

Designer drugs



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Have you ever heard of 'Specials' - officially defined as 'unlicensed formulas that are manufactured to the UK Government's required standards, by a manufacturer holding a Specials Licence, for the special needs of an individual patient'?

If that long-winded explanation sounds rather complicated, simply think of 'Specials' as a kind of made-to-measure service for the pharmaceutical industry - a provision made by the UK Medicines Act which allows the production of a formula that's required for a particular patient, when there is no specific licensed product available. For example, it may be that the drug you require has been discontinued in which case the Act allows the drug to be made as a 'Special'. You may want a cardiovascular drug at an unusual strength, a cancer drug in a different presentation (as an injection rather than an oral medication, for instance), a renal drug that's animal free to comply with Halal and other dietary requirements, or a paediatric drug that's colour free if the patient is sensitive or allergic to additives.

Recent indicators show that although 'Specials' have been popular in the UK for some time, there's an increased use of 'Specials' in the Middle East.

These products really are of the highest quality - thanks to obligatory compliance with the Good

Manufacturing Practice (GMP) and the UK Government 1971 medicines regulations (Standard Provisions for Licenses and Certificates). This means the manufacture or assembly is approved by the UK Medicines and Healthcare products Regulatory Agency (MHRA) and carried out under the strict supervision of qualified staff, including named quality controllers and production managers.

The release of 'Specials' can only be authorised by the quality controller. The GMP medicines inspector is also legally obliged to inspect the assembly sites and take into account labelling, product specifications, expiry date and stability data. If one is requested, 'Specials' manufacturers are usually able to supply a Certificate of Analysis.

A word of warning: when a healthcare professional

orders or uses a 'Special', it is essential to be aware that the medicine is unlicensed which means that the prescriber takes complete responsibility for its use. Saying that, what better way to ensure you're asking for and receiving exactly what your patient needs? And at the end of the day, isn't that what this business is all about?

• In the next issue, Leslie Morgan will be talking about international distribution. ■

Durbin PLC is a British company based in South Harrow, London. Established in 1963, the company specialises in supplying quality assured pharmaceuticals, medical equipment and consumable supplies to healthcare professionals and aid agencies in over 145 countries. As well as reacting rapidly to emergency situations, Durbin PLC responds to healthcare supply needs from local project level to national scale programmes. Email: Lmorgan@durbin.co.uk