

Recall of Medicines

Background

The Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The MHRA's Defective Medicines Report Centre (DMRC) issues alerts to healthcare professionals, hospitals, GP surgeries and wholesalers to tell them when a medicine is being recalled or when there are concerns about the quality that will affect its safety or effectiveness. Alerts are graded according to the seriousness of the threat to the public's health. There are four grades; Class 1-4. This report refers to Class 2 - a recall within 48 hours, because the defect could harm the patients but is not life threatening.

NHS England's Arden Herefordshire and Worcestershire Area Team is responsible for having a Central Alerting System (CAS) to cascade alerts to its primary care contractors for action, where appropriate, and to monitor the implementation of alerts by contractors. The Area Team is recommended, as good practice, to consider compliance with alerts as part of regular assurance and contract review processes to support delivery of safe services.

Report to Healthwatch Worcestershire

In January 2014 a patient who had severe allergies and carried two Jext adrenaline pens in case of an anaphylactic life threatening reaction contacted HWW to report their concern about how their GP surgery had dealt with the MHRA Class 2 Medicines Recall of the Jext Adrenaline Pen (Appendix 1). The patient was concerned for their safety and felt they had been put at risk. This Alert was sent to GPs on 9th December 2013 and in this case the patient did not receive notification until 16th January 2014. The length of time it took for the GP surgery to send the notification prompted the patient to question how the Alert was reported to the surgery and why the surgery took so long to carry out the recall. In this case the email sent to GPs by the Area Team CAS on 9th December was titled CAS alert EL 13 A 28 - FAO GPs, pharmacists and dentists - for INFORMATION ONLY - NO RESPONSE REQUIRED. On the 10th December South Worcestershire Clinical Commissioning Group (CCG) sent an email to GPs asking them to take action.

What we did

Due to the seriousness of the potential consequences to patients and the ambiguous nature of the Area Teams CAS alert HWW wrote to every GP surgery in the county to ask what actions they took to put the recall into effect and the date and means used to inform patients of the recall (Appendix 2). Out of the 68 practices we have received responses from 54. The 14 practices who failed to respond to the initial letter and a follow up letter can be seen in Appendix 3. The 54 responses demonstrate inconsistency with how the CAS Alerts are actioned. Whilst some practices contacted patients immediately by telephone other took a number of weeks to send out letters. One practice did not contact their patients until they had received our letter requesting information. A number of practices raised concerns with how MHRA Recalls are communicated to GPs with one practice highlighting the ambiguous nature of the recall in question suggesting a more obvious title of 'ACTION NOW' be used and a flagging mechanism to ensure that Alerts are dealt with be put in place.

The issue around the CAS Alert prompted us to ask NHS England about their role in the Recall of Medicines and what Quality Assurance procedures are in place to ensure safe and effective recall and it was also raised the Area Teams Quality Surveillance Group. We have logged the issue on the Healthwatch England Hub as a central place for other Local Healthwatches to access the information.

Recommendations

- NHS England Area Team to amend current practice of alerting GPs, Pharmacists and Dentists, using a consistent approach with clear instructions and put in place adequate Quality Assurance processes to ensure safe and effective recall of medicines
- GPs to have procedures in place to safely and effectively manage the recall of medicines to prevent patients being put at risk
- Escalate to Healthwatch England as a potential national issue

The Local Area Team have told us they intend to amend their procedures and we will continue to monitor these changes to practice to ensure they work.

Practices failed to respond to information request

South Worcestershire CCG

Ombersley Medical Centre, Droitwich

Barbourne Health Centre, Worcester

Severn Valley Medical Practice, Worcester

St Johns House, Worcester

St Peters, Worcester *

Grey Gable Surgery, Worcester

Lick End Surgery, Malvern

Wyre Forest CCG

Hagley Surgery, Hagley

York House Medical Centre, Stourport

Redditch and Bromsgrove CCG

Catshill Village Surgery, Bromsgrove

Elgar House Surgery, Redditch

Hillview Medical Centre, Redditch

St Stephens, Redditch

Woodrow Medical Centre, Redditch

N.B. Since the publication of this report we have become aware that St Peters Surgery is part of St Martins Gate Surgery for which we had a response. We have since confirmed with the practice that the response submitted for St Martins Gate covered their activity for patients attending St Peters Surgery.