
 STATUTORY INSTRUMENTS

1977 No. 1399

MEDICINES

The Medicines (Certificates of Analysis) Regulations 1977

<i>Made - - - -</i>	<i>10th August 1977</i>
<i>Laid before Parliament</i>	<i>22nd August 1977</i>
<i>Coming into Operation</i>	<i>12th September 1977</i>

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 1977 and shall come into operation on 12th September 1977.

(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.

Revocation

2. The Medicines (Certificates of Analysis) Regulations 1976(d) are hereby revoked.

(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 section 1(3) of, and paragraph 2(1)(b) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(c) 1889 c. 63.

(d) S.I. 1976/1970 (1976 III, p. 5241).

Form of certificates of analysis or examination

3.—(1) Every certificate of analysis issued under section 115(6) of the Act shall be in the form set out in Part I of the Schedule to these regulations.

(2) Every certificate of analysis issued under paragraph 19(1) of Schedule 3 to the Act shall be in the form set out in Part II of the Schedule to these regulations.

(3) 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 III of the Schedule to these regulations.

Fees

4. 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.

1st August 1977.

S. B. Jones,
Parliamentary Under-Secretary of State for Wales.

2nd August 1977.

Bruce Millan,
Secretary of State for Scotland.

3rd August 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 9th August 1977.

(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 10th day of August 1977.

(L.S.)

J. H. Copeland,
Deputy Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 10th day of August 1977.

(L.S.)

W. H. Jack,
Deputy Secretary.

PART II

CERTIFICATE OF ANALYSIS OF SAMPLE

This certificate is issued under paragraph 19(1) of Schedule 3 to the Medicines Act 1968 by me, the undersigned, public analyst for the⁽¹⁾

I hereby certify that I received on the day of 19 , from⁽²⁾
 submitted by⁽³⁾ , *[[]to whom the sample had been
 ,] one part of a sample of⁽⁴⁾
 fastened up and marked⁽⁵⁾ for analysis; which was undamaged, duly sealed and
 ; 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⁾

 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 the name of the sampling officer who submitted the sample for analysis, or the name of the public analyst to whom the sample was originally submitted.
- (3) Here insert the name of the sampling officer who submitted the sample for analysis.
- (4) Here insert the name or description of the substance or article.
- (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 specifications 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 III

CERTIFICATE OF ANALYSIS OR EXAMINATION OF SAMPLE

This certificate is issued under paragraph 19(2) of Schedule 3 to the Medicines Act 1968 by me, the undersigned, *[having the management or control] [being a person appointed for the purpose 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. I 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⁾

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 substance or article.
- (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 revoke the Medicines (Certificates of Analysis) Regulations 1976. They prescribe fresh forms of certificates of analysis and examination of samples 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 re-enact the provision as to fees contained in the Regulations now revoked.

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