JUST WHAT IS AN ADVERSE INCIDENT WHERE WHEELED MOBILITY IS CONCERNED?

The MHRA (Devices) aims to prevent adverse incidents happening and, where they have already happened, to prevent them happening again. No device should ever be considered 100% safe and constant effort is therefore required to reduce both the rate at which adverse incidents occur and the severity of the outcome. Reporting incidents to the Agency provides information that may be directly responsible for preventing similar incidents from happening again.

During 2002 MHRA (Devices) received over 8,700 adverse incident reports covering all types of medical devices. Although approx 1,400 of these were reports concerned with the safety or quality of wheelchairs, cushions and seating systems there still appears to be confusion about what should actually be reported. In discussions at various meetings it appears that many of you may not be reporting the risk of or the potential for injury to users, carers or healthcare staff even though many cases of 'near misses' or the potential for reduced safety levels in the future may arise during your work.

In addition to actual harm the **potential** for harm to a user, carer or healthcare staff or others should be reported even though actual harm has not occurred or has been averted by good fortune or the timely intervention of carers or healthcare staff. This **potential** may arise due to:

- shortcomings in the design or manufacture of the device itself;
- inadequate instructions for use;
- inadequate servicing and maintenance;
- locally initiated modifications or adjustments;
- inappropriate user practices (which may in turn result from inadequate training);
- inappropriate management procedures;
- the environment in which a device is used or stored;
- selection of the incorrect device for the purpose

Conditions of use may also give rise to potential:

- environmental conditions (e.g. rain, sun, wind etc);
- location (e.g. devices designed for use indoors may not be suitable for use outdoors or at day centres etc).

The information from adverse incident reports received by MHRA (Devices) helps to build up a picture of what is happening with medical devices across the UK. This is supplemented by reports from around the world. All this information is reviewed to identify trends and, where appropriate, early action is taken on specific problems.

The variety and use of wheelchairs, cushions and seating systems is continuing to increase and is not expected to decrease in the near future as the elderly population increases and improvements in healthcare continues to occur. With this background it is surprising to see that during the first 9 months of 2003 there was a reduction in the number of adverse incident reports received by MHRA (Devices).

Is it that wheelchairs and related equipment is becoming safer as the reducing number of adverse incident reports suggests or is it that the **potential** element is not being reported?

If you wish to report it can be done on line via the MHRA web page at www.mhra.gov.uk or by submitting the details in writing. Guidance on the options available for reporters is given on the web page and within MDA 2003/001.

MHRA (Devices) also issue guidance on the reporting of adverse incidents within the first Medical Device Alert in each year. This year it was MDA/2003/001 and it is available for download from the MHRA web site at www.mhra.gov.uk if you have not already received a copy.