# Orphan Medicines Regime

Maintained

| Jurisdiction | Source Information | Is there an orphan medicines regime? | Are there set criteria a medicinal product must meet to be designated an orphan medicine? | Can an orphan designation be obtained prior to a marketing authorisation? | Is market exclusivity awarded for authorised orphan medicines? | Once market exclusivity is granted, can any exceptions be made to this? | Are there other financial incentives for orphan medicines (for example, fee waivers or reductions)? | Is free scientific or regulatory advice offered for orphan medicines development? | Is there a separate accelerated assessment procedure for licensing orphan medicines? | Can variations be made to orphan designations? | Do specific pricing and reimbursement policies exist for orphan medicines? | Are any additional incentives available for orphan medicines with paediatric indications? | Can decisions on orphan designation be appealed? | Is there a national policy for rare diseases? | Is there a register of orphan medicines? |
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| Switzerland | Law stated as at 1 March 2023<br>(Chrissian Roos, Sarah Drukarch, and Norina Messerli, Pestalozzi) | ✓ | ✓ | ✓ | ✗ | Not applicable | ✓ | ✗ | ✗ | ✓ | ✗ | ✗ | ✓ | ✓ | ✓ |
| | | Upon application, the Swiss Agency for Therapeutic Products (Swissmedic) grants a medicinal product the status of an orphan drug within the meaning of Article 4, paragraph 1(a)(decies) of the Therapeutic Products Act (TPA). Orphan drugs are subject to authorisation as medicinal products if they are to be marketed in Switzerland (Article 9, TPA), whereby they are eligible for a simplified authorisation procedure. | Upon application, the orphan drug status (ODS) is granted to a medicinal product for human use if the applicant establishes that either:<br>• It is indicated for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating disease affecting no more than 5 in 10,000 people in Switzerland when the application was submitted.<br>• It or its active substances are granted the status of important medicinal products intended to treat rare diseases by another country with an equivalent system of medicinal product control. | The applicant is free to submit the application for orphan designation before or at the same time as the marketing authorisation application or even after receiving the drug's marketing authorisation. The application for orphan designation is processed independently of the marketing authorisation application. | The Swiss Therapeutic Products Act (TPA) does not provide market exclusivity for orphan drugs. However, the submitted documents for orphan drugs, in particular the pharmacological, toxicological, and clinical trial data, are protected from use by third parties through document protection for a period of 15 years (Article 11b, TPA). Eligible for protection are medicines with new active substance as well as those with already approved active substances, however this is limited to products for which a marketing authorisation or variation application has been submitted to Swissmedic after 1 January 2019. Document protection is granted only upon application and should be requested simultaneously with the application for marketing authorisation. | - | The fee for new marketing authorisation is waived for orphan drugs according to Article 9 of the Swissmedic Ordinance on Fees. | At the request of the applicant, or if deemed necessary by Swissmedic, the applicant may receive scientific advice from Swissmedic prior to the submission of an application or also during its processing. However, services in this regard are subject to fees and are charged at an hourly rate of CHF200. | The orphan drug status granted by Swissmedic gives applicants access to a simplified authorisation procedure according to Article 14, paragraph 1(f), TPA. The rarity of a disease and the associated difficulty of conducting clinical trials will be considered in the simplified authorisation procedure. However, no special acceleration is foreseen in the approval process for orphan drugs. Where possible, applications for authorisation for orphan drugs are, however, prioritised by Swissmedic. | Indication extensions for authorised medicinal products with or without orphan drug status (ODS) are possible irrespective of whether the new indications meet the criteria of ODS or not (but based on different application forms). Depending on the initial set-up, however, a medicinal product may lose its ODS. | The competence to set prices and to decide on the reimbursement of medicinal products lies within the Federal Office of Public Health (FOPH). Medicinal products that must be reimbursed by health insurers (provided they have been prescribed by a healthcare professional) are included in the list of specialties provided for this purpose by the FOPH. This also applies to orphan drugs. Under certain circumstances, the costs of orphan drugs that are not included in the list of specialties can also be reimbursed in the individual case. However, the health insurers have a great deal of discretion in this regard. | While the introduction of a 12-year document protection for orphan drugs with paediatric indications was discussed in the context of the Therapeutic Products Act revision, it was finally decided to grant the document protection for all orphan drugs for a period of 15 years. Thus, there are no specific incentives that apply exclusively to paediatric indications. | Decisions issued by Swissmedic by means of a ruling may be appealed to the Federal Administrative Court as the first instance as well as to the Federal Supreme Court as second instance. The general provisions regarding the administrative procedure in public law apply. | In October 2014 the Federal Council passed the National Rare Disease Policy. Within this framework, the FOPH and the parties involved formulated a plan to implement the 19 measures of the National Rare Disease Policy, which should be implemented until the end of 2022. In 2017, the National Coordination of Rare Diseases (kosek) was founded. Kosek's main goal is the improvement of the healthcare situation for those affected by rare diseases. As such, it has the main lead in the implementation of the National Rare Disease Policy. | Swissmedic maintains a publicly accessible list of all medicinal products with orphan drug status online . |

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