Medicines and Healthcare Products Regulatory Agency

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Re: Mr James Michael HEDGE.

Dear Mr Barkley

I write with reference to your Regulation 28 report (dated 27 July 2016) following the inquest into the death of Mr James Michael Hedge.

The referenced incident was reported to the MHRA on 5 February 2016 by Roche, the manufacturer of the insulin pump.

During the investigation into the reported incident, MHRA received notification from Roche Diabetes Care in June 2016 that a Field Safety Corrective Action would be undertaken which would update the handling instructions and user manual provided to users of the Accu-Check Insight Pump System and NovoRapid Pump Cart insulin cartridges. A Field Safety Notice (FSN) was published on 6 June 2016 and sent to healthcare professionals and patients who are registered Accu-Chek Insight users and those who have ordered associated consumable devices and accessories.

In addition, MHRA conducted a further risk assessment and decided the manufacturer's safety message should be reinforced through centralised communication channels to the healthcare service. On 15 August 2016 MHRA published a Medical Device Alert (MDA) to ensure that healthcare providers were made aware of the new instructions for changing the insulin cartridge and the importance of communicating the risk to the patient's health, if the manufacturer's instructions are not followed. A copy of this MDA has been attached to this letter. Furthermore a press release highlighting key action points was also issued by MHRA.

The MHRA investigation has not yet been concluded. Roche Diabetes Care has indicated that they are reviewing technical enhancements to the design of the system. MHRA will monitor the progress of the manufacturer with this long term preventative action plan.

In order to fulfil the requirements of the Medical Devices Directive and place a medical device on the market, the manufacturer must provide sufficient information and instructions to enable users of the device to operate it in accordance with its intended function. This should include any warnings and precautions to take and any undesirable side effects. The manufacturer should take into consideration the training and capacity of the intended user and, where appropriate, instructions should be provided in symbol form.

MHRA is not responsible for training healthcare professionals and patients; however, we issue device specific guidance such as the MHRA Device Bulletin (DB) on infusion systems and general guidance on managing medical devices. These documents address the need for healthcare professionals to be trained in the use of a device prior to the use of the device (see appendices 3 and 4). We recommend health care professionals carry out a risk assessment ensuring that the device is suitable for the patient and that adequate training and support is available for users of the device.

MHRA raised awareness of the published MDA and manufacturer's FSN, which includes updated handling instructions during the last National Medical Device Safety Officers' (MDSO) Webex which took place on 7 September 2016. MDSOs are responsible for supporting local medical device incident reporting and learning. The Webex is a joint MHRA/NHS initiative designed to improve communication and address medical device issues.

MHRA has not identified a systemic problem relating to the inadequacy of instructions for use and product labelling from other manufacturers of insulin delivery systems.

MHRA will continue to monitor the progress of the Roche Field Safety Corrective Action and will investigate any further incidents that we receive. We conduct signal detection activities whereby incident reports received for any given category of medical device are periodically reviewed.

Thank you for drawing our attention to this incident and I should like to assure you that MHRA always strives to improve patient safety through the monitoring of adverse incidents with medical devices and by working with manufacturers to improve design and the instructions for use of their products, as appropriate.

Yours sincerely

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