Pharmaceutical company fined for manufacturing defective medicine

Today, Syri Ltd, a pharmaceutical manufacturer based in Ruislip, Hillingdon, London has been fined £51,000 and ordered to pay costs of £104,898 by Aylesbury Crown Court. Following an investigation by the Medicines and Healthcare products Regularly Agency (MHRA) and a prosecution brought by the Crown Prosecution Service (CPS), the company was convicted of supplying a medicinal product which was not of the nature or quality specified in a prescription. The investigation was prompted by a child suffering multiple seizures and their admission to hospital.

The child was prescribed magnesium glycerophosphate to help prevent seizures. However, the medicine made by the company contained just 12% of the strength specified in the prescription, which resulted in it failing to work effectively.

The Medicines and Healthcare products Regulatory Agency (MHRA) was alerted to the issue following a report from Milton Keynes University Hospital. MHRA inspectors visited the site and found the methods used to manufacture the medicine and the checks in place to ensure appropriate standards were not met at the time the medicine was supplied. This resulted in the medicine being manufactured with insufficient levels of the active ingredient, making it ineffective and causing the child to become seriously ill.

The medicine was made to a specific prescription (known as a special) for the child. The company has improved their quality assurance procedures to prevent a recurrence.

Dr Alison Cave, MHRA Chief Safety Officer, said:

“Pharmaceutical companies such as Syri Ltd have a legal obligation to ensure they produce and supply medicines that work and are manufactured to the required standards. The patient has recovered, but the consequences could have been much more serious if it hadn’t been for the swift action of hospital staff.

“Patient safety is our top priority. The Agency will not hesitate to take robust enforcement action when serious failings that put patients at risk are identified.”

Laura Walters, Special Crown Prosecutor of the Crown Prosecution Service said:

“Syri Limited, as with all pharmaceutical providers, have a vital responsibility to produce medicines accurately and safely, in the form specified in a prescription. Fortunately, the mistake they made was not fatal in this case. This was not an isolated mistake although our prosecution was only concerned with this one serious incident.

“These types of prosecutions are thankfully rare, but this conviction and sentence should serve as a reminder for all pharmaceutical companies of the need for absolute care in providing essential medications to the public.”

Anyone who suspects that they, or a member of their family, may have experienced a side effect from a medicine can report it to the MHRA’s Yellow Card scheme, which collects and monitors information on suspected safety concerns involving healthcare products.

Notes to Editor

- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
- The MHRA is an executive agency of the Department of Health and Social Care.