SCHEDULE 2

The manufacture of veterinary medicinal products

# PART 1

## Manufacturing authorisations

### Duties on a qualified person E+W+S

**11.**—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from **[**F1another**]** country,F2..., the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested F3..., including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply **[**F4where the exporting country has demonstrated equivalent standards to those of the United Kingdom or **]** where appropriate arrangements have been made F5...with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

**Extent Information**

**E1** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

**Textual Amendments**

**F1** Word in Sch. 2 para. 11(2) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F2** Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F3** Words in Sch. 2 para. 11(2) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(b)(iii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F4** Words in Sch. 2 para. 11(3) inserted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU

Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(i)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**F5** Words in Sch. 2 para. 11(3) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(33)(c)(ii)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## Duties on a qualified person N.I.

**11.**—(1) The qualified person (manufacture) must ensure that each batch of veterinary medicinal product manufactured under that person's responsibility is manufactured and checked in compliance with these Regulations and in accordance with the data submitted in support of the application for the marketing authorisation.

(2) If a manufacturer imports a veterinary medicinal product from a third country, including a product manufactured in a member State, the qualified person (manufacture) must ensure that, following importation, each production batch imported is fully tested in a member State, including a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or controls necessary to ensure the quality of a veterinary medicinal product is in accordance with the requirements of the marketing authorisation.

(3) Sub-paragraph (2) does not apply where appropriate arrangements have been made by the European Union with the exporting country to ensure that the manufacturer of the veterinary medicinal product applies standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and to ensure that the controls in sub-paragraph (2) have been carried out in the exporting country.

(4) At each stage of manufacture, including release for sale, the qualified person (manufacture) must certify in writing that all control tests required under the marketing authorisation have been carried out, and that the production batch complies with the marketing authorisation.

**Extent Information**

**E2** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

**Status:**
There are multiple versions of this provision on screen. These apply to different geographical extents.
**Skip to:**

- E+W+S - England, Wales and Scotland extent
- N.I. - Northern Ireland extent

**Changes to legislation:**
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Paragraph 11.