EFPIA Patients W.A.I.T. Indicator 2019 Survey

May 2020
In this study the term ‘availability’ is used throughout. The definition of ‘availability’ is as follows and should be considered when interpreting the data:

**ACCESSIBILITY ON THE PUBLIC REIMBURSEMENT LIST IN A COUNTRY**

This definition allows a standardised measure to compare across countries. 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.**
Introduction (1)

- “Patients W.A.I.T.” stands for Patients Waiting to Access Innovative Therapies. The INDICATOR provides a benchmark of the rate of availability and waiting times in European countries.

- The Patients W.A.I.T. Indicator shows, for new medicines (i.e. medicines including a substance that has not been previously available in Europe) within a (rolling) 4 year cohort:

  1. The **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.

  2. The **average time between marketing authorisation and patient access**, measured by the number of days elapsing from the date of EU marketing authorisation (or Swissmedic approval in the case of Switzerland) to the day of completion of post-marketing authorisation administrative processes.

- Source of information: EFPIA member associations, who either refer to information available from official sources or gather this information directly from member companies.

- Some country associations did not submit full datasets. Countries with substantially limited datasets were Bosnia (16% complete), Macedonia (26% complete), Serbia (40% complete). This is noted on each slide with an asterisk (*).
Introduction (2)

• The Patients W.A.I.T. Indicator gives a snapshot of the 2 parameters at a cut-off date (1\textsuperscript{st} January 2020) – data from medicines cohorts dropping out of the reference period are not included.

• Waiting times reflected in the Patients W.A.I.T. Indicator includes time to access, whether attributable to companies or to competent authorities.

• Rate of availability in a country does not necessarily indicate medicine uptake. Some medicines may be available in a market with no uptake (sales or volume).

• 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.
Method for product selection

1397

310

213

172

EMA list

• List of all historic Marketing Authorisations for human and veterinary medicines (European Public Assessment Reports) accessed November 2019
• Human medicines only

Products in scope

• Products with EMA authorisation year: 2014, 2015, 2016, 2017, 2018
• Status: Authorised, Withdrawn, Suspended
• Non-generic; Non-biosimilar
• Include combinations (both products can have already been approved before)
• Remove ATC K, V & T*

Survey cohort (5-years)

• Remove products with an active substance approved pre-2014
• New combination products (those containing already approved active substances are included)
• New formulations were excluded
• New indications of already approved active substances, leading to a separate marketing authorisation only for an orphan drug are included
• For molecules with multiple names from the same company only one molecule is included

Report cohort (4-years)

• Medicines in the 4-year rolling cohort 2015 - 2018
Study scope

• 172 products approved by EMA between 1st January 2015 to 31st December 2018

• The 2019 study provides an analysis of products approved between 2015-2016-2017-2018, for the following datasets:
  a) All 172 products: 45 in 2015, 35 in 2016, 38 in 2017, 54 in 2018
  b) 43 Oncology products: 10 in 2015, 10 in 2016, 11 in 2017, 12 in 2018
  c) 54 Orphan products: 12 in 2015, 9 in 2016, 12 in 2017, 21 in 2018
  d) 39 Non-oncologic orphan products: 9 in 2015, 7 in 2016, 7 in 2017, 16, in 2018
  e) 34 Combination products: 10 in 2015, 8 in 2016, 6 in 2017, 10 in 2018

• Definitions:
  - Orphan status from EMA (September 2019)
  - Oncology products flagged using IQVIA MIDAS Oncology market definition*
  - Combination products include any product with more than one molecule, including branded/generic combinations

• The date of availability cut off point was 1st January 2020 (to account for Estonia, Iceland, Czech Republic, Latvia, Slovakia which had a few products with a reimbursement decision on 1st January 2020).

• 34 countries included in the study (including split of UK into England and Scotland).
Definition of Availability

- The aim of the W.A.I.T. indicator is to measure the differences in time to reimbursement across European countries.
- A medicine is **available** on the market if patients can receive the medicine under a reimbursement scheme.
- The **availability date** is the first date when doctors can prescribe/hospitals can administer the medicine to patients in the country, who will be able to benefit from reimbursement conditions applicable in the country (i.e. administrative procedures to be included in the positive reimbursement list have been completed, where applicable).
- IQVIA have defined a set of “rules” to determine **market availability**:

<table>
<thead>
<tr>
<th>Reimbursement status of medicine</th>
<th>Is the medicine available?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reimbursed through the 'normal' reimbursement system</td>
<td>Available</td>
</tr>
<tr>
<td>Automatically reimbursed or financed by a different budget (e.g. hospital) or managed entry</td>
<td>Available</td>
</tr>
<tr>
<td>Reimbursed on an individual basis, and/or to a subpopulation*, and/or in some cases whilst reimbursement is pending</td>
<td>Available (LA*)</td>
</tr>
<tr>
<td>Available only within the private market at the patients expense</td>
<td>Only privately available</td>
</tr>
<tr>
<td>Not reimbursed, or pending reimbursement (excluding availability at the patients expense)</td>
<td>Not available</td>
</tr>
</tbody>
</table>

In cases where a product has been categorised as “not available”, their dates will not be included in the delay analysis; *In most countries patient access equates to granting of access to the reimbursement list, except for: hospital products in DK, FI, NO; SE some products are not covered by the general reimbursement scheme and so this shorter delay is artificially declining the median and average. LA*: product available for limited availability.*
Definition of products with limited availability

- IQVIA has differentiated between products which are reimbursed through the regular process in a country, and products with “limited availability” (LA)

- Products with LA have **special reimbursement conditions**, where reimbursement is only granted for certain patients, indications, or only through special programs (e.g. early access schemes)

- Restricted or optimised recommendations may be due to either the company or HTA body

- Products which have been reimbursed with the following criteria are marked as “Available”, however have been flagged in the “Rate of Availability %” charts:

<table>
<thead>
<tr>
<th>Reimbursement conditions for medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restricted patient cohort (specific populations)</td>
</tr>
<tr>
<td>Individual reimbursement (case by case / named patient program)</td>
</tr>
<tr>
<td>Special programs (e.g. early access scheme)*</td>
</tr>
</tbody>
</table>
Definition of Availability

For most countries a product is available if it gains access to the national reimbursement list.

For countries where this differs, the definition of Availability is below:

- Austria: A medicine is available if it is included in the reimbursement system (EKO) or available through the Austrian pharmacies list.
- Belgium: Medicine is available if it is listed on the official website of INAMI-RIZIV as a definitive reimbursement or as a temporary reimbursement (code T) under a Managed Entry Agreement.
- Czech Republic: A medicine is available if it is on the reimbursement list, or funded through the hospital.
- England: Medicines are deemed available if NICE has issued a positive recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
- Estonia: A pharmacy product is available if it is reimbursed (pharmacy products) or added to the hospital service list.
- Finland: A pharmacy product is available if it is reimbursed (pharmacy products). Hospital products become available straight away.
- Germany: Following marketing authorisation, prescription drugs automatically receive reimbursed status. These products are classified as available.
- Hungary: Medicines are either reimbursed through the "normal" reimbursement system, are available through a Name Patient Program or are available but financed by the hospital budget.
- Lithuania: A medicine is available if it is on the Lithuanian market (the State Medicines Control Agency has data on the sales volume of this medicinal product).
- North Macedonia (referred to as Macedonia in the slides): The medicine is included on the positive drug list or reimbursement list. No new medicines have been included on the reimbursement list for the past 10 years.
- Norway: The medicine has received a positive reimbursement decision by NoMA (out-patient drugs), or the Decision Forum for New Technologies has recommended the introduction of the new drug into hospitals (hospital drugs).
- Scotland: Medicines are deemed available if SMC has issued a positive recommendation. For the remaining medicines, IQVIA sales data are analysed to determine if routinely available.
- Slovakia: Primary data source used is National Health Information Center, but where not available, consumption data recorded through IQVIA is used.
- Slovenia: A medicine is available if it is reimbursed through the regular system, or automatically reimbursed (e.g. all medicines for TBC).
- Sweden: A medicine is classified as available if it is currently marketed in Sweden (listed supplied FASS), and has received either: (a) a positive TLV reimbursement decision (non hospital drug), (b) a positive NT recommendation (hospital drug), (c) lacks an NT recommendation but is assessed to have a relevant level of sales based on rough estimation number patients treated in relation to the size of the patient population (hospital drug), or (d) is indicated in the treatment of a communicable disease (i.e. reimbursement decision/NT recommendation not requirement).
- Switzerland: The medicine gained market approval by Swissmedic. Delay calculated using local market authorisation dates.
- Turkey: A medicine is available if it gains access to the reimbursement list.
For most countries a product has limited availability if a restriction is placed upon the SmPC

Definition of Limited availability (LA)

For countries with specific considerations, the definition of Limited availability is below:

- Austria: Products only reimbursed on an individual basis
- Croatia: Products are available for specific patient cohorts (reimbursement guidelines outline specific criteria describing patient eligibility for treatment).
- Czech Republic: Only reimbursed for limited indications (compared to what was approved at market authorisation)
- Denmark: Products which don’t automatically receive public reimbursement, however, the patient can obtain an individual reimbursement if the doctors apply on their behalf.
- England: Recommended for a restricted patient cohort relative to licensed indication, either through an optimised NICE decision (including optimised CDF decisions) or an individual funding request
- Estonia: Only reimbursed for restricted patient cohort.
- France: Some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations
- Greece: Only reimbursed for restricted patient cohort, or by case by case reimbursement if the responsible committee judges its use necessary.
- Hungary: Medicine is pending reimbursement decision or has not been reimbursed, but is available through a Name Patient Program.
- Iceland: Products are available to the patients with full reimbursement, but only through individual reimbursement, which can be applied for on individual basis by the patient’s doctor.
- Ireland: Only reimbursed for restricted patient cohort
- Latvia: Only available through individual reimbursement
- Lithuania: Only reimbursed for limited indications (compared to what was approved at market authorisation)
- Netherlands: Only reimbursed under certain therapeutic conditions (annex 2 on the positive reimbursement list).
- Norway: Only reimbursed for restricted patient cohort
- Poland: Only reimbursed for limited indications (compared to what was approved at market authorisation)
- Portugal: Product is only available on a patient by patient basis and after an Exceptional Authorisation has been granted
- Scotland: Recommended for a restricted patient cohort relative to licensed indication through restricted SMC recommendation
- Serbia: Products are reimbursed with significant restrictions. Sometimes these restrictions are based on number of patients (e.g. for new generation HepC medicines, there is a cap on only 60 patients per year), sometimes on the number of indications, or there is some other limit.
- Slovakia: Drugs included in the Reimbursement List have some limitation (prescription limitation, indication limitation and limitation based on prior insurance company approval), or are reimbursed for individual patients
- Slovenia: Only reimbursed for restricted patient cohort
- Spain: Only reimbursed for restricted patient cohort
- Sweden: Only reimbursed for restricted patient cohort
- Switzerland: For products pending reimbursement, patients have restricted reimbursement access. Such restricted access includes ‘individual reimbursement’ regulated by Art. 71a-d of KVV ordinance.
- Turkey: Products only available through a “Named Patient Scheme”. These medicines do not require TITCK (Turkish Medical Agency) approval but are reimbursed.
Visual of the limited availability definition

Comparable across markets and highlights major restrictions

- Hospital restrictions
- Price volume agreements
- Limited subpopulation
- Partial access during decision pending
- Individual basis / Named Patient Population

Indirect restrictions
(e.g. care setting, specialist usage, or confidential managed entry agreements)

Direct patient availability restrictions
(e.g. restrictions of eligible patients upon Summary of Product Characteristics)

Definition of Limited Availability
All medicines

Availability by approval year ➔ Rate of availability ➔ Channels of availability ➔ Time to availability
Total availability by approval year (2015 - 2018)

The total of availability by approval year is 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*) split by the year in which the EMA granted marketing authorisation.
Rate of availability (2015 – 2018)

The rate of availability is 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*), inc. limited availability.
Rate of availability (% 2015 – 2018)

The rate of availability is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.
Time to availability (2015 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).

*Serbia

Netherlands

Bulgaria

Switzerland

Denmark

Poland

Germany

Austria

Spain

Turkey

Belgium

Italy

Greece

Ireland

**France

**Macedonia

*** England

***Scotland

* Macedonia

Turkey

**Macedonia

Spain

Iceland

Switzerland

Estonia

Czech

Portugal

Lithuania

Belgium

**Macedonia

Northern Ireland

Romania

Norway

Albania

Hungary

Slovakia

Croatia

Austria

Finland

Croatia

Iceland

Sweden

Finland

Italy

Spain

Turkey

Belgium

**Macedonia

Estonia

Czech

Portugal

***Scotland

**Macedonia

Sweden

Finland

Italy

Spain

Turkey

Belgium

**Macedonia

Estonia

Czech

Portugal

***England

*** Scotland

**Macedonia

*** England

*** Scotland

**Macedonia

*** England

*** Scotland
Median time to availability (2015 – 2018)

The time to availability (previously known as length of delay) is the days between EMA 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*).
All medicines study comparison

Rate of availability 2018 vs 2019 W.A.I.T study  Time to availability 2018 vs 2019 W.A.I.T study
Comparison of availability (2018 study vs 2019 study)

The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019, compared to the rate of availability in the 2018 W.A.I.T. indicator study.

The table below shows the **Delta in % availability** (2018 / 2019) for each country.

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>86</td>
<td>84</td>
<td>-2%</td>
</tr>
<tr>
<td>Denmark</td>
<td>83</td>
<td>84</td>
<td>1%</td>
</tr>
<tr>
<td>Austria</td>
<td>81</td>
<td>81</td>
<td>0%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>74</td>
<td>77</td>
<td>3%</td>
</tr>
<tr>
<td>Finland</td>
<td>72</td>
<td>72</td>
<td>0%</td>
</tr>
<tr>
<td>Italy</td>
<td>60</td>
<td>67</td>
<td>7%</td>
</tr>
<tr>
<td>France</td>
<td>67</td>
<td>67</td>
<td>0%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>69</td>
<td>69</td>
<td>0%</td>
</tr>
<tr>
<td>Sweden</td>
<td>63</td>
<td>63</td>
<td>0%</td>
</tr>
<tr>
<td>Norway</td>
<td>59</td>
<td>62</td>
<td>3%</td>
</tr>
<tr>
<td>Spain</td>
<td>58</td>
<td>62</td>
<td>4%</td>
</tr>
<tr>
<td>Belgium</td>
<td>56</td>
<td>53</td>
<td>-3%</td>
</tr>
<tr>
<td>Portugal</td>
<td>43</td>
<td>51</td>
<td>8%</td>
</tr>
<tr>
<td>Ireland</td>
<td>42</td>
<td>45</td>
<td>3%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>45</td>
<td>42</td>
<td>-3%</td>
</tr>
<tr>
<td>Czech</td>
<td>36</td>
<td>42</td>
<td>6%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>45</td>
<td>42</td>
<td>-3%</td>
</tr>
<tr>
<td>Croatia</td>
<td>14</td>
<td>14</td>
<td>0%</td>
</tr>
<tr>
<td>Greece</td>
<td>40</td>
<td>34</td>
<td>-16%</td>
</tr>
<tr>
<td>Hungary</td>
<td>38</td>
<td>38</td>
<td>0%</td>
</tr>
<tr>
<td>Iceland</td>
<td>34</td>
<td>40</td>
<td>6%</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>33</td>
<td>33</td>
<td>0%</td>
</tr>
<tr>
<td>Estonia</td>
<td>31</td>
<td>24</td>
<td>-7%</td>
</tr>
<tr>
<td>Poland</td>
<td>20</td>
<td>18</td>
<td>-11%</td>
</tr>
<tr>
<td>Latvia</td>
<td>18</td>
<td>16</td>
<td>-13%</td>
</tr>
<tr>
<td>Turkey</td>
<td>13</td>
<td>12</td>
<td>-8%</td>
</tr>
<tr>
<td>Lithuania</td>
<td>5</td>
<td>5</td>
<td>0%</td>
</tr>
<tr>
<td>Serbia</td>
<td>3</td>
<td>5</td>
<td>2%</td>
</tr>
</tbody>
</table>

*Note: Delta in % availability is calculated as (2019 availability - 2018 availability) / 2018 availability.*
Comparison of time to availability (2018 study vs 2019 study)

The time to availability (previously know as length of delay) is the days between EMA marketing authorisation and the date of availability to patients compared to the rate of availability in the 2018 W.A.I.T. indicator study.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>119</td>
<td>127</td>
<td>8</td>
</tr>
<tr>
<td>Denmark</td>
<td>146</td>
<td>164</td>
<td>18</td>
</tr>
<tr>
<td>Netherlands</td>
<td>158</td>
<td>220</td>
<td>62</td>
</tr>
<tr>
<td>Sweden</td>
<td>269</td>
<td>252</td>
<td>-17</td>
</tr>
<tr>
<td>Finland</td>
<td>281</td>
<td>269</td>
<td>-12</td>
</tr>
<tr>
<td>Austria</td>
<td>298</td>
<td>307</td>
<td>9</td>
</tr>
<tr>
<td>Turkey</td>
<td>392</td>
<td>292</td>
<td>-100</td>
</tr>
<tr>
<td>Spain</td>
<td>414</td>
<td>402</td>
<td>-12</td>
</tr>
<tr>
<td>Italy</td>
<td>436</td>
<td>436</td>
<td>0</td>
</tr>
<tr>
<td>Greece</td>
<td>439</td>
<td>439</td>
<td>0</td>
</tr>
<tr>
<td>Belgium</td>
<td>417</td>
<td>446</td>
<td>29</td>
</tr>
<tr>
<td>Slovenia</td>
<td>401</td>
<td>452</td>
<td>51</td>
</tr>
<tr>
<td>Iceland</td>
<td>492</td>
<td>512</td>
<td>20</td>
</tr>
<tr>
<td>Croatia</td>
<td>517</td>
<td>517</td>
<td>0</td>
</tr>
<tr>
<td>Latvia</td>
<td>486</td>
<td>521</td>
<td>35</td>
</tr>
<tr>
<td>Ireland</td>
<td>522</td>
<td>492</td>
<td>-28</td>
</tr>
<tr>
<td>Norway</td>
<td>522</td>
<td>566</td>
<td>44</td>
</tr>
<tr>
<td>France</td>
<td>512</td>
<td>634</td>
<td>122</td>
</tr>
<tr>
<td>Hungary</td>
<td>517</td>
<td>596</td>
<td>80</td>
</tr>
<tr>
<td>Slovakia</td>
<td>486</td>
<td>634</td>
<td>148</td>
</tr>
<tr>
<td>Estonia</td>
<td>333</td>
<td>603</td>
<td>270</td>
</tr>
<tr>
<td>Czech</td>
<td>492</td>
<td>618</td>
<td>126</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>512</td>
<td>682</td>
<td>170</td>
</tr>
<tr>
<td>Portugal</td>
<td>612</td>
<td>687</td>
<td>55</td>
</tr>
<tr>
<td>Lithuania</td>
<td>449</td>
<td>711</td>
<td>262</td>
</tr>
<tr>
<td>Serbia</td>
<td>119</td>
<td>547</td>
<td>429</td>
</tr>
<tr>
<td>Poland</td>
<td>925</td>
<td>812</td>
<td>207</td>
</tr>
</tbody>
</table>

*Delta in days represents the difference in days between the two studies for each country.
Key observations

All medicines

• **Patient access to new medicines is highly varied across Europe**, with the greatest rate of availability in Northern and Western European countries and lowest in Southern and Eastern European countries.

• In some countries, up to 30% of products are available and reimbursed but with specific conditions.

• The average delay between market authorisation and patient access can **vary by a factor greater than x 6 across Europe**, with patients in Northern/Western Europe accessing new products 100 - 350 days after market authorisation and patients mainly in Southern/Eastern Europe between 600-850 days.

• **Even within a country there is a large variation in the speed of patient access** to different products. Often the level of variation within a country is greater than between countries e.g. shortest versus longest delays in Scotland (159 vs. 1789 days), Austria (24 vs. 1689 days) and Estonia (52 vs. 1657 days).

• **Comparison to 2018 W.A.I.T. indicator study**: of the countries overlapping both analyses, 54% countries have a higher rate of availability, although 93% countries have a longer delay in the 2019 study.
Oncology medicines

Availability by approval year ★ Rate of availability ★ Channels of availability ★ Time to availability
Oncology availability by approval year (2015 - 2018)

The **total of availability by approval year** is 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*) split by the year in which the EMA granted marketing authorisation.

*The point at which the product gains access to the reimbursement list refers to the year in which the EMA granted marketing authorisation.
Oncology rate of Availability (2015 - 2018)

The rate of availability, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability
Oncology rate of availability (%, 2015 – 2018)

The rate of availability is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.

![Oncology rate of availability chart]

- **Full public availability**
- **Limited Availability**
- **Only available privately**
- **Not available**
- **Not submitted by association**
Oncology time to availability (2015 – 2018)

The time to availability (previously known as length of delay) is the days between EMA 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*).
Oncology median time to availability (2015 – 2018)

The time to availability (previously known as length of delay) is the days between EMA 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*).
Key observations

**Oncology medicines**

- Patient access to new Oncology medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.

- In 88% of the countries, the rate of availability is **higher for Oncology products** compared to all products approved between 2015-2018.

- In Germany, France, England, Netherlands, Belgium, Bulgaria, and Romania, the availability of oncology medicines is more than 10% above the rate of all medicines approvals.

- Limited availability is prevalent within the oncology medicines with over 20% of oncology medicines having a restriction placed upon them after SmPC in England (40%), Sweden (26%), Scotland, (21%), and Poland (21%).

- The average delay between market authorisation and patient access for Oncology products varies 2.5 months to over 2.5 years.
Orphans medicines

Availability by approval year  Rate of availability  Channels of availability  Time to availability
Orphan availability by approval year (2015 - 2018)

The **total of availability by approval year** is 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*) split by the year in which the EMA granted marketing authorisation.

*Indicates the point at which the product gains access to the reimbursement list. The total availability includes the EMA approvals and any additional approvals by individual countries.
The **rate of availability**, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability.
Orphan rate of availability (%, 2015 – 2018)

The rate of availability is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.
Orphan time to availability (2015 – 2018)

The time to availability (previously known as length of delay) is the days between EMA 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*).
Orphan median time to availability (2015 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).
Key observations

Orphan drugs

• Patient access to new Orphan medicines is highly varied across Europe, with the greatest rate of availability in Northern and Western European countries.

• In over 80% of the countries, the rate of availability is lower for Orphan drugs compared to all products approved between 2015-2018

• Only in Germany, England, Switzerland, Greece, and France is the rate of orphan medicines availability higher than all products approved 2015 - 2018

• Almost 80% of the countries have a longer average delay to EMA authorisation for Orphan drugs compared to all products approved 2015-2017

• The average delay between market authorisation and patient access for Orphan drugs is between 3.7 months to 3.2 years

• 15% of all countries studied do not have access to any of the orphan medicines approved between 2015 and 2018
Non-oncology orphans medicines

Availability by approval year › Rate of availability › Channels of availability › Time to availability
Non-oncology orphan availability by approval year (2015 - 2018)

The total of availability by approval year is 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*) split by the year in which the EMA granted marketing authorisation.
Non-oncology orphan rate of availability (2015 - 2018)

The rate of availability, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability.
Non-oncology orphan rate of availability (%, 2015 – 2018)

The **rate of availability** is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.
Non-oncology orphan time to availability (2015 – 2018)

The **time to availability** (previously know as length of delay) is the days between EMA 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*).
Non-oncologic orphan median time to availability (2015 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).

![Graph showing median time to availability for various countries](image-url)
Key observations

Non-oncology orphan drugs

- Patient access to new Orphan medicines is generally low across Europe versus other segments, with the greatest rate of availability in Northern and Western European countries.

- In 95% of the countries, the rate of availability is lower for non-oncology orphan drugs compared to all orphan medicinal products approved between 2015-2018.

- Only in Germany, and Norway is the rate of non-oncology orphan medicines availability equivalent to all orphan medicinal products approved 2015 - 2018.

- The average delay between market authorisation and patient access for Orphan drugs is between 3.7 months to 2.8 years.

- 15% of all countries studied do not have access to any of the non-oncology orphan medicines approved between 2015 and 2018.
Combination therapies

Availability by approval year ➔ Rate of availability ➔ Channels of availability ➔ Time to availability
Combination therapies availability by approval year (2015 - 2018)

The total of availability by approval year is 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*) split by the year in which the EMA granted marketing authorisation.

*Note: For some countries, the data may not include all available years due to data limitations.
Combination therapies rate of availability (2015 - 2018)

The rate of availability, measured by the number of medicines available to patients in European countries as of 2019: for most countries this is the point at which the product gains access to the reimbursement list, inc. limited availability.
Combination therapies rate of availability (%; 2015 – 2018)

The rate of availability is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.

The chart shows the availability breakdown (% of medicines available) across European countries, including different availability statuses such as Full public availability, Limited Availability, Only available privately, Not available, and Not submitted by association.

Key points:
- The rate of availability is calculated based on the medicines available to patients in each country.
- The chart includes data from 2015 to 2018.
- Countries are represented in the chart, with each country showing its availability status.
- Full public availability indicates that the medicine is available to all patients without any restrictions.
- Limited Availability indicates the medicine is available but with some restrictions.
- Only available privately means the medicine is available only through private channels.
- Not available indicates the medicine is not available in the country.
- Not submitted by association means the medicine has not been submitted by the manufacturer to the relevant authorities for approval.

*Note: The availability data is subject to the specific reimbursement and approval processes in each country, which can influence the rate of availability.
Combination therapies time to availability (2015 – 2018)

The time to availability (previously known as length of delay) is the days between EMA 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*).
Combination therapy median time to availability (2015 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).
Key observations

**Combination therapies**

- Patient access to new combination medicines is highly varied across Europe
- Over 40% of these combinations are for HIV or Hep-C, two products are Oncology combinations
- In 82% of the countries, the rate of availability is higher for combination products compared to all products approved between 2015-2018
- Over 75% of the countries have a shorter average delay to EMA authorisation for combination drugs compared to all products approved 2015-2018
- The average delay between market authorisation and patient access for combination therapies is between 4.7 months to 2.2 years
Appendix
5-year rolling cohort: 2014-2018
Study scope

• 213 products approved by EMA between 1st January 2014 to 31st December 2018

• The 2019 study provides an analysis of products approved between **2014-2015-2016-2017-2018**, for the following dataset:
  a) **All 213 products**: 41 in 2014, 45 in 2015, 35 in 2016, 38 in 2017, 54 in 2018
  b) **52 Oncology products**: 9 in 2014, 10 in 2015, 10 in 2016, 11 in 2017, 12 in 2018
  c) **66 Orphan products**: 12 in 2014, 12 in 2015, 9 in 2016, 12 in 2017, 21 in 2018
  d) **44 Combination products**: 10 in 2014, 10 in 2015, 8 in 2016, 6 in 2017, 10 in 2018

• Definitions:
  - Orphan status from EMA (September 2019)
  - Oncology products flagged using IQVIA MIDAS Oncology market definition*
  - Combination products include any product with more than one molecule, including branded/generic combinations

• The date of availability cut off point was **1st January 2020** (to account for Estonia, Iceland, Czech Republic, Latvia, Slovakia which had a few products with a reimbursement decision on **1st January 2020**).

• 34 countries included in the study (including split of UK into England and Scotland).
Total availability by approval year (2014 - 2018)

The total of availability by approval year is 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*) split by the year in which the EMA granted marketing authorisation.

Number of products

[Bar chart showing total availability by approval year for different countries from 2014 to 2018]
Rate of availability (2014 – 2018)

The **rate of availability** is 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*), inc. limited availability.
Rate of availability (%, 2014 – 2018)

The rate of availability is 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 includes all medicines status to provide a complete picture of the availability of the cohort of medicines studied.
Time to availability (2014 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).
Median time to availability (2014 – 2018)

The **time to availability** (previously known as length of delay) is the days between EMA 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*).
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