Sharp Packaging Solutions welcomes the EU Falsified Medicines Directive to Advance Pharmaceutical Authentication and Patient Safety

UDG Healthcare's pharma packaging division encouraged by safety directive that will improve pharmaceutical manufacturing

11 February 2016: Sharp Packaging Solutions, part of UDG Healthcare plc (LON: UDG), the leading international provider of healthcare services, is pleased to welcome the Delegated Regulation to complement the Falsified Medicines Directive (Directive 2011/62/EU) (FMD) published this week in the Official Journal of the European Union[1]. The aim of the directive is to reduce the occasions on which falsified medicines enter the legitimate supply chain.

Sales of counterfeit medicines are one of the most dangerous aspects of the worldwide trade in forged products. World Health Organisation (WHO) figures show that counterfeits account for one per cent of drug sales in developed countries and up to seven times that figure in the developing world[2]. The delegated Act on Safety Features will address these issues. Coming into force in Europe as of 9th February 2019, the Act includes safety features; (i) a unique identifier (UI) consisting of a 14 digit global product number, Serial Number, Lot Number, Expiry Date, National Reimbursement Number carried by a 2-D barcode and (ii) an anti-tampering device (ATD) on the packaging of prescription medicines and certain non-prescription medicines for the purposes of authentication and identification. This legislation will be enforced for all prescription medicines, with some exceptions.

Commenting on the announcement, Rick Seibert, Senior Vice President Project Management & Technology Services at Sharp Packaging Solutions, said: *"UDG Healthcare and its Pharmaceutical Packaging Division, Sharp, welcome the new FMD regulations. Sharp is well positioned to support companies in meeting this directive through their serialisation requirements. Our expertise and track record in this area, investment to date, and future access to capital leaves us well placed to accommodate the new legislation.*

"Having already been engaged in the serialisation of individual unit dose pharmaceutical products for over eight years, I am convinced that our service exceeds the standards called for by the directive. It is crucial that patients are protected from falsified medicines and recalled products. Now that the deadline for enforcement has been set, we strongly urge companies to prepare for this and bear in mind the scale and cost of the task ahead."

Sharp Packaging Solutions have serialised over two billion units of pharmaceutical products from their US and EU packaging facilities and currently have over 40 serialisation projects running with customers across several international serialisation legislations including the US, Europe, South Korea and China. Additionally, Sharp is rapidly expanding a roll out programme based on the company's expertise and use of proven software solutions.

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[1] Official Journal of the European Union. Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (1) 9 Feb 2016

[2] World Health Organization. http://www.who.int/mediacentre/factsheets/fs275/en/

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Notes to Editors

About Serialisation

Serialisation is the system to track and trace the passage of prescription drugs through the entire supply chain. Every product should be identified by a global product number, serial number, lot number, expiry date, and national reimbursement number. This will enable the product's lifecycle to be traced from production, through to distribution and finally to dispensation to patients at the pharmacy or hospital. The aims of serialisation are to decrease the impact of counterfeit and diverted product, improve supply chain visibility/management, strengthen pharmacovigilance efforts, and increase patient safety and engagement.

About Sharp Packaging Services

About UDG Healthcare plc

Listed on the London Stock Exchange, UDG Healthcare plc is a leading international provider of services to healthcare manufacturers and pharmacies, with operations in 20 countries including the US, UK, Ireland and Germany.

UDG Healthcare plc operates across three divisions: Ashfield Commercial & Medical Services, Sharp Packaging Services and Supply Chain Services.

Ashfield Commercial & Medical Services is a global leader in the provision of sales, marketing and healthcare communications services to pharmaceutical manufacturers with operations in major developed markets. It focuses on supporting healthcare professionals and patients at all stages of the product life cycle. The division provides sales teams, healthcare communications, telesales, nurse educators, medical information, pharmacovigilance, regulatory and event management services to healthcare companies in 19 countries.

Sharp Packaging Services is a leading international provider of pharmaceutical contract packaging and clinical trials materials services with facilities in the US, UK, the Netherlands and Belgium.

Supply Chain Services includes the United Drug Supply Chain Services and the Aquilant Specialist Healthcare Services businesses. The division provides logistics services to healthcare companies, pharmacies and hospitals in the UK and Ireland. United Drug Supply Chain Services is the largest pharmaceutical wholesaler and pre-wholesaler on the island of Ireland. Aquilant Specialist Healthcare Services is a leading provider of outsourced sales, marketing, distribution and engineering services to the medical and scientific sectors in Ireland and the UK.

For more information please go to: www.udghealthcare.com