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Industry Perspective - A New Regulatory Framework for Innovative Products Manufactured at or Close to the Point of Patient Care

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Abstract: ***The pharmaceutical and Medtech industries prioritize public health by ensuring the quality, safety, and efficacy of medicines. With an increasing product portfolio and advanced modalities, the industry faces significant challenges, including economic pressures, regulatory compliance, and ethical concerns. Keeping in view the manufacturing of new innovative medicines and to accelerate time to market and facilitate patient access, the Medicines and Healthcare products Regulatory Agency (MHRA), UK, has introduced an innovative regulatory framework for point - of - care (POC) manufacturing of advanced therapies, including cell and gene therapy, 3D - printed products, and medicinal gases. This framework promotes patient - centricity, cost reduction, supply chain efficiency, environmental sustainability, and the delivery of high - quality personalized treatments. Despite its benefits, the framework necessitates rigorous scrutiny, robust training, and effective knowledge management. By fostering collaboration and leveraging modular technology, it aims to transform the manufacturing landscape, ensuring rapid access to innovative therapies and enhancing local economies.***

Keywords: pharmaceutical innovation, point - of - care manufacturing, MHRA framework, personalized medicine, advanced therapies (ATPs)

1. Challenge & Need

Pharmaceutical manufacturing process is overly complex, challenging driven by regulations. It is costly, requires high degree of quality, compliance, and security. With increased challenges from various dimensions and evolving product portfolio, industry is trying to adopt practices to ensure safe & effective innovative medicines manufactured with high standard quality and compliance is easily and quickly accessible to patients in need.

2. Regulatory Framework

To manage and maintain the growing need of innovative medicines like CGT drugs, the new emerging framework /model from regulators will help to ensure compliance and streamline the market access. Medicines and Healthcare products Regulatory Agency (MHRA), UK is set to be the first country to introduce a new regulatory framework for innovative products manufactured at or close to the point of patient care[1]. Once implemented the manufacturing regulatory framework will apply to all point of care (POC) products manufactured in the UK, such as: Advanced therapy medicinal products (ATMPs), cell therapy, gene therapy and tissue engineered products; 3D printed products; blood products; medicinal gasses. The safe, quick production of such medicines requires more personalized approach and has a short shelf life, hence requires new ways of manufacturing while ensuring quality, safety, and efficacy. While UK (MHRA) being the first country to adopt this framework, other regulators also follow this framework e. g., FDA[2, 3].

While this framework will drive transformative initiatives in the manufacturing of innovative medicines with modular technology, collaboration, it will also ensure fast rapid access to quality therapies.

Key **advantages** of implementation of such frameworks include:

1) **Improved patient centricity:** Ease of access to innovative therapies can improve adherence to medication using better patient support care, engagement through digital health tools. It can result in better health outcomes.
2) **Reducing manufacturing cost:** Following standards (GMPs) and new global and local requirements based on type of innovative products and proper inspection and audits, it can improve overall cost of manufacturing by attracting right local talent, skillsets.
3) **Improves supply chain cost and delays:** Local manufacturing can reduce transactions and transport of supplies and burden of delays and overseeing, hence reduces cost.
4) **Supports safe environment:** Reduction of carbon foot printing and go green pharma can be another benefit achieved through this framework as fit for purpose medicines using 3D printing technology can reduce the excess disposition saving environment.
5) **Quality product viability:** Given the nature of products like proteins, gases, cell, and gene which are temperature sensitive and has short life, can be easily managed through this framework ensuring safe and effective and viable medicine reaching to patients.
6) **Reduce demand and supply gap:** The demand and supply gap will significantly reduce by analysing the demand locally and manufacture drugs in prompt manner to enable access.
7) **Better management of drug inventory:** Manageable size of drug supplies improves overall Quality & Compliance and better management of inventory.
8) **Patient safety:** Better patient safety tracking and management can reduce pressure on hospitals by delivering care in community settings and patients' homes, expanding 'hospital at home' services.
9) **Personalized health:** Ability to manufacture highly personalised medicines with a short life and make it available easily near a hospital setting can help in improving patient care and achieve better health outcomes. For example, cancer biopsies and blood -

derived components taken from a patient and sent to a local manufacturing site to manufacture a personalised cancer vaccine specific to that patient's disease.

10) **Overall, economy improvement locally:** Development of facility, new art of technology, more employment can improve overall economy locally.

Few **Implications** of the framework includes:

a) **More scrutiny & inspections:** With decentralized Point of Care Units (POCs) and nearby highly specialised GMP (Good Manufacturing Practice) units, it is a challenge to keep track on the compliance and daily practices in GMP environments. Need planning of more frequent compliance monitoring, audits, and inspections. Potential opportunities for remote, and intelligent monitoring.

b) **Robust trainings & education:** For localized manufacturing units, right ability needs to be onboarded to bring operational efficiencies, hence regular updates, trainings, and education needs to keep resources updated & empowered with knowledge and tools.

c) **Knowledge management:** Compliant operation of decentralized point of care units (POCs) require high knowledge transfer. Need to consider management of knowledge (External/Internal) using regulatory guidelines, internal SOPs, checklists, best practices and access to tacit knowledge, localization, and delivery mechanisms.

d) **Collaboration & traceability:** Use of collaboration tools with better workflows and tracking for traceability and visibility to make decisions.

e) **Labelling, artwork & packaging:** Labelling, artwork & packaging processes will get highly impacted due to the nature of manufacturing and type of products, regulatory needs (e. g., cryo labels, detailing and Instruction for Use, e - labels).

3. Conclusion

The implementation of the MHRA's regulatory framework marks a transformative step in the pharmaceutical and Medtech industries, addressing the growing demand for innovative, safe, and effective treatments. This framework enhances patient care through personalized therapies while reducing costs, environmental impact, and supply chain complexities. However, its success depends on robust compliance monitoring, education, and collaboration among stakeholders. By aligning processes, technology, and expertise, the industry can create a sustainable ecosystem, ensuring timely access to high - quality therapies and fostering economic growth. This initiative serves as a model for global adoption, reshaping the future of healthcare delivery.

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