



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

14 September 2016

Dear Sir,

As the General Manager of Roche Diabetes Care Limited UK, I am responding on behalf of [REDACTED] to your report to prevent future deaths issued on 27 July 2016, following the inquest into the death of Mr. James Hedge.

In your report you raise two matters of concern. In our response, we describe the product information and educational materials supplied by Roche and then proceed to respond to each of your concerns.

As a preliminary matter, please be aware that patient safety is our utmost priority. We have therefore carefully reviewed our user manuals and training materials in response to the evidence given at the inquest as well as to your matters of concern. In this response we focus on the Accu-Chek Insight insulin pump system, the pump used by Mr Hedge. However similar information and training is provided in relation to other Roche insulin pumps

#### **Materials and information provided by Roche**

The current materials provided to all users of the Accu-Chek Insight insulin pump system in the UK comprises:

#### **Device User Manuals**

These are regulated documents, obliged to be supplied with the medical device to ensure its safe and effective usage:

**Roche Diabetes Care Limited** Charles Avenue  
Burgess Hill  
West Sussex  
RH15 9RY  
United Kingdom  
Registration Number 9055599

Tel. +44 (0)1444 256000

- Accu-Chek Insight insulin pump Manual
- Accu-Chek Insight diabetes manager Manual
- Accu-Chek Insight Diabetes Therapy System Manual

#### **Additional Training documents**

These are documents created by Roche to supplement the User Manuals and provide a comprehensive view of the use of the device in the context of type I diabetes

- Accu-Chek Insight system Training Handbook Basic
- Accu-Chek Insight system Training Handbook Optional
- Accu-Chek Insight Pump Starter Guide

#### **Welcome Pack**

This is a third level of supporting information which includes summary information on the use of the accessories provided with the Accu-Chek Insight insulin pump system

- Welcome letter
- Accu-Chek Insight Quick reference guides (8 topics)
- Charging your Accu-Chek Insight Handset
- Accu-Chek Monitoring Diary
- Accu-Chek Pump Starter Guide
- Accu-Chek Fastclix brochure
- Accu-Chek Insight Flex training guide
- A USB containing the Accu-Chek Insight training handbooks (Basic and Optional) and e-learning modules

This material includes comprehensive information and warnings relating to the occurrence of hyperglycemia, its prevention, symptoms and management. Please find attached at Annex A to this response, a document which sets out the information contained in the documents supplied by Roche on the following topics;

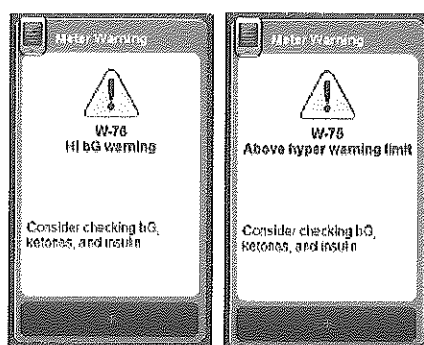
- the risks of hyperglycemia
- how to react in case of a hyperglycemic situation and diabetic ketoacidosis
- the correct handling of the insulin cartridge
- the incremental risk where the cartridge is not inserted correctly or in the context of any other misuse.

The welcome package contains a personal workbook (Accu-Chek Insight Pump Starter Guide) where the patient can fill out their individual data during the training and pump set-up session by the healthcare professional or diabetes specialist nurse. This was specifically designed to support healthcare professionals and diabetes specialist nurses in educating their patients. This personal workbook (Accu-Chek Insight Pump Starter Guide) includes explicit information about treating, correcting and preventing hyperglycemia and ketosis. Details can be found under the heading "Hyperglycemia" in Annex A.

All the materials mentioned above were provided to James Hedge at the time of his initial training on Accu-

Chek Insight. The only addition to these materials is the Field Safety Notice which reinforced instructions for insertion of the cartridge – this was supplied to all Accu-Chek Insight pump users who are registered with Roche and to relevant Healthcare Professionals in May 2016.

In addition to the above, the Accu-Chek Aviva Insight Diabetes Manager, (which is the handset component of the Accu-Chek Insight pump system) has compulsory hyperglycemia warning screens to remind the user to check ketones, blood glucose concentration and insulin when they experience a high blood glucose reading. This is an additional measure to support the patient in following the clinical actions recommended by their healthcare professional in such a circumstance.



Overall, the content included in the documentation listed above, including the reinforced instructions in the Field Safety Notice, the explicit warnings on the consequences of misuse as well as the additional warnings and instructions on the device itself provide a comprehensive cohort of information to pump users. This information, incorporating detailed device instructions and warnings and statements of risk, as well as the provision of extensive training information applies across the Accu-Chek portfolio to all Roche insulin pump systems.

In addition to the handling instructions and information materials that Roche Diabetes Care provides to all pump users, we offer a round-the clock technical support phone line that patients can contact to resolve technical issues and, where necessary to request next day deliveries of replacement devices and accessories. It is important to consider however that, as a manufacturer of medical devices, it would be inappropriate for us to provide individual therapy guidance to people with diabetes on insulin pump therapy. So for individual clinical matters we ask users of our Accu-Chek products to always contact their GP, diabetes specialist nurse or other treating healthcare professional, for guidance and advice.

### **Response to your matters of concern**

#### 1) Advice and guidance in relation to the use of the insulin pump and dangers of misuse

Your report states: “The evidence showed that the advice and guidance in relation to the use of the insulin pump, which is one of several on the market, does not adequately highlight the dangers of misuse and the potential consequences which may follow if the device is not used correctly - in this case, the incorrect insertion of the insulin cartridge leading to a leak and loss of insulin at a time when blood sugars were high”.

Roche Diabetes Care considers that information relating to hyperglycemia, diabetic ketoacidosis and associated clinical conditions should form part of the fundamental clinical training that all insulin patients should receive from their healthcare professional. Such advice is an important component of basic diabetes education and must have been provided to all insulin patients as a precondition for the use of our pump (see Accu-Chek Insight insulin pump user guide / preface). The patient information leaflet accompanying the insulin cartridge also includes similar information provided by the manufacturer of the insulin. By way of example, Novo Nordisk advises users of NovoRapid PumpCart:

*“Before using NovoRapid® PumpCart® in a pump, you must have thorough training in the use of the pump and information about any actions to be taken in case of illness, too high or too low blood sugar or failure of the pump. Follow your doctor’s instructions and advice about the use of NovoRapid® PumpCart® in the pump.”*

The clinical information provided to patients by Roche Diabetes Care (and by other companies) in relation to the effects and management of diabetes, including the proper response to hyperglycemia and the risks associated with a high blood glucose, is therefore intended to supplement and reinforce the information provided to the individual patient by healthcare professionals, but not to act as a substitute for such information. Roche is not in a position to provide information on clinical matters tailored to the medical condition and personal circumstances of particular patients and it would not be appropriate for us to seek to do so.

Nevertheless, as indicated by the information provided in Roche documents and referenced at Annex A, Roche supplies substantial generic (non-personal) information to users of its pumps in relation to the issues raised in your first matter of concern, including the following topics:

- Advice about checking blood glucose regularly
- Advice on preventing, treating and correcting hyperglycemia including the need for prompt action
- Advice on preventing, treating and correcting ketosis including the need for prompt action
- Advice on how to insert the cartridge correctly
- Advice to consult with HCP for correct therapy settings

We believe this information is clear and comprehensive, to the extent that general clinical information may properly be supplied to patients by a pump manufacturer.

With respect to the potential consequences of misuse, incorrect insertion of the insulin cartridge and the risks of insulin leakage are explained in the information provided to patients (see heading “Correct cartridge change” in Annex A) and are also addressed in the training provided to patients who commence on the Accu-Chek Insight insulin pump system. Roche additionally issued a Field Safety Notice (FSN) on May 30, 2016 (the patient version of the FSN is attached as Annex B) which reinforced the existing advice on correct insertion of the insulin pump cartridge in our Accu-Chek Insight insulin pump system and further emphasized the risks related to incorrect handling. This FSN was provided to all current users of Accu-Chek Insight, relevant HCP’s and is included with all new pumps dispatched. From October 2016, the reinforced information set out in the FSN will be incorporated in the Accu-Chek Insight insulin pump product manual

provided with all new pumps.

### The education of diabetic patients

Your report states: “The evidence showed that the education of diabetic patients does not adequately focus upon the potential consequences of failing to properly manage a hyperglycaemic state and in particular, how quickly such a state can become life threatening”.

As explained above, Roche strongly believes that education on diabetes, its symptoms and proper management should be directed by treating health professionals in the context of the needs and wishes of the individual patient. Knowledge of such matters are necessary for any patient with insulin dependent diabetes, irrespective of whether they are treated using an insulin pump or through injections.

However Roche provides educational material to patients regarding these issues, as set out in Annex A, to supplement the information provided by the patient’s health professionals.

In respect of your second matter of concern, we specifically dedicate a portion of our pump starter guide to addressing hyperglycaemia – its causes, symptoms, risks prevention and treatment. This information is provided to all patients and should be considered by them, prior to commencing use of the Accu-Chek Insight insulin pump system.

In addition, where asked to do so by the local NHS, Roche provides training, together with an NHS diabetes nurse specialist, to patients commenced on its insulin pumps. These training sessions address use of the insulin pump, including the appropriate response to hyperglycemia. In all cases where a Roche representative is invited by the patient’s healthcare professional to participate in the training of a new pump user, the educational material provided by Roche would be specifically discussed as part of a patient’s introduction to the device and its use.

As part of our Field Safety Notice we initiated updates to the pump training sessions with immediate effect. This focused on the use of the new Training Handling chart (see Annex B) as part of the reinforced instructions for correct insertion of the insulin cartridge.

In summary, Roche provides extensive, detailed information to patients, in relation to the use of our insulin pumps, through a range of documents and educational methods, including user manuals, training materials, face-to-face training sessions, integrated device warnings and a round the clock technical support telephone service. In addition, as part of our on-going continuous post market surveillance program, we also issue Field Safety Notices when information needs to be communicated or emphasized to our customers.

### Action taken

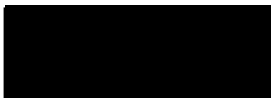
We therefore believe that the information and training provided by Roche is detailed and comprehensive and advises patients on use of the insulin pump and warns of the risks associated with misuse, including the proper response to hyperglycaemia, to the extent appropriate from the pump manufacturer.

In the context of reports of incorrect insertion of the insulin cartridge into Accu-Chek Insight insulin pumps including the case of Mr Hedge, Roche issued a FSN, which aimed to reinforce existing information on appropriate insertion. These reinforced instructions will be inserted in the user's manual for the product from October 2016.

Finally, Roche keeps its product information and training methods under constant review and we would welcome the opportunity to work more closely with the NHS to improve and reinforce our combined efforts to educate patients and health care professionals in the safe and effective use of insulin pumps.

We hope that this letter answers your matters of concern. Please feel free to contact us should you require further information.

Yours faithfully,

A large black rectangular redaction box covering the signature area.A black rectangular redaction box covering the name of the General Manager.

General Manager  
Roche Diabetes Care Limited

cc: Dr. Ian Hudson – Chief Executive, MHRA  
Dr. Andrew Goodall - Chief Executive, NHS Wales  
Mr. Simon Stevens – Chief Executive, NHS England

Enc.