

THE RECLASSIFICATION STRATEGY GROUP (RSG)

The establishment of the Reclassification Strategy Group (RSG) was first announced at the launch of the new reclassification procedure on 1 May 2002.

The Group was set up to see how appropriate advantage could be taken of the changes made to the law, which were introduced in April 2002 to streamline the reclassification process, in order to increase the number of medicines available over the counter (OTC).

The original group included representatives from the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health, the Royal Pharmaceutical Society of Great Britain (RPSGB), the Proprietary Association of Great Britain (PAGB) and the Association of the British Pharmaceutical Industry (ABPI).

The inaugural meeting of the Reclassification Strategy Group on 27 May 2002 set the agenda for switching. Since this meeting, the PAGB have published a business focussed guideline on switching and patient information. The RPSGB developed a list of potential switch candidates to stimulate debate about when, and in what circumstances, it is appropriate for people to be able to access new medicines in the pharmacy.

There have also been changes to the law – the MHRA introduced new regulations to lift the restrictions on advertising over the counter medicines to the public for certain disease area, which came into force on 30 June 2004. The restrictions on advertising for the remaining six indications are due to be lifted in November 2005. Furthermore a provision from the ‘2001 Review’ of European medicines legislation, to give one year’s data exclusivity for significant test or trial results used for reclassification, came into force in the UK on 1 January 2005.

Since 2002 36 products have been switched. This includes omeprazole 10mg and simvastatin 10mg, demonstrating that the aim to change the switching culture from acute, short term, self limiting conditions to new areas of chronic or recurrent disease management has delivered. Most recently, chloramphenicol eye drops have been switched to pharmacy availability. This is an important addition to the pharmacist’s therapeutic armoury and will allow patients to access treatment straight away without having to spend time visiting their doctor.

As the programme of work for the future has developed the membership of the group has grown. The National Pharmaceutical Association (NPA), the British Medical Association (BMA) and the Royal College of General Practitioners (RCGPs) are now represented in the group, and in the future representation of patient interests will be encouraged.