EFPIA Patients W.A.I.T. Indicator 2021 Survey: Diabetes analysis

Prepared for the EFPIA Diabetes Platform

December 2022

Agenda

+ **Study summary**

+ The Patients W.A.I.T Indicator: Diabetes
  - Rate of availability
  - Rate of full availability
  - Time to availability
  - Summary
  - Correlation to rate of diabetes complications (amputations)

This year's Patients W.A.I.T. indicator has expanded to 39 countries and now includes the full EU27 countries

New indicators have been added on rate of restrictions and time to local authorisation dates

Improving the availability of medicines authorised in the European Union (EU) is a key priority for the European medicines regulatory network and for the pharmaceutical industry. This year's iteration of the Patients W.A.I.T. (**W**aiting to **A**ccess **I**nnovative **T**herapies) Indicator has been running in evolving formats since 2004 and is the largest European study into innovative medicines availability and the time to patient access.

The charts in the following report covers an broader set of countries than in previous years. In the publication, data on 39 countries (27 EU, and 12 non-EU) are included giving a full European picture of availability.

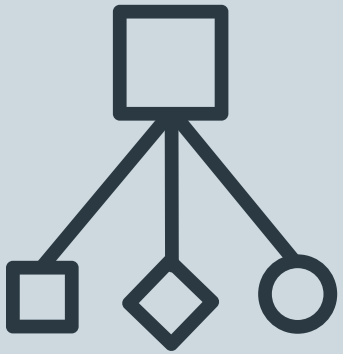
Information on the 160 innovative medicines with central-marketing authorisation between 2017 and 2020 are included within the coming pages, with a one year delay to permit countries to include these medicines on their public reimbursement list, meaning that the data on availability is accurate as of *January 1st 2022.* This period is therefore inclusive of the COVID-19 pandemic, although no significant impact is noted in the indicator the impact on uptake has been shown through other studies.

Local pharmaceutical industry associations provide the information directly to IQVIA and EFPIA, and their methods are now included within the appendix to ensure full transparency to the study.

EFPIA & the IQVIA team

The study is based on the core concept of “availability”

Definition of availability



In this study the term ‘**availability’** is used throughout to permit standarised measurement across 39 healthcare systems

“Inclusion of a centrally-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.

Country-specific nuances should be discussed with the local associations or EFPIA directly to ensure correct interpretation of the data, please see the appendix for further details.

Study summary

Full methodology and definitions by country are available in the appendix of the report

Core metrics

The Patients W.A.I.T. Indicator shows 2 main metrics for new medicines (i.e. medicines including a substance not previously available in Europe) within a 4 year rolling cohort:

1.) Rate of availability, measured by the number of medicines available to patients in European countries. For most countries this is the point at which the product gains access to the reimbursement list (this does not necessarily indicate uptake / usage).

2.) The time to availability*, measuring the average time between marketing authorisation and availability, using days from the date of marketing authorisation to the day of completion of post-marketing authorisation administrative processes (whether it is attributable to companies or competent authorities).

Availability definition

Description	Status
Full reimbursement through a national reimbursement system	Available
Full automatic reimbursement by a hospital budget (e.g. Nordic system)	
Limited reimbursement to specific subpopulations of approved indication	Available (marked LA*)
Limited reimbursement on a national named patient basis (individual patient)	
Limited reimbursement while decision is pending (where system permits)	
Availability through a special program (e.g. managed entry agreements)	
Available only within the private market at the patients expense	Only privately available
Not reimbursed, or not reimbursed while awaiting decision	Not available

Notes and caveats

Source of information: EFPIA member associations, who either refer to information available from official sources, gather the information directly from member companies or in some cases use IQVIA sales data.

Local marketing exceptions: Countries where local marketing authorisation dates are used to calculate the time to availability are: Bosnia and Herzegovina, Kazakhstan, Macedonia, Russia, Serbia, Switzerland and Turkey.

Completeness: Some country associations did not submit full datasets. Countries with substantially limited datasets are: Albania (<5% complete), Bosnia (59% complete), Croatia (34% complete), Cyprus (44% complete), Macedonia (79% complete), and Malta. This is noted on slides with an asterisk (*).

Average calculations: The EU averages noted throughout are averages for the 27 countries in the European Union. This is the first year that Cyprus, Malta, and Luxembourg have participated in the study meaning the averages use a different cohort of countries than 2020

* **The Patients W.A.I.T. Indicator is not a measurement of the delays as defined in the "Transparency" Directive (directive 89/105/EEC)**. Delays under the "Transparency" Directive reflect the number of days that national competent authorities need to make their decisions regarding price and inclusion of medicines in the positive list, where applicable. These delays do not include the time needed to prepare submissions under relevant national regulations, which may also include clock-stops for supply of additional information during the process; neither do "Transparency" Directive delays include time required to complete other formalities before a new medicine can be made available in a given country.

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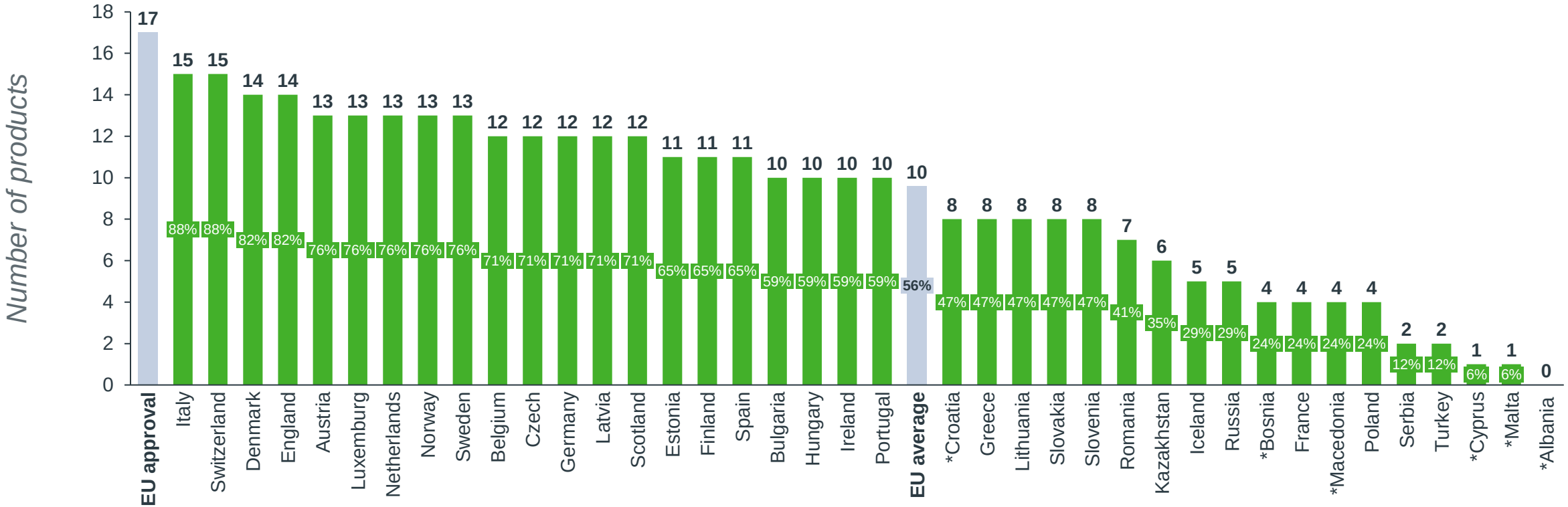
Diabetes rate of availability (2014-2020)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 1st January 2022. For most countries this is the point at which the product gains access to the reimbursement list†, including products with limited availability.

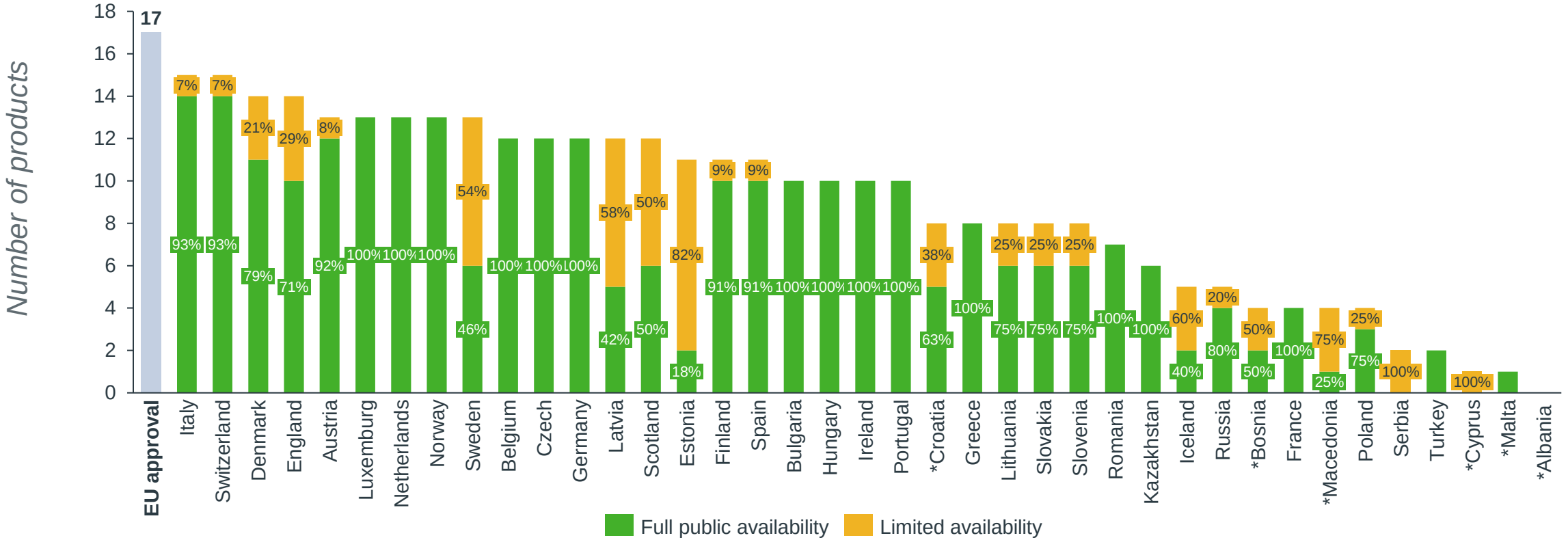


European Union average: 10 products available (56%) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

Note: The WAIT Indicator shows restrictions in availability of medicines across European countries at the national level, and does not consider differences in prescribing or regional limitations

Diabetes rate of full availability (%, 2014-2020)

The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.

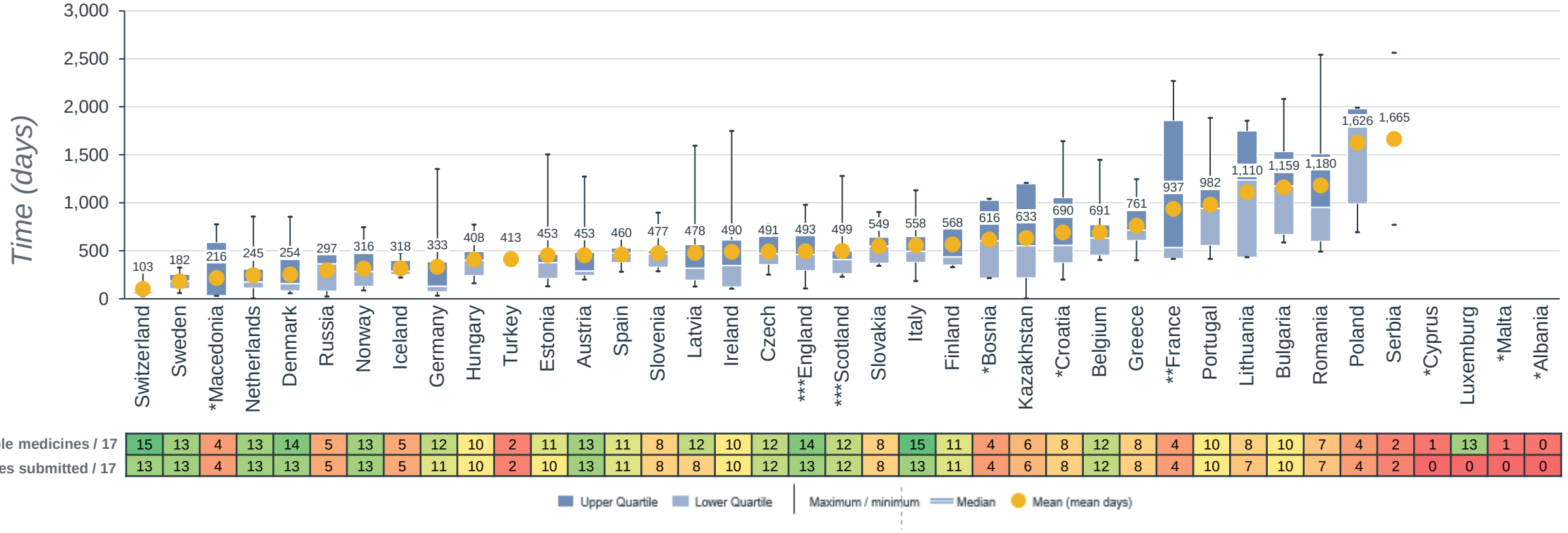


European Union average: 10 products available (56%), Limited Availability (18% of available products) Ireland, Norway and Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE 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.

Note: The WAIT Indicator shows restrictions in availability of medicines across European countries at the national level, and does not consider differences in prescribing or regional limitations

Diabetes time to availability (2014-2020)

The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 1st January 2022.



European Union average: 647 days (mean) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, LU, NO, SE 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 France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average would be lower. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

Note: The WAIT Indicator shows restrictions in availability of medicines across European countries at the national level, and does not consider differences in prescribing or regional limitations

Key observations

Executive summary, 2014-2020

Measure	EU Average for All products	EU Average for Diabetes	EU Average for Oncology	EU Average for Orphan	EU Average for Non-oncologic orphan
Rate of availability	**54%**	56%	63%	44%	38%
Average time to availability	**620 Days**	647 Days	653 Days	772 Days	790 Days

Summary:

- **No markets have all 17 products** available in their market, with Italy and Switzerland both having the highest availability of 88%
- The EU average availability and time to availability is **similar** for diabetes products and all products approved between 2014-2020
- The average delay between market authorisation and patient access for diabetes products varies from **3 months to over 53 months** (>4 years)

Metrics key:

Text colour indicates relative position versus the 2014-2020 EU average (*significantly higher than current EU average* / *significantly lower than current EU average*)

Average calculations:
Only a difference of +/- 5% (~30 days) is considered a significant change and therefore highlighted

The EU averages noted throughout are averages for the 27 countries in the European Union for the first time.

Note: The WAIT Indicator shows restrictions in availability of medicines across European countries at the national level, and does not consider differences in prescribing or regional limitations

For additional questions please contact:

Kelsey Stoddart, IQVIA
kelsey.stoddart@iqvia.com

Max Newton, IQVIA
maximilian.newton@iqvia.com

Per Troein, IQVIA
per.troein@iqvia.com