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Your Clinical Supply Solutions

White Paper

How Innovation in Commercial Medicines Impacts Clinical Supply Chains

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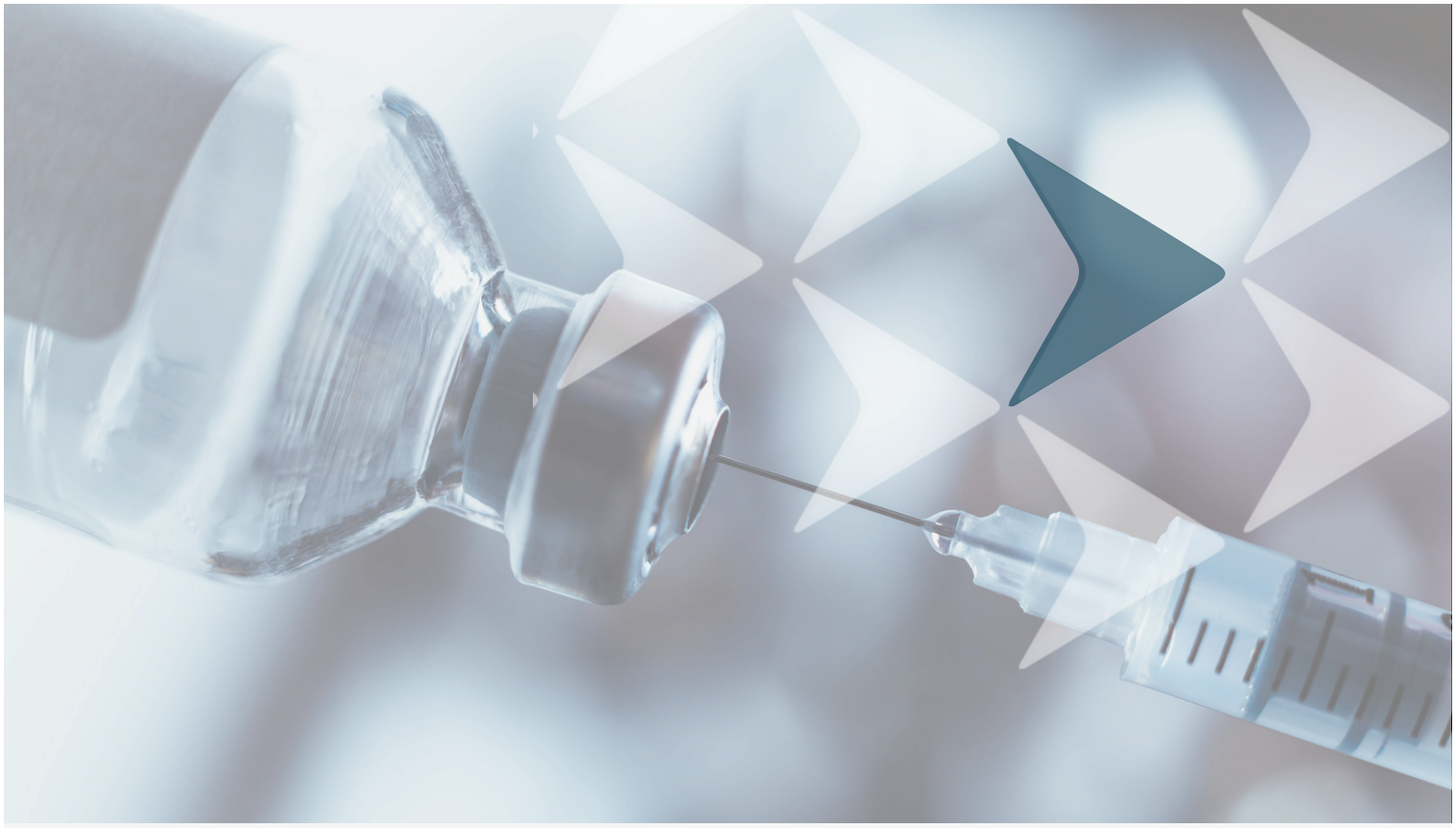

Why Are Medicines Changing?

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Our industry has seen many changes to pharmaceutical packaging and distribution in recent years. Perhaps the most notable example is the introduction of anti-counterfeiting measures such as tamper proof seals, holograms, barcodes to ensure compliance with the Falsified Medicines Directive (FMD) in the EU, and the Drug Supply Chain Security Act (DSCSA) in the US.

One example of a current change is the shift from printed patient information leaflets (PILs) to electronic product information (ePIL), including digital repositories, QR code access, and hospital-only exemptions where paper leaflets are not included in commercial packs.

Why Are Medicines Changing?

Across the industry, there is a growing emphasis on patient safety, ease of dosing, support for self-administration, and improving the efficiency of distribution and use within healthcare systems. This has contributed to increasing adoption of ready-to-administer presentations such as pre-filled syringes and pens, alongside advances in oral and simplified dosing formats designed to support adherence and reduce handling steps at the point of care.

While these changes all aim to improve accuracy, sustainability, and accessibility, they also introduce operational considerations—particularly for clinical supply chains, where packaging, labelling, and documentation requirements are tightly regulated.
It's important that vendors actively monitor these developments to ensure our clients are informed, supported, and prepared ahead of any change.

How Might These Changes Affect Clinical Supplies?

In clinical trials, the packaging, labelling and supply of medicines are regulated to ensure that site staff have access to the information needed for safe storage, handling and administration. When commercial products are used within a clinical trial, their format, presentation and accompanying documentation are influenced by the conditions of the commercial market from which they are sourced. Where commercial manufacturers (or regulators) introduce changes to the format of commercial products, these changes can flow directly into clinical supply chains.

As a result, these commercial packs may not always include the same supporting materials that are expected by sites and sponsors. It would be natural to expect a paper PIL within your pack of drug, but if a change to an ePIL has taken place without stakeholders in the clinical supply chain being made aware, then this discovery is likely to be the catalyst for some quick remedial action.

It's also possible that some markets (as explained later in this paper) may be ahead of others in adopting these innovations, meaning locally sourced drug may differ in presentation from site to site, and some of those sites may require additional support when handling medicines presented in unfamiliar formats.

These changes can influence sponsor expectations, site workflows, and patient confidence. Clear, proactive communication is therefore essential.

It will be of increasing importance that vendors maintain active awareness of evolving market practices and communicate potential impacts early, helping study sponsors and clinical sites prepare, and continue to support safe and consistent patient care.

Listed below are two of the main examples of how innovation is taking place in the manufacture of commercial medicines, and what we feel are sensible steps to take to both be aware of the changes, and to help mitigate any impact on your clinical supply chain. We start with a slightly more in depth look at the ePIL already mentioned.

How Might These Changes Affect Clinical Supplies?

The EU pharmaceutical landscape (governed by the EMA) is seeing a phased adoption to ePILs, with the overall goal being a more efficient digital framework for patients to access information.
Several EU countries have taken their own steps on this journey; we highlight the main ones below.

Baltic Countries (Estonia, Latvia, Lithuania)
These three agencies jointly permit hospital-only medicines to be supplied without a printed PIL.
Information is accessed electronically via regulator-controlled systems, with some packs including a QR code or URL.

France
Beginning 1 October 2025, France implemented a two-year pilot in which selected medicines are supplied with a QR code instead of a printed PIL.
Scanning the code directs the user to the official Base de Données Publique des Médicaments (BDPM) product information database.

Belgium & Luxembourg
Both markets already operate hospital-only electronic leaflet pathways, where packs may legally omit printed PILs if digital access is ensured.

Implications and steps for Clinical Supply Chains

- Site staff must have be aware of, and have reliable access to, the digital leaflet.
- Vendors should confirm the leaflet format before order placement, particularly for hospital-administered products.
- Any absence of a printed PIL should be recorded and justified within trial documentation.
- Where protocols or ethics guidance require printed materials, PILs may need to be provided separately.

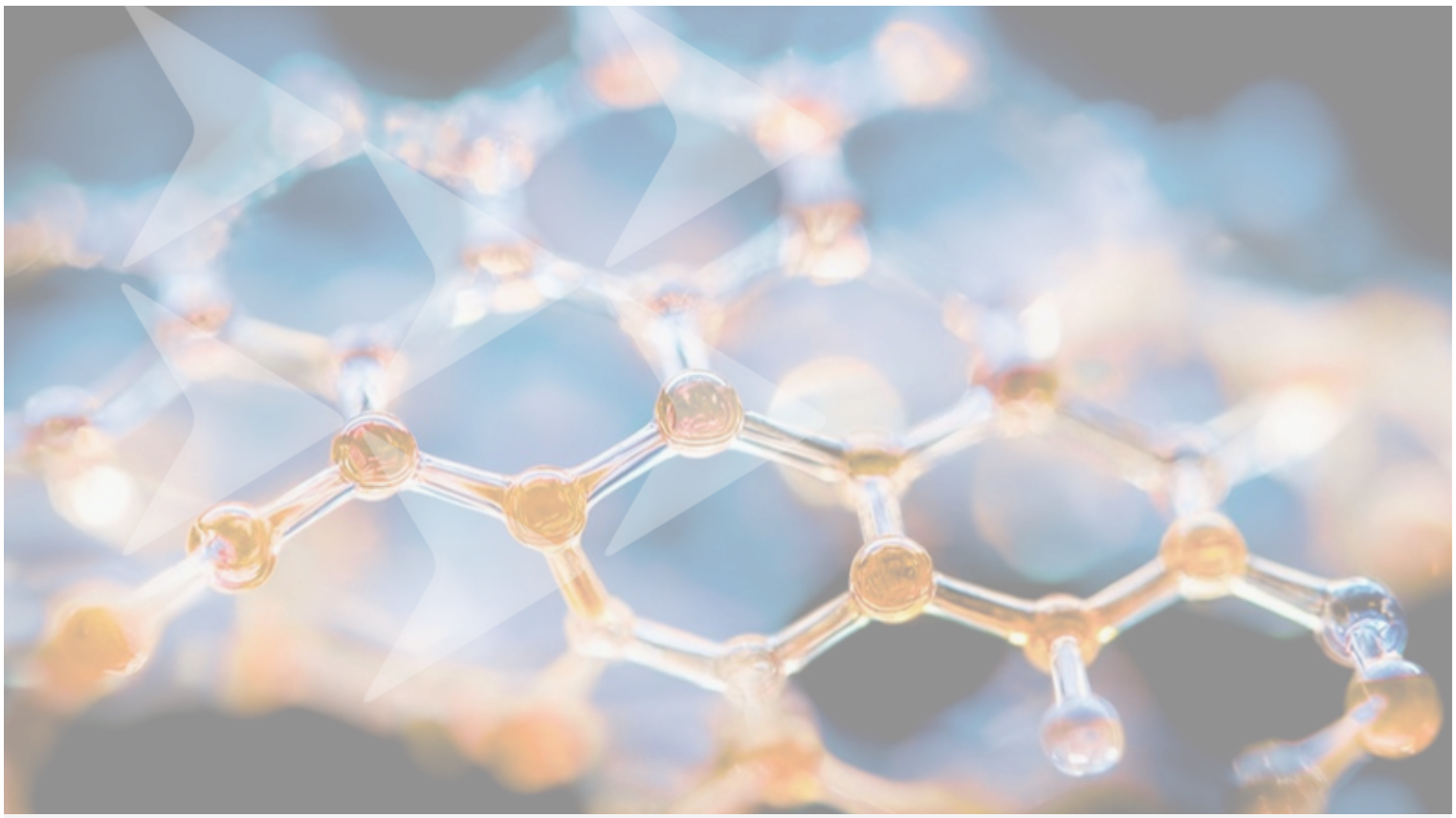
Example Change Area: Increasing Use of Pre-Filled Syringes (PFS) and Pre-Filled Pens (PFP)

There is a wider movement towards ready-to-administer medicine formats. For injectable dosage forms, Pre-Filled Syringes (PFS) and Pre Filled Pens (PFP) are increasingly favoured because they reduce the risk of dosing errors and simplify their administration, for both healthcare providers and patients alike. They often reduce waste when compared to a vial as they contain a measured dose and can boast better sterility due to less handling.

This shift is most visible in biologic and injectable therapies, where vial presentations are gradually being supplemented or replaced by PFS and PFP versions. Often, new drugs are presented in this format from the outset, but for older drugs there are examples of PFS and PFP being introduced during the products lifecycle, meaning a change in the presentation of your comparator in the middle of a trial is possible.

Implications and steps for Clinical Supply Teams

- Presentation type should be confirmed early during comparator planning, and where possible flexibility in product presentations should be built into the study design.
- Labelling may require adaptation due to reduced surface area.
- Sites may require device-handling training.
- Storage and transport conditions may differ due to device size and shape.
- In some circumstances/regions, these formats may be regulated as combined medicinal products and medical devices, requiring additional compliance steps.



Looking Forward

As always, our White Paper is not an exhaustive list, merely a flavour of the changes and challenges that are upon our industry.

Innovation is a constant. In addition to the current and specific examples above, there will be an ongoing search for efficiencies and improvements in all areas, and it's likely that the pressures that drive these changes will come from multiple angles.

Eco-friendly and sustainable packaging remains a big focus for pharmaceutical manufacturers looking to reduce their carbon footprint. Smart Packaging and Patient Centric Packaging are a key area of improving patient safety by, for example, supporting visually impaired or elderly users, or further child-proofing medicines that are designed to be stored at home. And Artificial Intelligence and Blockchain Technology are widely expected to play a greater role in securing our pharmaceutical supply chains in the future.

Summary

The transition toward electronic product information, pre-filled delivery systems, and simplification of medicine administration is accelerating.

While the direct impact on clinical supplies is still evolving, awareness and early planning remain key.
All of the changes above are manageable if discovered later than desired, but to maximise the efficiency of our clinical supply chains, and reduce unnecessary risks and delays, it's imperative that your vendor is on top of these changes and regularly sharing any changes to the commercial drugs that are part of your study.

1. **Confirm product presentation and information format prior to drug sourcing, rather than after delivery.**
2. **Ensure site teams know what to expect**
3. **Provide supplemental materials where needed (for example, a verified PDF copy of product information).**
4. **Record sourcing details and rationale in study documentation, including the Trial Master File (TMF) and QP release records, to support inspection readiness.**

Midwinter Solutions will continue to track regulatory developments and communicate meaningful updates that may affect clinical supply operations, to our partners.

For further support or for any questions on this, please feel free to contact:
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