Regulatory compliance in unprecedented times: how to adapt but stay on track

A guide for the European life sciences industry

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The COVID-19 pandemic has had an unprecedented impact on stakeholders in the UK and EU's life sciences industry - from companies, to third parties, governments, regulators and insurers.

The actions of relevant European life sciences regulators have been comprehensive and varied, aimed at maintaining high levels of product safety whilst mobilising the life sciences industry in the fight against the pandemic, either through measures aimed at COVID-19 products themselves and/or peripheral measures that assist to that end. New policies introduced, whatever their nature, are generally specific, defined and temporary in nature, however.

Regulators' actions have been supplemented in parallel by the actions of governments, including the UK Government – who have provided indemnities in respect of future liability (in contrast to immunities granted by other countries) – and the actions of technical standards bodies – who have made their products available free of charge.

Against this backdrop, companies and their insurers need to continually assess compliance with this ever-changing product safety framework, and review reliance on short-lived regulatory derogations. They also need to consider long-term product liability exposure in order to avoid strict liability, contractual and tortious claims that may expose companies to fines or, on some occasions, criminal sanctions.

We will be publishing further articles on a range of current and emerging topics, followed by a webinar later this year to provide a forum for discussion and practical tips.

Below is a high-level list of some of the more noteworthy actions taken by regulators and third parties during the course of the COVID-19 pandemic across the EU and UK medical devices and medicines industries.

	Medical devices		Medicines	
	UK **Medicines and Healthcare products Regulatory Agency (MHRA)**	**EU** **The European Commission (EC)**	**UK** **Medicines and Healthcare products Regulatory Agency (MHRA)**	**EU** **The European Medicines Agency (EMA)**
Provision of guidance	The MHRA has produced guidance on: ■ Rapidly manufactured ventilator system (RMVS) and "Minimally clinically acceptable" Continuance Positive Airways Pressure System (CPAP). ■ Design, technical criteria and regulatory framework for tests for detection of COVID-19 virus and antibodies which do not yet have UKCA, CE or CE UKNI marks. ■ The availability of British Standards Institution's (BSI) ventilator standards free of charge.	The EC has published guidelines on: ■ Conformity assessment requirements, regulatory pathways and factors for classifying borderline products for Personal Protective Equipment (PPE) and medical devices. ■ Choice of technical standards (WHO-recommended versus harmonised standards) to ensure safety of PPE. ■ The availability of the European Committees (CEN and	The MHRA has released the following materials: ■ Guidance on available temporary regulatory flexibilities. ■ Guidance on exceptional flexibilities on Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) for medicines manufacturers. ■ Information for hospital blood banks on flexible approaches to requirements. ■ Information concerning temporary relaxation of pharmacovigilance risk minimisation measures.	The EMA has: ■ Published guidelines on regulatory expectations and flexibilities for human medicines. These cover authorisation and renewal, regulatory procedures, manufacturing and importation, quality variations, GMP and GDP, pharmacovigilance, audits and Individual Case Safety Reports (ICSRs). ■ Produced a paper on the regulatory requirements that manufacturers need to satisfy when adapting their vaccines to deal with virus variants. ■ Chaired workshops for those who are developing

		CENELEC) technical standards for a number of medical devices and PPE products free of charge for both EU and third party countries.		COVID-19 vaccines and treatments. Workshop topics include observational studies, real-world data, data requirements, virus variants, COVID-19 vaccines and therapies in pregnant and breastfeeding women.
Granting derogations/ exemptions/expedited pathways	The MHRA has introduced the following measures: ■ Exemption of certain medical devices from compliance marking in limited circumstances, e.g. testing kits for COVID-19 virus and antibodies, ventilators and PPE. ■ Expedited process for clinical investigations of medical devices directly related to COVID-19. ■ Setting aside the need to notify small deviations to clinical investigation procedures, except where patient safety is impacted.	The EC has: ■ Confirmed it maintains a flexible and pragmatic approach to the regulatory requirements for clinical testing and investigation of medical devices in relation to COVID-19. ■ Expedited any amendments to clinical investigations of medical devices related to COVID-19. ■ Allowed remote audits for all	The MHRA has: ■ Granted temporary authorisation for emergency supply of newly developed COVID-19 vaccines in certain circumstances. ■ Provided flexibility in temporary GDP in order to address the current exceptional circumstances and meet supply needs. ■ Postponed or waived the requirement for the submission of Periodic Safety Update Reports (PSURs) for active ingredients authorised only in the UK.	The EMA has: ■ Launched the PRIority MEdicines (PRIME) scheme which provides support to developers of promising medicines, who also can expect to be eligible for accelerated assessment for a marketing authorisation. ■ Recommended expanding the “compassionate use” of the investigational medicine remdesivir through its human medicines committee (CHMP). ■ Recommended the EC grant a Conditional Marketing Authorisation

	■ Waiving the need for application for limited changes of use of pre-existing devices. ■ Removing the requirement to conduct non-essential on-site Good Practice inspections in relation to manufacturing and distribution.	medical devices. ■ Through the Medical Device Coordination Group (MDCG), allowed certain temporary extraordinary measures in relation to Notified Body audits to minimise the risk of shortages and allow continued availability of all medical devices, including COVID-19 essential medical equipment.	■ Relaxed risk minimisation measures and assessments on a case-by-case basis. ■ Allowed remote auditing where on-site auditing is not practical. ■ Continued conducting only essential on-site inspections of laboratories, clinical trials, manufacturing, distribution and pharmacovigilance.	for certain COVID-19 vaccines where data is robust and meets safety, efficacy and quality criteria. ■ Introduced labelling and packaging flexibilities for authorised COVID-19 vaccines. ■ Adopted a series of regulatory measures to improve the supply and distribution of COVID-19 vaccines within the EU.
Broader policy and system reforms	The MHRA has implemented a coronavirus section within the existing Yellow Card system to encourage reporting of incidents involving COVID-19 products (medical devices and medicines). The UK Government has granted manufacturers of RMVSs indemnities in respect of product liability claims and IP infringement issues. The	The EC has delayed the date of effect of the EU's Medical Device Regulation for one year (to May 26 2021), citing the pandemic as a contributing factor to this decision.	The MHRA published guidance on tips and examples for successful submissions in the area of nitrosamine risk evaluations and extended deadline for responses of assessments and confirmatory testing. The UK Government has added COVID-19 to the existing Vaccine Damage Payments Scheme which ensures that where someone	The EMA has implemented the enhanced fast-track monitoring system for medicines for treating COVID-19 patients, irrespective of authorisation route. The EU Commission has introduced a transparency and authorisation mechanism for exports of COVID-19 vaccines outside of the EU. The EU Commission confirmed that advance purchase

	details of such contractual indemnities are commercially sensitive and on a case-by-case basis per contract.		is severely disabled as a result of the vaccine they can access financial assistance if certain criteria are met. The UK Government confirmed that it has granted legal indemnities to COVID-19 vaccine manufacturers in supply contracts.	agreements with manufacturers for COVID-19 vaccines contain indemnity clauses relating to possible liabilities incurred under specific conditions set out in the agreements.