European Federation of Pharmaceutical Industries and Associations

EFPIA Market Access Delays Analysis for Orphan Products

Author: Claire Machin * **Date:** 14/03/2018 * **Version:** Final






Presentation

Introduction (1)

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) 3 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 effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes.

The 2017 analysis uses a sample of 38 products approved with an orphan designation by EMA between January 2014 to December 2016 (12 in 2014, 12 in 2015, 14 in 2016).

Introduction (2)

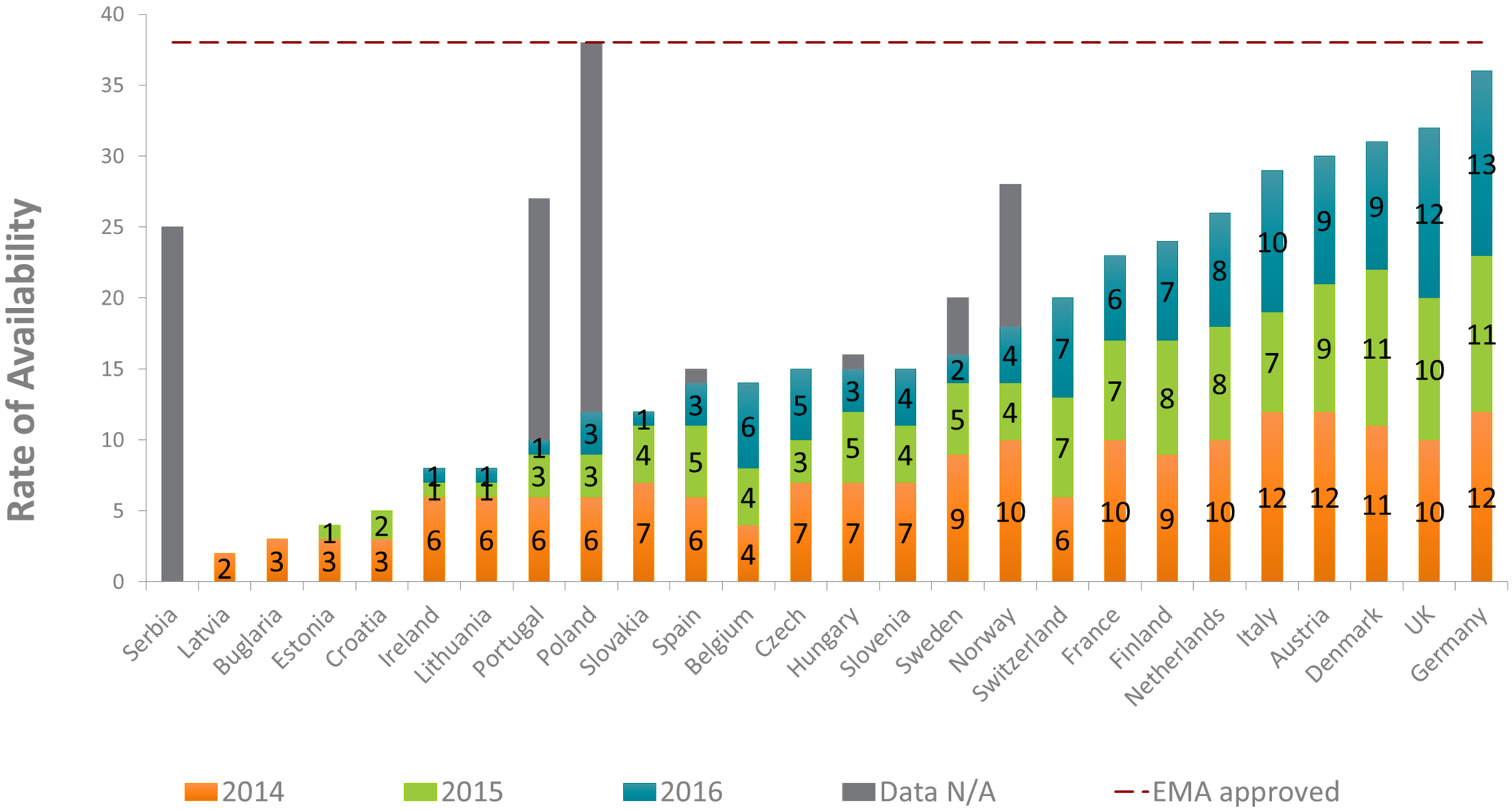
The Patients W.A.I.T. Indicator gives a snapshot of the 2 parameters at a cut-off date (December 2017)– data from medicines cohorts dropping out of the reference period are not updated in subsequent surveys.

Waiting times reflected in the Patients W.A.I.T. Indicator include any delay, whether attributable to companies or to competent authorities.

The Patients W.A.I.T. Indicator is not a measurement of the delays as defined in the "Transparency" Directive. 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.

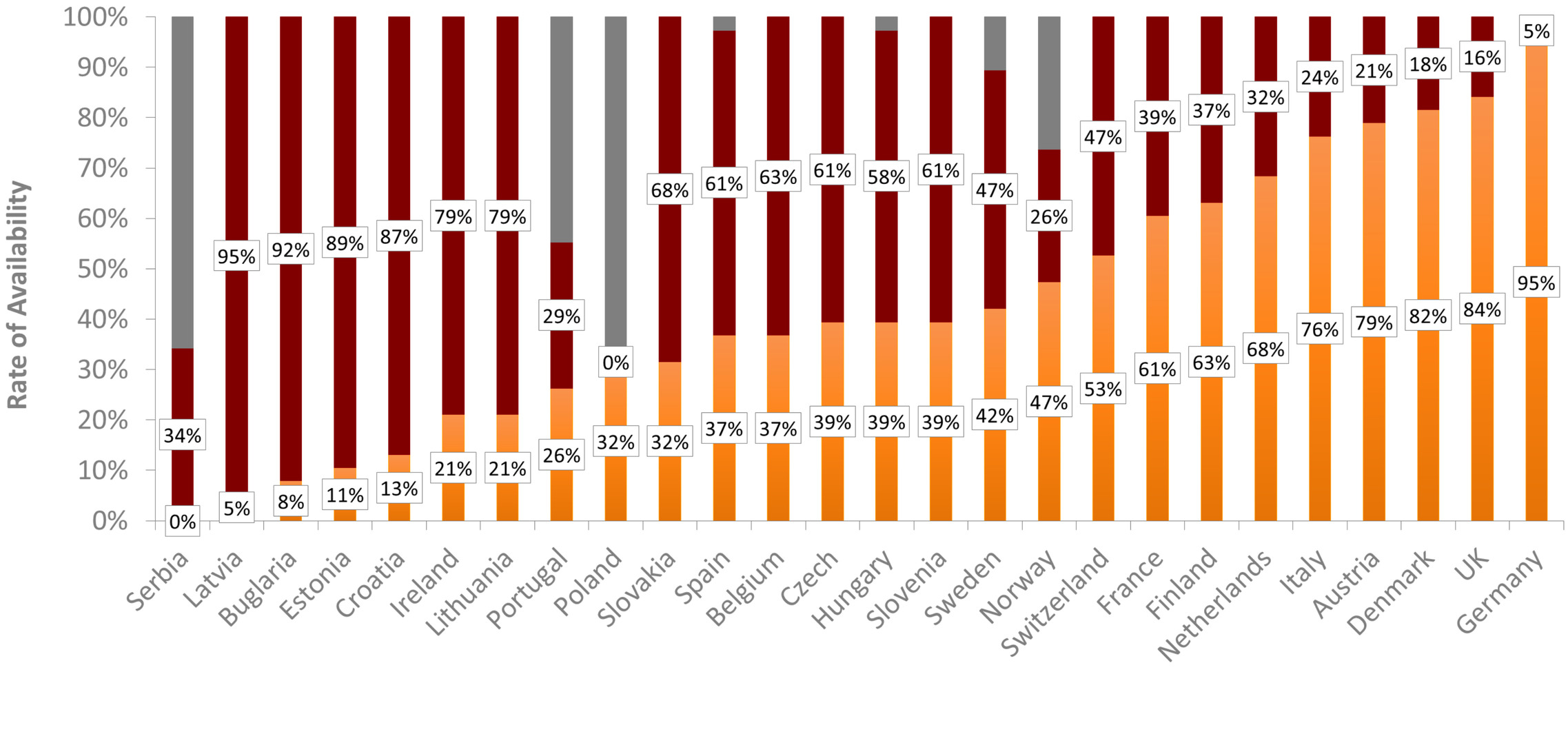
Rate of Availability of Orphan Products

The rate of availability, measured by the number of orphan medicines available to patients in European countries as of 2017: for most countries this is the point at which the product gains access to the reimbursement list.



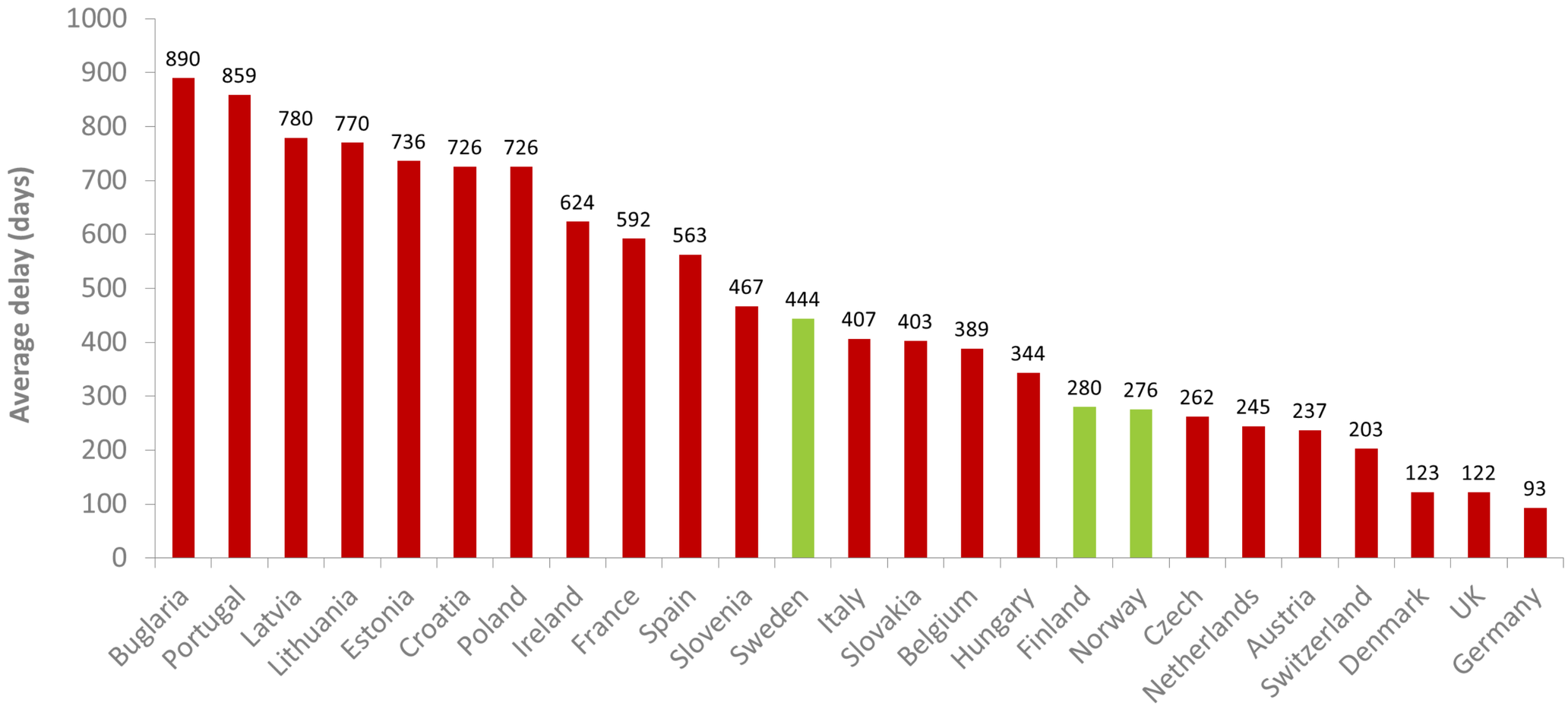
Rate of Availability (%)

The rate of availability, measured by the number of orphan medicines available to patients in European countries as of 2017: for most countries this is the point at which the product gains access to the reimbursement list.



Length of market access delays (average) for orphan medicines

The average time between marketing authorisation and patient access - the number of days elapsing from the date of EU marketing authorisation (or effective marketing authorisation in non-EEA countries) to the day of completion of post-marketing authorisation administrative processes



For most countries patient access equates to granting of access to the reimbursement list, except for hospital products in FI, NO, SE where some products are not covered by the general reimbursement scheme and so the zero-delay is artificially declining the median and average.

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 for France is higher than in reality.