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STATUTORY INSTRUMENTS

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**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 and now vested in them<sup>(1)</sup> 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 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.

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(1) 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).

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## Revocation

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

## 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.

1st August 1977

*David Ennals*  
Secretary of State for Social Services

2nd August 1977

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

3rd August 1977

*Bruce Millan*  
Secretary of State for Scotland

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

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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

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## SCHEDULE

Regulation 3

### FORMS OF CERTIFICATE OF ANALYSIS OR EXAMINATION

#### PART I

CERTIFICATE OF ANALYSIS OF SAMPLE

#### PART II

CERTIFICATE OF ANALYSIS OF SAMPLE

#### PART III

CERTIFICATE OF ANALYSIS OR EXAMINATION OF SAMPLE

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#### EXPLANATORY NOTE

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.