Swiss new regulations for orphan drugs

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New regulations have been in force in Switzerland for important medicinal products for rare diseases (orphan drugs) since 1 January 2019.

The regulatory authority Swissmedic grants orphan drug status (ODS) to medicinal products that treat a condition affecting no more than 5 out of 10,000 people in Switzerland, or that have been granted ODS in another country with equivalent medicinal product control.

The procedure with prior notification has been used for the recognition of ODS since 1 August 2019. The accelerated approval procedure applies for medicinal products with ODS. The approval documentation of medicinal products with ODS is protected for 15 years. ODS designations issued by EU regulatory authorities are not protected in Switzerland.

Christian Roos

Partner
Attorney at law, lic. iur.
Co-head Life Sciences

Pestalozzi Attorneys at Law Ltd
Feldeggstrasse 4
8008 Zurich
Switzerland
T +41 44 217 92 00
christian.roos@pestalozzilaw.com

