WRITTEN QUESTION TO THE MINISTER FOR HEALTH AND SOCIAL SERVICES BY DEPUTY C.S. ALVES OF ST. HELIER ANSWER TO BE TABLED ON TUESDAY 12th NOVEMBER 2019

Question

How are instances where patients suffer adverse side effects from medication recorded and investigated in Jersey?

Answer

All medicines can cause side effects (commonly referred to as adverse drug reactions or ADRs by healthcare professionals). ADRs can be reported by healthcare professionals and the public using the Yellow Card Scheme which is coordinated by the UK medicines regulator – the Medicines and Healthcare Products Regulatory Agency (MHRA).

https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/

Jersey does not operate its own separate scheme but feeds into the MHRA Yellow Card Scheme, with all healthcare professionals encouraged to report any suspected ADRs via the online reporting system.

The Yellow Card Scheme is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. Reports can be made for all medicines including vaccines, blood factors and immunoglobulins, herbal medicines and homeopathic remedies, and all medical devices available on the UK market. From 20 May 2016, the MHRA also started collecting reports of safety concerns associated with e-cigarette products through the Yellow Card Scheme.

The Scheme collects information on suspected problems or incidents involving:

- 1. side effects (also known as adverse drug reactions or ADRs)
- 2. medical device adverse incidents
- 3. defective medicines (those that are not of an acceptable quality)
- 4. counterfeit or fake medicines or medical devices
- 5. safety concerns for e-cigarettes or their refill containers (e-liquids).

It is important for people to report problems experienced with medicines or medical devices as these are used to identify issues which might not have been previously known about. The MHRA will review the product if necessary and take action to minimise risk and maximise benefit to patients. The MHRA is also able to investigate counterfeit or fake medicines or devices and, if necessary, take action to protect public health.

Side effects reported on Yellow Card are evaluated, together with additional sources of information such as clinical trial data, medical literature or data from international medicines regulators, to identify previously unknown safety issues. These reports are assessed by a team of medicine safety experts made up of doctors, pharmacists and scientists who study the benefits and risks of medicines. If a new side effect is identified, the safety profile of the medicine in question is carefully looked at, as well as the side effects of other medicines used to treat the same condition. The MHRA takes action, whenever necessary, to ensure that medicines are used in a way that minimises risk, while maximising patient benefit.