STATUTORY INSTRUMENTS

2023 No. 377

The Medical Devices and Blood Safety and Quality (Fees Amendment) Regulations 2023

PART 2

Amendment of the Medical Devices Regulations 2002

Amendment of regulation 16 in relation to England, Scotland and Wales (procedures for general medical devices for clinical investigations)

5. After regulation 16(1)(**1**), insert—

"(1A) A manufacturer or their UK responsible person may request a meeting with the Secretary of State in advance of giving notice in writing to the Secretary of State pursuant to paragraph (1) in order to—

(a) obtain advice on regulatory requirements relating to an intended clinical investigation; or

(b) obtain a statistical review in relation to an intended clinical investigation.".

(**1**) Relevant amending instruments are S.I. 2008/2936, 2013/2327 and 2019/791.