

Where regulation falls down

Making Britain the safest place to take medicines is a laudable aim espoused by the President of the Royal Pharmaceutical Society. It is a principle worth aspiring to, but there are many difficulties in defining what it might mean in practice. One aspect of this is analysed in the current issue of the *BMJ*, as we report this week (p353).

“Over the counter medicines: proceed with caution” examines the impact of increasing

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people’s access to OTC medicines and concludes that the risks may outweigh the benefits. And these risks are in situations where medicines availability is already heavily regulated.

Over the past few years, the Government has been encouraging pharmaceutical companies to apply for a range of prescription medicines to be reclassified as pharmacy medicines on the grounds that it will reduce the burden on GPs and be easier for patients to obtain symptomatic relief of a range of ailments. Coupled with this has been the development of minor ailment schemes and the development of patient group directions to give

specific patient groups easier access to certain POMs. Techniques to minimise the hazards of taking medicines include restricting the strengths of formulations available OTC, although the downside of this is that drugs like omeprazole or simvastatin may be less effective in OTC doses than in doses prescribed by a GP.

The authors also explore the increasing availability of unregulated medicines through the internet. Although the Royal Pharmaceutical Society is now able to point patients to reliable registered internet pharmacies which carry its logo, there will be many people who want to obtain medicines quickly and anonymously and who are willing to take the risk of being sent an inappropriate or worthless counterfeit medicine from abroad.

In addition, the authors point out that although pharmacists can give clinical advice to a customer buying an OTC medicine, there will be times when that advice is rudimentary — particularly if the pharmacy is busy. At the same time, they acknowledge that ensuring a medicine is only obtainable with a prescription is no guarantee that it will be used safely.

There can never be a completely safe place to take a medicine: regulators and health professionals can work hard to minimise the hazards to patients who are prescribed medicines within a health service. But it is up to the individual to decide what risks he or she is prepared to take either by not taking a medicine, by taking more of a particular medicine than recommended or by buying one from an unauthorised source. Educating patients and customers about these risks is essential but no regulatory system can control human behaviour.

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