STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 11

Pharmacovigilance

Obligations on licensing authority in relation to pharmacovigilance

General obligations of the licensing authority

178. The licensing authority must—

(a) take all appropriate measures to encourage the reporting to it of suspected adverse reactions;

(b) facilitate reporting through the provision of alternative reporting formats in addition to web-based formats;

(c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;

(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner, through publication on the UK web-portal, and through other means of publicly available information as necessary; and

(e) ensure that all appropriate measures are taken to identify any biological medicinal product (including name and batch number) prescribed, dispensed or sold in the United Kingdom which is the subject of a suspected adverse reaction report through—

(i) the methods for collecting data, and

(ii) where necessary, the follow up of suspected adverse reaction reports.

Obligation on licensing authority to operate pharmacovigilance system

179.—(1) The licensing authority must operate a pharmacovigilance system.

(2) The pharmacovigilance system must in particular enable the collection of information on the risks that medicinal products present to patients' health or public health, including information on—

(a) adverse reactions in humans arising from use of a medicinal product (irrespective of whether the use was within the terms of an authorisation or registration); and

(b) adverse reactions associated with occupational exposure.

(3) The licensing authority must on an ongoing basis—

(a) evaluate scientifically the information collected under the pharmacovigilance system;

(b) consider options for minimising and preventing risks presented by medicinal products; and

(c) take appropriate regulatory action, if any.

Obligation on licensing authority to audit pharmacovigilance system

180.—(1) The licensing authority must perform a regular audit of its pharmacovigilance system and report the results of that audit to the European Commission.

(2) The results of the audit referred to in paragraph (1) must be reported to the European Commission—

(a) on the first occasion no later than 21st September 2013; and

(b) every two years after the first occasion.

Delegation of obligations under this Part

181.—(1) The licensing authority may delegate any of its obligations under this Part to another EEA State where the conditions in paragraph (2) are met.

(2) The conditions in this paragraph are that the EEA State to whom the obligations are to be delegated—

(a) has given its written agreement to the delegation; and

(b) is not performing delegated obligations under this Part on behalf of another EEA State.

(3) Where the licensing authority has delegated any of its obligations under paragraph (1), it must—

(a) inform the European Commission, the EMA and all other EEA States in writing of the delegation as soon as is reasonably practicable; and

(b) make the delegation public as soon as is reasonably practicable.

(4) The licensing authority may agree to carry out any of the obligations of another EEA State under Title IX of the 2001 Directive on a delegated basis, but may carry out obligations under that Title only for one EEA State at any time.

Status:
Point in time view as at 09/02/2019.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Cross Heading: Obligations on licensing authority in relation to pharmacovigilance.