'Specials' – a made-to-measure service for doctors and patients

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In my last column I reflected on the importance of pharmacovigilance across the whole of the supply chain. I also explained how it was not until the mid-1990's that European legislators started to tackle the issue of reporting and trending possible problems or reactions that could have been caused by a particular medication. This leads me to the related subject of 'Specials', as it seems likely that these too will be included in any future updates to EU pharmacovigilance legislation. But what exactly is a "Special"?

The Medicines Act in the UK specifies that all products marketed in the UK must hold a Marketing Authorisation/Product Licence. It further recognises however that there are some patients who have special requirements for drugs or formulations that are not economically viable as licensed medicines. The act therefore allows for these to be manufactured by pharmacies as "nostrums" or by licensed manufacturers as "Specials" in response to a bona fide unsolicited order from a physician. Perhaps the easiest way to think of a Special then is as a kind of made-to-measure service for the doctor and patient, which allows the production of a formula for a particular patient where there is no specific licensed product available. It might take the form of a liquid medicine that is normally only available as a tablet; a drug that does not contain any animal ingredients so as to comply with Halal or other dietary requirements; a drug that is colour free for a patient that is sensitive or allergic to additives, or a new formulation to ensure the continued availability of a discontinued product that was licensed.

Some key points to note about Specials are that they may not be advertised, nor may claims be made as to their efficacy or use in any particular disease. Furthermore, as all Specials medicines are unlicensed the prescriber must take complete responsibility for their use. The UK requirement that a Specials formulation be manufactured to required standards and only by a manufacturer holding a Specials Licence, is, I feel, an important one. It ensures that the same standards applied to licensed drugs in terms of Quality Control, GMP (Good Manufacturing Practice), Release and Certificates of Analysis etc. are applied to Specials as well. A patient can therefore receive exactly the product they need in an appropriate formulation. I do believe however, that it is just as important that medicines manufactured under a Specials Licence should also be governed by the same principles of pharmacovigilance as any other drug.

Durbin has had products manufactured in Durbin livery for the international market for many years and became involved in the supply of products as Specials in the UK in the early 1990s. I'm pleased to say that we have always applied the same quality system for pharmacovigilance of Specials as we do to all other medicines. Indeed, we regard it as part of our responsibility to do so. It can surely only be a matter of time before it becomes a global requirement and legislation is enacted in all countries reflecting this requirement so that not only can patients get the medicines they need, but can have peace-of-mind that the standards applied to monitoring the use of these is as robust as possible. MEH

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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 180 countries. As well as reacting rapidly to emergency situations, Durbin PLC responds to healthcare supply needs from local project level to national scale programmes.
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