



Licensed to supply

Two years in, one recession under its belt, and Clinigen is proving it can successfully carve a niche in the increasingly competitive market of supplying unlicensed drugs on an ethical, named-patient basis. *Katrina Megget* talks to the company's Commercial Director

Scott Smith, Commercial Director at Clinigen

Named-patient supply is a trend that appears to be on the increase, says Clinigen's Commercial Director Scott Smith. Pharmaceutical companies are now using named-patient supply for drugs that may be licensed in one country but are in pre-launch and pre-approval phase in another. In other cases, drugs might still be undergoing clinical trials or have been developed to treat a rare disorder. "There are a number of patients where there is no licensed medicine for their condition, and if there is an unlicensed product that meets their clinical needs it can be provided on a named-patient basis," Smith says.

This contrasts with the more traditional named-patient supply of drugs that have been discontinued, either because of product safety or for commercial reasons, but which many patients still find effective and safe to use.

"There is a growing awareness of the importance among both clinicians and pharmaceutical companies to satisfy unmet patient needs on a more structured basis," he comments. "Previously pharmaceutical companies may have only offered treatment on a restrictive ad-hoc basis, but now they are looking at named-patient programmes as a key part of managing the lifecycle of products more effectively. It becomes a core part of the product strategy."

Indeed, Clinigen was set up two years ago on the premise of partnering with the pharmaceutical industry to provide the expert management, flexible infrastructure and compliant distribution systems required for named-patient supply. And the company is seeing significant interest from companies in the 'managed provision' of both pre-launch and discontinued programmes.

Indeed, in August, Clinigen concluded an agreement with US firm Three Rivers Pharmaceuticals to distribute Infergen (interferon alfacon-1) on a named patient basis in the UK and Europe for treating hepatitis C. The antiviral had previously been approved and available in Europe, but was withdrawn by the previous licence holder. However, recent clinical data suggest a new licence could be

forthcoming and, while this is in progress, Clinigen will supply the drug within a structured named-patient programme.

Clinigen's most widely distributed drug, however, is the painkiller co-proxamol, which has 30,000 prescriptions written per month in the UK. At its peak, the drug was responsible for around 7.5 million prescriptions per year but, after safety concerns, the Medicines and Healthcare products Regulatory Agency advised the drug should be withdrawn. At the time, many charities criticised the move saying patients would be left without suitable pain relief.

The ensuing outcry and sheer number of patients who still used the drug led to its availability on an unlicensed named-patient basis and the start of Clinigen's partnership in 2008 with manufacturer Meda. Distributing Meda's co-proxamol – branded as Distalgesic – has been an excellent base from which to build the company, says Smith.

But co-proxamol is not Clinigen's only success story. The company also provides Virazole (ribavirin) in injectable form for hospitalised infants and young children with severe lower respiratory tract infections due to respiratory syncytial virus. The drug is rarely used except in emergencies and because of this, Clinigen has set up a system for hospitals to be able to obtain the drug within hours in urgent situations.

Then there is Nabilone, a synthetic cannabinoid available in both a licensed and unlicensed form. However, even in the licensed form the product is used off-label in 90% of cases as a relief from muscle pain. "Nabilone has highlighted a number of complexities that can also be typical of other products. They place real challenges on the type of communication and distribution to health professionals and Clinigen has managed these successfully as a specialist distributor," says Smith.

These products highlight the different, flexible, but solid service that Clinigen provides – from high prescription rates to low volume supply, from urgent demand to controlled substances. As Smith reiterates, Clinigen provides different supply approaches for products that have



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different requirements. The company also provides additional services such as assisting pharmacies to source products and communication with patient associations, as in the case of co-proxamol.

Clinigen can also provide valuable information about the drug in question, says Smith. For instance, it is providing patient outcome data for Virazole and Nabilone, which is fed back to the pharmaceutical company to help in its future licensing decisions.

"We differentiate ourselves by recognising that each product requires a different approach," Smith points out. "Clinigen tailors a named-patient programme to the needs of the patient and the pharmaceutical company. This is our expertise and companies may not be able to find it elsewhere."

Indeed, the company is moving into a new phase and is already expanding its operations beyond the UK into Europe and the USA in order to supply unlicensed drugs on a global basis. The firm has the regulatory expertise, compliant systems and experienced personnel in place and is expecting to secure further exclusive arrangements with both pharmaceutical and biotechnology companies in the near future. Smith describes it as a win-win situation: "Named-patient supply benefits patients but also enables companies to successfully and efficiently manage a complex situation."

And, as patients become more informed about treatment options, this is an area of the market that is likely to continue growing.

To learn more go to: www.clinigen.co.uk