

Yr Adran Iechyd a Gwasanaethau Cymdeithasol  
Cyfarwyddwr Cyffredinol a Prif Weithredwr, GIG Cymru

Department for Health and Social Services  
Director General and Chief Executive, NHS Wales



Llywodraeth Cymru  
Welsh Government

Mr Andrew Barkley  
Senior Coroner  
South Wales Central  
The Coroner's Office,  
1st Floor,  
Rock Grounds,  
Aberdare,  
CF44 7AE

Our Ref: AG/AMC/SB

16 September 2016

Dear Mr Barkley

**Regulation 28: Report to Prevent Future Deaths – James Michael Hedge**

Thank you for your bringing to our attention the regulation 28 report following the investigation into the death of James Michael Hedge. We have considered the concerns carefully and are taking the following action.

We have contacted the Medicines and Healthcare Products Regulatory Agency (MHRA) and are aware they issued a Medical Device Alert, on the 15 August 2016, in response to the concerns raised in your report. The Medical Device Alert raises awareness that *'Cartridges inserted incorrectly can leak insulin into the cartridge compartment, resulting in an under-delivery of insulin, which may lead to rapid deterioration of health, diabetic ketoacidosis or death'*.

We are also aware that the manufacturers (Roche) of the insulin pump used in this particular incident issued an urgent field safety notice in June 2016 in response to feedback from people experiencing leaking insulin cartridges. The safety notice informs that handling instructions will be updated in response to the feedback received and of the dangers the under-delivery of insulin can lead to e.g. hyperglycaemia.



BUDDSODDWYR | INVESTORS  
MEWN POBL | IN PEOPLE

Parc Cathays • Cathays Park  
Caerdydd • Cardiff  
CF10 3NQ

Ffôn • Tel 02920 801182/1144  
Andrew.Gouldall@wales.gsi.gov.uk  
Gwefan • website: [www.wales.gov.uk](http://www.wales.gov.uk)

The urgent field safety notice has been sent to all insulin pump teams and all people using this pump to warn them of the potential for the cartridge to leak and updated handling instructions.

The National Diabetes Delivery Plan for Wales recognises the importance of insulin pump provision and structured diabetes education (SDE). With regard to insulin pumps, the plan commits health boards to the provision of an insulin pump service in line with National Institute for Health and Care Excellence (NICE) guidance. As a result, our Diabetes Implementation Group has identified insulin pump provision as one of its national priority areas and has a specific line of activity aimed at health boards ensuring standards of safety comply with NICE guidelines including annual education updates.

The national plan is currently being refreshed and extended to 2020; insulin pump provision and SDE will remain key areas of priority in the revised plan which will be monitored by the Diabetes Implementation Group.

I hope this reassures you of the action Welsh Government are taking.

Yours sincerely

