Expert View

PRESSURE ON THE SUPPLY CHAIN: TARIFFS, REGULATIONS AND TRANSPARENCY

Jacob Tyson at IMed Consultancy and **Jon Lawrence** at JAGGAER consider the changes in the regulatory landscape for medical device manufacturers; the critical role that suppliers, distributors and importers play in ensuring effective post-market surveillance; and the technologies that companies are adopting to support traceability solutions.

"MANUFACTURERS NEED TO COLLECT, ANALYSE AND ACT ON A MUCH WIDER RANGE OF POST-MARKET DATA, MAINTAINING TRANSPARENCY IN DATA ACQUIRED THROUGHOUT A DEVICE'S LIFECYCLE."

The burden on medical device manufacturers is increasing with new tariffs on key components, such as polymers and steel, taking effect in the US, as well as regulatory frameworks such as the EU Medical Device Regulation (MDR), the *In Vitro* Diagnostics Regulation (IVDR) and the UK's Statutory Instrument, which require more stringent post-market surveillance (PMS). In particular, manufacturers may find themselves stuck between a rock and a hard place as their usual suppliers are subjected to increasing costs, while regulators also increase the requirements surrounding PMS and extend them to ongoing, systematic procedures to monitor the real-world safety and performance of medical devices, as well as the safety and reliability of the supply chains involved in their production.

Now, manufacturers need to collect, analyse and act on a much wider range of post-market data, maintaining transparency in data acquired throughout a device's lifecycle. By monitoring user feedback and adverse event reports, makers of drug delivery devices – such as insulin pumps, transdermal drug patches, metered dose inhalers, implantable infusion pumps and autoinjectors – can make data-driven decisions to improve product design, provide updated training or issue safety communications. These devices interact closely with patients and often operate autonomously, increasing the potential for unnoticed failures or misuse.

These new requirements call for tools and practices to help businesses collect the data from both suppliers and device end users that will enable them to achieve this kind of 20:20 vision. If effectively collected and analysed, these data can become a treasure trove for device design improvements, supporting manufacturers' efforts to identify possible risks early on, improve sustainability and usability, and meet new emerging regulatory standards across the world.

This mindset shift calls for manufacturers to expand their focus on direct product performance and hone in on their supply chains. In the US, as a 10% flat tariff hits medical device manufacturers sourcing components from abroad, a seismic rethink of the supply chain is in order. Devices that include chips may be particularly affected by semiconductor tariffs, as will drug delivery devices and implants that rely on medical-grade polymers – such as polypropylene and polyethylene – and high-grade metals such as titanium and stainless steel, which are mostly imported from China, India and Southeast Asia.

Insulin pumps often include polyurethane, polycarbonate (PC) and silicone for their tubing and reservoirs, for example, while transdermal patches – which administer drugs through the skin, including nicotine and hormones – use polymers such as ethylene vinyl acetate, polyethylene, silicone and acrylates to ensure skin adhesion and controlled drug diffusion. Drug-eluting stents employ polymers such as poly(lactic-co-glycolic) acid, polycaprolactone and polyethylene-co-vinyl acetate to deliver therapeutic agents, such as sirolimus, directly to arterial walls while offering controlled biodegradation. Finally, prefilled syringes for biologics and vaccines use advanced materials such as cyclo-olefin polymer and PC, which ensure chemical inertness and clarity.

Suppliers, distributors and importers play a key role in ensuring effective PMS and, as supply chains are redesigned due to market pressures, it is critical that

"A MORE COMPLEX PICTURE IS PROVIDED BY 3PL DISTRIBUTORS, WHO ARE RARELY CONSIDERED WHEN IT COMES TO ESTABLISHING TRANSPARENCY AND ACCOUNTABILITY FOR PMS DATA COLLECTION."

manufacturers ensure that they engage with providers that are able to meet their own obligations under the EU MDR and IVDR. Suppliers, distributors and importers also need to maintain complaint registers and collaborate with authorities in case of recalls or potential non-conformities. To date, the contractualisation of PMS reporting duties is rarely requested by manufacturers, but as supply chains need to be reviewed, it is critical that this important aspect is not overlooked.

The legal requirements concerning reporting for importers, distributors and authorised representatives include the obligation to co-operate to achieve an appropriate level of traceability.[1] Distributors specifically are required to keep a register of complaints, non-conforming devices, recalls and withdrawals.[1]

In addition to these, the European Authorised Representatives and UK Responsible Persons – local representatives for companies without a physical location in the EU or UK, respectively – must meet their own specific set of legal requirements. They must, for example, verify that technical documentation meets regulatory standards, maintain copies of essential compliance documents and liaise with competent authorities in case of safety concerns or incidents.[1]

A more complex picture is provided by third-party logistics (3PL) distributors, who are rarely considered when it comes to establishing transparency and accountability for PMS data collection. Despite their grassroots role in delivering devices to hospitals, care homes or directly into the hands of users, they are rarely contractually asked to collect and report storage conditions, transport times or complaints received.

As more and more stakeholders gather and handle critical data for PMS, it is clear that the systems and processes required to interpret and store this information also need to evolve. To keep up with this demand, businesses are increasingly turning to advanced artificial intelligence (AI) and machine learning technologies that support traceability solutions, while also offering automation and real-time visibility across the entire supply chain. Sharing demand forecasts, for instance, helps both manufacturers and suppliers to optimise production processes – minimising waste, lowering operational costs and, subsequently, reducing prices.

These technologies provide powerful tools to formalise supplier collaboration, such as by incorporating explicit clauses in contracts that obligate suppliers and 3PLs to contribute actively to PMS activities. This includes responsibilities such as sharing customer feedback, reporting product complaints and providing critical data for safety evaluations.

In addition to helping formalise partnerships with efficient contractual agreements, these technologies can enhance data sharing by establishing robust, real-time communication channels among all stakeholders. This enables faster identification and resolution of potential risks. Automated data collection further strengthens this process by reducing reliance on manual entry, minimising human error and ensuring the availability of accurate and timely information.

Moreover, new algorithms can be used to drive predictive analytics, identifying trends and anomalies within data that may signal potential supply chain disruptions or quality concerns. This capability allows manufacturers to take pre-emptive action, thereby maintaining regulatory compliance and ensuring patient safety. Enhancing supplier collaboration is therefore critical

"NEW ALGORITHMS CAN BE USED TO DRIVE PREDICTIVE ANALYTICS, IDENTIFYING TRENDS AND ANOMALIES WITHIN DATA THAT MAY SIGNAL POTENTIAL SUPPLY CHAIN DISRUPTIONS OR QUALITY CONCERNS."

to achieving a whole host of benefits that go beyond PMS compliance.

Tariff pressure, the UK's new PMS Statutory Instrument and the EU Directive on Liability for Defective Products all provide a clear call to action to review contractual agreements with suppliers, which should be reshaped to form mutually beneficial partnerships for the safeguarding of patient safety and industry growth.

ABOUT THE COMPANIES

Founded in 2012, **IMed Consultancy** offers a wide range of expert services to the global medical and health technology industry. The company supports medical device and *in vitro* medical device manufacturers to drive innovation and improve patient care and outcomes worldwide, providing assistance through all stages of the product lifecycle from concept and design through clinical studies and post-market surveillance.

JAGGAER specialises in enterprise procurement and supplier collaboration, enabling organisations to manage complex, responsible, highly resilient and efficient supplier bases. Backed by 30 years of expertise, the company's AI-powered, industry-specific solutions, services and partnerships form JAGGAER One – serving directly and indirectly, upstream and downstream in settings demanding a comprehensive solution.

REFERENCES

1. *"Factsheet for Authorised Representatives, Importers and Distributors of medical devices and In vitro diagnostic medical devices". European Commission, Aug 2020.*

Jacob Tyson

Following completion of an MSc degree in Medical Genetics from the University of Sheffield's (UK) Molecular Biology and Biotechnology department (MBB), Jacob Tyson is now working full time as a Senior Medical Writer for IMed Consultancy Ltd. Mr Tyson has a passion for scientific writing, especially in medicine and disease. He has authored 60+ clinical evaluations for a wide range of medical devices (including class IIIs and drug-device combinations) under the scope of the EU MDR, the EU MDD and the UK MDR 2002. Mr Tyson has also authored numerous performance evaluations for IVDs under the scope of the IVDR.

E: jacob@imedconsultancy.com

IMed Consultancy

Bloxham Mill Business Centre, Barford Road, Bloxham,
Banbury, Oxfordshire, OX15 4FF, United Kingdom
www.imedconsultancy.com

Jon Lawrence

As Chief Product Officer at JAGGAER, Jon Lawrence oversees the entire product portfolio, ensuring that the product offerings continue to solve today's critical market challenges while addressing the future of procurement. Before joining JAGGAER, Mr Lawrence was tasked with leading innovation and the overall product strategy at CBORD, where he contributed to developing a strong product based on accurate and insightful market fit, in order to deliver high-value returns to clients and customers. Prior to CBORD, Mr Lawrence, who holds a Bachelor of Science degree from Cornell University (NY, US), covered senior product leadership roles in spend monitoring, supply chain management and retail operations.

E: jlawrence@jaggaer.com

JAGGAER

PO Box 12768, 700 Park Offices, Research Triangle Park,
Durham, NC 27709, United States
www.jaggaer.com

