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Brexit: Key Considerations for Swiss Pharmaceutical Companies

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Starting January 1, 2021, new medicines legislation will come into force in the UK subject to a negotiated trade agreement between the UK and the EU. While the substantive body of EU pharmaceutical law will be preserved in the UK as "retained EU law", there will be substantial changes to

(i) ensure that the UK regulatory framework can continue to function in accordance with the Withdrawal Agreement and the Northern Ireland Protocol (agreed in October 2019)

(ii) implement some UK policy changes introduced by UK statutory instruments

As Switzerland is not an EU member state, the aforementioned agreements do not directly concern Swiss companies operating out of Switzerland. However, on February 11, 2019, UK and Switzerland signed a bilateral trade agreement to maintain the *status quo ante* Brexit in the UK-Swiss trade relationship. This agreement will enter into force as soon as the bilateral agreements between Switzerland and the EU no longer apply to the UK, that is, as of January 1, 2021. The agreement allows both parties to continue to apply the preferential terms of trade currently applicable between Switzerland and the UK and to maintain the mutual recognition of certain regulatory acts performed by the competent agencies of both parties. With regard to medicinal products, this concerns the continued mutual recognition of the results of inspections of good manufacturing practices and of batch certificates for medicinal products.

That is not to say that Swiss companies with business in the UK will not be affected by changes to the UK laws and guidance. Below, we provide a high-level overview of some of the key considerations for Swiss companies that market medicines in the UK. For more detail, see Sidley's Brexit feed.

'Grandfathering' Community Marketing Authorizations

Community marketing authorizations (CAPs) authorized under the EU centralized procedure will automatically be converted to Great Britain marketing authorizations (UK MAs) on January 1, 2021. This means that Swiss companies with existing CAPs will not need to apply for separate UK MAs. However, they will have a period of one year to submit baseline data to the UK regulator, the Medicines and Healthcare Products Regulatory Agency (MHRA). Furthermore, non-UK-based MA holders with CAPs converted into UK MAs must establish a

legal presence in the UK by January 1, 2023. For Northern Ireland, existing CAPs will remain valid independently under the Northern Ireland Protocol. See further MHRA guidance here.

New UK Marketing authorization routes

The MHRA is introducing new MA procedures to prioritize access to new medicines and to create new routes of evaluation for novel products and biotechnological products in the UK. This may provide companies with new opportunities for expedited regulatory approvals in the UK:

(1) A new, 150-day, **accelerated assessment procedure** will be created to reduce the time to patient access for new medicines and technologies.

(2) A new **rolling review route** will be created to enhance the development of novel medicines by offering ongoing regulatory input and feedback enabling the applicants to get it right first time.

(3) Under the **reliance route**, for a period of two years, the UK will adopt medicines authorized under the EU centralized procedure and will have the power to take into account marketing authorization decisions of EU member states in national, decentralized, and mutual recognition procedures.

(4) A national **conditional marketing authorization** scheme will be created for products that fulfill an unmet need where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon.

(5) The existing **exceptional circumstances** scheme will continue to be available for medicines where a comprehensive data package cannot be provided because the condition to be treated is rare or because collection of full information is not possible or is unethical.

See further MHRA guidance here. Additionally, the UK will be joining Switzerland, and a number of other countries in Project Orbis, and the Access consortium, which aim to enable faster patient access to medicines through international regulatory collaboration. See further details here. Notably the collaboration in the Access consortium may lead to a closer relationship between MHRA and Swissmedic, the Swiss regulator for therapeutic products.

Importing medicines from EEA countries into Great Britain (England, Scotland, Wales)

From January 1, 2021, Qualified Person (QP) certified medicines from the European Economic Area (EEA) will be accepted in Great Britain if certain checks are made. These medicines will not require retesting or recertification by a UK QP if imported and checked by a wholesale dealer in Great Britain. Existing wholesale dealer's licences will remain in force.

Existing wholesale dealers must

(i) within six months from January 1, 2021, notify the MHRA of the company's intention to continue to import medicinal products from a country on the list *and*
(ii) within two years from January 1, 2021, nominate and have a Responsible Person (import) (RPi) on the wholesale dealer's licence who will carry out specific functions.

The requirement to name a RPi on the wholesale dealer's licence will apply immediately to all new licence applications made from January 1, 2021, for companies wishing to import a licensed medicine from a listed country. See Sidley Brexit feed here and MHRA guidance here.

Pharmacovigilance

Starting January 1, 2021, UK MA holders will be required to operate a pharmacovigilance system for UK-authorized products. MA holders must have at their disposal an appropriately qualified person responsible for pharmacovigilance (QPPV) who resides and operates in the EU or the UK.

If the QPPV is not in the UK, the MA holder must appoint a "national contact person for pharmacovigilance" who resides and operates in the UK and reports to the QPPV within 12 months from January 1, 2021.

The MA holder must maintain, and make available upon request of the MHRA, a pharmacovigilance system master file (PSMF) that describes the pharmacovigilance system for UK-authorized products. For MAs that cover the whole of the UK or are specific to Northern Ireland, the PSMF must be located either at the site in the European Union where the main pharmacovigilance activities are performed or at the site where the QPPV operates. For the aforementioned MAs and MAs that are specific to Great Britain, the PSMF must be accessible electronically at the same site at which reports of suspected adverse reaction may be accessed. The PSMF needs to be permanently and immediately available for inspection at the stated location in the UK. See Sidley Brexit feed here.