Department of Health

From the Rt Hon Jeremy Hunt MP
Secretary of State for Health

Richmond House
79 Whitehall
London
SW1A 2NS

Tel: 020 7210 3000
Mb-sofs@dh.gsi.gov.uk

POC1_838751

Mr W Coverdale
Senior Coroner
Sentinel House
Peasholme Green
York
YO1 7PP

31 MAR 2014

Dear Mr. Coverdale,

Thank you for your letter following the inquest into the death of Mrs Judith Marshall. You conclude that Mrs Marshall died from bronchopneumonia and the effects of morphine. I was very sorry to read about the circumstances that led to the death of Mrs Marshall and wish to extend my sincere sympathies to her family.

I understand that on 28 September 2009 Mrs Marshall was correctly prescribed sixty 10mg of morphine sulphate capsules by her GP. Unfortunately when the prescription was dispensed by a pharmacist at a local pharmacy, she was given sixty capsules at 60mg strength rather than the 10mg strength prescribed. Although the box of capsules carried numerous clear references to its containing 60mg capsules, a trainee dispensing technician checked the medication dispensed by the pharmacist and confirmed it.

Mrs Marshall took the capsules twice a day as prescribed which meant she took 120mg of morphine per day rather than 20mg. She was found dead in her bed by her husband on the morning of 30 September 2009.

You ask me to consider the following concerns:

- The Pharmacy's Errors Book shows a number of drug errors (including higher or lower dose tablets and the wrong drugs) over a number of years. It is not clear whether and to what extent such internal records are policed.
- Despite a system of checking by a colleague it is apparent that there can be a mistake in dispensing medication which in this case was a controlled opiate drug. The consequences were fatal.
- It is not clear whether there is any software, obtainable from the Department of Health or else-where, that could read prescriptions and raise an alert if the

label sought to be created or if the drug sought to be dispensed is wrong in identity or amount. This would be of particular significance when a high risk drug is dispensed or when a drug is dispensed in an unusual quantity, dosage or form.

- Mandatory procedures requiring a 'read-back' of the drug, its dosage, its frequency of administration and its total quantity may prevent such dispensing errors. In so far as the error in this case can be attributable to 'Human Error' it is concluded that the dispensing pharmacist focused on the figure of 60 and incorrectly attributed that to the dosage as well as to the number of capsules.
- A mandatory check, by a suitably qualified pharmacist or by a third party, at the end of the day after cashing up on the till, of records of each (prescription only) drug dispensed against the prescription would be a further precaution against a repetition of these circumstances.
- There is evidently no central database of all prescription errors so there can be no central monitoring of such errors and no means of determining trends or particular repeat errors.

It may help if I briefly explain my Department's role as steward of the health system in England and the part played by other relevant organisations.

As Secretary of State for Health, I am responsible for setting national priorities, monitoring the whole system's performance and supporting the integrity of the system to protect the best interests of patients, the public and the taxpayer. Since 1 April 2013, most day to day decisions are taken by NHS England. NHS England is responsible for commissioning primary care services, including pharmaceutical services.

The Medicines, Healthcare and Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and pharmacy premises, while the Royal Pharmaceutical Society (RPS) is the professional body for pharmacists and pharmacy in Great Britain, representing all sectors of pharmacy.

I note that you sent your report to NHS England and that [redacted] Director of Patient Safety at NHS England has already replied with a detailed response which addresses each of your concerns. He has included an explanation of the current system of reporting of, and issuing alerts resulting from, pharmacy errors. He has also outlined NHS England's plans to increase reporting and learning from community pharmacy.

My officials have consulted the General Pharmaceutical Council about this case. The Council has a key role in setting standards for, and the regulation of, pharmacies and pharmacists. It also sets standards for the education and training of pharmacists and ensures, through inspections, that educational standards are being maintained at pharmacy schools. The Council is aware of the need for regulators and professional bodies to find ways to maximise learning from events such as this one and I understand there are plans to ensure that the lessons learned from this specific case are passed on to all registered pharmacy staff.

I understand that the Royal Pharmaceutical Society has also written to you with its observations on the concerns you have raised.

I can also advise that the MHRA has contacted the marketing authorisation holder for morphine sulphate MR capsules who has agreed to make improvements to the packaging for all capsule strengths. This new packaging will be phased into use shortly and should reduce the likelihood of similar medication errors occurring in the future.

The MHRA will also send a reminder to pharmacists about the risks of confusing quantity with strength when dispensing morphine sulphate MR capsules. This alert will appear in the April edition of MHRA's monthly publication, *Drug Safety Update*. Information on the updated packaging will also be included.

As part of new European pharmacovigilance legislation that came into effect in July 2012, the definition of an 'adverse drug reaction' was expanded to include noxious and unintended effects resulting not only from the authorised use of a medicine but also from use outside the terms of authorised use. This encompasses suspected adverse drug reactions from overdose, medication errors, off-label use, misuse and abuse of a medicinal product. Further details can be found in the "Guideline on good pharmacovigilance practices (GVP) Annex I – Definitions" which is available at:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/06/WC500129131.pdf

The MHRA continues to operate the UK's Yellow Card Scheme for reporting suspected adverse drug reactions. This scheme collects reports for all types of medicines across the UK and includes adverse reactions occurring as a result of a medication error.

The MHRA is now working with NHS England to simplify and increase reporting of medication errors and maximise learning from these reports to minimise harm in clinical practice arising from medication errors.

An integrated reporting route has been introduced so that reports submitted to the National Reporting and Learning System will be shared between NHS England and the MHRA. A National Medication Safety Network is being established which will act as a forum to discuss safety issues, identify trends and actions to improve the safe use of medicines. This network will also work with NHS England's new Patient Safety Improvement Collaboratives that will be set up during 2014. Within hospital trusts and primary care 'Medication Safety Officers' (MSOs) will be appointed to be part of the National Medication Safety Network. MSOs will act as points of contact for NHS England and the MHRA for reporting incidents and to allow better communication and improved learning at a local and national level.

I hope that this response is helpful and I am grateful to you for bringing the circumstances of Mrs Marshall's death to my attention.

Yours sincerely

Jeremy Hunt

JEREMY HUNT