

Edited by Claire Bowie/Jenny Hone

PharmaTimes Magazine talks to Masters about the success of its recently launched GAP programme and why the company is uniquely poised to optimise its clients' market access capabilities

# Masters: Improving lives through patient access

A key component of the term 'market access' is the management of unlicensed, orphan or discontinued products on a named patient supply basis, a speciality that is at the heart of Masters' ethos.

The Masters Global Access Partnership programme delivers a truly global solution to optimising access to medicines where availability may be restricted, for example if a product is not yet registered or has been withdrawn or discontinued.

So the phrase '*Improving lives through patient access*' is particularly relevant. While all businesses have commercial considerations this is a win-win situation for both patients and suppliers; the Masters structured supply programme guarantees the integrity of supply chains, restricts profiteering by dubious third parties and ensures the product reaches those patients for whom it can make a positive difference.

Since its inception 27 years ago, Masters has established itself as a global player with offices in London, Miami, El Salvador, São Paulo, Singapore, Mumbai and soon Japan – a reach



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that is fundamental in order to be able to manage an international access programme.

Shilpa Gohil, regulatory and compliance manager for Masters, and a board member at the Royal Pharmaceutical Society of Great Britain where she represents both manufacturers and pharmacists, points to the criticality of having experienced staff on the ground who are able to understand the nuances of local regulatory requirements and import laws.

Certainly biopharmaceutical companies are looking for an all-encompassing solution-based programme and a partner that not only gives them peace of mind and security but that can also communicate with local affiliates, explains Roger Schmid, general manager, Masters Asia Pacific. “We have worked with Korean and Japanese companies and it is a huge advantage to be able to liaise across four continents with a staff spanning more than 20 nationalities and 15 languages,” he says.

This is a view echoed by Guisela Fabian, general manager, Central America, who sees Masters as both

## What are ‘Specials’?

**Named Patient Supply, also known as ‘Specials’, describes the provision of unlicensed medicines where a patient has a special need that cannot be fulfilled through traditional prescription. This includes:**

- » Access to a treatment that is awaiting a marketing authorisation
- » A licensed preparation is available, but the dose or form is not suitable for the patient, eg paediatric
- » A previously prescribed product has been discontinued
- » Supply chain problems with a licensed product
- » The medicine is still undergoing clinical trials
- » The product is identified for off-label use to treat a rare condition, often termed an orphan disease.

a local supplier and a global partner; she is based in El Salvador where she distributes controlled drugs for Mundipharma as well as supplying the government with products discontinued by big pharma. Enhancing her local credibility are two sales managers – qualified doctors – who are skilled in talking with both medical professionals and regulators.

In Brazil, Masters operates out of an ANVISA-approved facility under country manager Daniela Carrera who has been instrumental in ensuring recognition across all government bodies. Indeed over the past 10 years the company has supplied a number of blockbuster medicines through pre-launch programmes, including the cancer treatment Avastin (bevacizumab) and more recently Ventavis (iloprost) for pulmonary arterial hypertension.

Of course it is impossible to define a typical GAP programme because by its very nature it needs to be bespoke to the organisation, ranging from a single product for a single country to full management of a company’s portfolio – managing global demand by filling the ‘gap’ between launch dates



L-R, David Moran, CEO, Heather Gamble, business development director and Nuno Mario, customer service manager, Latin America

in different markets. It can also involve the supply of clinical trial comparators, the continuation of investigative therapy post-trial or even management of a discontinued product range and can provide the manufacturer with pre-launch market intelligence, which can increase a product’s commercial potential.

But although each GAP programme is unique in its requirements, every project has a central pharmacovigilance element that is carried out in liaison with the manufacturer and a feedback mechanism to ensure the product is being used appropriately and under the right conditions so any adverse events are reported promptly. In this way Masters is able to manage traceability and counterfeit concerns, while additional services include liaison with key opinion leaders or cold chain management. All offer clients the following benefits:

- Optimised patient access
- Supply chain integrity
- Key pre-marketing data
- (Emerging) market penetration
- Maximised product revenue
- Enhanced corporate reputation

Masters’ central tenet of improving lives through patient access has been given weight recently with the addition of Bill Burns to the team as non-executive chairman. Following his retirement as chief executive of Roche Pharmaceuticals in 2009, Burns has taken non-executive posts at Roche, Shire and Chugai. But why Masters? It is Burns’ desire to work on a project that not only adds value from the big pharma perspective but one that has a simple goal in mind – to improve patient wellbeing.

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