PRESS RELELASE 24 May 2016

Recipharm unveils serialisation pricing model

Contract development and manufacturing organisation (CDMO) Recipharm has unveiled plans to improve the affordability of serialisation, with the introduction of a novel pricing model aimed at keeping investment costs down for clients.

The company has devised a pricing structure that will see the removal of any upfront investment costs for pharmaceutical companies looking to access the CDMO's serialisation capabilities.

Recipharm will offer a standard solution across 14 locations in Europe and more than 70 production lines, with a fixed service fee per pack for all customers. Each serialised product will be compliant with the pending US and EU regulations, with any customisation of the pack offered separately.

The announcement comes as the pharmaceutical industry faces the daunting task of meeting new legal requirements for the serialisation of licensed drug products from November 2017 in the US and early 2019 in Europe.

Companies must adapt their packs, implement their tamper evidence capability and establish the systems, processes and data to comply with the EU Falsified Medicines Directive 'Safety Features' Commission Delegated Regulation 2016/161 and the US Drug Supply Chain Security Act (DSCSA), something that is expected to require significant financial investment.

As part of its commitment to actively help pharmaceutical companies prepare for the regulatory changes, Recipharm recently announced plans to invest €40m over the next three years to ensure state-of-the-art solutions for serialisation processes. As soon as the service is operational, the company will provide serialisation free-of-charge until the legal requirements come into effect to ensure drug developers are prepared ahead of the deadlines.

The CDMO's company-wide serialisation project is being led by Staffan Widengren, Director Corporate Projects at Recipharm. He said: "We have spoken to our clients and conducted extensive research to help us fully understand the main challenges associated with the looming requirement for serialisation. Many companies are behind in their preparations, not fully aware of the scale and complexity of the task ahead and concerned about the required financial investment.

"As a result of this consultation exercise, we have created a pricing model designed to spread the cost of serialisation across each customer's on-going supply agreement as opposed to them needing to make a major upfront investment. From 2023, we will extend this further, ensuring that serialisation is included as standard as part of our product manufacturing costs.

"Having provided serialised products in Asia for a number of years, we understand the scale of the investment involved so are utilising our experience, technologies and capabilities to reduce costs for companies in Europe and the US."

The industry-wide serialisation, aggregation and verification directive is expected to improve traceability of drugs, help in the fight against counterfeit products entering the supply chain and ultimately improve patient safety.

Recipharm serves 250+ customers and expects 85% of its production to require serialisation.

Kjell Johansson, President Manufacturing Services Europe, added: “Those companies who fail to prepare for the new regulations will face major disruption to their product supply. Recipharm aims to simplify the process by offering a standard solution with a fixed price per unit with the option to customise packs to individual requirements. There will also be no volume commitment needed from customers wishing to access our serialisation services.

“We have also considered the financial implications of aggregation and can include this service from 2017 on customer request. The ability to minimise upfront investment will enable compliance with the new regulations, while reducing financial burden.”

Recipharm is preparing a range of educational papers aimed at training staff internally across its global network and supporting customers with the challenges of serialisation, verification and complying with new regulatory requirements.

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About serialisation

Serialisation is a means to trace and track pharmaceuticals from manufacture through to prescription, using bar codes to record information about product origin, shelf life and batch. This will help the fight against counterfeit products entering the supply chain and ultimately improve patient safety.

About Recipharm

Recipharm is a leading CDMO (Contract Development and Manufacturing Organisation) in the pharmaceutical industry employing some 3,500 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material and APIs, and pharmaceutical product development. Recipharm manufactures several hundred different products to customers ranging from Big Pharma to smaller research- and development companies. Recipharm’s turnover is approximately SEK 5.0 billion and the Company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and is headquartered in Jordbro, Sweden. The Recipharm B-share (RECI B) is listed on Nasdaq Stockholm.

For more information on Recipharm and our services, please visit www.recipharm.com