STATUTORY INSTRUMENTS

1976 No. 1970

MEDICINES

The Medicines (Certificates of Analysis) Regulations 1976

Made - - - -	18*th November* 1976
Laid before Parliament	30*th November* 1976
Coming into Operation	21*st December* 1976

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by subsection (9) of section 112 and subsection (7) of section 115 of, and paragraphs 19(3) and 20(1) and (2) of Schedule 3 to, the Medicines Act 1968(**a**) and now vested in them(**b**) and of all other powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Certificates of Analysis) Regulations 1976 and shall come into operation on 21st December 1976.

(2) In these regulations, unless the context otherwise requires, "the Act" means the Medicines Act 1968 and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment or instrument shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(**c**) shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and paragraph 2(1)(*b*) of Schedule 1 to the Northern Ireland Act 1974 (c. 28).

(**c**) 1889 c. 63.

Form of certificates of analysis or examination

2.—(1) Every certificate of analysis issued under section 115(6) or paragraph 19(1) of Schedule 3 to the Act shall be in the form set out in Part I of the Schedule to these regulations and shall be signed by the public analyst who issues the certificate.

(2) Every certificate of analysis or examination issued under paragraph 19(2) of Schedule 3 to the Act shall be in the form set out in Part II of the Schedule to these regulations and shall be signed by the person who issues the certificate.

Fees

3. For the purposes of paragraph 20 of Schedule 3 to the Act the prescribed fee shall be 5 pence.

David Ennals,
Secretary of State for Social Services.

9th November 1976.

John Morris,
Secretary of State for Wales.

11th November 1976.

Bruce Millan,
Secretary of State for Scotland.

15th November 1976.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 15th November 1976.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 16th day of November 1976.

(L.S.) *N. Dugdale,*
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 18th day of November 1976.

(L.S.) *J. A. Young,*
Permanent Secretary.

Regulation 2

SCHEDULE

FORMS OF CERTIFICATE OF ANALYSIS OR EXAMINATION

PART I

CERTIFICATE OF ANALYSIS OF SAMPLE

I, the undersigned, public analyst for the (1) ,

in pursuance of the provisions of the Medicines Act 1968, hereby certify that I received on the day of , 19 , from(2) , *[to whom the sample had been submitted by(3) ,] one part of a sample of (4)

for analysis; which was undamaged, duly sealed and fastened up and marked(5) ; and that the said part has been analysed by me or under my direction. I further certify the results of analysis to be as follows:—(6)

and I am of the opinion that(7)

As witness my hand this day of 19 .

(Signature and address of analyst)

[*Delete words in square brackets if not required].

NOTES

These notes and the numbers referring to them are for guidance only and do not form part of and need not appear on the certificate.

(1) Here insert the name of the local authority.

(2) Here insert, as appropriate, the name of the person who submitted the sample for analysis, or the name of the public analyst to whom the sample was originally submitted. If the former was a sampling officer, this fact should be stated.

(3) Here insert the name of the person who originally submitted the sample for analysis; if such person was a sampling officer, this fact should be stated.

(4) Here insert the name or description of the medicinal product.

(5) Here insert the distinguishing mark on the sample and the date of sampling shown thereon.

(6) Here insert relevant results as appropriate, eg physical characteristics, impurities microbial or chemical, cross-contamination with other medicines, uniformity of dosage, conformance with specification or label claims.

(7) Here enter whether the sample complies with the appropriate monograph standard (if any, or other appropriate interpretation of the results.

PART II

CERTIFICATE OF ANALYSIS OR EXAMINATION OF SAMPLE

I, the undersigned, *[having the management or control] [being a person appointed for the purposes of issuing this certificate by (1)
the person having the management or control] of the (2)
with which arrangements have been made in pursuance of the provisions of the Medicines Act 1968, hereby certify that *[I] [the said(1)
] received on the day of 19 ,
from(3)
one part of a sample of (4)

for *[analysis] [examination]; which was undamaged, duly sealed and fastened up and marked(5)

;

and that the said part has been *[analysed] [examined] *[by me] [by the said(1)
] [under the direction of the said(1)].
I further certify the results of *[analysis] [examination] to be as follows:—(6)

and I am of the opinion that (7)

As witness my hand this day of 19 .

(Signature and address of the person who issues the certificate)

[*Delete words in square brackets as necessary.]

NOTES

These notes and the numbers referring to them are for guidance only and do not form part of and need not appear on the certificate.

(1) Here insert the name of the person having the management or control of the laboratory.

(2) Here insert the name of the laboratory.

(3) Here insert the name of the sampling officer who submitted the sample.

(4) Here insert the name or description of the medicinal product.

(5) Here insert the distinguishing mark on the sample and the date of sampling shown thereon.

(6) Here insert relevant results as appropriate, eg physical characteristics, impurities microbial or chemical, cross-contamination with other medicines, uniformity of dosage, conformance with specification or label claims.

(7) Here enter whether the sample complies with the appropriate monograph standard (if any) or other appropriate interpretation of the results.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations apply throughout the United Kingdom and prescribe the form of certificates of analysis and examination of samples of medicinal products by public analysts and certain other persons in accordance with provisions in section 115 of, and Schedule 3 to, the Medicines Act 1968. These Regulations also prescribe the fee payable in certain circumstances for a copy of a certificate of analysis or examination.

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