

From Data Silos to Streamlined Connectivity: How Biopharma Can Prepare for ESMP

Sponsors that centralise their product information will not only help pre-empt drug shortages but also improve their own capacity for collaboration through connected systems and data.

New Platform Accelerates Move to Single View of Product Information

Improving patient access to life-enhancing treatments is a central mission of companies ranging from the world's largest biopharmas to early-stage biotechs. Each pursues its own path to get there. For some, the focus is responsibly-priced medicines. Others are amplifying patient voices during the medicine life cycle or using ESG bonds to reach underserved communities.

Patient access to life-enhancing treatments is a struggle without being able to ensure the timely delivery of medicines. Between 2000 and 2018, Europe experienced a 20-fold increase in drug shortages. On average, each pharmacy in the European Union spends more than six hours a week dealing with scarce supplies of medicines; in some countries, they spend as much as 20 hours per week.

The European Medicines Agency (EMA) has responded to the lack of a standardised EU-wide registry, by launching the European Shortages Monitoring Platform (ESMP). In reality, the failure to meet patient demand for specific drugs is not limited to Europe. Healthcare systems worldwide are straining under rising costs. In the U.K., intermittent supplies are causing a medicine shortage crisis that risks harming patient outcomes as physicians ration medicines in short supply or switch to less effective alternatives.

Biopharmas have limited influence over many of the contributing factors obstructing patient access like transportation issues, physician availability, or healthcare funding. Although these may be out of companies' scope of impact, what they can improve is how quickly they communicate and make decisions when managing supplies. Robust product definitions used consistently across functions, greater control of their data and documents, and an organisation-wide

understanding of regulatory approval status in each market would all help. Companies that centralise their product information will not only ensure regulators receive timely indicators of imminent shortages but also improve their own capacity for internal and external collaboration.

Earlier Warning Signs on Critical Shortages

Drug shortages have many complex and interdependent causes, ranging from biopharma sector consolidation and a limited number of suppliers to government pricing strategies and patent laws for innovative medicines. Such complexity makes it difficult for regulatory authorities to anticipate shortages, with few warning signs when stocks of critical medicines run low. Having launched the ESMP in January 2025, EMA should soon be able to monitor drug supply, demand, and availability continuously. Marketing authorisation holders (MAHs) are playing their part by providing product supply forecasts, availability, manufacturing details, and production plans to both national competent authorities (NCAs) and the ESMP.

To ensure that the product data currently held by EMA is accurate, biopharma sponsors will have to correct and enrich their authorised product datasets, either through direct data entry into the Product Management System UI (PMS) or by completing data loading templates with relevant information. As product data still sits across different functions (including clinical, regulatory, and pharmacovigilance), sponsors are getting ready to share information with ESMP by locating relevant data sources within their organisations – and, sometimes uncovering too late that their product information is inconsistent.

Sponsors need full transparency and control of their data to provide accurate sales and supply forecasts for critical medicines to ESMP. Data used to be copied and pasted as text when shared between departments; it should now be captured once at the source and then stored securely in the right format and place. In many instances, this means taking data out of documents and converting it into structured formats. As sponsors increasingly rely on outsourcing partners

such as contract research organisations (CROs) and contract development and manufacturing organisations (CDMOs), they need to connect seamlessly when exchanging information externally.

Single Source of Product Information for Regulators

In the past, major stockouts in key markets were more common than they should have been, partly because some biopharmas did not know which regulatory information management (RIM) systems held the correct dates for approval and supply. Some companies tried to compensate for the limited connectivity between regulatory, packaging, and logistics by preparing product supplies before receiving the regulatory go-ahead, which could mean an extra step of reworking labels and product packaging if only partial approvals were eventually obtained.

Recent regulatory developments are making a single source of product information a priority for sponsors. Modern RIM platforms can centralise registration data: including marketing status (and dates), product information, active substances, pack sizes, packaging details, and packaging medicinal product identifiers (PCID). Once companies license a product in a market (done by pack), its registration data will be recorded in RIM and become easier to share with ESMP. This can mitigate potential shortages. For instance, if a manufacturer has issues with a product, the regulator can see alternatives containing the same active pharmaceutical ingredient (API).

Post-approval manufacturing changes also lead to drug scarcity. Typically, a large biopharma may manage as many as 200 post-approval changes per product a year – or thousands across its global portfolio. Processing and preparing each change submission can take six months to two years for a company to complete because key systems (QMS, RIM, LIMS, ERP) and data are disconnected. Bringing together the systems underpinning quality and RIM would make it easier to identify which countries and internal documents are affected across multiple markets during a post-approval manufacturing change.

During a drug shortage event, manufacturing sites would not lose time trying to find which specification is registered in each market for each product. Because regulatory and quality teams would see the same product data and documents, quality change controls automatically trigger when a regulatory event occurs affecting multiple markets. Market authorisations in each country would be tracked in real time, ensuring quality teams learn of Health Authority (HA) approvals as soon as they are received.

When different functions and authorities can efficiently exchange the latest data, they can make confident decisions for faster delivery of medicines to patients. As Juhi Saxena, associate director of regulatory and clinical platforms at Moderna Therapeutics, explains: "After connecting quality and regulatory, the data and information required for change control doesn't have to be requested or sit in someone's inbox for two days. This has significantly reduced the time required to perform regional impact assessments and send that information on to supply chain and quality departments."

Centralising access to data and documents would also improve external collaboration between sponsors, CROs, and CDMOs. Given accountability lies with sponsors, some are consolidating their system landscape and prioritising partners that can provide immediate access to live data. Contract partners are also doing their part by eliminating manual activities and non-secure external communication (such as email and shared drives) for greater traceability. For example, CDMO Forge Biologics moved toward a connected quality management platform for better compliance and faster turnaround on reviews and approvals with its clients.

Finally, sponsors with a good handle on data quality, ownership, and governance will drive business benefits beyond ESMP. At one global enterprise that initiated regulatory change through its master data management initiative almost a decade ago, the result is that the organisation "now speaks one language." Data integration means quality, regulatory, and safety will all work from the same set of product definitions across the value chain. Having standardised product definitions sets the stage for accelerated batch release decisions by making them traceable to quality and regulatory data.

One Shared Record, Systemic Benefits
EMA's enhanced monitoring of drug



availability through the ESMP has rightly shifted the focus to accurate and consistent product data. Getting this data in order sets the foundation for the strategic use of predictive analytics. Sponsors, their partners, and regulators will be capable of predicting shortages and mitigating their impact proactively.

For this to work, greater automation when interacting with regulatory bodies will be essential, both for ESMP and CTIS (the platform underlying EU CTR). That's because automation supports data integrity by minimising the chance of human error during data entry or other manual activities.

Seemingly intractable problems can be overcome by breaking them down into their constituent parts. By focusing on what they can control, biopharma companies and regulatory authorities will do their part in helping the industry meet its patient access goals and ensure timely delivery of medicines to those waiting for them.

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