

MAKING SENSE OF THE MHRA

By Nesta Thomas takes a look at the Medicines and Healthcare products Regulatory Agency and explains what it is really all about

Nesta Thomas works as a locum pharmacist in London

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The Medicines and Healthcare products Regulatory Agency (MHRA) is a government agency that ensures that all UK medicines, medical devices, blood products and tissue-engineered products are of an acceptable standard in terms of safety, quality, performance and effectiveness. This article will concentrate on the regulation of medicines and medical devices and the role of the yellow card scheme since these are of most relevance to the majority of pharmacists. An article of this length cannot do the entire functions of the MHRA justice so further information on all the activities of the MHRA can be found by visiting www.mhra.gov.uk.

Medicines regulation

All prescription and over-the-counter medicines in the UK are subject to a comprehensive investigation by the MHRA before they become licensed medicines. Food supplements and products that claim to help "support" a healthy lifestyle are not normally considered medicinal.

There are certain conditions that allow medicines to be exempt from licensing, ie, if a product needs to be made up (referred to as a "special") or imported to meet the particular clinical needs of a patient. Currently, some herbal and homoeopathic medicines are licensed, but they do not have to be. A procedure is now in place to regulate these types of products and should be in force by 2011.

A marketing authorisation (previously called a product licence) is granted to each medicine once its quality, safety and efficacy has been assessed. Before issuing a market authorisation the

MHRA evaluates the balance between the harmful effects and the beneficial effects. This is a complex process and the active ingredient, dosage form, dose, nature of disease, duration of treatment and type of patient (eg, age, gender) need to be taken into account. Safety monitoring and inspection is continuously performed by the MHRA throughout the lifetime of the medicine. This ensures that patient information leaflets, product labels, prescribing advice and advertising remain up to date and accurate.

The MHRA also controls the reclassification of medicines from prescription only medicine (POM) to pharmacy (P) status. After a medicine has had several years as a POM, pharmaceutical companies may apply to get it reclassified to P status. This will be carried out if the adverse effects are few and minor and it is shown that the medicine can be used safely without a doctor's supervision. Recent reclassifications include sumatriptan tablets, which may be supplied by a pharmacist for acute relief of migraine attacks in patients with a stable, well-established pattern of symptoms. Also amorolfine nail lacquer is now available without prescription for the treatment of mild fungal infections of the nails. P to general sale list (GSL) reclassifications can occur once the MHRA is satisfied that a medicine can be sold with reasonable safety without the supervision of the pharmacist.

Medical devices

Dressings, examination gloves, condoms, urine test strips, needles and syringes are all examples of medical devices that are regulated by the MHRA. Effectively, all products used in

health care for the diagnosis, monitoring, prevention and treatment of illnesses are considered medical devices. As with medicines, the MHRA has to ensure that medical devices are of an appropriate standard of safety, quality and performance, and that they comply with the provisions of the European medical devices directives. Manufacturers must ensure that their devices are safe and fit for intended purpose before they can be marked with a "CE" (ensures the product meets relevant legislation and fit for intended purpose) and placed on the market. Manufacturers are legally bound to report all serious or potentially serious adverse events.

The MHRA is able to provide help and advice to pharmacists on the use of medical devices. Reciprocally, pharmacists can help the MHRA by encouraging patients to report any problems encountered with their devices.

Yellow card scheme

Since pharmacists are the experts in medicines they have a substantial part to play in recording adverse drug reactions (ADRs). In a study conducted in 2004 by the *British Medical Journal*, 6.5 per cent of hospital admissions were judged to be related to an ADR. The estimated cost of such admissions was £466 million.

Pharmacists need to use the knowledge they have to help reduce this cost. We must hope that the recently implemented medicines use reviews taking place in community pharmacy will identify unnecessary medicines and potential interactions but data on the actual success of these reviews is not



available yet. Hospital pharmacists are in a much better position to anticipate and detect ADRs since they have access to patients' clinical information and often take part in prescribing decisions.

Spontaneous ADRs are reported via the yellow card scheme. The scheme is also used to report adverse reactions to any therapeutic agent including vaccines, blood products, radiographic contrast material and herbal products. This scheme is run jointly by the MHRA and the Commission on Human Medicines.

Yellow cards can be found in the back of the British National Formulary and the "Over-the-counter directory". Reports can also be made online at www.yellowcard.gov.uk. This reporting scheme has been in place for nearly 40 years. Hospital pharmacists have been able to report since 1997 and community pharmacists were invited to report two years later, in 1999. More recently the scheme has been extended to include direct reports from patients.

The continuous monitoring of drugs, even after they have been on the market for years, is necessary. Before a

medicine gains a marketing authorisation the experience of its side effect profile is limited to its use in clinical trials, ie, a relatively small number of people have taken it for a short time. The yellow card scheme helps monitor the use of medicines in everyday practice to provide a better assessment of the risk to benefit ratio. The data may be used to amend prescribing information and, in some situations, could even lead to the withdrawal of a drug.

So what needs to be reported? First of all, when reporting, one does not have to be 100 per cent sure that a drug is causing a particular side effect. The yellow card scheme gathers data on suspected side effects. All suspected adverse reactions (no matter how trivial) for any newly licensed medicines, identified with a black triangle symbol in the BNF, should be reported. In the case of established medicines, all serious adverse reactions need to be reported. Examples of "serious" adverse reactions, as listed in the BNF, are anaphylaxis, blood disorders, endocrine disturbances, effects on fertility, haemorrhage from

any site, renal impairment, jaundice, ophthalmic disorders, severe central nervous system effects, severe skin reactions, reactions in pregnant women and any drug interactions. Remember, some reactions can manifest themselves months or even years after exposure. Data on ADRs in children and for herbal products are limited and the MHRA welcomes reports on any adverse reactions in these groups, no matter how trivial. Currently, warning labels are being added to black cohosh, a herbal medicine commonly used to treat menopausal symptoms, as a result of yellow card reports which have shown a causal, but rare, relationship between the use of black cohosh and the risk of liver disorders.

In the future, be confident when reporting an ADR. Statistics show that ADRs are grossly under-reported. Never assume that someone else will report. Err on the side of caution and fill out a yellow card if you are not sure if the reaction is considered serious enough — all data are important data for the MHRA. ■