



Building on the Patients W.A.I.T. Indicator 2023 Survey

Switzerland Market Access Data

August 2024



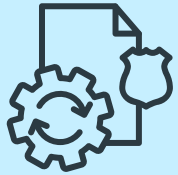


Agenda

- + **EFPIA W.A.I.T. indicator overview**
- + Status of availability in Switzerland
- + Authorisation challenge
- + Reimbursement challenge

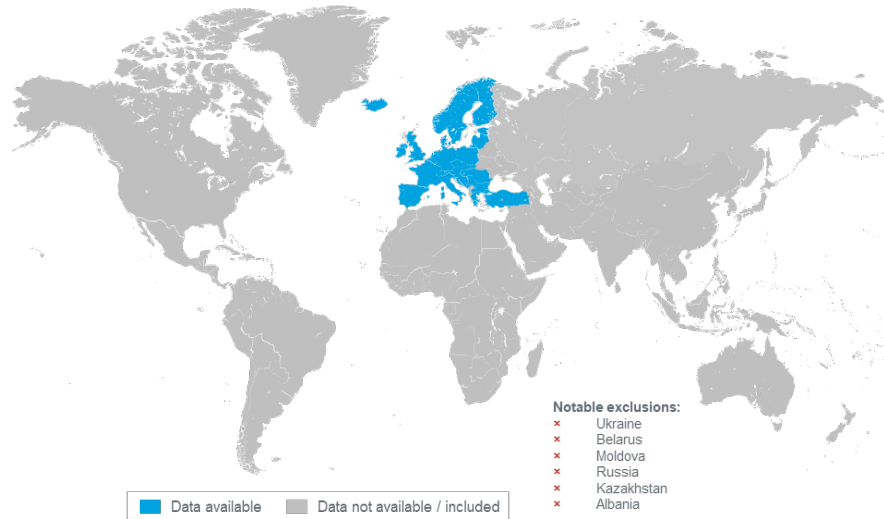
EFPIA Patients W.A.I.T. is an annual project and considered the gold-standard data source for access in European availability

Study shows the 'availability' of innovative medicines in Europe since 2004*



'W.A.I.T.'
stands for:

**Waiting to
Access
Innovative
Therapies**



36
European
countries



167
innovative
medicines



4
year cohort
published

What does it show?

1. **How many** innovative medicines are available in a country?
2. **How long** did it take from EMA or local authorization to a decision?
3. **Access nuances:** restrictions, impact of decisions, country disparities, system comparisons

*Availability is defined across all markets as: inclusion of an EMA approved medicine on the public reimbursement list in a country. Where appropriate it takes into consideration things like managed entry agreements, line-of-therapy or formulary restrictions. However, it does not have a correlation to the use / uptake of the medicines.

This study builds on the W.A.I.T. indicator, and focusses on the nuances of the system in Switzerland

STUDY AIM

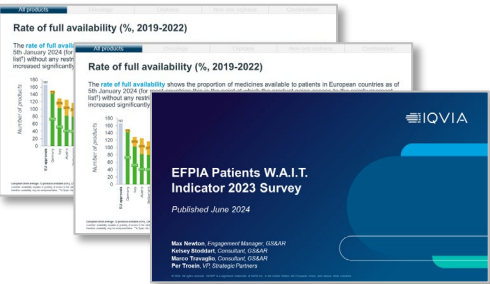
Build upon the latest results of the EFPIA W.A.I.T. Indicator and its historic data to deep-dive on the status of access to innovative medicines in Switzerland

SCOPE



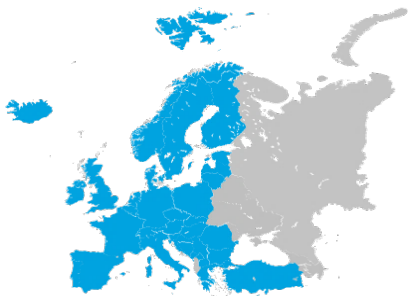
Focus on Switzerland (and key comparator countries in the European region)

Patients W.A.I.T. Indicator study



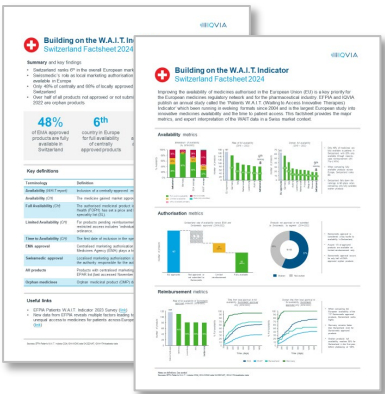
36 European countries
167 innovative medicines
4 year cohort ('19-'22)

Patients W.A.I.T. dataset



36 European countries
372 innovative medicines
9 year cohort ('14-'22)

■ Covered in Patient's W.A.I.T. ■ Not covered in Patient's W.A.I.T.



Factsheet of Swiss-specific data to facilitate discussion

It is important to align upon the key definitions of availability used in the W.A.I.T. report, and specifically for Switzerland

Key definitions

Term	Standard definition 	Swiss-specific definition 
Availability	Inclusion of a centrally-approved medicine on the public reimbursement list in a country.	› The medicine gained market approval by Swissmedic.
Full Availability	Full reimbursement through a national reimbursement system.	› The authorised medicinal product is available to all patients once the Federal Office of Public Health (FOPH) has set a price and has placed the medicinal product on the so-called speciality list (SL).
Limited Availability	Only reimbursed for restricted patient cohort.	› For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes ‘individual reimbursement’ regulated by Art. 71a-b of KVV ordinance.
Time to Availability	The first date of availability on the public reimbursement list.	› The first date of inclusion in the specialities list (full availability products only).

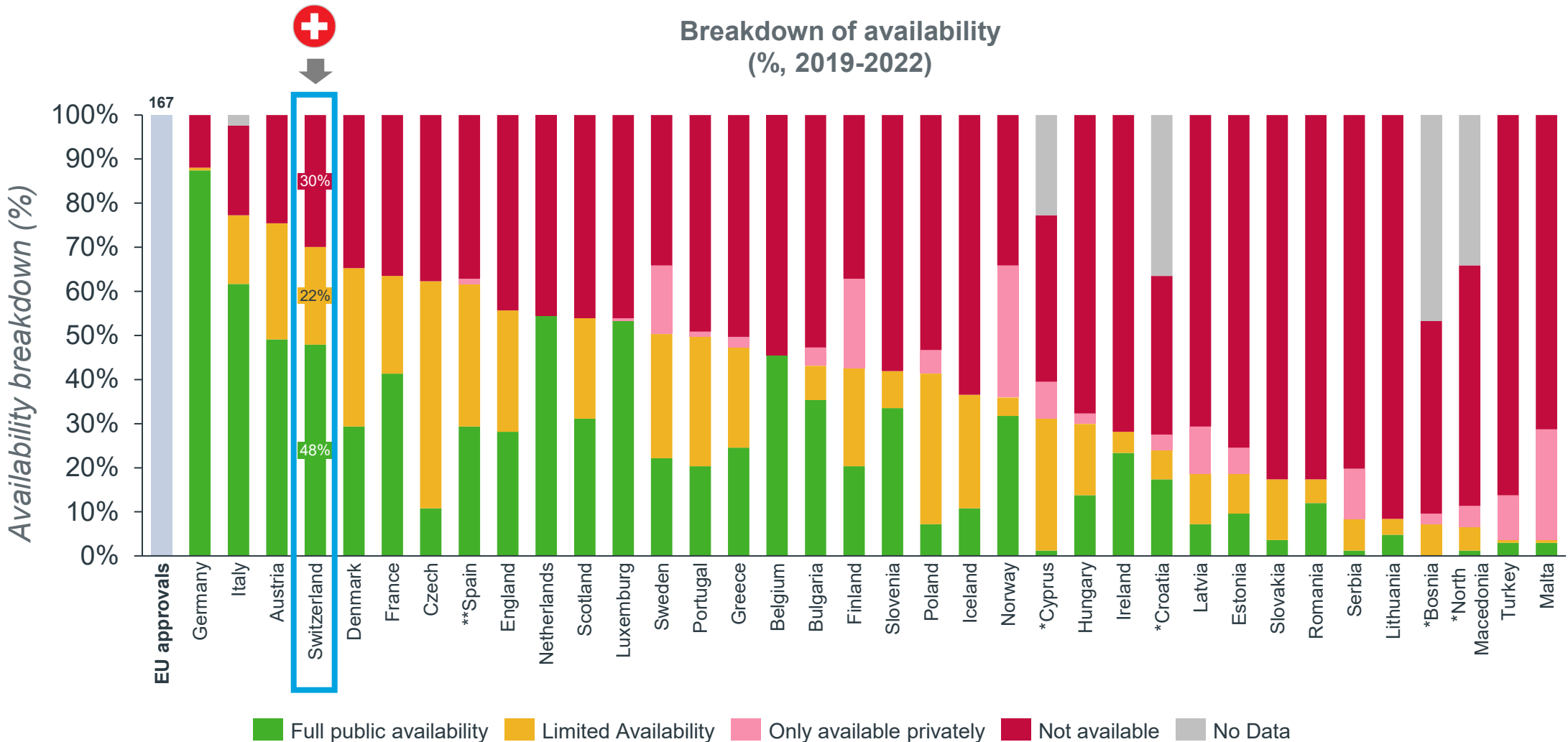
Term	Definition
EMA approval	Centralised marketing authorisation of a medicine for human use in the EU. The European Medicines Agency (EMA) plays a key role in this procedure.
Swissmedic approval	Marketing authorisation of a medicine for human use in Switzerland. Swissmedic is the authority responsible for the authorisation and supervision of therapeutic products in Switzerland.
Innovative medicines	A medicine that contains an active substance or combination of active substances that has not been authorised before.
All products	All innovative medicines with centralised marketing authorisation between 2019-2022, sourced from EMA EPAR list (accessed Nov 2023).
Orphan products	Orphan medicinal product (OMP) designation from EMA.



Agenda

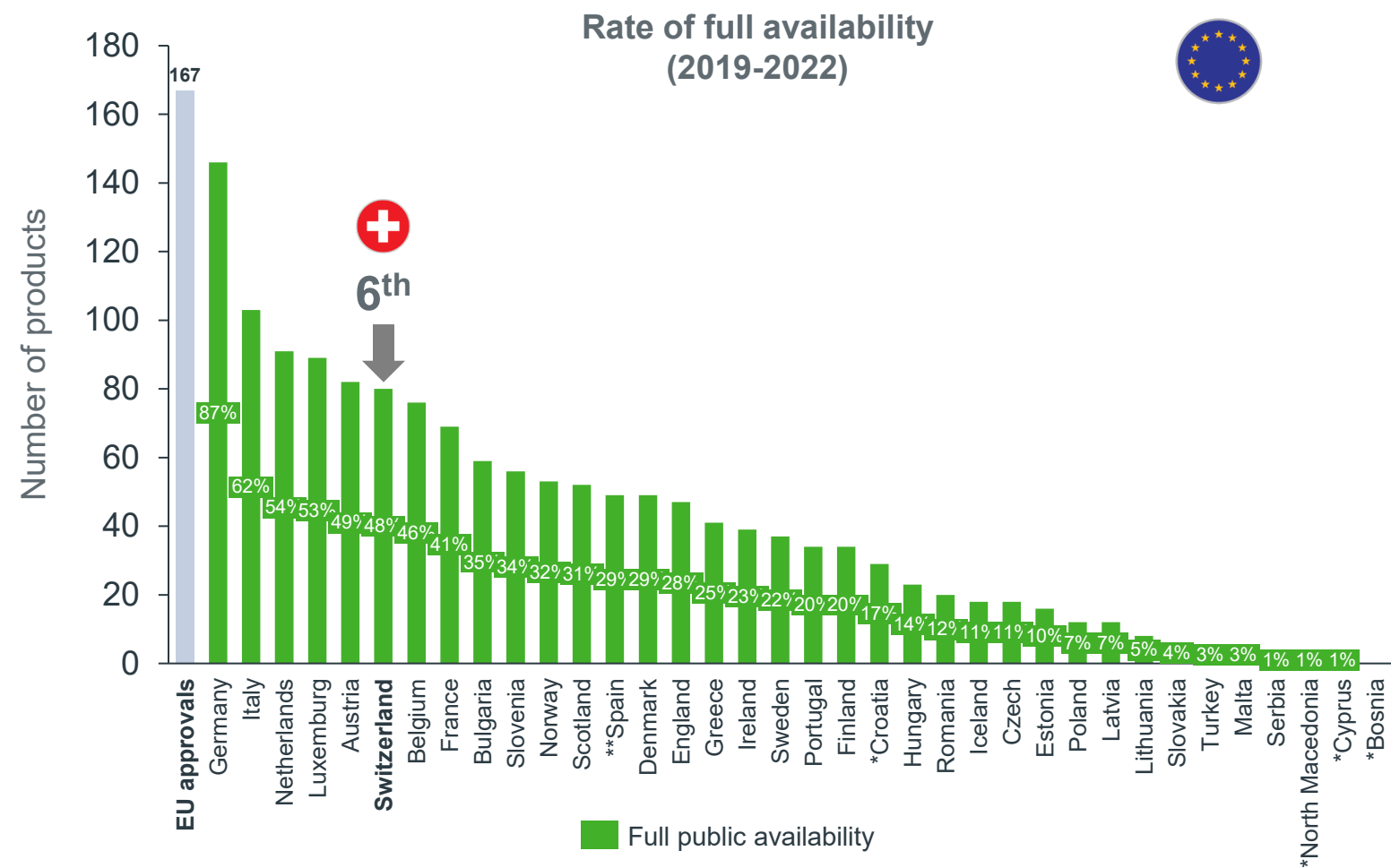
- + EFPIA W.A.I.T. indicator overview
- + **Status of availability in Switzerland**
- + Authorisation challenge
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A key KPI in the W.A.I.T. report breaks down the availability of innovative medicines across all European countries



European Union average: 72 products available (43%), Limited Availability (16% of all products) Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. ¹In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE where some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative. **In Spain, the W.A.I.T. analysis does not identify those medicinal products being accessible earlier in conformity with Spain's Royal Decree 1015/2009 relating to Medicines in Special Situations

When comparing only fully available products across Europe, Switzerland ranks 6th



Summary

- Switzerland ranks 6th when comparing only fully available products
- Switzerland ranks far behind Germany but is **well above the EU27 average** of 27% full availability

Chart details:

Scope

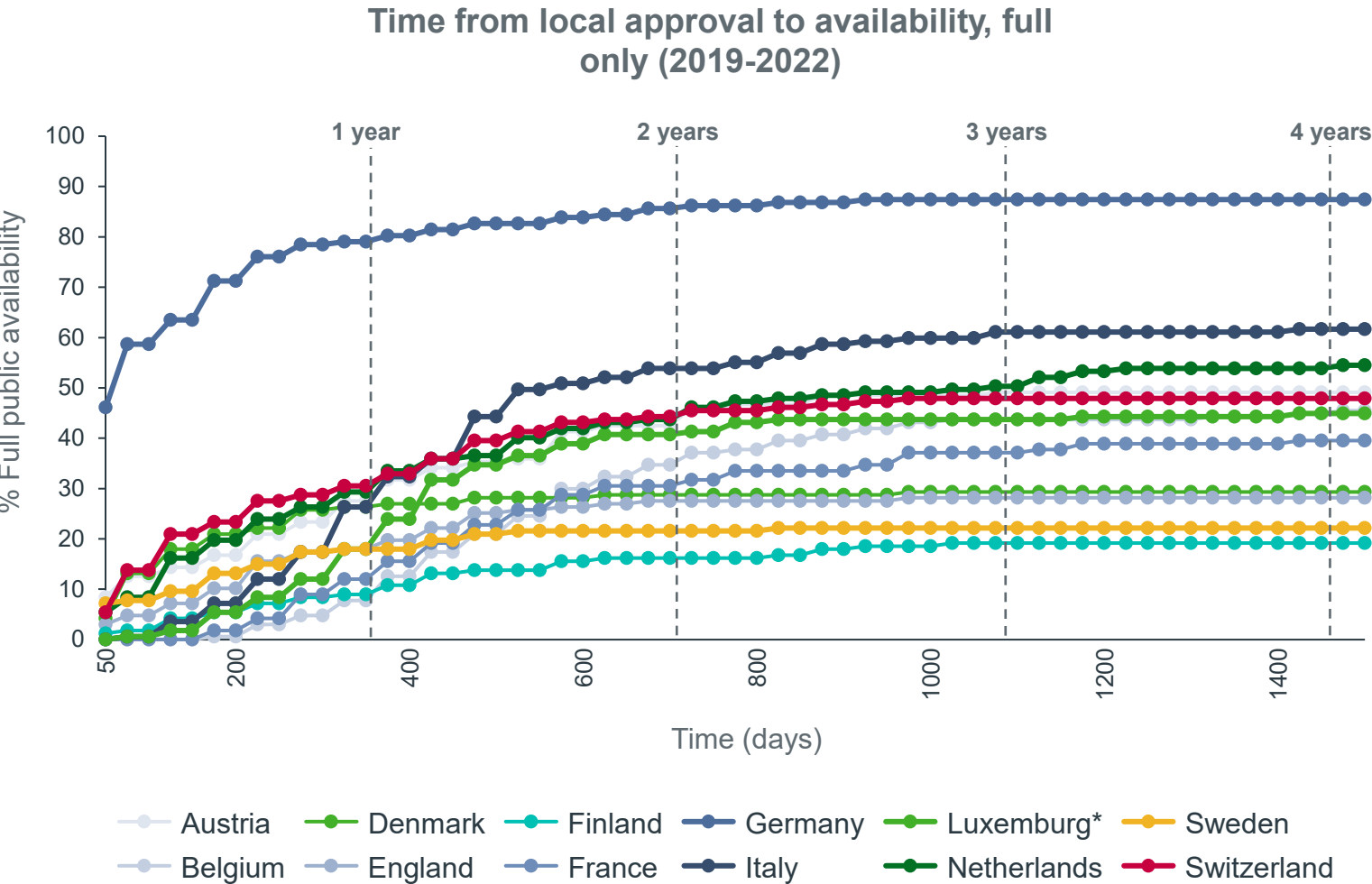
EMA approvals (n=167)

Definition

Full availability

Chart notes: Not all countries are directly comparable using full availability only. Notable exceptions include England for which medicines available through the Cancer Drugs Fund are considered as limited availability in the W.A.I.T. indicator and account for a large proportion of all available medicines. Additionally, Netherlands did not submit complete information on restrictions to available medicines meaning it is not captured in this country (all medicines classified as fully available).

In year 1, Switzerland is one of the fastest countries to make products fully available; however, the trajectory is not sustained



Summary

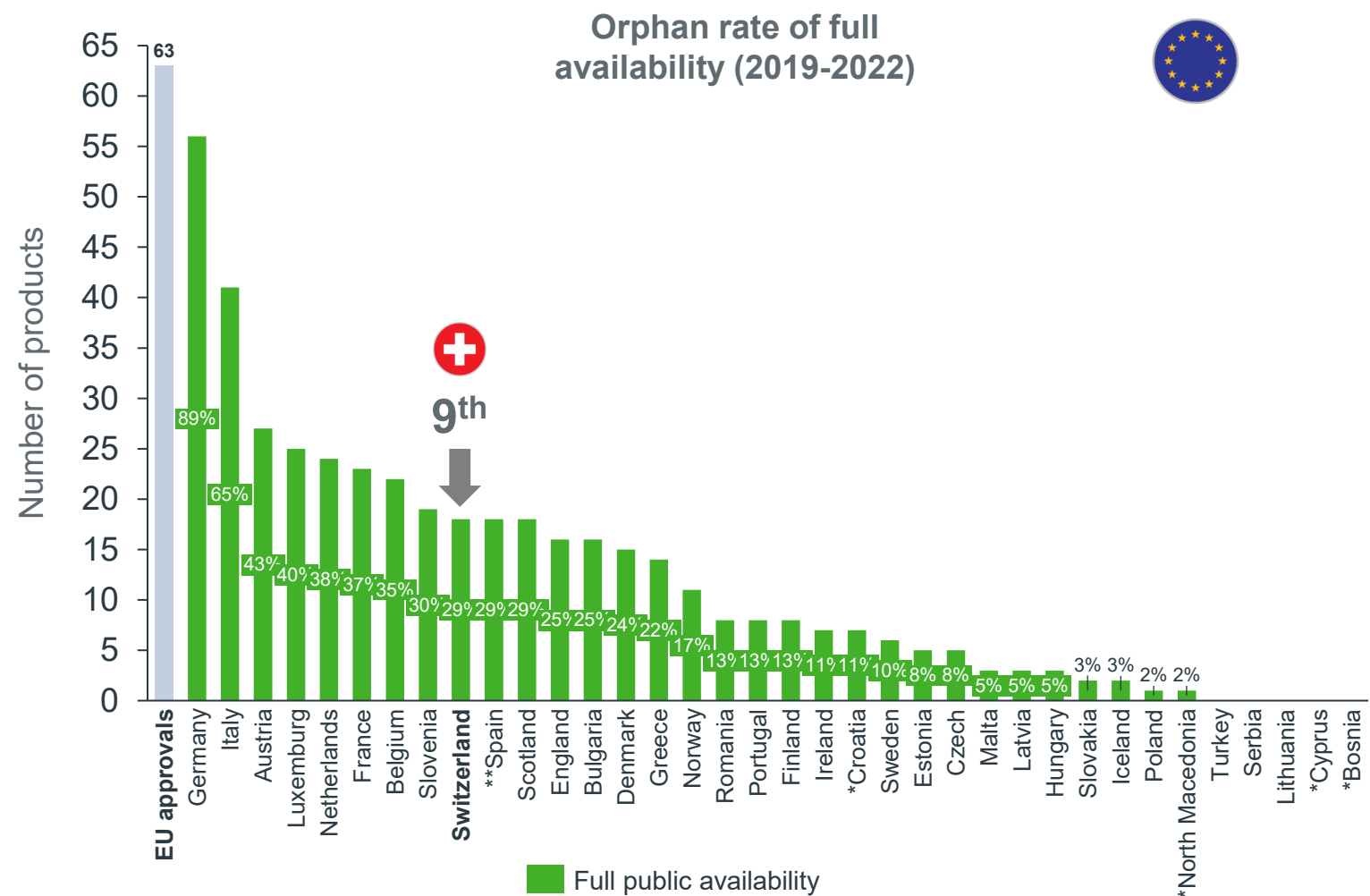
- Germany is the only country where ~80% of all EMA approvals are available within the first year
- Switzerland is the second fastest country in the first year, and then availability plateaus

Chart details:

Scope	EMA approvals (n=167)
Definition	Full availability
Approval dates	Local approval dates

*The line for Luxembourg should be higher as there are 14 available products that have been excluded from this analysis because no date of availability was provided.
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When comparing fully available orphan products across Europe, Switzerland ranks 9th, below Slovenia



Summary

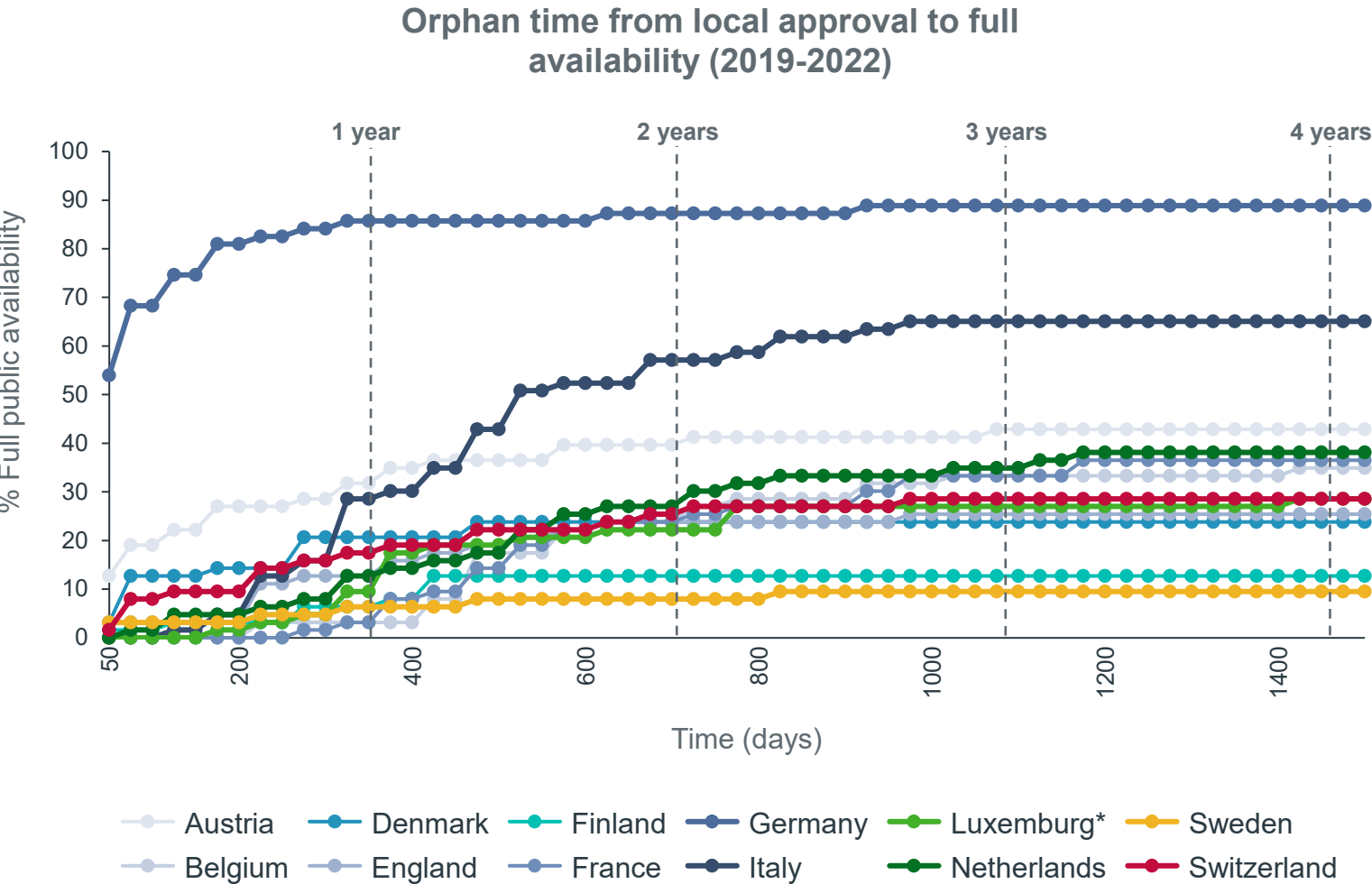
- Switzerland falls down the rankings to **9th place** when comparing only fully available orphan products
- Switzerland has a lower rate of fully available orphan products versus Slovenia

Chart details:

Scope	EMA approvals (n=63)
Definition	Full availability

Chart notes: Not all countries are directly comparable using full availability only. Notable exceptions include England for which medicines available through the Cancer Drugs Fund are considered as limited availability in the W.A.I.T. indicator and account for a large proportion of all available medicines. Additionally, Netherlands did not submit complete information on restrictions to available medicines meaning it is not captured in this country (all medicines classified as fully available).
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Orphan product availability continues to increase in comparable EU markets after 2 years, but Switzerland plateaus



Summary

- In Germany, ~70% of orphan products are fully available within 100 days
- 1 year after approval, the share of fully available orphan products is higher in most comparable markets, including Germany, Austria and Italy

Chart details:

Scope	EMA approvals (n=63)
Definition	Full availability
Approval dates	Local approval dates

*The line for Luxembourg should be higher as there are 7 available products that have been excluded from this analysis because no date of availability was provided.
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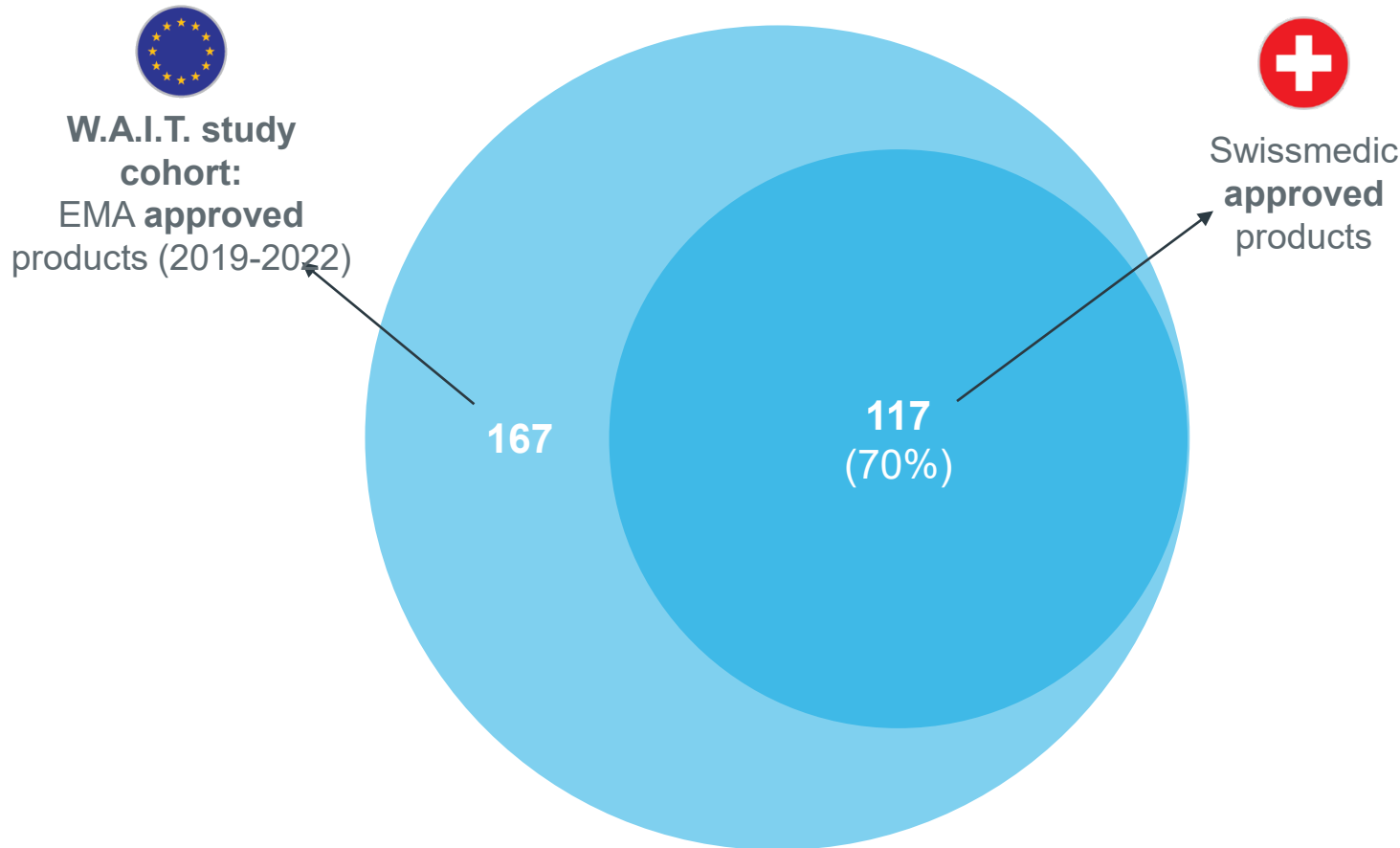


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30% of EMA approvals are not (yet) approved or not (yet) submitted in Switzerland

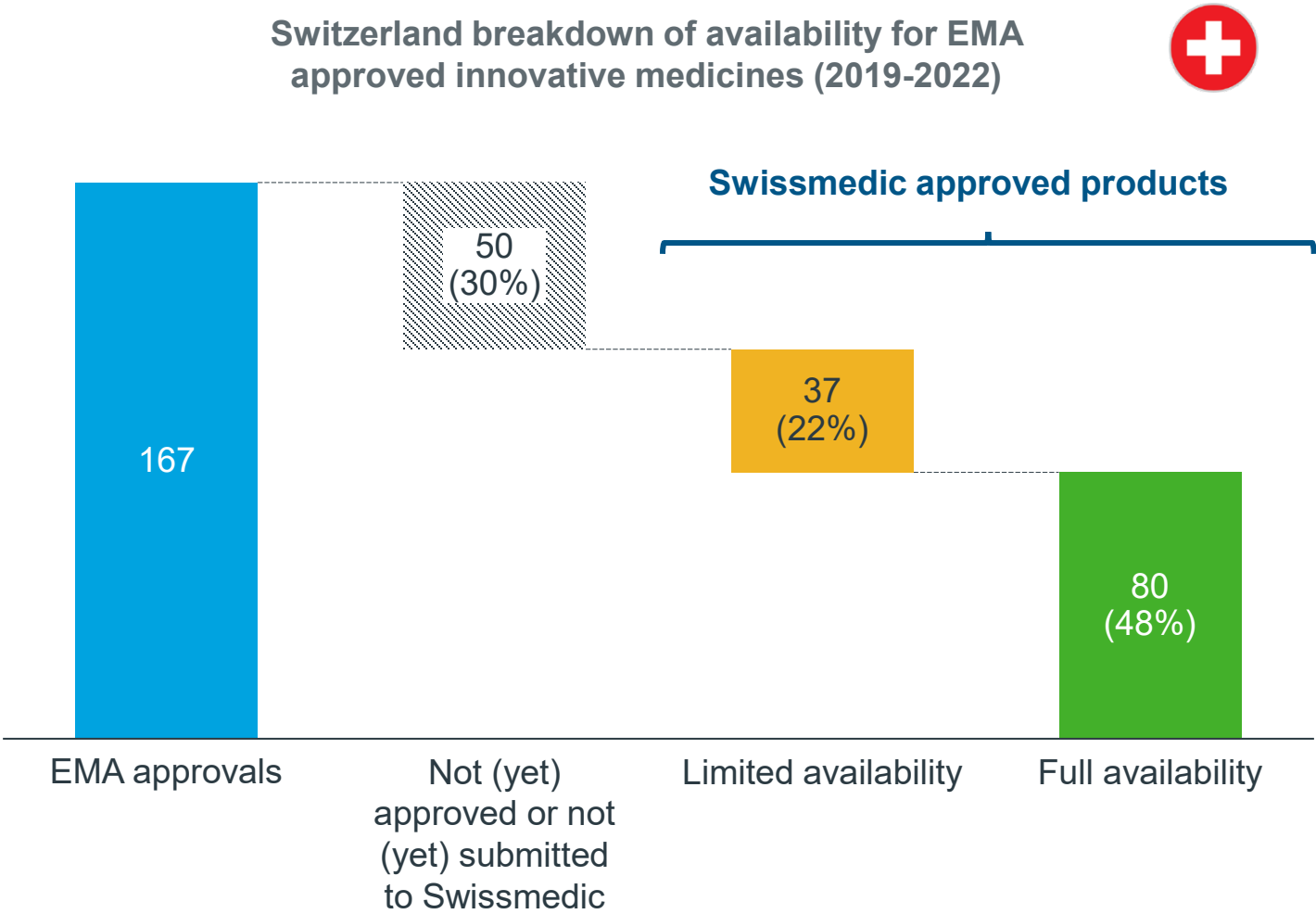
Comparison of EMA approvals (2019-2022)
and Swissmedic approvals



Summary

- Products not approved by Swissmedic have **either not (yet) been submitted by manufacturer or not (yet) been approved** by Swissmedic
- **30% of EMA approved products** (2019-2022) included in the W.A.I.T. study have either not (yet) been locally approved or not (yet) submitted to Swissmedic

Both missing Swissmedic approvals and outstanding reimbursement decisions are hurdles to availability

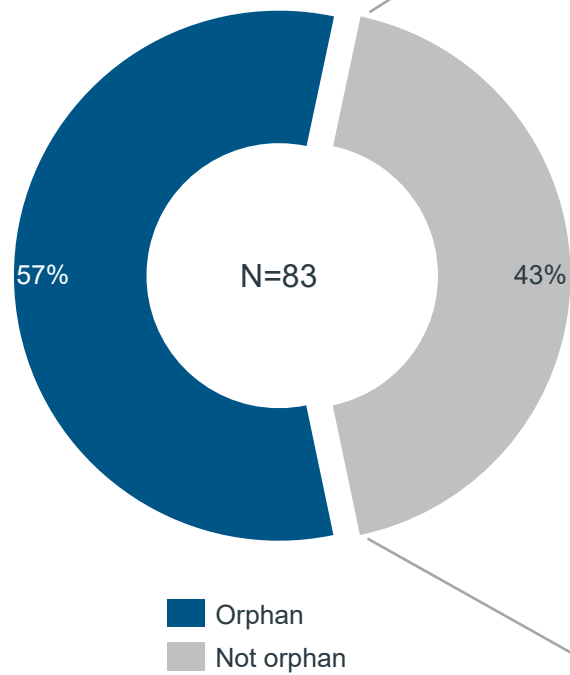


Summary

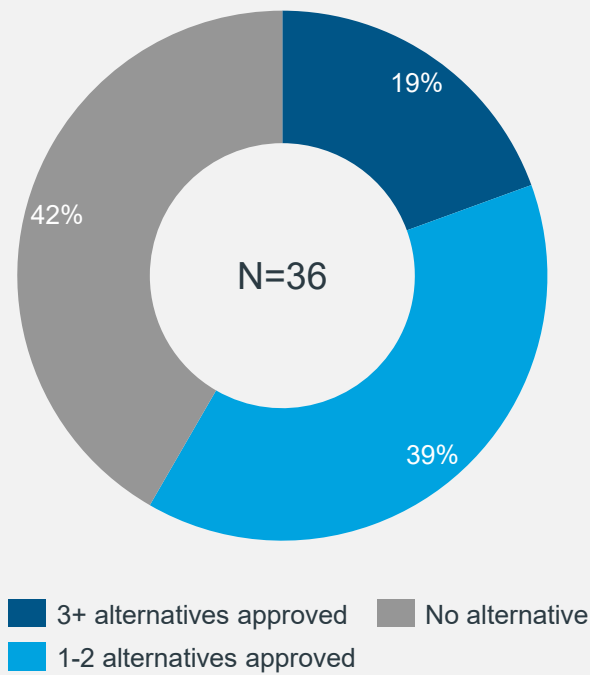
- 48% of EMA approved medicines are **fully available** for patients
- 22% of EMA approvals are only available through case-by-case reimbursement (Art 71a-b KVV)

In total, 75% of products not (yet) approved or not (yet) submitted to Swissmedic have no alternative available in Switzerland

Products not (yet) approved or not (yet) submitted to Swissmedic, by segment (2014-2022)



Breakdown of alternatives approved (non-orphan medicines, ATC4 level)*



Summary

- 57% of products not (yet) approved or not (yet) submitted to Swissmedic are orphan products, which by definition are products with **no alternative therapeutic approved**
- A further 18% non-orphan have **no alternatives approved**
- **In total, 75%** of products not (yet) approved or not (yet) submitted to Swissmedic have no alternative available

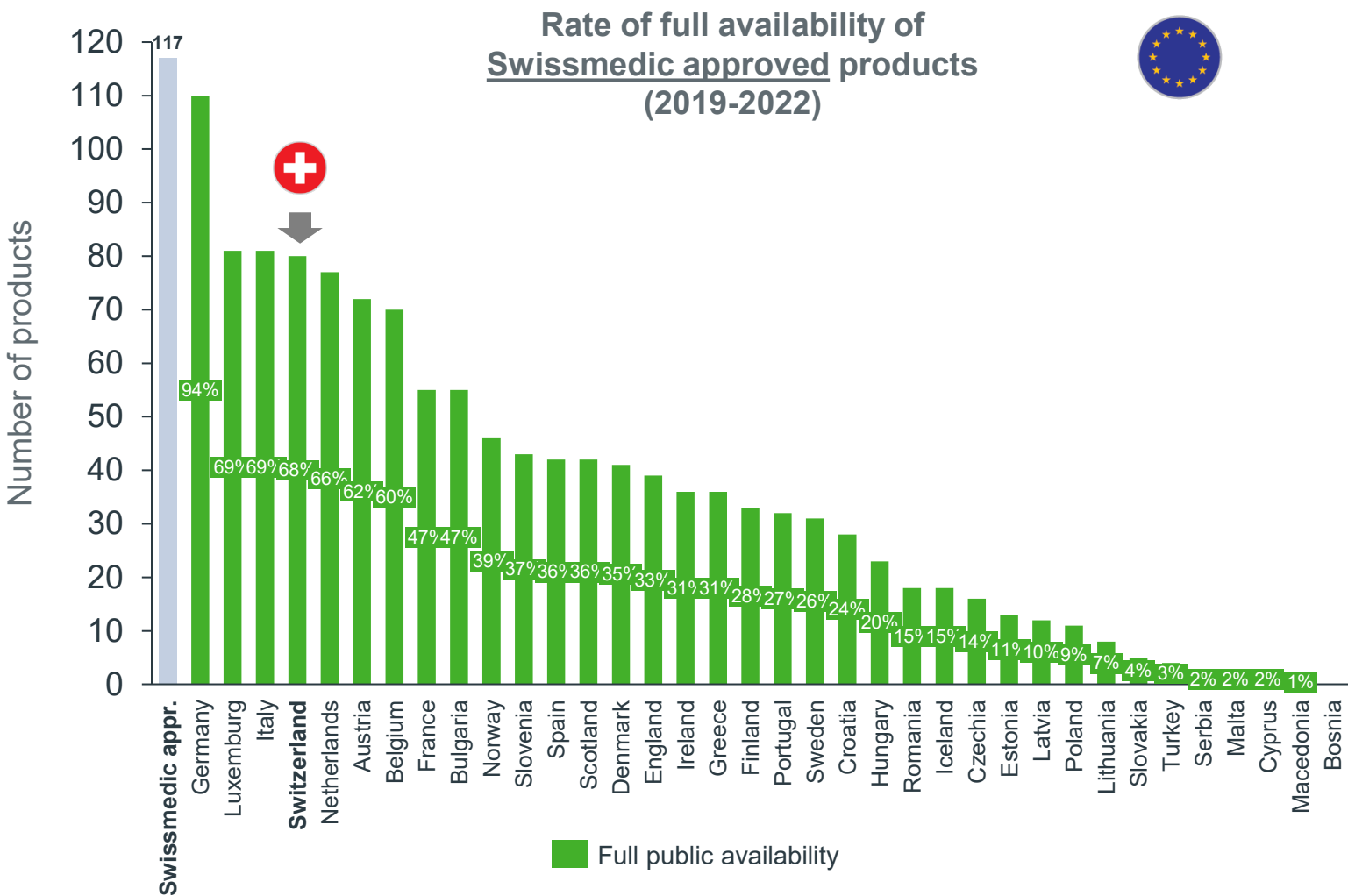
*Caveat: the analysis is based on products included in the most recent 9-year cohort (2014-2022) and does not include products that received marketing authorization before 2014 / non-innovative products.
ATC4 = A level of the Anatomical Therapeutic Chemical (ATC) classification system, in which the active substances are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
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- + **Reimbursement challenge**

Even when comparing the European availability of the 117 Swissmedic approved products, only 68% are fully available



Note

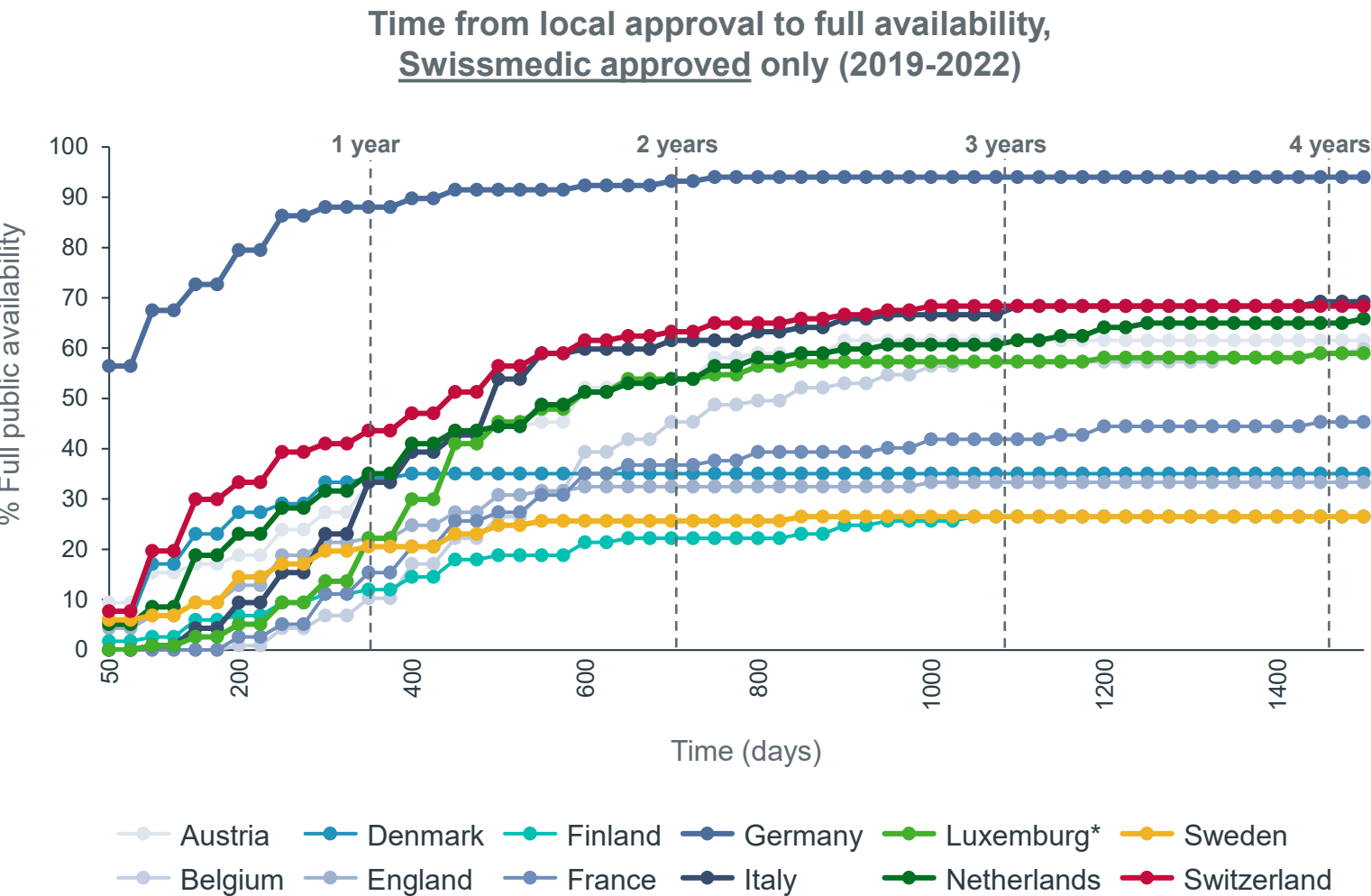
- In EU27 countries, the **average availability rate for products also approved by Swissmedic** is generally higher than for all EMA-approved products (52% compared to 43%)

Chart details:

Scope	Swissmedic (n=117)
Definition	Full availability

Chart notes: Not all countries are directly comparable using full availability only. Notable exceptions include England for which medicines available through the Cancer Drugs Fund are considered as limited availability in the W.A.I.T. indicator and account for a large proportion of all available medicines. Additionally, Netherlands did not submit complete information on restrictions to available medicines meaning it is not captured in this country (all medicines classified as fully available).
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When comparing the full availability of Swissmedic approved products, Switzerland is fast but ~30% are never fully reimbursed



Summary

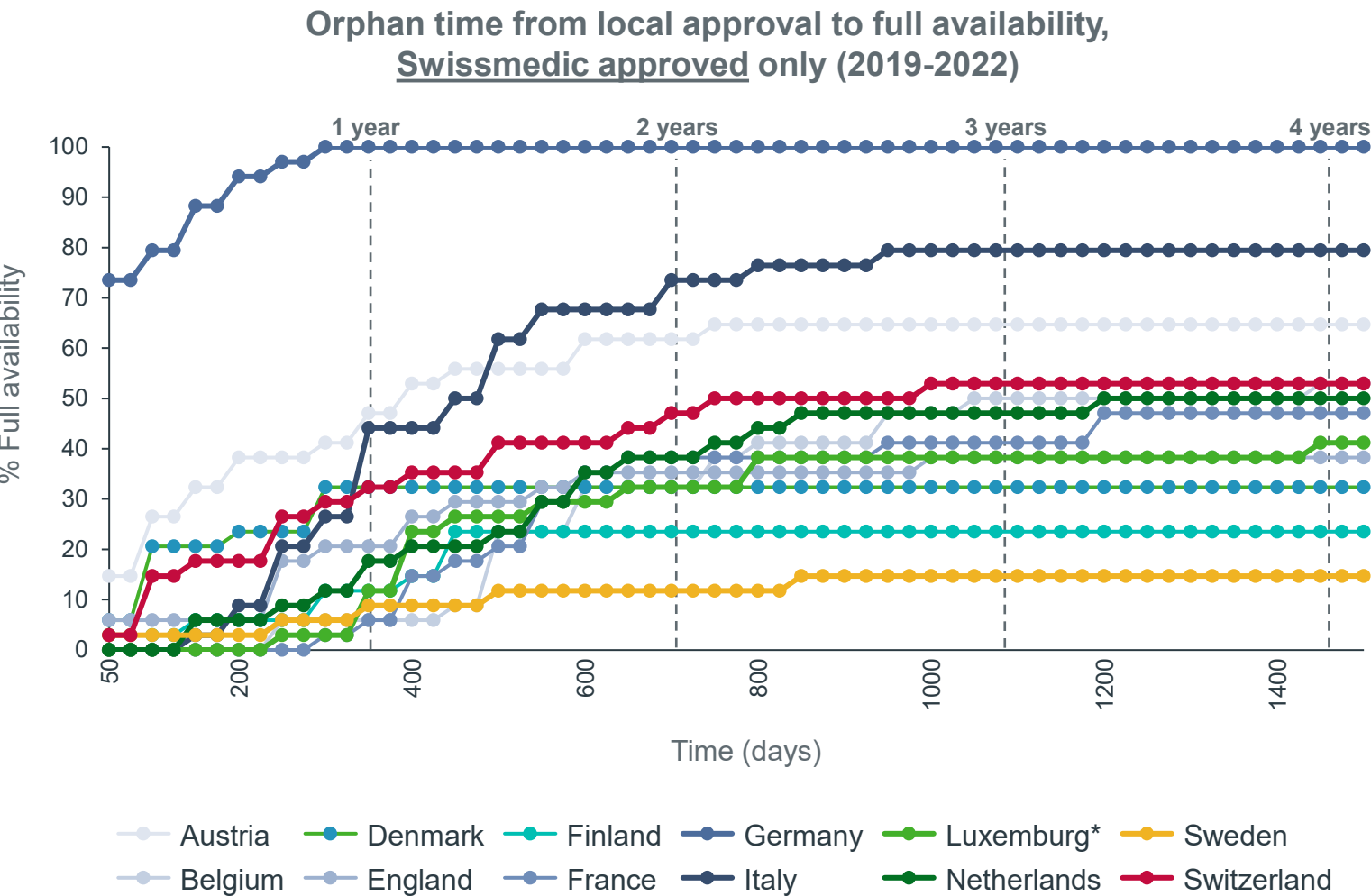
- 90% of all Swissmedic approved products are fully available in Germany 1 year after approval
- Initially, a higher share of products are available in Switzerland than in other high income countries

Chart details:

Scope	Swissmedic (n=117)
Definition	Full availability
Approval dates	Local approval dates

*The line for Luxembourg should be higher as there are 12 available products that have been excluded from this analysis because no date of availability was provided.
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Swissmedic approved orphan products' full availability reaches 30% for Switzerland in the first year, before plateauing at ~45%



Summary

- 100% of all Swissmedic approved products are fully available in Germany 1 year after approval
- Switzerland rate of full availability is among the highest in the first year, but slows down after

Chart details:

Scope	Swissmedic (n=34)
Definition	Full availability
Approval dates	Local approval dates

*The line for Luxembourg should be higher as there are 7 available products that have been excluded from this analysis because no date of availability was provided.
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