
STATUTORY INSTRUMENTS

2018 No. 677

The Health Service Products (Provision and Disclosure of Information) Regulations 2018

PART 10

Miscellaneous

Transitional provisions

35.—(1) Until the coming into force of the repeal of section 27 of the 1978 Act by Schedule 3 to the Smoking, Health and Social Care (Scotland) Act 2005⁽¹⁾, any reference in these Regulations to pharmaceutical care services under section 2CA(1) of the 1978 Act is to be read as a reference to pharmaceutical services under section 27(1) of that Act.

(2) Schedule 5 makes transitional provision—

- (a) in respect of the recording, keeping and provision of information about the supply of unbranded generic health service medicines by UK producers who are members of Scheme M or Scheme W, and
- (b) in respect of the recording, keeping and provision of information about the supply of special health service medicines by UK producers who are participating manufacturers for the purposes of the Specials MoU.

(3) In this regulation—

“Scheme M” means the Scheme made by the Secretary of State and the British Generic Manufacturers Association which is dated March 2010 and known as the “Revised long-term arrangements for reimbursement of generic medicines (Scheme M)”⁽²⁾;

“Scheme W” means the Scheme made by the Secretary of State, the British Association of Pharmaceutical Wholesalers and the British Association of Generic Distributors which is dated June 2005 and known as the “New long-term arrangements for reimbursement of generic medicines (Scheme W)”⁽³⁾;

“Specials MoU” means the Memorandum of Understanding agreed by the Secretary of State and the Association of Commercial Specials Manufacturers for the purpose of the provision of information to inform Drug Tariff specials reimbursement prices.

Annual review

36.—(1) The Secretary of State must from time to time—

(1) 2005 asp 13.

(2) Scheme M is available from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU or online at: http://webarchive.nationalarchives.gov.uk/20130123201658/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_115260.

(3) Scheme W is available from the Department of Health and Social Care, 39 Victoria Street, London, SW1H 0EU or online at: http://webarchive.nationalarchives.gov.uk/20130123204650/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4114370

- (a) carry out a review of the regulatory provisions contained in these Regulations,
 - (b) set out the conclusions of the review in a report, and
 - (c) publish the report.
- (2) The first report under these Regulations must be published before 1st July 2019.
- (3) Subsequent reports must be published at intervals not exceeding one year.
- (4) A report published under this regulation must, in particular—
- (a) set out the objectives intended to be achieved by the regulatory provisions contained in these Regulations,
 - (b) assess the extent to which those objectives are achieved,
 - (c) assess whether those objectives remain appropriate, and
 - (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provisions.