General
Pharmaceutical
Council

Donald Coverdale
HM Senior Coroner, York
Sentinel House
Peasholme Green
York
Y01 7PP

19 March, 2013

Dear Mr Coverdale

**Re: Judith Marshall deceased**

It is with deep regret that I read about the circumstances surrounding Ms Marshall's death in your letter dated 26 January 2014. This is clearly a very sad case and our sympathy goes out to Ms Marshall's family and friends.

We have considered the issues arising from the inquest into Ms Marshall's death and the role of the pharmacist in this situation. We are already aware of the circumstances surrounding this case, as the pharmacist was referred to the previous regulator, the Royal Pharmaceutical Society of Great Britain in October 2009. When the regulation of pharmacy was transferred the GPhC in September 2010, this case was transferred also. The GPhC has waited for the outcome of the inquest before considering the case further.

Our regulation of registered pharmacies (through the standards and inspection process outlined below) is complemented by our work to regulate individual members of the pharmacy profession. Under this heading we set the mandatory regulatory standards which professionals are accountable for upholding. These include an overarching professional obligation to make the care, well-being and safety of patients their first concern, and a specific requirement that pharmacists 'make sure the services [they] provide are safe and of acceptable quality'.

In order to qualify as a pharmacist in Great Britain in the first place it is necessary to succeed in a four year Master of Pharmacy degree programme, followed by satisfactory completion of a pre-registration placement, at the end of which a GPhC registration examination must be passed. We set the standards which university pharmacy schools must meet and we carry out inspections of courses to check that these standards are being maintained. These include a requirement that students successfully completing the course have the knowledge and skill to supply medicines safely and efficiently, consistently within legal requirements and best professional practice.

In your report to prevent future deaths you set out a number of matters of concern, and it is important that wherever possible, we ensure that learning takes place to prevent any future similar deaths. I have sought to address the areas of concern below:

1. We set standards for registered pharmacies which focus on the outcomes we expect to see in registered pharmacies. We inspect registered pharmacies against the standards and produce reports of our findings.

   As part of the inspection, our inspectors look at records maintained in the pharmacy, including error records. Our inspection outcomes reflect on the recording, learning and risk management in place instead of the numbers of errors. However as part of our work we will review whether our approach to inspection on this matter should include further interrogation of errors recorded.

2. The GPhC has published guidance which contains information about minimising the risk of dispensing errors (http://www.pharmacyregulation.org/sites/default/files/Responding%20to%20complaints%20and%20concerns%20g.pdf )
   The guidance explains that two people should be involved in the dispensing process where this is possible. Whilst I understand that in this case, two people were involved in the dispensing process, we can highlight our guidance in the next edition of our newsletter through Regula+e.

3. There is research that shows the use of automation within a dispensing process can reduce the rate of errors. Whilst we cannot require registered pharmacies to use automation, we do ensure that the way in which we regulate does not stifle the introduction of new technology.

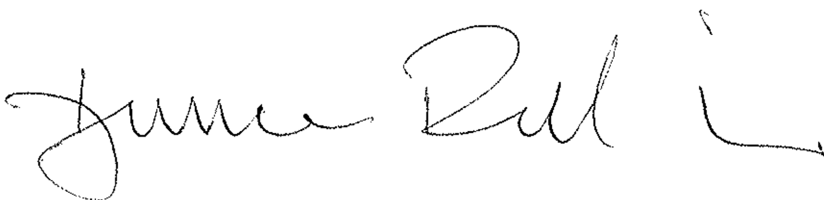
4. We are considering publishing a high level summary of the case you have described to us (fully anonymised of course) in one of the next editions of our newsletter 'Regulate', which goes to all registered pharmacists and pharmacy technicians 6 times per year. Regulate contains a section entitled 'learning points' where we use case studies to highlight important safety and standards points.

5. There are a number of organisations that provide guidance and advice to pharmacy professionals, and the professional body for pharmacists, the Royal Pharmaceutical Society (RPS) are well placed to provide guidance to pharmacists on this area.

6. The medicines regulator, the MHRA, has been working with NHS England to develop draft Patient Safety Alerts and guidance to increase adverse incident reporting via the National Reporting and Learning System (NRLS), which is a central database of patient safety incident reports. We continue to work with the MHRA and NHS England to ensuring that pharmacists and pharmacy technicians use the NRLS.

Let me conclude by thanking you for raising your concerns with us. It is in all our and, most importantly, the public's interest that regulators and professional bodies try to find ways to maximise the learning that needs to be facilitated on the back of distressing events such as these.

Yours sincerely



Duncan Rudkin
Chief Executive & Registrar