Draft Regulations laid before Parliament under section 47(3) and (6)(a) of the Medicines and Medical Devices Act 2021, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2024 No.

MEDICAL DEVICES

The Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024

Made - - - -	***
Coming into force	***

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 15(1), 16(1)(a), (b), (g), (i) and (j), 17(1)(b) and (c) and 43(2) of the Medicines and Medical Devices Act 2021(**a**).

The Secretary of State has carried out a public consultation in accordance with section 45(1) of that Act.

In accordance with section 15(2) to (4) of that Act, the Secretary of State's overarching objective in making these Regulations is safeguarding public health, the Secretary of State has had regard to the matters specified in section 15(3) of that Act, and the Secretary of State considers that, where these Regulations may have an impact on the safety of medical devices, the benefits of making these Regulations outweigh the risks.

In accordance with section 47(3) and (6)(a) of that Act, a draft of this instrument has been laid before and approved by a resolution of each House of Parliament.

Citation, commencement, extent and application

1.—(1) These Regulations may be cited as the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024.

(2) These Regulations come into force 6 months after the day on which they are made.

(3) Subject to paragraph (4), these Regulations extend to England and Wales, Scotland and Northern Ireland.

(4) Regulation 4 extends to England and Wales and Scotland only.

(**a**) 2021 c. 3. Section 17 was amended by S.I. 2021/905. There are other amendments to the Act not relevant to these Regulations.

Amendments to the Medical Devices Regulations 2002

2. The Medical Devices Regulations 2002(**a**) are amended in accordance with regulations 3 to 6.

Amendment to regulation 2 (interpretation)

3. In regulation 2(1)(**b**)—

(a) for the definition of "relevant essential requirements" substitute—

""relevant essential requirements"—

(a) in Part 4A, has the meaning given in regulation 44ZC;

(b) in all other Parts, in relation to a medical device, means the essential requirements set out in Annex 1 of Directive 90/385, Annex I of Directive 93/42 or Annex I of Directive 98/79 which apply to it, but not including, in the case of a device intended for clinical investigation, such of those requirements, or aspects of them, as are the subject of the investigation;";

(b) for the definition of "Regulation (EU) No 722/2012" substitute—

""Regulation (EU) No 722/2012"—

(a) in Part 4A, has the meaning given in regulation 44ZC;

(b) in all other Parts means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (as retained under section 3 of the European Union (Withdrawal) Act 2018 and modified under section 8 of that Act);";

(c) after the definition of "UK responsible person" insert—

""working day" means any day which is not Saturday, Sunday, Christmas Day, Good Friday or a day which is a bank holiday in any part of Great Britain under the Banking and Financial Dealings Act 1971.".

New Part 4A (post-market surveillance requirements)

4. After regulation 44ZB(**c**) (obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746) insert—

"PART 4A

Post-market surveillance requirements

Interpretation of Part 4A

44ZC. In this Part—

"corrective action" means action taken in order to—

(a) eliminate the cause of a potential or actual non-conformity of a device, or

(b) reduce any other risk posed by a device,

that has already been manufactured and may include recalling the device, withdrawing it from the market, and taking it out of service;

(**a**) S.I. 2002/618.
(**b**) Relevant amending instruments are S.I. 2003/1697, 2013/2327, 2021/873.
(**c**) Regulation 44ZB was inserted by S.I. 2019/791.

"field safety corrective action" means a corrective action taken by the manufacturer to prevent or reduce the risk of a serious incident in relation to a device which has already been placed on the market or put into service;

"incident" means in relation to a device that has been placed on the market or put into service—

(a) a malfunction or deterioration in the characteristics or performance of the device when used in accordance with the instructions for use,

(b) a side-effect that has a negative impact on—

(i) the health of an individual,

(ii) patient management, or

(iii) public health,

(c) an inadequacy in the design of the device, including an ergonomic feature, to enable the user to use the device safely and as intended by the manufacturer,

(d) an inadequacy in the information supplied with the device by the manufacturer to enable the user to use the device safely and as intended by the manufacturer, or

(e) an erroneous result provided by a diagnostic medical device, which informs a decision in relation to medical treatment;

"lifetime of a device" means the shelf life of a device (if there is one) plus the period that the manufacturer expects that device to perform as intended;

"PMS period" means the period—

(a) beginning with the day on which the first device of a device model is put into service by the manufacturer or placed on the market, whichever is sooner, and

(b) ending with the end of the lifetime of the last device of that device model that is put into service by the manufacturer or placed on the market, whichever is later;

"post-market surveillance" means activities carried out by manufacturers to proactively collect and review experience gained from devices placed on the market or put into service for the purposes of identifying any need to apply corrective or preventive actions;

"preventive action" means action taken by the manufacturer before completion of the manufacturing phase in order to eliminate the cause of a potential non-conformity or reduce a potential risk that could be posed by the finished device;

"Regulation (EU) No 722/2012" means Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, as it had effect in the EU on 25 May 2021;

"relevant device" means a device that is a "relevant device" for the purposes of Part 2, 3 or 4;

"relevant essential requirements" means—

(a) in relation to a device placed on the market in accordance with regulation 19B, the essential requirements set out in Annex I of Directive 93/42 and, where applicable, Regulation (EU) No 722/2012 which apply to it;

(b) in relation to a device placed on the market in accordance with regulation 19C, the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 which apply to it;

(c) in relation to a device otherwise placed on the market or put into service in accordance with Part 2, the requirements referred to in regulation 8 (essential requirements for general medical devices) which apply to it;

(d) in relation to a device placed on the market in accordance with regulation 30A, the essential requirements set out in Annex I of Directive 90/385 and, where applicable, Regulation (EU) No 722/2012 which apply to it;

(e) in relation to a device otherwise placed on the market or put into service in accordance with Part 3, the requirements referred to in regulation 22 (essential requirements for active implantable medical devices) which apply to it;

(f) in relation to a device placed on the market in accordance with regulation 44ZA, the essential requirements set out in Annex I of Directive 98/79 which apply to it;

(g) in relation to a device placed on the market in accordance with regulation 44ZB, the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/746 which apply to it;

(h) in relation to a device otherwise placed on the market or put into service in accordance with Part 4, the essential requirements referred to in regulation 34 (essential requirements for in vitro diagnostic medical devices) which apply to it;

"required risk analysis" means the analysis required to weigh the risks posed by a device against the intended performance and benefits for the purposes of confirming conformity with the relevant essential requirements;

"serious deterioration of any person's state of health" means any of the following—

(a) life-threatening illness or injury;

(b) permanent impairment of a body structure or a body function;

(c) hospitalisation or prolongation of hospitalisation;

(d) medical treatment, including surgical intervention and self-administered treatment, that is required to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function;

(e) chronic disease;

(f) foetal distress, foetal death or a congenital physical or mental impairment or birth defect;

"serious incident" means an incident that directly or indirectly led, might have led or might lead to any of the following—

(a) the death of any person;

(b) the serious deterioration of any person's state of health;

(c) a serious public health threat;

"serious public health threat" means an event which could result in a risk—

(a) of death, serious illness, or serious deterioration of any person's state of health,

(b) that affects a significant population, and

(c) that requires prompt remedial action;

"similar device" means a device which—

(a) has the same or a similar intended purpose, and

(b) is based on the same or similar technology;

"system or procedure pack" has the same meaning as in regulation 5(1).

Scope of Part 4A

44ZD.—(1) Subject to paragraphs (2) and (3), the requirements of this Part apply in respect of relevant devices that are—

(a) put into service by the manufacturer, or

(b) placed on the market,

in accordance with Parts 2, 3 or 4 on or after the date on which the Medical Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024 come into force.

(2) The following regulations in this Part apply in respect of custom-made devices—

(a) regulation 44ZC (interpretation of Part 4A);

(b) regulation 44ZE (post-market surveillance system);

(c) regulation 44ZF (post-market surveillance plan) except paragraphs (3)(g) and (h);

(d) regulation 44ZG (preventive and corrective actions);

(e) regulation 44ZH (initial reporting of serious incidents);

(f) regulation 44ZI (investigation and final reporting of serious incidents);

(g) regulation 44ZJ (field safety corrective actions and field safety notices);

(h) regulation 44ZO (reports received by the Secretary of State);

(i) regulation 44ZP (analysis of information received under Part 4A);

(j) regulation 44ZQ (retention of post-market surveillance documentation);

(k) regulation 44ZR (requests for post-market surveillance documentation).

(3) This Part does not apply to—

(a) devices intended for clinical investigation or performance evaluation;

(b) devices placed on the market or put into service in accordance with an authorisation issued by the Secretary of State under regulation 12(5), 26(3) or 39(2).

(4) In this Part, the relevant devices to which this Part applies are referred to as "devices"

(5) In this regulation, "custom-made device" means a device within the meaning of that term as defined in regulation 5 or regulation 20.

Post-market surveillance system

44ZE.—(1) The manufacturer must maintain a post-market surveillance system ("PMS system") for each device that is placed on the market or put into service.

(2) The manufacturer must ensure the PMS system—

(a) is proportionate to the risk posed by the device;

(b) is appropriate to the type of device;

(c) includes the analysis of data relevant to the quality, performance and safety of the device throughout its lifetime, and a record of the manufacturer's conclusions based on that analysis.

(3) The manufacturer must ensure that the PMS system is used throughout the PMS period to identify—

(a) preventive actions and corrective actions, including field safety corrective actions;

(b) trends in incidents, including those on which the manufacturer must report under regulation 44ZN (trend reporting);

(c) options to improve the usability, performance and safety of the device;

(d) any impact on the post-market surveillance of other devices.

(4) The manufacturer must ensure that data gathered through the PMS system is used to update the following—

(a) for devices placed on the market or put into service in accordance with Part 2 or 3—

(i) the instructions for use and labelling of the device;

(ii) design and manufacturing information;

(iii) the required risk analysis;

(iv) the evaluation of clinical data referred to in regulations 9(2) and 23(2) for the purposes of confirming conformity with the relevant essential requirements;

(v) any other technical documentation required by the conformity assessment procedure carried out in respect of the device in accordance with Part 2 or 3.

(b) for devices placed on the market or put into service in accordance with Part 4—

(i) the instructions for use and labelling of the device;

(ii) design and manufacturing information;

(iii) the required risk analysis;

(iv) any evaluation of performance evaluation data confirming conformity with the relevant essential requirements;

(v) any other technical documentation required by the conformity assessment procedure carried out in respect of the device in accordance with Part 4.

(5) Paragraph (4) does not apply in respect of a device placed on the market in accordance with regulation 19B, 19C, 30A, 44ZA or 44ZB.

Post-market surveillance plan

44ZF.—(1) The manufacturer must base the post-market surveillance system on a post-market surveillance plan ("PMS plan") that complies with this regulation.

(2) A PMS plan must be—

(a) clear, organised and searchable, and

(b) maintained for the PMS period of the device model.

(3) A PMS plan must specify the lifetime of the device and must include—

(a) processes for the collection and assessment of the following information in relation to the device—

(i) information about serious incidents, other incidents and side-effects;

(ii) information about field safety corrective actions;

(iii) information for the purposes of identifying trends in incidents and if applicable, reporting those trends under regulation 44ZN (trend reporting);

(iv) feedback and complaints provided by users and suppliers of the device;

(v) information about user experience in relation to safety and performance, including through patient and public engagement, where appropriate;

(vi) other information relevant to the post-market surveillance of the device, including information relating to similar devices available on the market and available outside Great Britain.

(b) suitable indicators and threshold values to be used in the reassessment of the required risk analysis;

(c) effective and appropriate processes to investigate complaints and analyse feedback and information about user experience;

(d) processes to manage incidents and trends (whether or not they must be reported under regulation 44ZN (trend reporting)), including—

(i) the statistical methodology to be used to determine a significant increase in the frequency or severity of incidents, and

(ii) in relation to a device placed on the market or put into service in accordance with Part 4, the statistical methodology to be used to determine a significant increase in expected erroneous results;

(e) a process for communicating effectively with the Secretary of State, the approved body for the device (if there is one), the UK responsible person (if there is one), users and suppliers of the device;

(f) processes that provide for how the manufacturer will comply with their obligations under this Part;

(g) a plan for any post-market clinical follow-up required under Part 2 or 3;

(h) the post-market surveillance report required by regulation 44ZL (post-market surveillance report) or the periodic safety update report required by regulation 44ZM (periodic safety update report) and any reports issued by an approved body under paragraph (9) of regulation 44ZM.

(4) The information collected under paragraph (3)(a) must enable—

(a) an accurate characterisation of the performance of the device, and

(b) a comparison between the device and similar devices available on the market.

(5) The manufacturer and the UK responsible person (if there is one) must provide the PMS plan, including any post-market surveillance reports or periodic safety update reports and any reports issued by an approved body, to the Secretary of State upon request and within 3 working days of the date of any such request.

Preventive and corrective actions

44ZG.—(1) If the manufacturer of a device—

(a) identifies a risk that following evaluation is deemed to compromise the performance or safety of the device, or

(b) otherwise has reason to believe that the device is not in conformity with the relevant essential requirements,

they must take the necessary preventive or corrective action as soon as possible to reduce that risk and bring the device into conformity.

(2) The manufacturer must notify the action to—

(a) the UK responsible person (if there is one);

(b) the approved body for the device (if there is one);

(c) if the action is a field safety corrective action, the Secretary of State in accordance with regulation 44ZJ (field safety corrective action).

(3) The approved body must review the notification to determine whether there is any impact on the certification it has issued for the device.

(4) The manufacturer must monitor the action to identify if any further action is required to reduce the risk posed and bring the device into conformity.

Initial reporting of serious incidents

44ZH.—(1) The manufacturer must report to the Secretary of State any serious incident involving the manufacturer's device.

(2) The report must include—

(a) the manufacturer's name and contact details;

(b) the UK responsible person's name and contact details (if there is one);

(c) details of the initial reporter of the serious incident;

(d) a description of the device, including its current location and any unique device identifiers;

(e) a description of the serious incident;

(f) the manufacturer's preliminary conclusions in relation to the cause of the serious incident;

(g) consideration of whether any field safety corrective action is required to prevent or reduce the risk of a further serious incident;

(h) details of any preventive or corrective action taken by the manufacturer.

(3) The manufacturer must submit the report—

(a) immediately after the manufacturer has established the causal (or reasonably possible causal) relationship between the device and the serious incident, and

(b) unless paragraph (4) or (5) applies, no later than 15 days after the manufacturer becomes aware of the serious incident.

(4) If the serious incident being reported involves a serious public health threat, the report must be submitted no later than 2 days after the manufacturer becomes aware of the threat.

(5) If there is a death or an unanticipated serious deterioration in a person's state of health, the report must be submitted no later than 10 days after the manufacturer becomes aware of the incident.

(6) If the same device model or a variant of that model is involved in similar serious incidents and the manufacturer has either—

(a) identified the cause, or

(b) implemented a field safety corrective action,

the manufacturer and the Secretary of State may agree that the manufacturer can submit periodic summary reports instead of individual serious incident reports.

Investigation and final reporting of serious incidents

44ZI.—(1) After submitting a serious incident report under regulation 44ZH (initial reporting of serious incidents), the manufacturer must as soon as possible—

(a) investigate the serious incident and the device or devices concerned,

(b) review the required risk analysis for the device or devices concerned taking into account the serious incident and any proposed preventive and corrective actions, and

(c) submit a final report to the Secretary of State setting out—

(i) the methods and conclusions of the investigation;

(ii) consideration of whether any field safety corrective action is required to prevent or reduce the risk of a further serious incident;

(iii) details of any field safety corrective action the manufacturer has taken or intends to take;

(iv) details of similar serious incidents involving the same device model or a variant of that model.

(2) The Secretary of State may—

(a) give advice to a manufacturer regarding the serious incident investigation;

(b) initiate a separate investigation;

(c) require the approved body (if there is one) to provide information and assessments relevant to the serious incident and field safety corrective action.

(3) A manufacturer must—

(a) cooperate with the Secretary of State in relation to the investigations referred to in paragraphs (1)(a) and (2)(b);

(b) upon request, provide the Secretary of State with updates and documents relevant to an investigation referred to in paragraphs (1)(a) and (2)(b) and do so within 3 working days of the date of any such request;

(c) not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the

causes of the serious incident, before informing the Secretary of State of such action.

Field safety corrective actions and field safety notices

44ZJ.—(1) Unless paragraph (4) applies, before taking any field safety corrective action ("FSCA") in relation to a device, a manufacturer must—

(a) produce a risk assessment of the proposed FSCA, and

(b) submit to the Secretary of State—

(i) an initial report on the proposed action, and

(ii) the proposed field safety notice setting out the details in paragraph (6).

(2) The initial report must include—

(a) the manufacturer's name and contact details;

(b) the UK responsible person's name and contact details (if there is one);

(c) a description of the devices, including any unique device identifiers;

(d) a description of the FSCA and its proposed implementation;

(e) the reason why the FSCA is required and the justification for the manufacturer's chosen FSCA, based on the conclusions of the risk assessment produced under paragraph (1)(a);

(f) the number of devices placed on the market or put into service in Great Britain and the estimated number of users affected.

(3) After submitting the initial report and proposed notice under paragraph (1), the manufacturer must implement the FSCA as soon as possible and monitor its progress.

(4) A manufacturer may submit an initial report and a copy of the field safety notice after taking the FSCA if the manufacturer believes the FSCA needs to be taken urgently.

(5) When taking an FSCA, the manufacturer must take all reasonable steps to ensure the field safety notice is sent to users of the device.

(6) The field safety notice must—

(a) identify the devices involved and include any unique device identifiers in a searchable format within the notice;

(b) explain the reasons for the FSCA with reference to the risks to any person;

(c) describe all actions to be taken by users in response.

(7) After completing the FSCA, the manufacturer must submit a final report to the Secretary of State setting out the outcome of the action and including evidence to demonstrate its effectiveness.

(8) The manufacturer must provide the Secretary of State with—

(a) the risk assessment produced under paragraph (1)(a), and

(b) updates and evidence of the progress of the FSCA;

upon request and within 3 working days of any such request.

Field safety corrective actions outside Great Britain

44ZK.—(1) A manufacturer of a device placed on the market or put into service in Great Britain must report to the Secretary of State when taking any field safety corrective action ("FSCA") outside Great Britain, if—

(a) the FSCA relates to a device which is of the same model as the device that has been placed on the market or put into service in Great Britain, and

(b) the manufacturer is not taking the same FSCA in Great Britain.

(2) The report must include—

(a) the manufacturer's name and contact details;

(b) the UK responsible person's name and contact details (if there is one);

(c) descriptions of the devices, including any unique device identifiers;

(d) the number of devices placed on the market or put into service in Great Britain and the estimated number of users;

(e) a description of the FSCA and the reason why the FSCA is required outside Great Britain;

(f) the reason the same FSCA is not required in Great Britain.

Post-market surveillance report

44ZL.—(1) Subject to paragraph (4), the manufacturer must produce a post-market surveillance report ("PMSR") for the following—

(a) a device placed on the market in accordance with regulation 19B and classified as belonging to class I under Directive 93/42;

(b) a device placed on the market in accordance with regulation 19C and classified as belonging to class I under Regulation (EU) 2017/745;

(c) a device otherwise placed on the market or put into service in accordance with Part 2 and classified as belonging to class I under regulation 7 (classification of general medical devices);

(d) a device placed on the market in accordance with regulation 44ZB and classified as belonging to class A or B under Regulation (EU) 2017/746;

(e) a device otherwise placed on the market or put into service in accordance with Part 4 that is not a device referred to in the lists in Annex II of Directive 98/79.

(2) The PMSR must include—

(a) a summary of the results and conclusions of the analyses of the information collected as a result of the post-market surveillance plan, and

(b) a description of any preventive or corrective action that has been taken by the manufacturer in relation to the device and the reason for doing so.

(3) A PMSR must be—

(a) produced within 3 years of the device being placed on the market or put into service, whichever is sooner, and

(b) updated by the manufacturer at least every 3 years until the end of the PMS period for the device model.

(4) This regulation shall not apply to a relevant device which is a system or procedure pack, unless–

(a) the system or procedure pack incorporates a medical device which does not bear a UKCA marking or a CE marking; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(5) In paragraph (2)(b) the reference to "any preventive or corrective action" includes any action taken before the device was placed on the market or put into service if—

(a) for devices with a certificate that was issued by an approved body or notified body before the declaration of conformity was drawn up, the action was taken after that certificate was issued;

(b) for any other devices, the action was taken after the declaration of conformity was drawn up.

Periodic safety update report

44ZM.—(1) Subject to paragraph (4), unless regulation 44ZL (post-market surveillance report) applies to the device, the manufacturer must produce a periodic safety update report ("PSUR") for each device placed on the market or put into service.

(2) The manufacturer may prepare a single PSUR for a category or group of devices if—

(a) the devices are covered by the same clinical evaluation report under Regulation (EU) 2017/745 or performance evaluation report under Regulation (EU) 2017/746, or

(b) the devices are similar devices and the manufacturer considers that the similarity between the devices justifies preparing a single PSUR for those devices.

(3) The PSUR must include—

(a) a summary of the results and conclusions of the analyses of the information collected as a result of the post-market surveillance plan;

(b) a description of any preventive or corrective action that has been taken by the manufacturer in relation to the device and the reason for doing so;

(c) the required risk analysis;

(d) the conclusions of any post-market clinical follow-up required under Part 2 or 3;

(e) the number of—

(i) devices placed on the market in the UK; and

(ii) devices put into service in the UK without being placed on the market;

(f) a description of the characteristics of the population using the device;

(g) an estimate of—

(i) the size of the population using the device in the UK;

(ii) the size of the population using the device outside the UK;

(iii) the usage frequency of the device, where it is practicable to make such an estimate.

(4) This regulation shall not apply to a relevant device which is a system or procedure pack, unless–

(a) the system or procedure pack incorporates a medical device which does not bear a UKCA marking or a CE marking; or

(b) the chosen combination of medical devices is not compatible in view of their original intended use.

(5) In paragraph (3)(b), "any preventive or corrective action" includes any action taken before the device was placed on the market or put into service, if that action was taken after an approved body or notified body issued a certificate in respect of the device.

(6) Unless paragraph (7) applies, the manufacturer must—

(a) produce the first PSUR within 1 year of the device being placed on the market or put into service, whichever is sooner, and

(b) update the PSUR at least every year until the end of the PMS period for the device model.

(7) This paragraph applies to—

(a) a device placed on the market in accordance with regulation 19B and classified as belonging to class IIa under Directive 93/42;

(b) a device placed on the market in accordance with regulation 19C and classified as belonging to class IIa under Regulation (EU) 2017/745;

(c) a device otherwise placed on the market or put into service in accordance with Part 2 and classified as belonging to class IIa under regulation 7 (classification of general medical devices).

(8) Where paragraph (7) applies, the manufacturer must—

(a) produce the first PSUR within 2 years of the device being placed on the market or put into service, whichever is sooner, and

(b) update the PSUR at least every 2 years until the end of the PMS period for the device model.

(9) The manufacturer must submit the PSUR and each updated PSUR to the approved body for the device (if there is one).

(10) The approved body must take into account the PSUR and updated PSURs when carrying out its surveillance activities as part of a conformity assessment procedure set out in these Regulations.

(11) In respect of a device listed in paragraph (12), the approved body must, as soon as reasonably practicable following receipt—

(a) review the PSUR and each updated PSUR to determine whether there is any impact on the certification issued for the device, and

(b) issue a report to the manufacturer and the UK responsible person (if there is one), setting out the conclusions of that review.

(12) The devices referred to in paragraph (11) are—

(a) a device placed on the market or put into service in accordance with Part 2 and classified as belonging to class III under regulation 7 (classification of general medical devices);

(b) a device placed on the market or put into service in accordance with Part 2 and considered to be an implantable device under Directive 93/42;

(c) a device placed on the market or put into service in accordance with Part 3;

(d) a device placed on the market or put into service in accordance with Part 4 that is referred to in the lists in Annex II of Directive 98/79.

(13) The approved body must provide a copy of its completed reports under paragraph (11) to the Secretary of State upon request and within 3 working days of the date of any such request.

Trend reporting

44ZN.—(1) The manufacturer must report to the Secretary of State any significant increases in the frequency or severity of incidents involving a device if the manufacturer considers that increase could have a significant adverse impact on the required risk analysis.

(2) A "significant increase" under paragraph (1) is to be determined in comparison to the foreseeable frequency or severity of the incidents and in accordance with the statistical methodology set out in the post-market surveillance plan.

(3) In relation to a device placed on the market or put into service in accordance with Part 4, the manufacturer must also report to the Secretary of State any significant increase in expected erroneous results in comparison to the stated performance of the device in the instructions for use.

(4) The reporting duties in paragraphs (1) and (3) apply throughout the PMS period for the device model.

(5) An initial report under this regulation must include—

(a) the manufacturer's name and contact details;

(b) the UK responsible person's name and contact details (if there is one);

(c) a description of the device, including any unique device identifiers;

(d) the number of devices placed on the market or put into service in Great Britain and the estimated number of users affected;

(e) information in relation to the identified trend.

(6) As soon as possible after submitting an initial report, the manufacturer must—

(a) investigate the identified trend and the device or devices concerned, and

(b) submit a final report to the Secretary of State setting out—

(i) the manufacturer's conclusions into causes of the identified trend;

(ii) a description of any preventive and corrective actions taken or to be taken by the manufacturer in response to the identified trend.

(7) The manufacturer must provide the Secretary of State with updates and documents relevant to the investigation under paragraph (6)(a) upon request and within 3 working days of the date of any such request.

Reports received by the Secretary of State

44ZO.—(1) The Secretary of State must record reports of incidents involving devices.

(2) If the Secretary of State notifies a manufacturer about a reported incident, the manufacturer must consider whether the incident is a serious incident and take action in accordance with this Part.

(3) If the manufacturer of the device considers that the incident is not a serious incident, the manufacturer must provide an explanatory statement to the Secretary of State as soon as possible.

(4) If the Secretary of State notifies the manufacturer that the Secretary of State does not agree with an explanatory statement provided under paragraph (3), the manufacturer must take action in accordance with this Part as if the manufacturer considered the incident to be a serious incident.

Analysis of information received under Part 4A

44ZP.—(1) The Secretary of State must have processes for monitoring the information received under this Part, in order to identify trends, patterns or signals that may reveal new risks or safety concerns.

(2) If the Secretary of State notifies a manufacturer of an identified risk or safety concern, the manufacturer must investigate the risk or safety concern and submit a report to the Secretary of State as soon as possible setting out—

(a) the methods and conclusions of the manufacturer's investigation, and

(b) any preventive action or corrective action the manufacturer has taken or intends to take.

(3) Paragraph (2) is without prejudice to any other investigation and reporting requirements in this Part.

Retention of post-market surveillance documentation

44ZQ.—(1) The manufacturer and the UK responsible person (if there is one) must retain the documentation drawn up for the purposes of this Part for the period set out in paragraph (2).

(2) The period is the longer of—

(a) the PMS period for the device model, and

(b) 15 years in the case of an implantable device, or 10 years in the case of any other device.

Requests for post-market surveillance documentation

44ZR. Where any provision of this Part requires information or documentation to be provided to the Secretary of State within 3 working days of a request, the Secretary of State

may extend the time within which the information or documentation is to be provided if the Secretary of State considers it reasonable to do so.".

Amendment to Schedule 2A

5.—(1) Subject to regulation 6, Schedule 2A(**a**) is amended as follows.

(2) For paragraph 3(f)(ii) substitute—

"(ii) omit the fifth indent;".

(3) In paragraph 5, in the substituted Annex 4, omit Section 4.

(4) In paragraph 6, in the substituted Annex 5, omit the sixth indent in Section 3.1.

(5) For paragraph 7(e) substitute—

"(e) omit Section 5.".

(6) In paragraph 13(da)—

(a) omit paragraph (iii);

(b) at the end insert—

"(iv) omit the seventh indent;".

(7) For paragraph 15(f) substitute—

"(f) omit Section 3;".

(8) In paragraph 16 for sub-paragraph (e) substitute—

"(e) omit the eighth indent of Section 3.1;".

(9) For paragraph 17(e) substitute—

"(e) in Section 3.1–

(i) for "a notified body" substitute "an approved body";

(ii) for "other notified body" substitute "other approved body";

(iii) omit the eighth indent;".

(10) For paragraph 18(e) substitute—

"(e) omit Section 4;".

(11) For paragraph 19(f) substitute—

"(f) omit Section 5.".

(12) For paragraph 26(e) substitute—

"(e) omit Section 5;".

(13) In paragraph 27(d) after paragraph (ii) insert—

"(iii) omit the final indent;".

(14) In paragraph 29 after sub-paragraph (d) insert—

"(da) omit Section 3;".

Saving provision

6.—(1) The modifications made by Schedule 2A continue to apply, as if they had not been amended by regulation 5, to relevant devices—

(a) put into service by the manufacturer, or

(b) placed on the market,

in accordance with Parts 2, 3 or 4 before the date on which these Regulations came into force.

(**a**) Schedule 2A was inserted by S.I. 2019/791.

(2) In this regulation, "relevant device" means a device that is a "relevant device" for the purposes of Part 2, 3 or 4 of the Medical Devices Regulations 2002.

Name
Parliamentary Under Secretary of State
Department of Health and Social Care

Address
Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618) ("the 2002 Regulations") to insert new post-market surveillance requirements. The 2002 Regulations were made under section 2(2) of the European Communities Act 1972 to implement Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

Regulation 3 amends regulation 2 of the 2002 Regulations to update definitions that will apply for the purposes of new Part 4A.

Regulation 4 inserts a new part, Part 4A, into the 2002 Regulations. Part 4A contains new post-market surveillance requirements for medical devices and accessories to medical devices that are placed on the market or put into service in Great Britain.

New regulation 44ZE requires manufacturers to have a post-market surveillance system based on a post-market surveillance plan under new regulation 44ZF. New regulations 44ZG, 44ZJ and 44ZK set requirements in relation to preventive actions, corrective actions and field safety corrective actions. New regulations 44ZH and 44ZI, and 44ZL to 44ZP impose investigation and reporting requirements on manufacturers in relation to serious incidents, trends in incidents and the post-market surveillance of their devices generally. New regulation 44ZQ provides for the retention of the documentation produced by manufacturers under new Part 4A and new regulation 44ZR allows the time for providing requested information to be extended.

Regulation 5 amends Schedule 2A to the 2002 Regulations to remove the existing post-market surveillance requirements that are replaced by Part 4A. Regulation 6 makes provision to save those existing post-market surveillance requirements for devices placed on the market or put into service by their manufacturers before new Part 4A comes into force.

An impact assessment of the effect that this instrument will have on the costs of business, the voluntary sector and the public sector will be available from the Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London, E14 4PU and published alongside this instrument at www.legislation.gov.uk.

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