



UK Life Sciences and Healthcare Newsletter

August 2021

Legal Updates: Hot Topics



RHC Recommendations for the Reform of Medical Devices Regulation

A report by the Regulatory Horizons Council on the regulation of medical devices was recently published. The report makes a number of recommendations to ensure that the UK's medical devices regulatory framework continues to support the continued growth of the life sciences sector.

[Read more »](#)



Revised FCA Rules for SPAC Listings

SPAC transactions in the life sciences and healthcare sector are increasingly popular. Following its recent consultation, the FCA has published its policy statement setting out the final changes to the UK Listing Rules applicable to SPACs and it is hoped that these changes remove barriers to SPAC listings in the UK.

[Read more »](#)

Notable Dechert-led Transactions:

Dechert has recently been involved in advising on a number of significant life sciences transactions, including advising:

- **A group of minority shareholders (and initial founders)** in the sale of 35 percent of the shares of Newpharma Group, the Belgian market leader in online sales of parapharmacy and OTC products, to Euronext-listed Colruyt Group and Korys, the investment company of the Colruyt family.
-

Knowledge:

- **Federal Circuit Tailors its Decision on Skinny Labels:** A legal update from Dechert's intellectual property group on the future of skinny labeling and its impact on the pharmaceutical industry.
-

Dechert Events:

- **Dechert Healthcare Deals Conference 2021, 23 September:** This one-day event will bring together senior pharma, biotech, PE and VC leaders across the life sciences and healthcare industry to network and share their outlook on trends and opportunities across the sector.

Events Sponsored by Dechert:

- **HealthTech Innovation Days, 4 – 5 October:** This conference organised by HealthTech For Care, an endowment fund launched by France Biotech, brings together over 700 members of the Life Science investment community for a hybrid event.

Other Industry Events:

- **The European Pharma Law Academy, 6–10 September:** A course designed to offer insights into the long-standing conventions, the latest updates, and best practices from some of the leading experts in the pharma law field.

- **The Future of American Healthcare, 14 September:** This digital conference will discuss where American healthcare is going in terms of legislation, innovation and investment.
- **Pharmaceutical Compliance Congress, In-Person: 28–29 September | Virtual: 5–6 October:** A leading bio/pharma event for compliance and legal professionals. An event for staying on the pulse of enforcement trends, supercharging your best practice playbook and expanding your network.

Regulatory Updates:

- **MHRA consults on regulatory framework for point of care medicinal products**

On 12 August 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) launched a consultation on a proposed new regulatory framework for point of care (POC) medicinal products. POC products include blood products, medical gas products, Advanced Therapy Medicinal Products (ATMPs) and small molecule products. One of the issues outlined is the short shelf life of POC products, which presents issues for manufacturing and quality control testing. As several new products are undergoing clinical trials, the MHRA is aware of the need for imminent regulation. The framework proposed by the MHRA is based around a “Control Site” concept, a physical site specified in the clinical trial or marketing authorisation application that would oversee all aspects of the POC manufacturing system.

- **UK Government's new Innovation Strategy to support investment in the life sciences sector**

On 22 July 2021, the UK Department for Business, Energy and Industrial Strategy announced the launch of a new Innovation Strategy in the UK. The report outlines points and case studies specific to the life sciences sector, such as bio informatics, and genomics, engineering biology and artificial intelligence. They also provide case studies of innovative companies, such as Zentraxa Ltd, a company that manufactures biopolymers for use in highly functional adhesives in medical and industrial settings (which received funding from the UK Innovation and Science Seed Fund). The Innovation Strategy will also invest £200 million via the British Business Bank's Life Sciences Investment Programme.

Market News:

Recent notable industry transactions:

- Otsuka Pharmaceutical and Denka Company have entered into a collaboration agreement to co-market the rapid diagnostic test kit. QuickNavi™- COVID-19 Ag to medical institutions across Japan. From 1 September 2021, the kit will be the latest product in Otsuka's QuickNavi™ series of in vitro diagnostics with 100,000 tests to be delivered daily.
- Santen and Sydnexis entered into a licence agreement to licence SYD-101, an investigational treatment for progressive childhood myopia, in Europe, Middle East and Africa.
- Cardinal Health, Abbot and Quidel Corporation entered into a collaboration for the development in distributing over-the-counter (OTC) rapid COVID-19 tests. Cardinal Health's distribution network plans to complement Quidel's QuickVue® At-Home OTC COVID-19 test and Abbott's BinaxNOW™ COVID-19 antigen self-test.
- Kite entered into a licence agreement with Appia Bio to research and develop hematopoietic stem cells (HSC)-derived cell therapies for cancer. Appia Bio will lead preclinical and early clinical research of two HSC-derived chimeric antigen receptor (CAR)-engineered invariant natural killer T (CAR-iNKT) product candidates engineered with CARs provided by Kite. Appia Bio will receive a payment, an equity investment, tied royalties and additional milestone payments for a total value of up to US\$875 million.
- Novavax and the European Commission entered into an advance purchase agreement for Novavax to ensure access to vaccines against COVID-19 in Q4 of 2021 and in 2022. Member States can purchase up to 100 million doses of the Novavax vaccine, with an option for an additional 100 million doses over the following 3 years. Member States can then also donate vaccines to other countries or re-direct them to other European countries.
- Minovia Therapeutics, Ltd and Astellas Pharma Inc. announced a worldwide strategic collaboration and license agreement to accelerate the creation of mitochondrial cell therapy programs. Minovia's Mitochondrial Augmentation Therapy (MAT) technology complementing Astella's genetically engineered, induced pluripotent stem cells. Minovia will receive an upfront cash payment of £20 million, with US\$420 million per product in milestone payments.
- Loxo Oncology at Lilly and Kumquat Biosciences have announced an exclusive collaboration focused on the development of novel small molecules that stimulate tumour specific immune responses. Kumquat will utilise its small molecule immune-oncology (IO) platform for the discovery of novel clinical candidates for selection by Lilly for co-commercialisation. Kumquat will receive upfront US\$70 million, with US\$2 billion in potential milestone payments.
- AstraZeneca and Regeneron have entered into a collaboration to research, develop and commercialise small molecule modulators directed against the new GPR75 target that has genetic validation in metabolic disorders. The businesses will split and share R&D costs and future profits.
- Arvinas and Pfizer have announced a second collaboration agreement for the development and commercialisation of ARV-471, Arvinas' proteolysis-targeting chimera (PROTAC) oestrogen receptor

protein degrader. Pfizer will pay Arvinas US\$650 million up front with a US\$350 million equity investment.

This update was authored by:



Robert Darwin
Partner | London
T: +44 20 7184 7603
robert.darwin@dechert.com



Sean Geraghty
Partner | London
T: +44 20 7184 7540
sean.geraghty@dechert.com



Patrick Lyons
Partner | London
T: +44 20 7184 7356
patrick.lyons@dechert.com



Jennifer Rees
Partner | London
T: +44 20 7184 7352
jennifer.rees@dechert.com



Thomas Clarke
Associate | London
T: +44 20 7184 7425
thomas.clarke@dechert.com



Anthony Frost
Associate | London
T: +44 20 7184 7574
anthony.frost@dechert.com



Rose Limaye
Associate | London
T: +44 20 7184 7448
rose.limaye@dechert.com



Nick Quarrie
Associate | London
T: +44 20 7184 7819
nick.quarrie@dechert.com

We would also like to thank trainees Charles Ashie and Michael Sunkin for their contributions.

[Photo credits](#)

[Print email](#) / [Unsubscribe](#) / [Update your marketing profile](#)

dechert.com

© 2021 Dechert LLP. All rights reserved. This publication should not be considered as legal opinions on specific facts or as a substitute for legal counsel. It is provided by Dechert LLP as a general informational service and may be considered attorney advertising in some jurisdictions. Prior results do not guarantee a similar outcome. We can be reached at the following postal addresses: in the U.S.: 1095 Avenue of the Americas, New York, NY 10036-6797 (+1 212 698 3500); in Hong Kong: 31/F Jardine House, One Connaught Place, Central, Hong Kong (+852 3518 4700); and in the UK: 160 Queen Victoria Street, London EC4V 4QQ (+44 20 7184 7000).

Dechert internationally is a combination of separate limited liability partnerships and other entities registered in different jurisdictions. Dechert has more than 900 qualified lawyers and 700 staff members in its offices in Belgium, China, France, Germany, Hong Kong, Ireland, Luxembourg, Russia, Singapore, the United Arab Emirates, the UK and the U.S. Further details of these partnerships and entities can be found at dechert.com on our [Legal Notices](#) page.