Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R made by manufacturers

Green = related to/any special considerations for OMPs/UOMPs

Liechtenstein (based on Switzerland)	**Standard process (non-orphan drugs)**
Overview of health system and P&R/HTA process	Social insurance based health system [1] The amt für Gesundheit (AG) provides information on how Liechtenstein manages drug reimbursement. The Ministry of Health regulates drug reimbursement. [2] *Liechtenstein does not have its own reimbursement process, it is connected to Switzerland and follows their reimbursement list. Thus, medicines approved by the Swiss Agency for Therapeutic Products (Swissmedic) are automatically approved in Liechtenstein with one exception: Swissmedic approvals of drugs containing *new* active substances are not automatically recognized in Liechtenstein. Recognition occurs only with delay, usually after 12 months. These drugs are included in the NCE negative list (list of Swiss medicines with new active substances that are not authorized in Liechtenstein). [3] For all other drugs: The Federal Bureau for Health in Switzerland (Bundesamt für Gesundheit Gesundheit (BAG) - Federal Office of Public Health) receives applications and makes the final decision on whether to add the drug to the specialist list (SL) (positive list). Swissmedic authorizes drugs. The Swiss Federal Drug Commission (eidgenössische Arzneimittelkommission (EAK)) advises the BAG. [4] These drugs are then automatically approved in Liechtenstein by the Ministry of Health. [3]
Differentiation of rare disease treatments in the P&R system	None

Eligible medicines	All new products and indications [4] The reimbursement of orphan drugs is often limited to a special population and specific inclusion criteria or control parameters.
Process	As Liechtenstein does not have its own process for drug appraisal, the information below refers to the Swiss process: a) - In a regular and accelerated procedure, all applications will be submitted to the EAK at a meeting. - In a simple procedure, the BAG may submit requests to the EAK for comments when there are outstanding questions on effectiveness, suitability or cost-effectiveness. The BAG decides whether a request must be submitted to the EAK. (Art. 31 (3) KLV). - The EAK receives a fact sheet from the BAG four weeks before the meeting on each application. The fact sheet is based on the information in the submitted application. In it, the BAG presents the information on the application clearly, makes a summary of the most important basic data in the application and answers any specific questions posed by the BAG to the EAK. - The EAK issues a recommendation to the BAG (Article 31 (4) KLV). Applications are sent to BAG. They can be submitted six times per year, and the procedure last about 18 weeks. ** In the accelerated procedure, the BAG immediately sends applications to the EAK and compiles an appropriate fact sheet as soon as possible. In order to be able to handle a request for a meeting, it must be submitted no later than 30 days before the meeting in question. It facilitates the planning of the BAG if applications that are to be dealt with under the expedited procedure are pre-registered (ideally until the deadline for submission of applications in the ordinary procedure) (Article 31a) [5]. HTA has 3 phases: - *Assessment*: BAG assesses whether applications are transparent, include a comprehensible assessment, and correspond to the application and summary requirements of BAG - *Appraisal*: evaluation taking into account the regional /national framework conditions, as recommended by the EAK - *Decision*: actual decision. Corresponds to admission or rejection by BAG b) Reimbursement may be limited in time and for further listing in the SL a new application must be submitted, which will be evaluated as described above (a). c) After the inclusion of a drug on the SL, it is reviewed every three years to see if it still complies with the conditions of reception. [4] d) In addition to the standard process applying to all new medicines, the federal administration has launched an HTA program to re-evaluate benefits currently paid under the compulsory health insurance. The program to re-evaluate medical technologies (including pharmaceuticals) focuses on reviewing potentially obsolete technologies paid under compulsory health insurance with the goal of removing them from the catalogue of benefits or limiting insurers' liability to pay them (disinvestment). (Article 32 KVG).

Disease specific expert input (e.g. clinicians or patients in any stage of the process)	Input from experts is occasionally used for evaluation
Key domains in assessment	- Clinical-effectiveness - Cost-effectiveness - Other
Evidentiary requirements	RDTs are subject to the same evidence requirements as all other drugs.
PROMs	None
Appraisal framework	In addition to key domains, they consider: - Convenience
Reimbursement decision	The BAG generally decides on the admission (or not) on the SL within 60 days of the definitive approval by Swissmedic, provided that the application was submitted by Swissmedic before the definitive approval and all the documents were complete (Art. 31b KLV). The change in the SL is made publicly available on the 1st of a month. For administrative reasons, the latest available date is usually the 15th of the previous month. [4]
Pricing process	- External reference pricing with Denmark, Germany, the Netherlands, the UK, Austria, France, Sweden, Belgium and Finland. [6] - Comparison with other medicines (Article 65*b* KVV)
Managed entry agreements	May be used (Art. 65 abs 5 KVV)
Main challenges in appraising medicines for rare diseases (tick all that apply)	☐ X Lack of good quality clinical data ☐ Lack of real world data ☐ Introducing value for money ☐ X Monitoring treatment efficacy ☐ X Managing budget impact ☐ X Lack of criteria/transparency of OMP P&R processes ☐ X Making arrangements to work for all stakeholders ☐ X Lack of long-term meaningful outcomes ☐ Other, please specify
SOURCES	

1	https://international.commonwealthfund.org/countries/switzerland/
1=2	https://www.regierung.li/gesundheit
3	https://www.llv.li/inhalt/11591/amtsstellen/zugelassene-arzneimittel
4	https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antragsprozesse/AntragsprozessArzneimittel.html
5	https://www.admin.ch/opc/it/classified-compilation/19950275/index.htm https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/bezeichnung-der-leistungen/antragsprozesse-arzneimittel/handbuch-betreffend-die-spezialitaetenliste-gueltig-ab-01.05.2017.pdf.download.pdf/Handbuch%20betreffend%20die%20Spezialit%C3%A4tenliste%20G%C3%BCltig%20ab%2001.05.2017.pdf
6	https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html

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This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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