2. Any proposals as to expiry dates to be stated on labels should be given.

3.6 Importation: If the product is to be imported and the licence holder is not the actual importer, please state the name and address of the importer.

3.7 Applications in other countries: If authorisation to market this product has been granted, revoked or refused by the appropriate regulatory agency in any other country, give the country, date and outcome. Any explanatory details you consider relevant may be given here.

3.8. Scientific Evidence: This form should be accompanied by detailed information on Chemistry and Pharmacy, Experimental and Biological Studies and Clinical Trials, as appropriate. See paragraph 5.13 - 5.17 and Parts 3,4 and 5 of MAL 2 - Notes on Applications for Product Licences.