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Global Access to New Medicines Report

April 2023

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Introduction

A record number of new, innovative medicines launched globally in 2021. PhRMA's **Global Access to New Medicines Report** examines the launch and public reimbursement of new medicines across 72 different markets, broken out by G20, OECD and geographic regions.

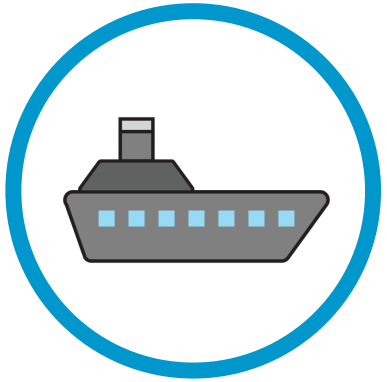
Throughout the report, a new medicine refers to all new active substances approved by the United States Food and Drug Administration, European Medicines Agency and/or Japan Pharmaceuticals and Medical Devices Agency and first launched in any country between January 1, 2012, and December 31, 2021.

Countries Need Pro-innovation Policies To Ensure Timely Patient Access to New Medicines

Strong intellectual property rights and enforcement

Science-based and globally-harmonized regulatory review

Transparent pricing and reimbursement that values innovation



Open and nondiscriminatory trade

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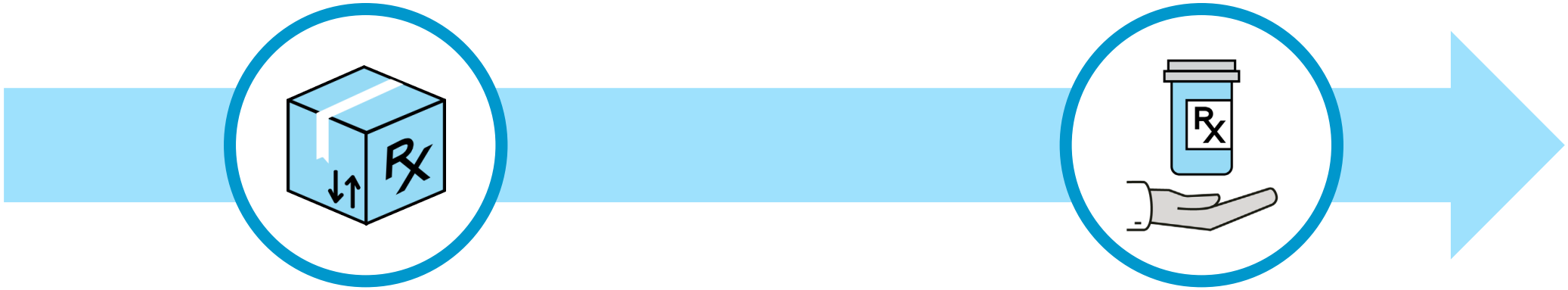
Understanding Patient Access to New Medicines

In Many Countries, Patient Access Depends on Public Insurance Plan Coverage



Launched in Country

- Medicine has been shipped to country
- Patients can have prescriptions filled
- Patients use private insurance or pay out-of-pocket because public insurance does not cover the medicine

Reimbursed by Public Insurance Plan

- Medicine is covered by public insurance
- At least some patients can use a public insurance plan to pay for the medicine
- Patients face access restrictions if the plan only covers some approved uses

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Global Trends

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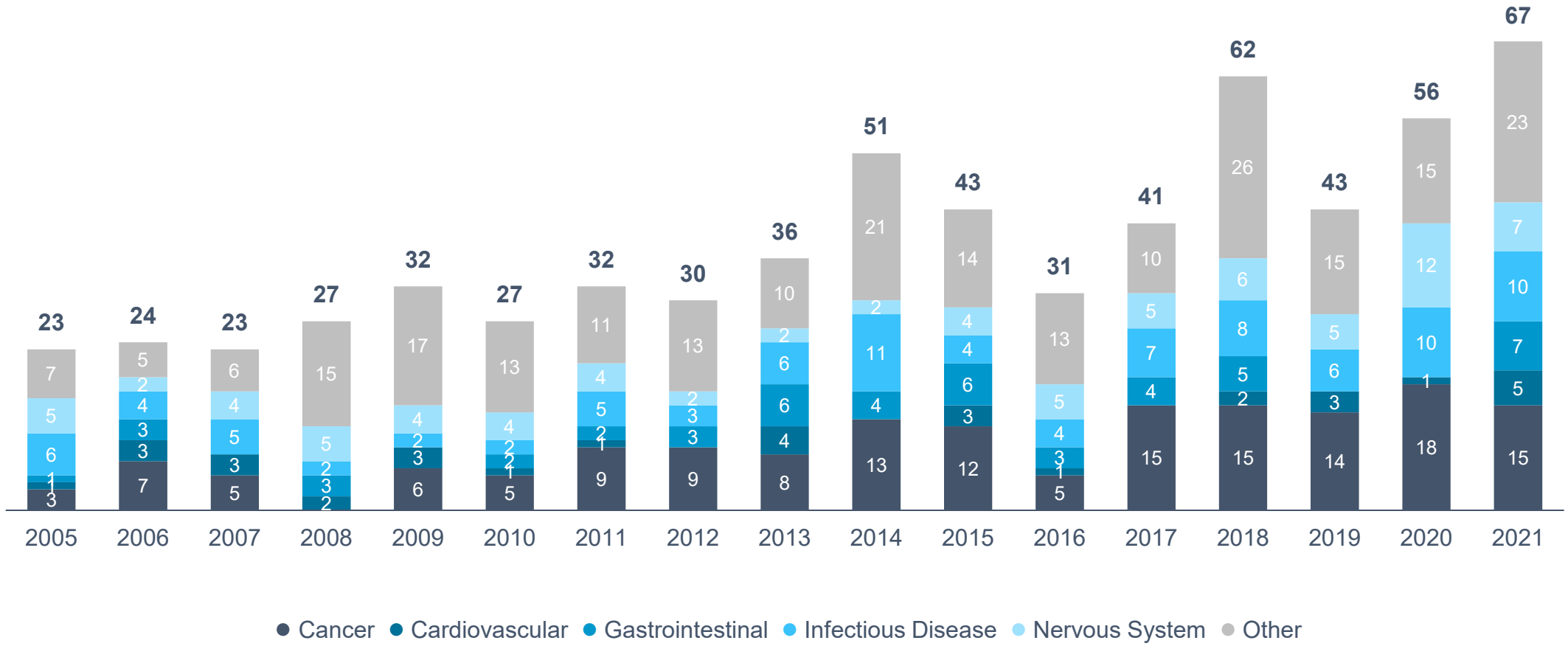
A Record Number of New Medicines Launched in 2021

Number of New Medicines Launched Globally by Year and Therapy Area (of all 648 new medicines launched from 2005 to end of 2021)



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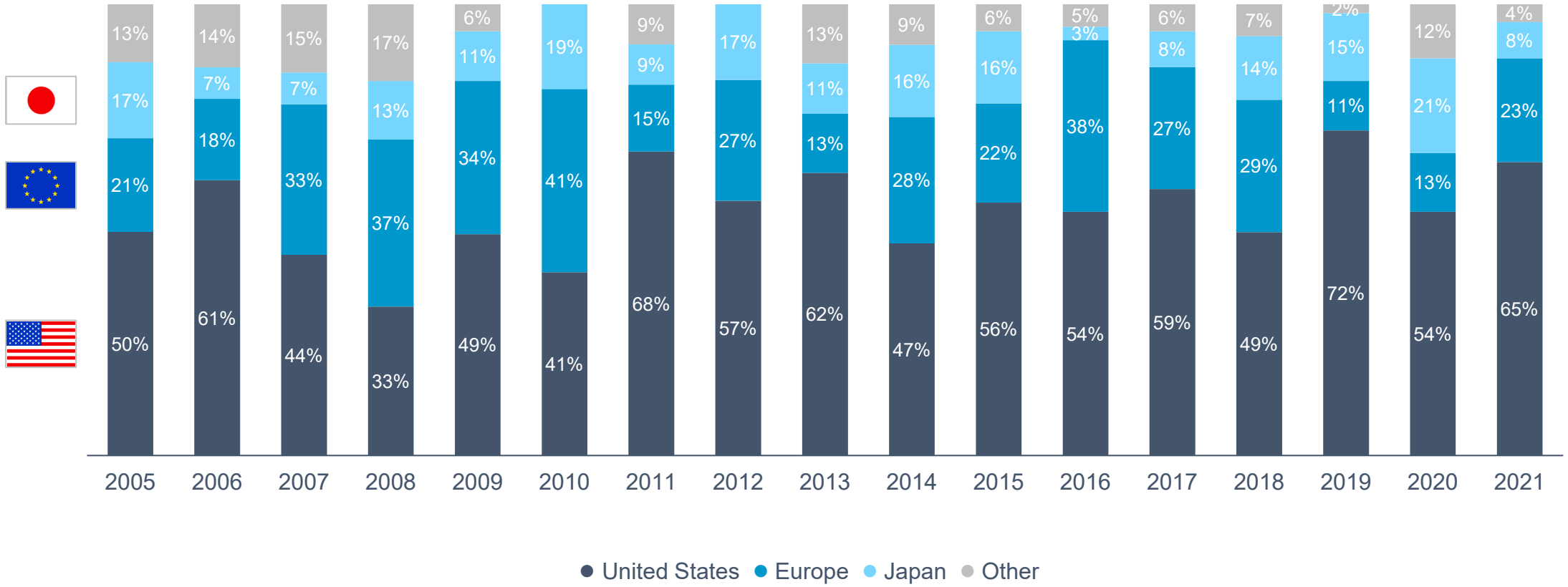
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021.

Global Launched

New Medicines Most Often Launch First in the United States

Share of Global First Launches of New Medicines by Geography and Year (of all new medicine launches from 2005 to end of 2021)



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Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021. Switzerland and the United Kingdom are included in Europe for purposes of this analysis. Shares include new medicines that have launched simultaneously in multiple countries.

International Comparisons

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Access to New Medicines in G20 Countries


Argentina


Australia


Brazil


Canada


China


France


Germany


India


Indonesia


Italy


Japan


Korea


Mexico


Russia


Saudi Arabia


South Africa


Turkey


United Kingdom


United States


European Union

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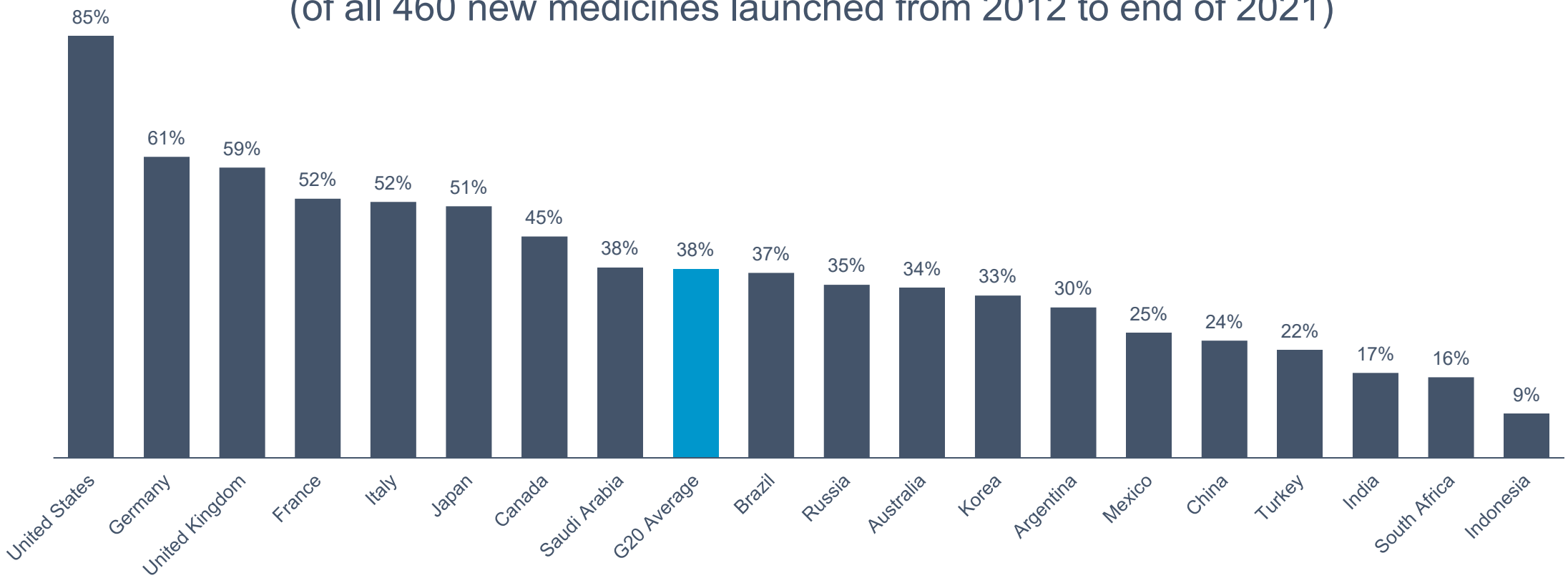
Availability of New Medicines Varies Significantly Across G20 Countries

Percentage of New Medicines Launched by G20 Country (of all 460 new medicines launched from 2012 to end of 2021)



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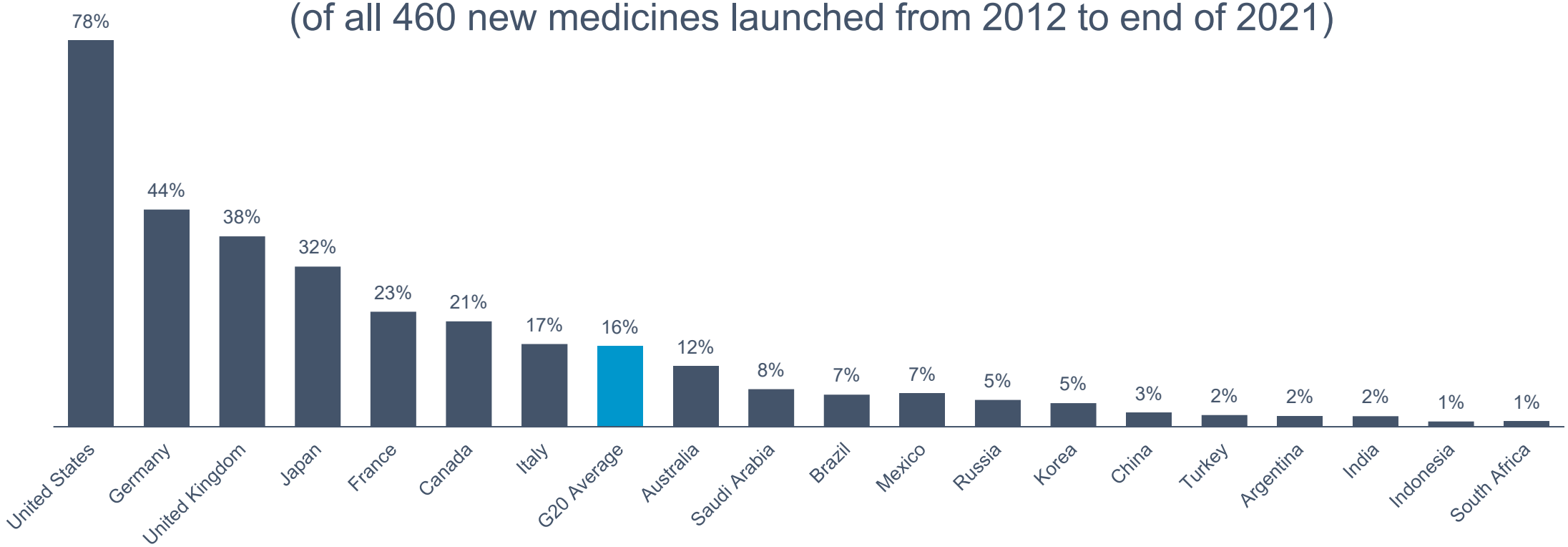
G20
Launched

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

On Average, G20 Countries Have 16% of New Medicines Available Within One Year of Global First Launch

Percentage of New Medicines Launched Within One Year of Global First Launch by G20 Country (of all 460 new medicines launched from 2012 to end of 2021)



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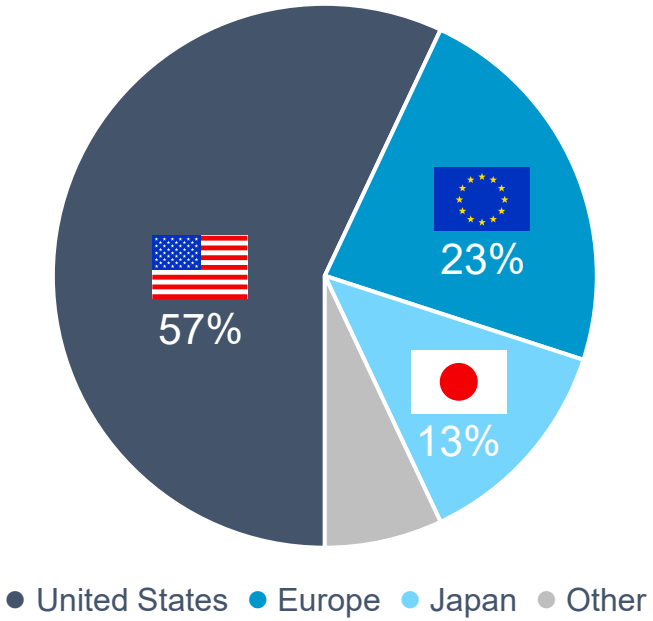
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

G20
Launched

New Medicines Generally Launch First and Fastest in the United States Among G20 Countries

Global First Launch of New Medicines by Country (2012 to end of 2021)



Average Months of Delay in Launch of New Medicines (of new medicines launched by country from 2012 to end of 2021)

G20 Launched

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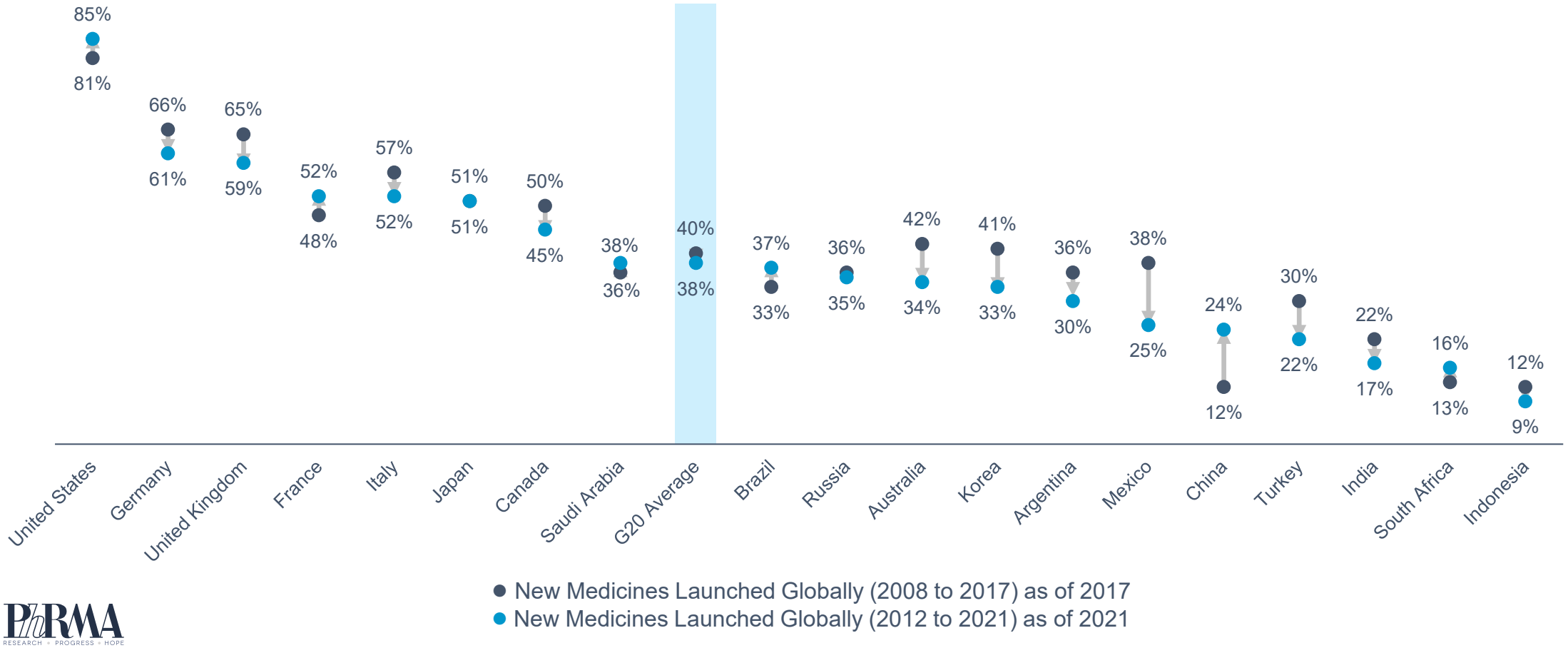
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Switzerland and the United Kingdom are included in Europe for purposes of this analysis. Shares include new medicines that have launched simultaneously in multiple countries.

Availability of New Medicines Declined Over Time in Most G20 Countries

China Improved Most and Mexico Declined Most



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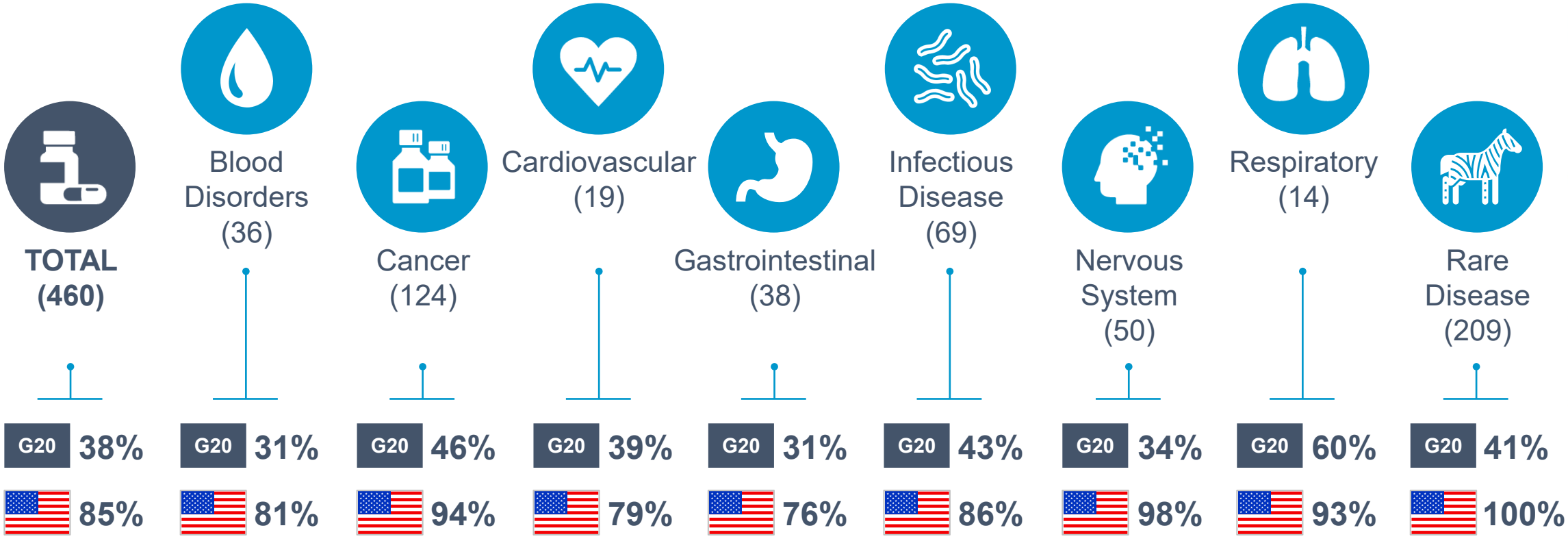
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021.

G20
Launched

Availability of New Medicines in G20 Countries by Therapy Area

Average vs. Leading G20 Country Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)



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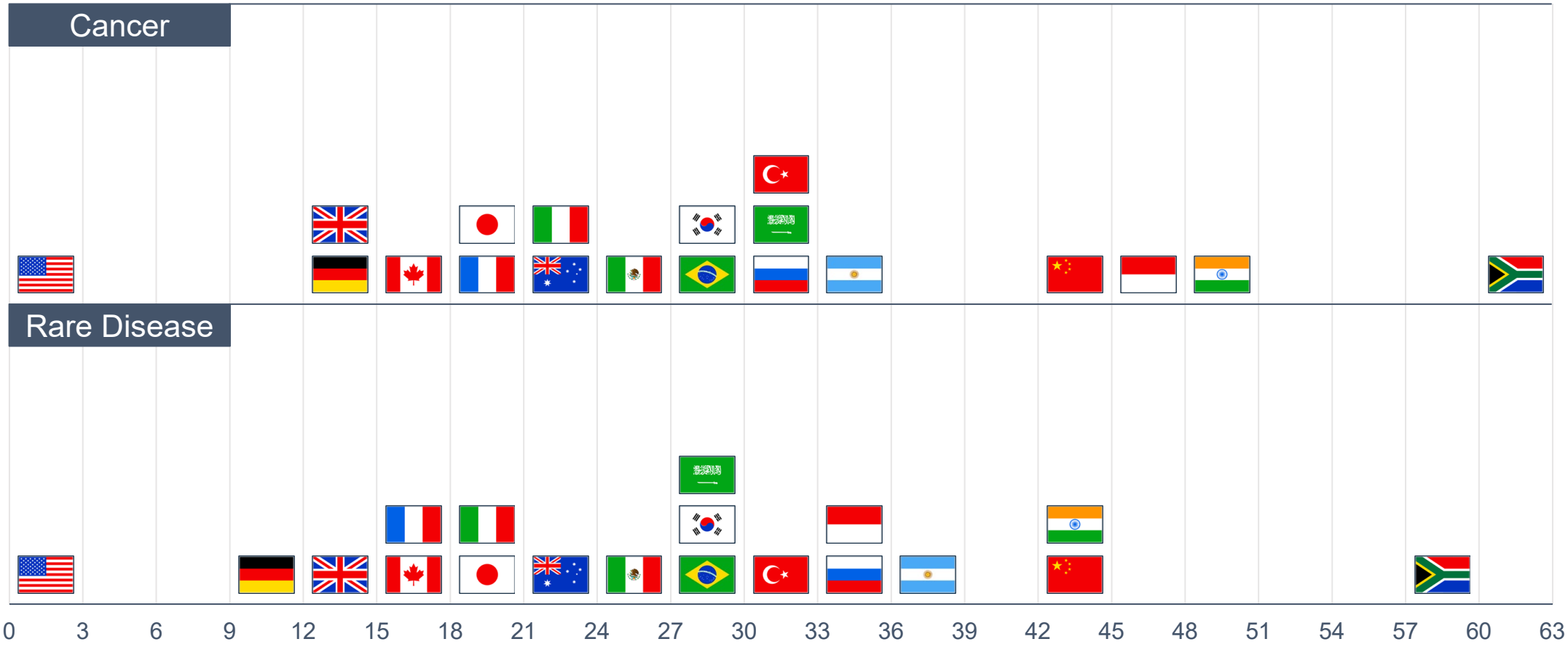
G20 Launched

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Therapy areas are mutually exclusive except for rare disease.

New Medicines For Cancer and Rare Diseases Launch Fastest in the United States Among G20 Countries



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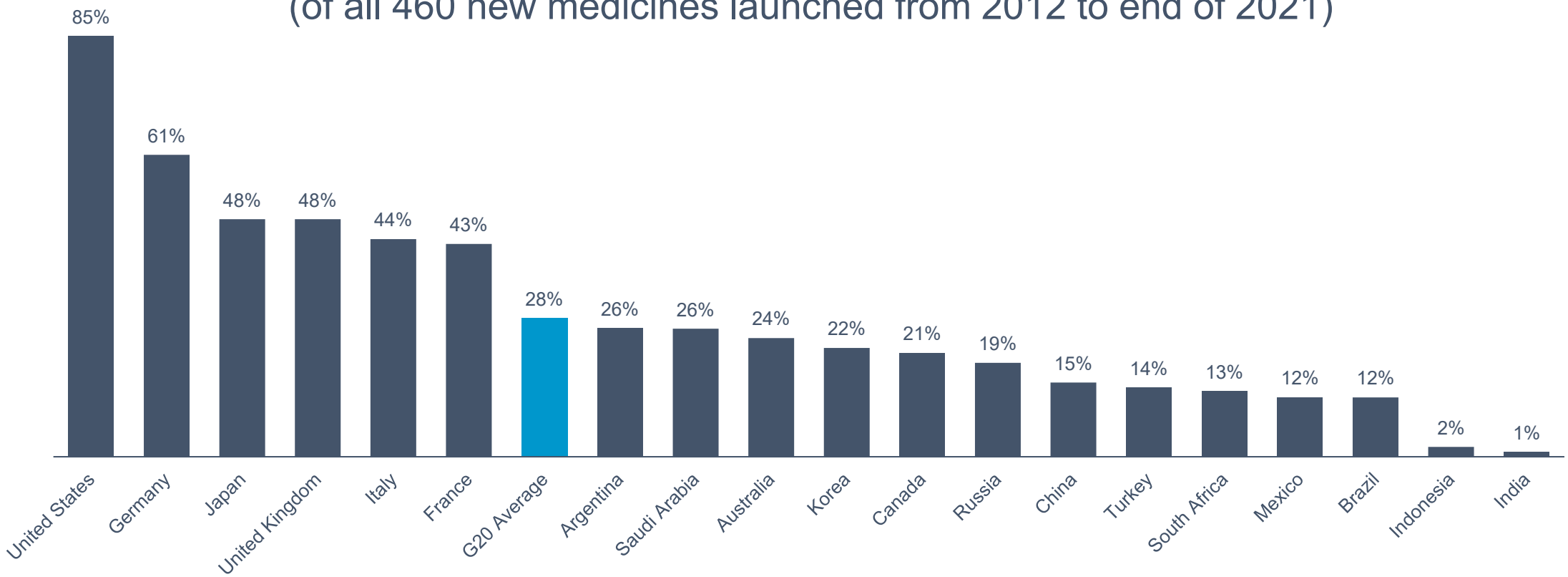
G20
Launched

On Average, G20 Countries Have 28% of New Medicines Reimbursed by Public Insurance Plans

Percentage of New Medicines Reimbursed by Public Insurance Plans by G20 Country (of all 460 new medicines launched from 2012 to end of 2021)



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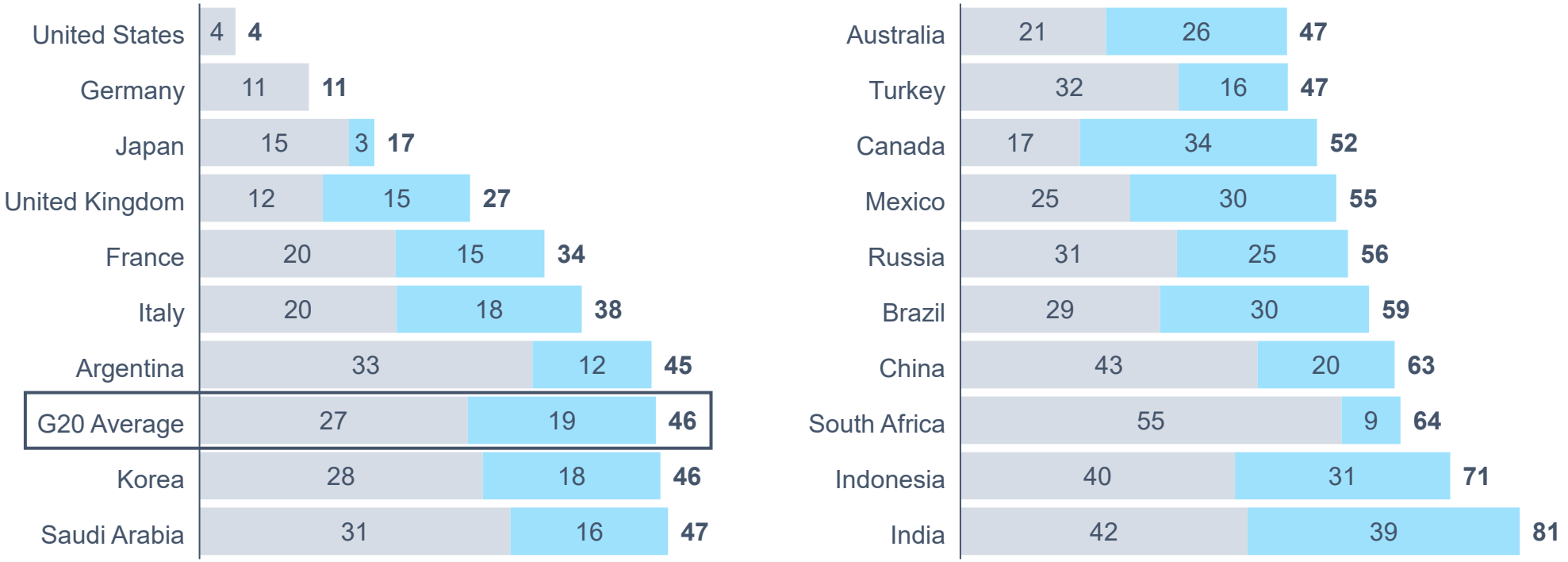
G20
Reimbursed

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

Time from Global First Launch to Public Reimbursement in G20 Countries Varies from 4 to 81 Months on Average

Number of Months from Global First Launch to Public Reimbursement by G20 Country (of all new medicines launched and reimbursed by country from 2012 to end of 2021)



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G20 Reimbursed

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
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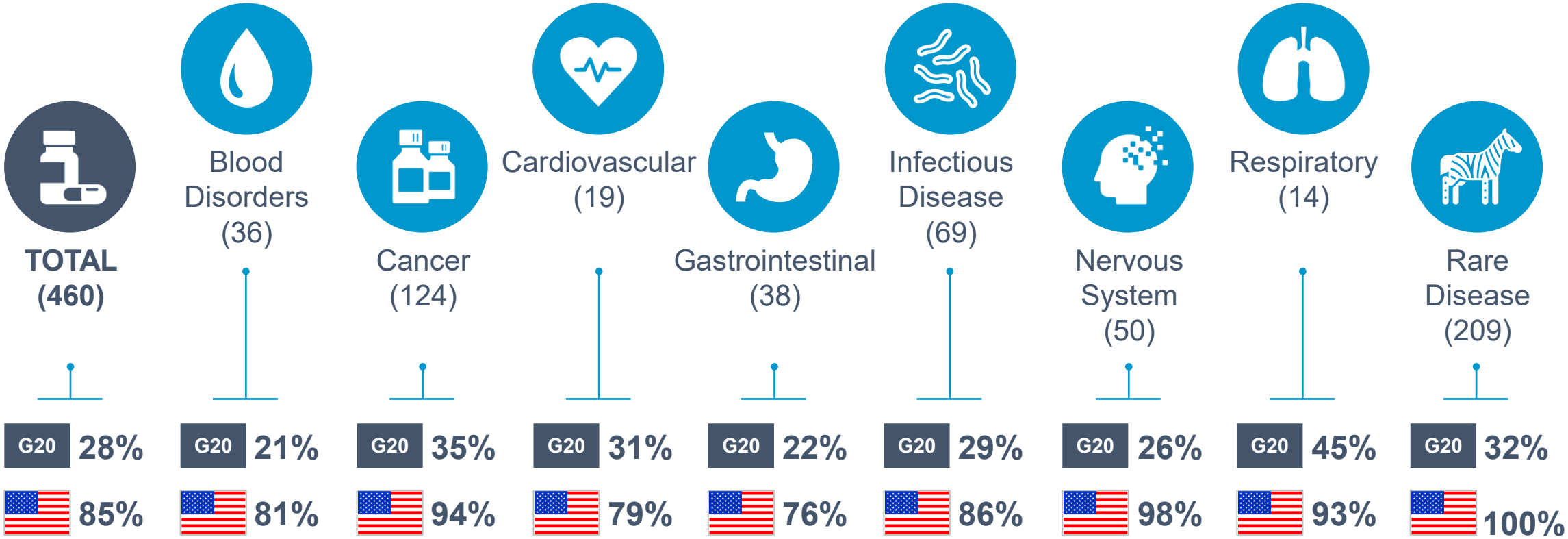
Public Reimbursement of New Medicines in G20 Countries by Therapy Area

Average vs. Leading G20 Country Percentage of New Medicines Reimbursed by Public Plans (of all 460 new medicines launched from 2012 to end of 2021)



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G20 Reimbursed

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Access to New Medicines in OECD Countries

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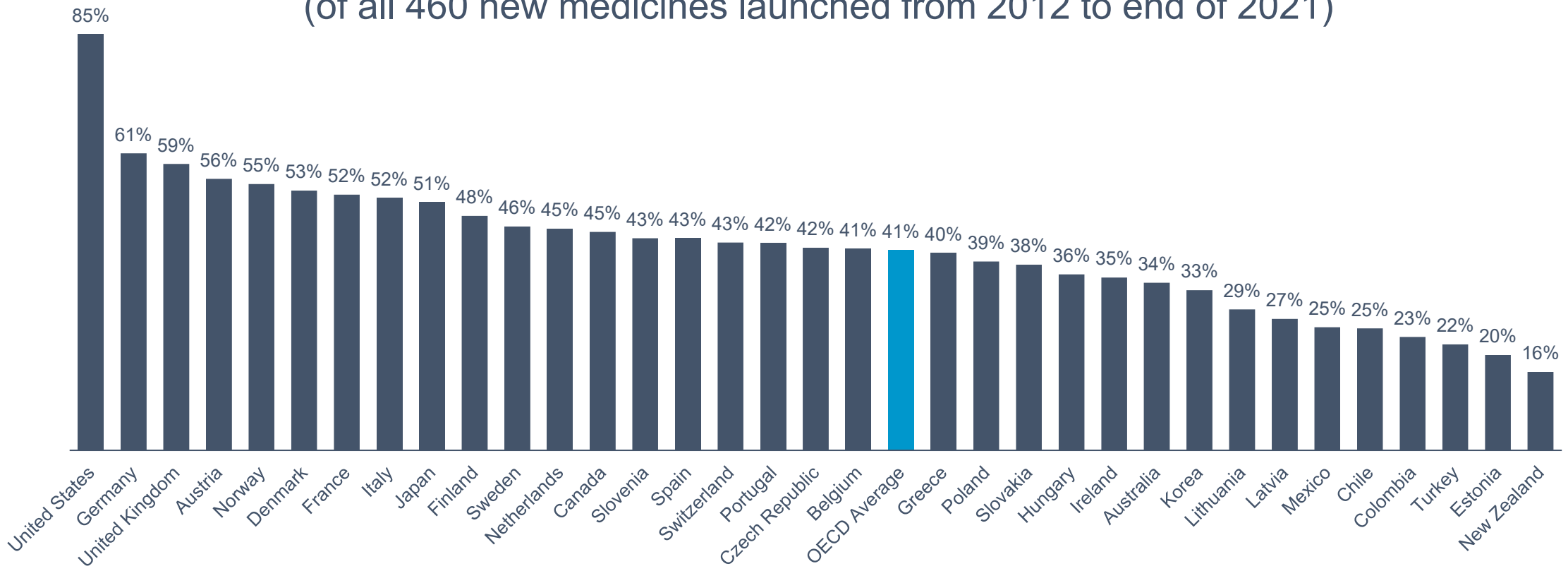
Availability of New Medicines Varies Significantly Across OECD Countries

Percentage of New Medicines Launched by OECD Country (of all 460 new medicines launched from 2012 to end of 2021)



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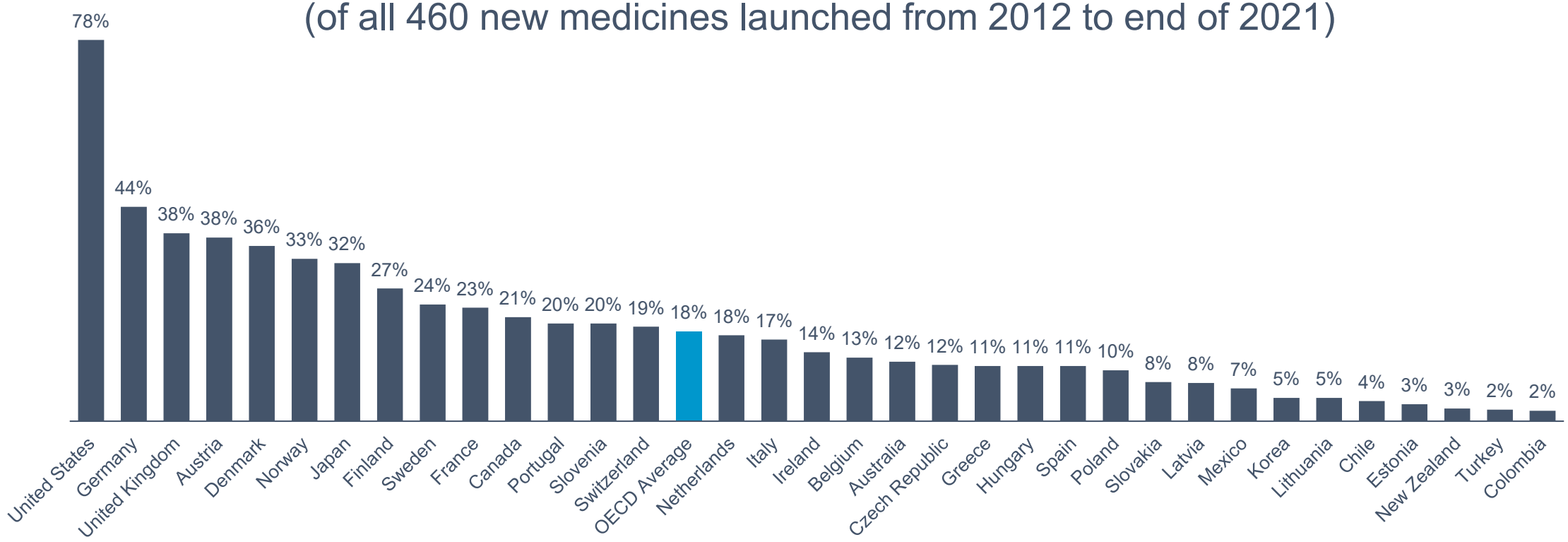
OECD
Launched

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Costa Rica, Iceland, Israel and Luxembourg.

On Average, OECD Countries Have 18% of New Medicines Available Within One Year of Global First Launch

Percentage of New Medicines Launched Within One Year of Global First Launch by OECD Country (of all 460 new medicines launched from 2012 to end of 2021)



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OECD
Launched

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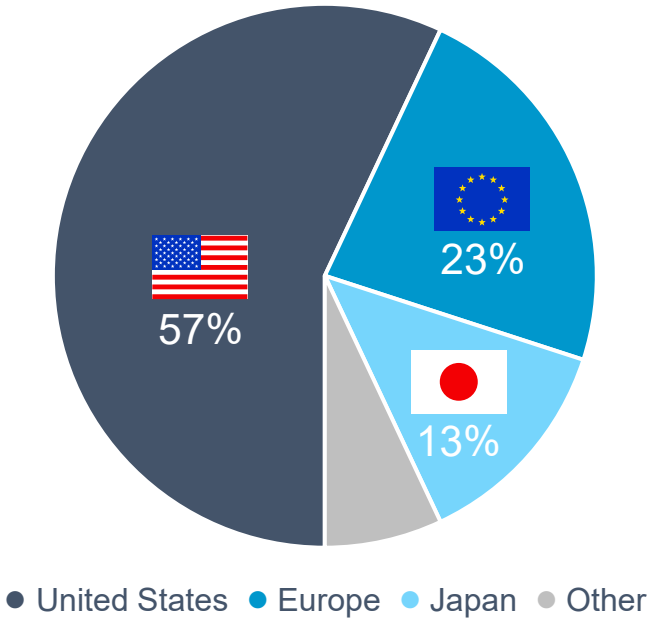
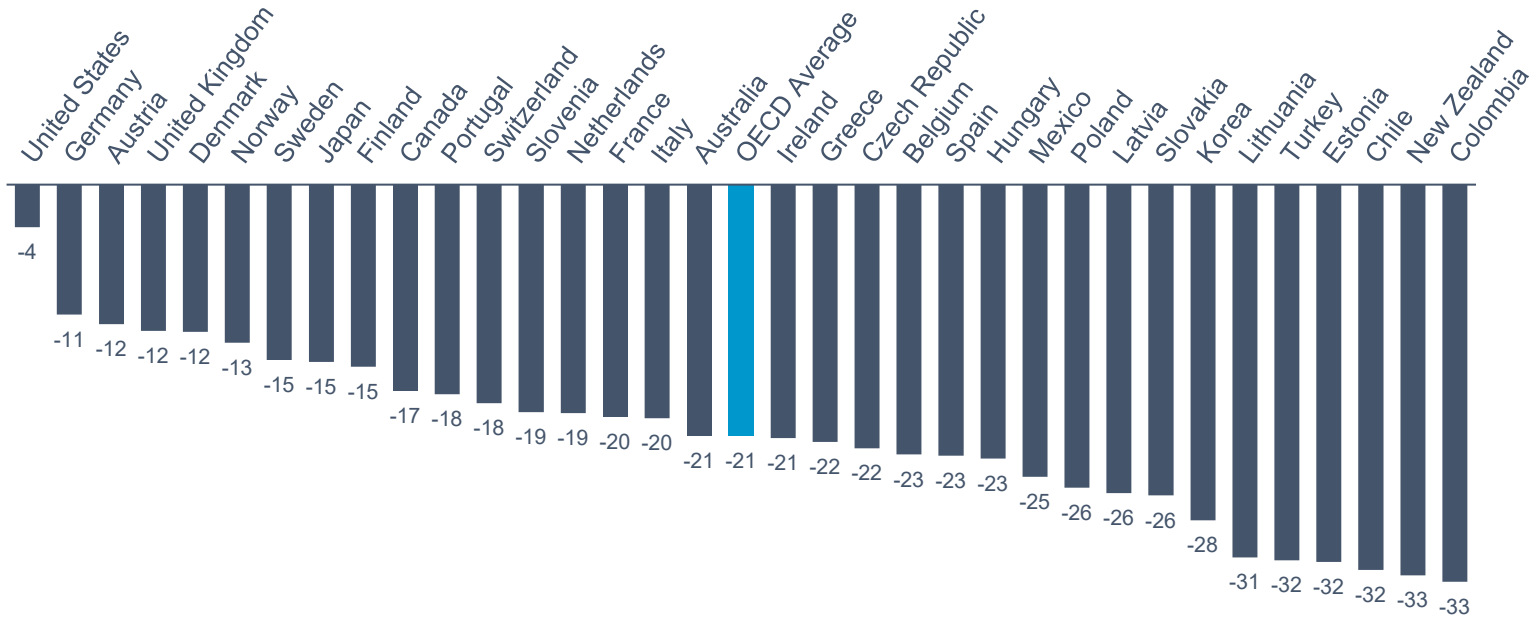
New Medicines Generally Launch First and Fastest in the United States Among OECD Countries

Global First Launch of New Medicines by Country (2012 to end of 2021)



Average Months from Global First Launch to Local Launch (of new medicines launched by country from 2012 to end of 2021)



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OECD
Launched

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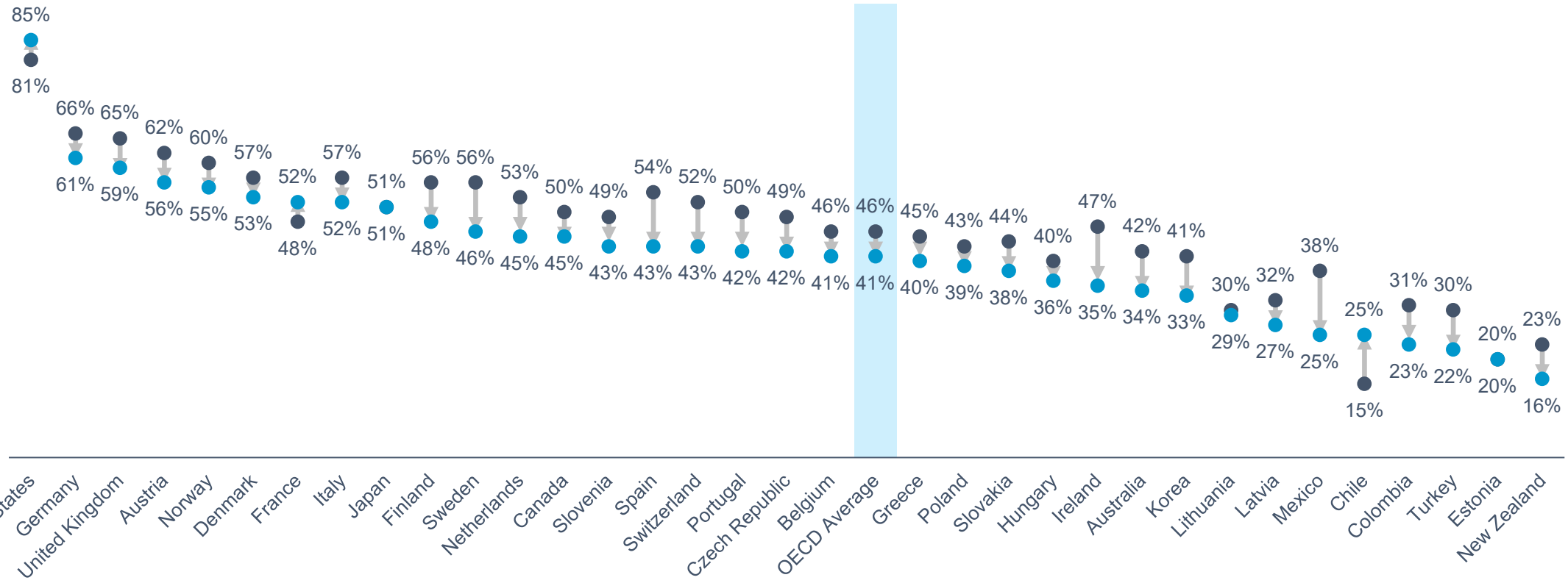
Availability of New Medicines Declined Over Time in Most OECD Countries

Chile Improved Most and Mexico Declined Most



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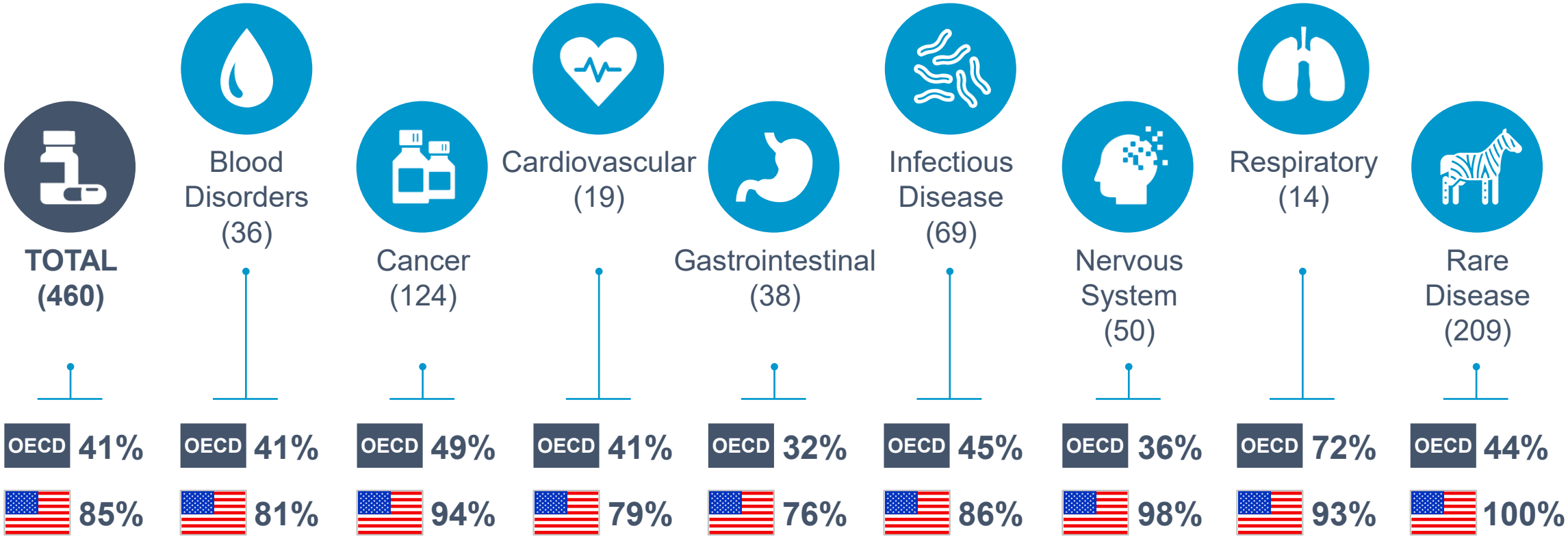
OECD
Launched

Availability of New Medicines in OECD Countries by Therapy Area

Average vs. Leading OECD Country Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)



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OECD
Launched

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New Medicines For Cancer and Rare Diseases Launch Fastest in the United States Among OECD Countries

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OECD
Launched

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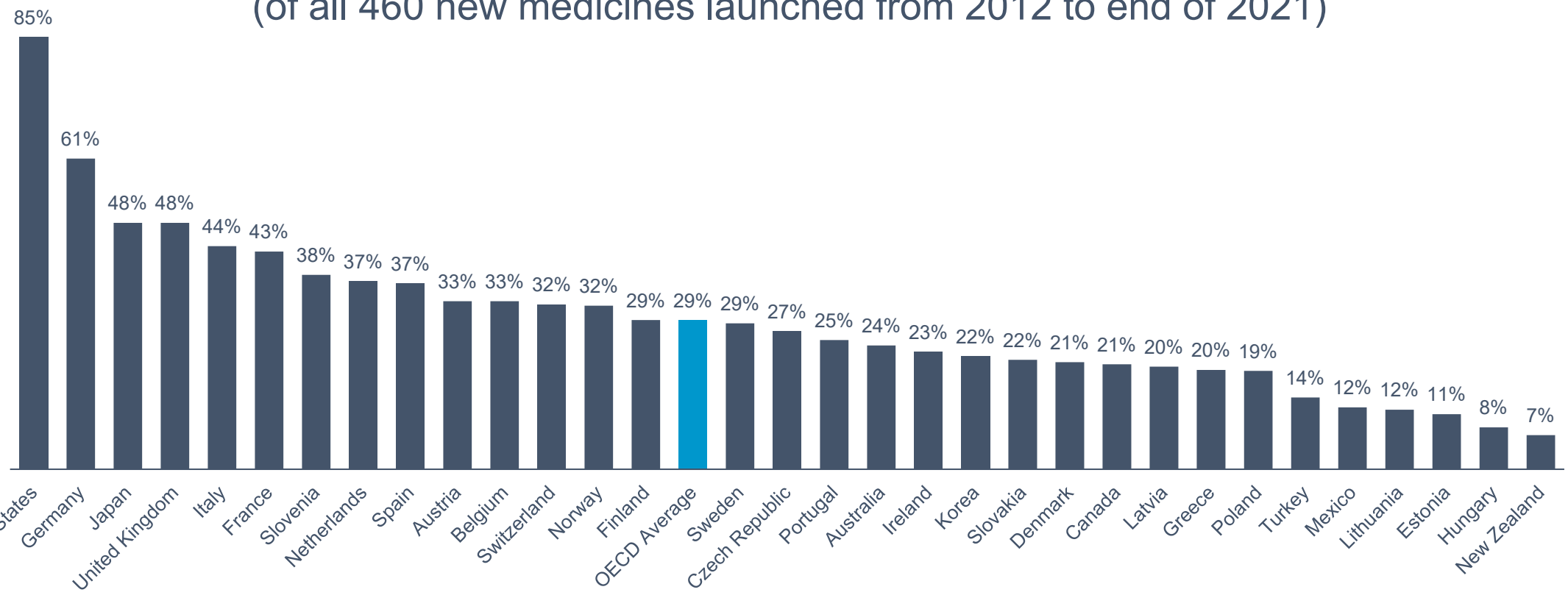
On Average, OECD Countries Have 29% of New Medicines Reimbursed by Public Insurance Plans

Percentage of New Medicines Reimbursed by Public Insurance Plans by OECD Country (of all 460 new medicines launched from 2012 to end of 2021)



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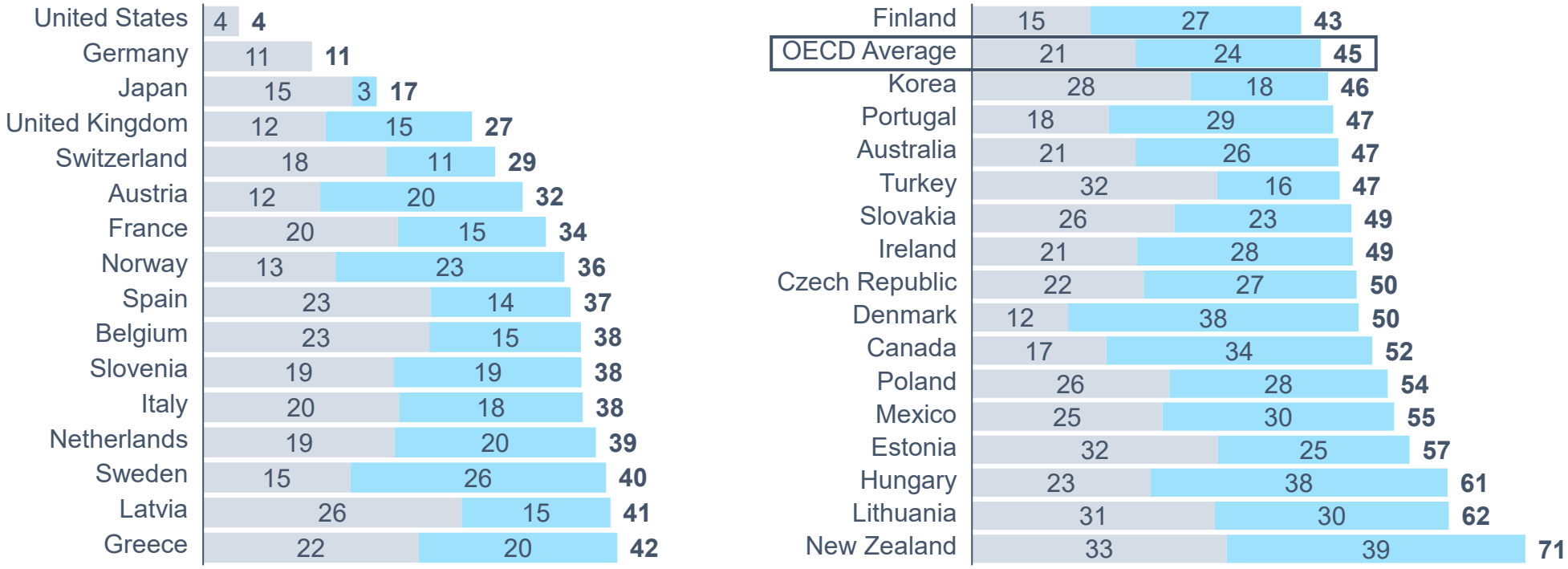
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Chile, Colombia, Costa Rica, Iceland, Israel, and Luxembourg. A medicine is considered publicly reimbursed in Canada if 50 percent or more of the population lives in a province where it is publicly reimbursed.

OECD
Reimbursed

Time from Global First Launch to Public Reimbursement in OECD Countries Varies from 4 to 72 Months on Average

Number of Months from Global First Launch to Public Reimbursement by OECD Country (of all new medicines launched and reimbursed by country from 2012 to end of 2021)



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OECD
Reimbursed

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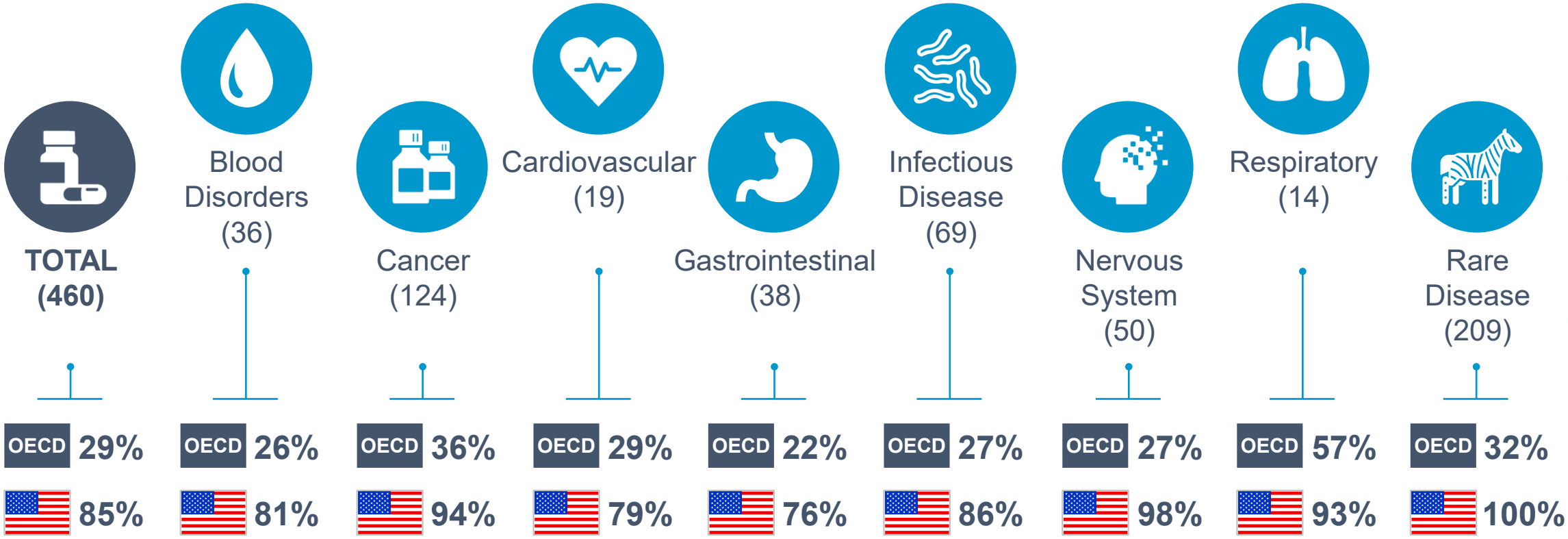
Public Reimbursement of New Medicines in OECD Countries by Therapy Area

Average vs. Leading OECD Country Percentage of New Medicines Reimbursed by Public Plans (of all 460 new medicines launched from 2012 to end of 2021)



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OECD
Reimbursed

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Access to New Medicines in the Americas


Argentina


Brazil


Canada


Chile


Colombia


Dominican Republic


Ecuador


Mexico


Peru


Uruguay


United States


Venezuela

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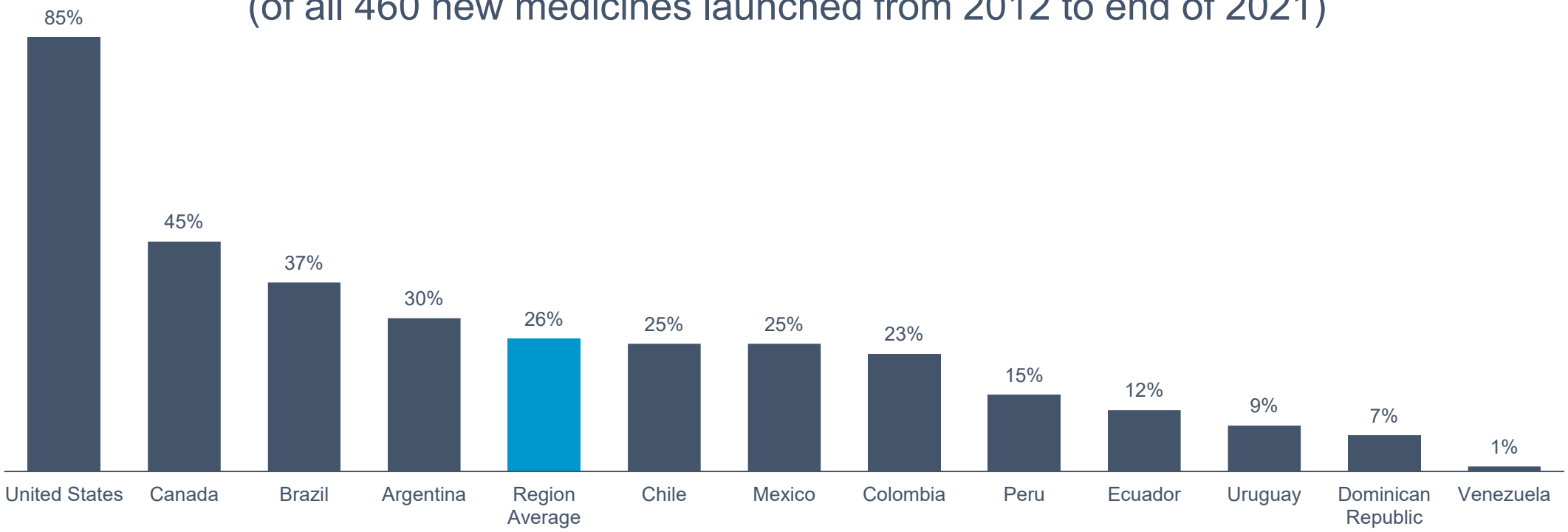
On Average, Countries in the Americas Have 26% of New Medicines Available

Percentage of New Medicines Launched by Country in the Americas (of all 460 new medicines launched from 2012 to end of 2021)



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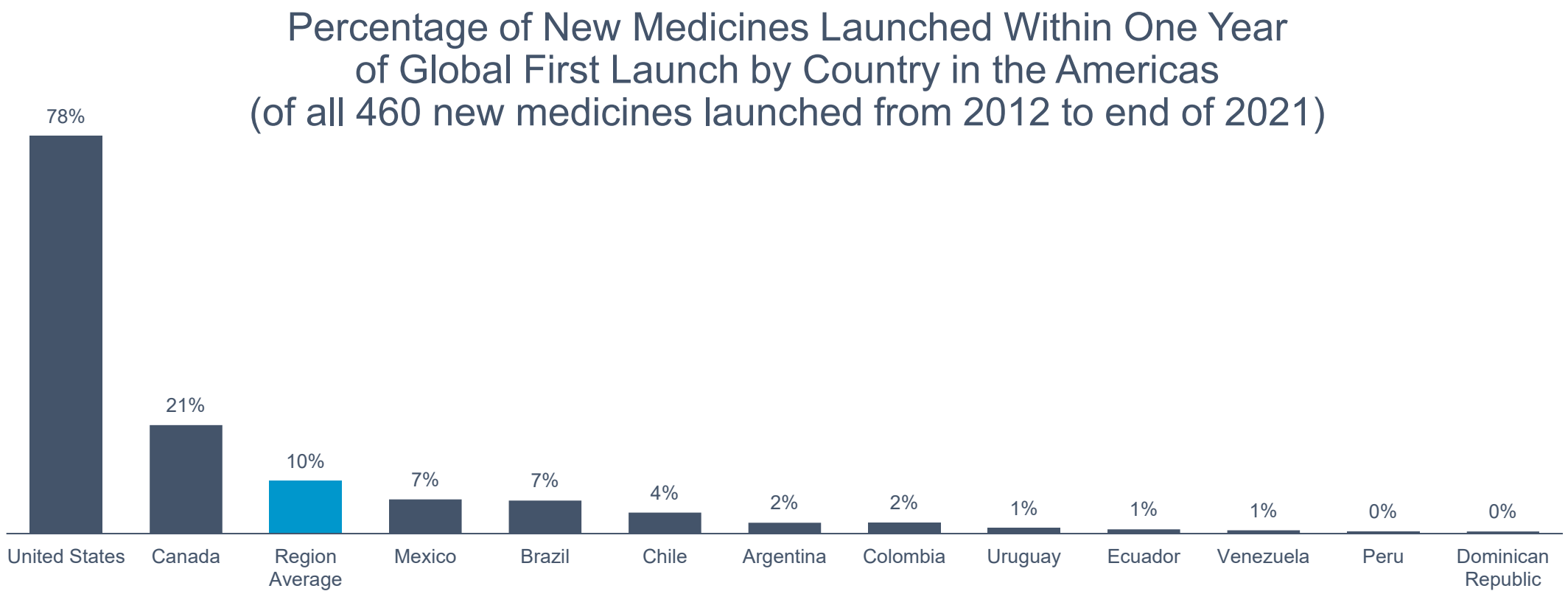
On Average, Countries in the Americas Have 10% of New Medicines Available Within One Year of Global First Launch



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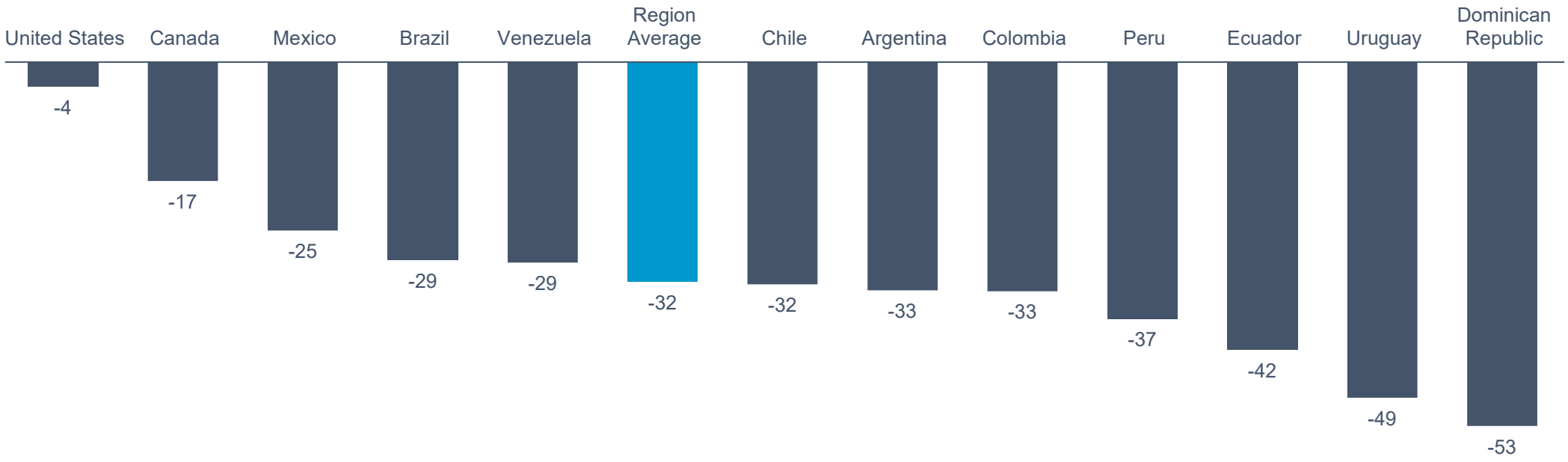
On Average, New Medicines Launch 32 Months After Global First Launch Among Countries in the Americas

Average Months from Global First Launch to Local Launch by Country in the Americas (of new medicines launched by country from 2012 to end of 2021)



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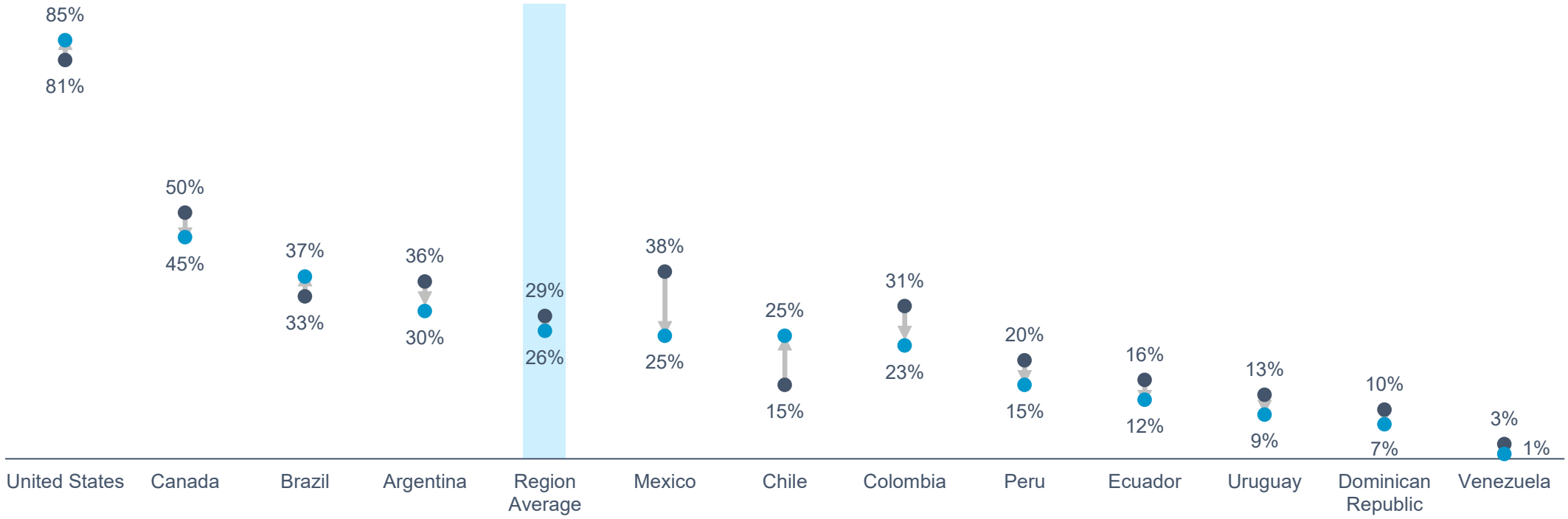
Availability of New Medicines Declined Over Time in Most Countries in the Americas

Chile Improved Most and Mexico Declined Most



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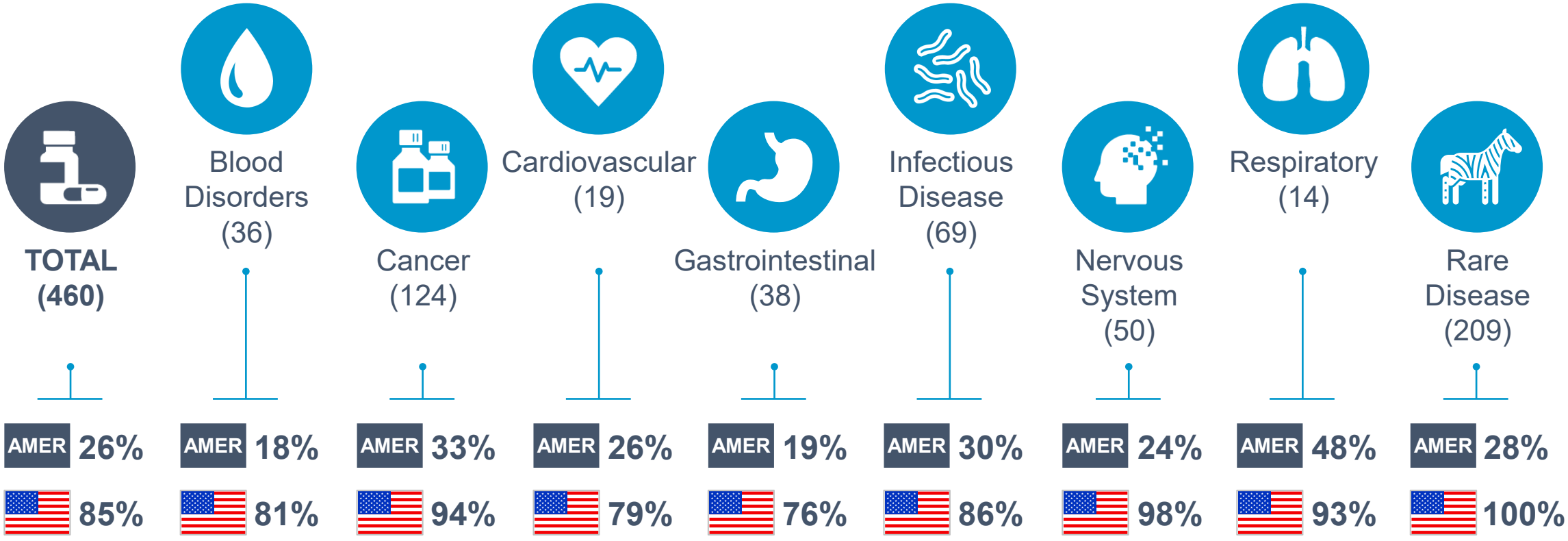
Availability of New Medicines in the Americas by Therapy Area

Average vs. Leading Regional Country Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)



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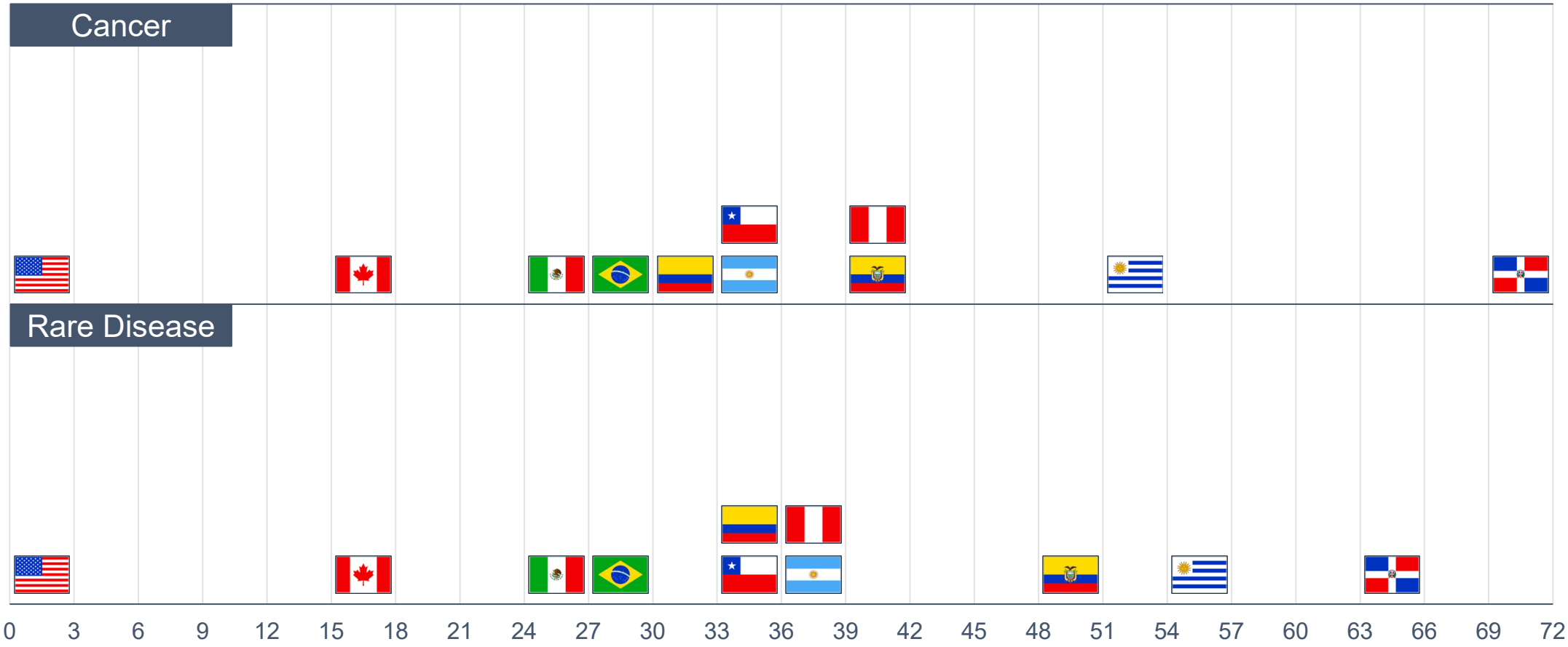
Americas
Launched

New Medicines For Cancer and Rare Diseases Launch Fastest in the United States Among Countries in the Americas



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Access to New Medicines in Asia-Pacific


Australia


Bangladesh


China


India


Indonesia


Japan


Kazakhstan


Korea


Malaysia


New Zealand


Pakistan


Philippines


Singapore


Sri Lanka


Taiwan


Thailand


Vietnam

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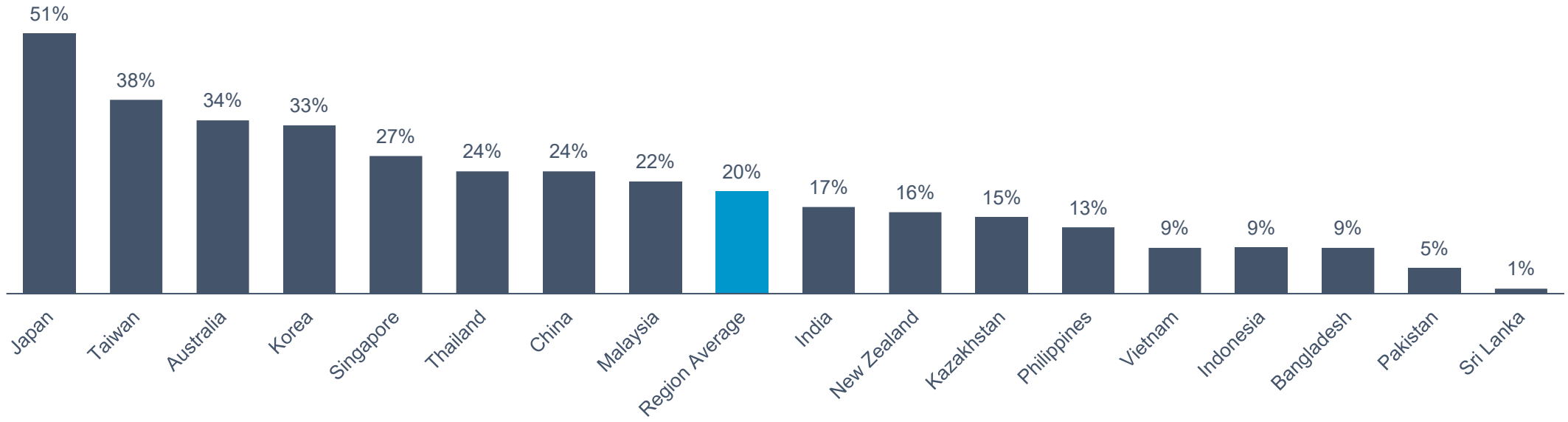
On Average, Asia-Pacific Markets Have 20% of New Medicines Available

Percentage of New Medicines Launched by Asia-Pacific Market (of all 460 new medicines launched from 2012 to end of 2021)

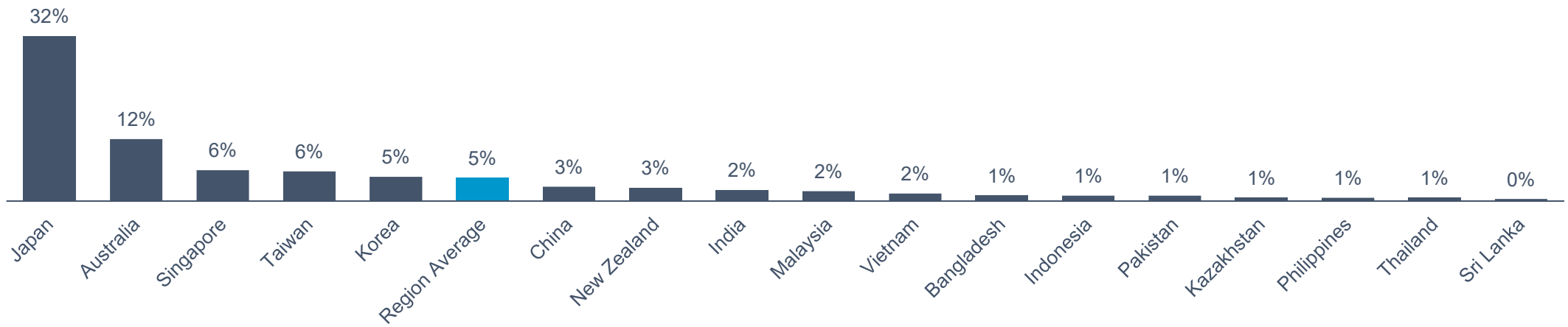


PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

On Average, Asia-Pacific Markets Have 5% of New Medicines Available Within One Year of Global First Launch

Percentage of New Medicines Launched Within One Year of Global First Launch in Asia-Pacific by Market (of all 460 new medicines launched from 2012 to end of 2021)

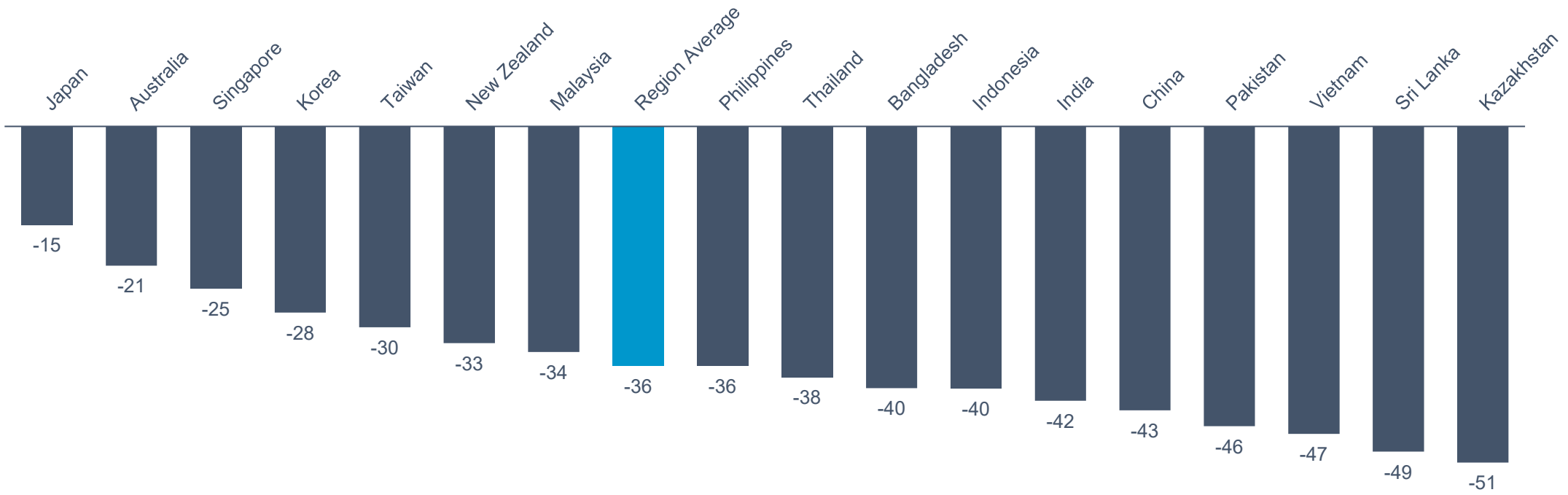


PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

On Average, New Medicines Launch 36 Months After Global First Launch Among Asia-Pacific Markets

Average Months from Global First Launch to Local Launch by Asia-Pacific Market (of new medicines launched by market from 2012 to end of 2021)

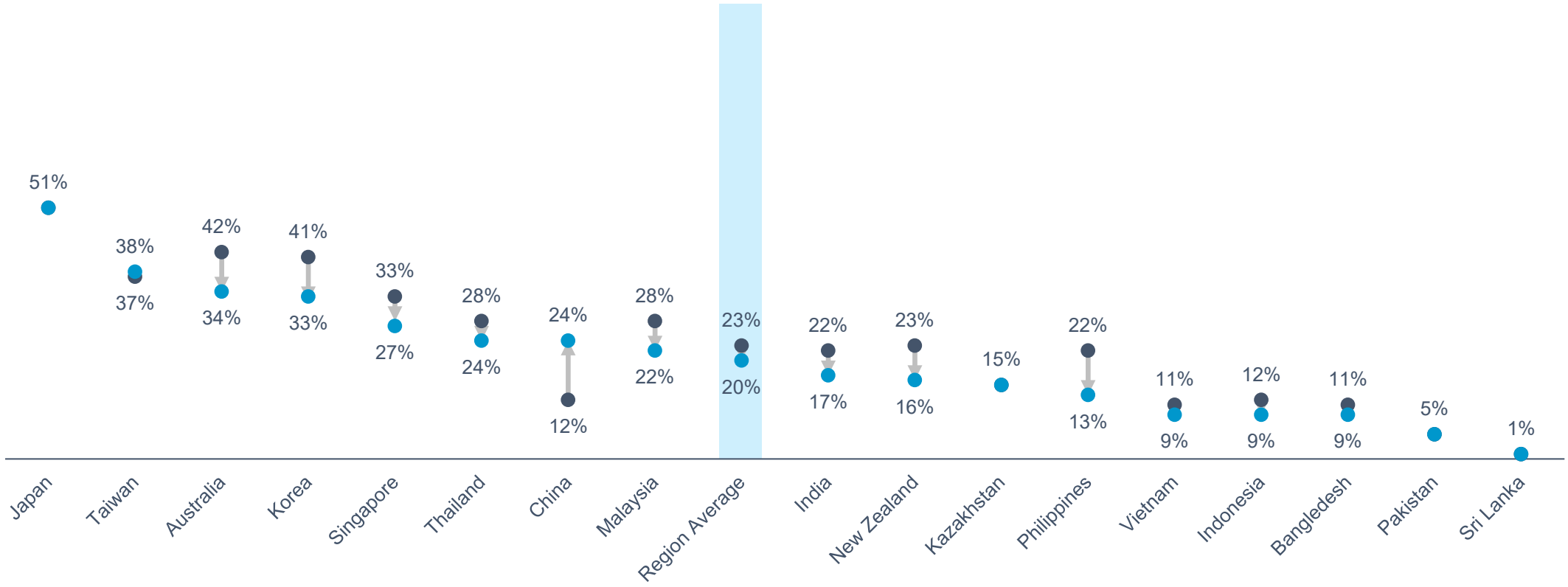


PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

Availability of New Medicines Declined Over Time in Most Asia-Pacific Markets

China Improved Most and Australia, Korea and the Philippines Declined Most

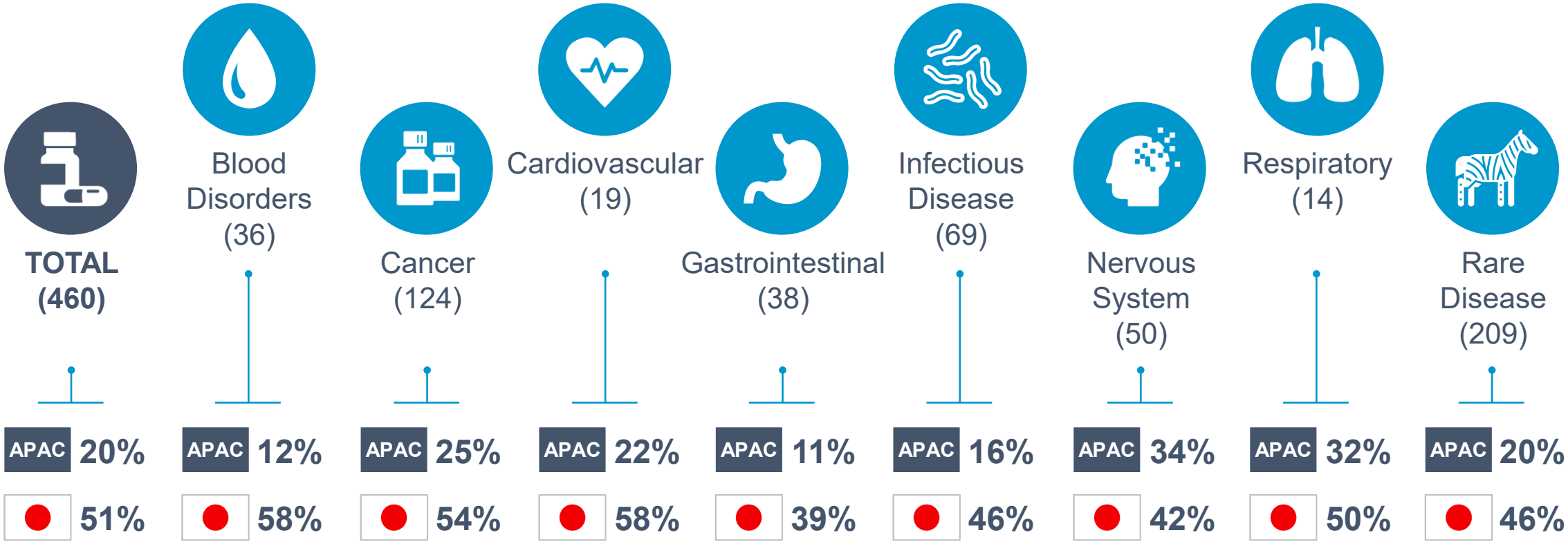


PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021.

Availability of New Medicines in Asia-Pacific Markets by Therapy Area

Average vs. Leading Regional Market Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)

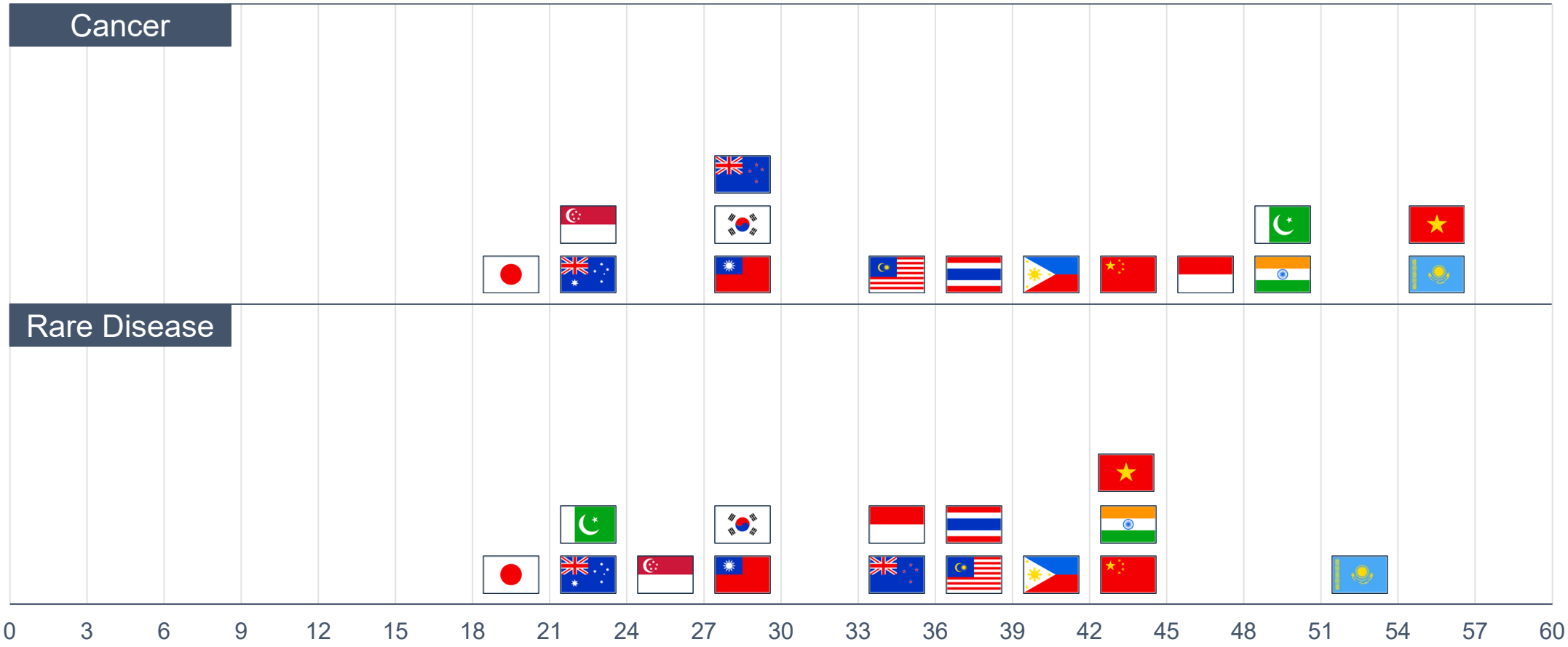


PhRMA
RESEARCH • PROGRESS • HOPE

APAC
Launched

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Therapy areas are mutually exclusive except for rare disease.

New Medicines For Cancer and Rare Diseases Launch Fastest in Japan Among Asia-Pacific Markets



PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

APAC
Launched

Access to New Medicines in Europe


Austria


Belarus


Belgium

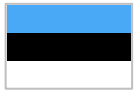

Bosnia


Bulgaria


Croatia


Czech Republic


Denmark


Estonia


Finland


France


Germany


Greece


Hungary


Iceland


Ireland


Italy


Latvia


Lithuania


Luxembourg


Netherlands


Norway


Poland


Portugal


Romania


Russia


Serbia


Slovakia


Slovenia


Spain


Sweden


Switzerland


Turkey


United Kingdom

PhRMA
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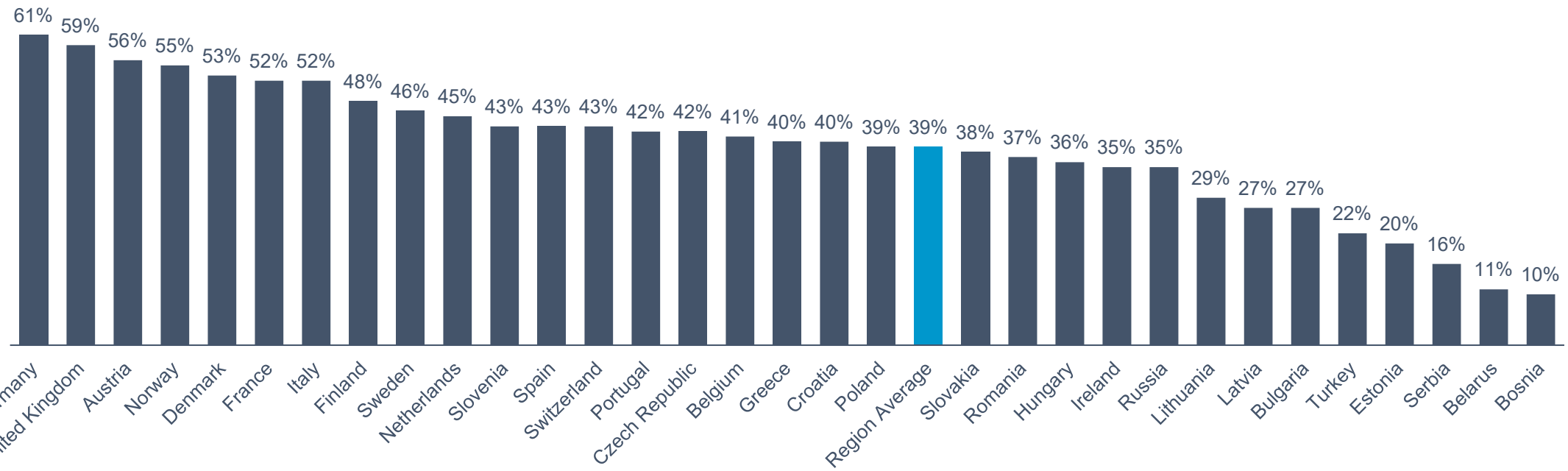
On Average, European Countries Have 39% of New Medicines Available

Percentage of New Medicines Launched by European Country (of all 460 new medicines launched from 2012 to end of 2021)

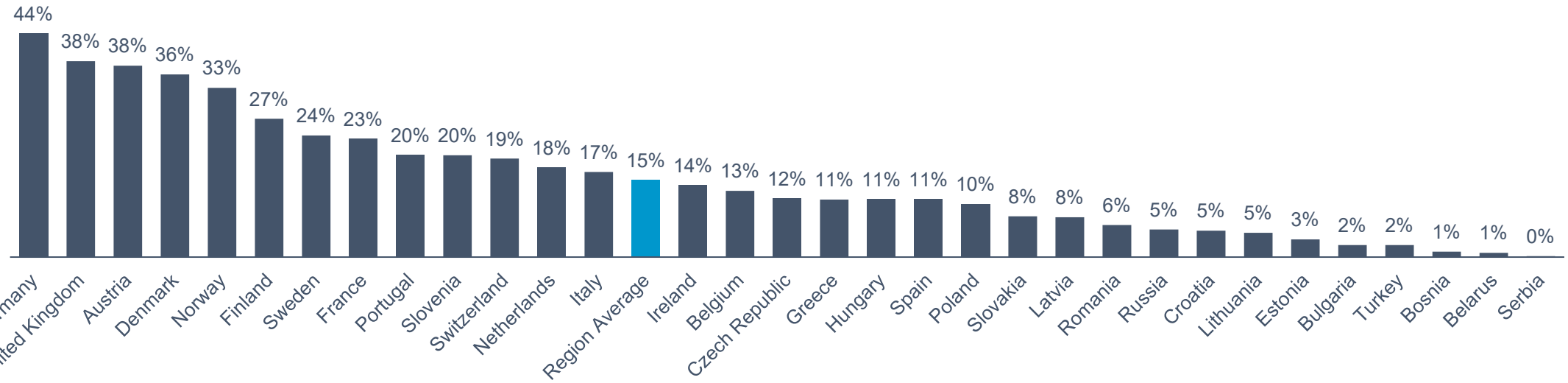


PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

On Average, European Countries Have 15% of New Medicines Available Within One Year of Global First Launch

Percentage of New Medicines Launched Within One Year of Global First Launch by European Country (of all 460 new medicines launched from 2012 to end of 2021)

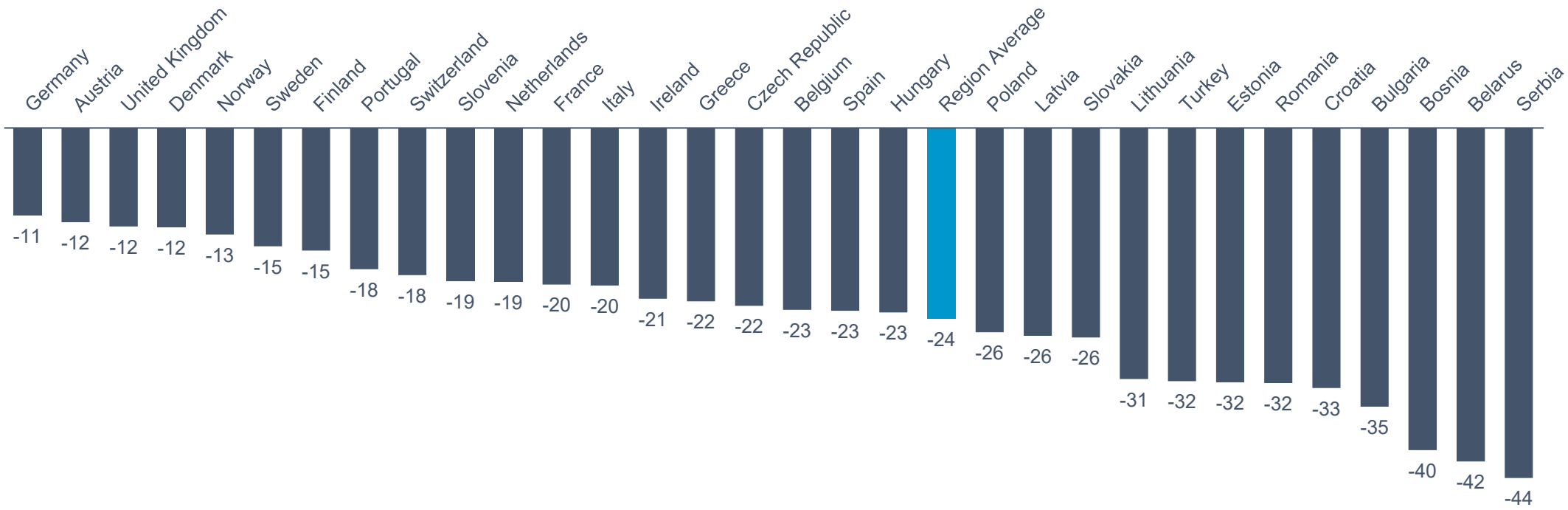


PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

On Average, New Medicines Launch 24 Months After Global First Launch Among European Countries

Average Months from Global First Launch to Local Launch by European Country (of new medicines launched by country from 2012 to end of 2021)

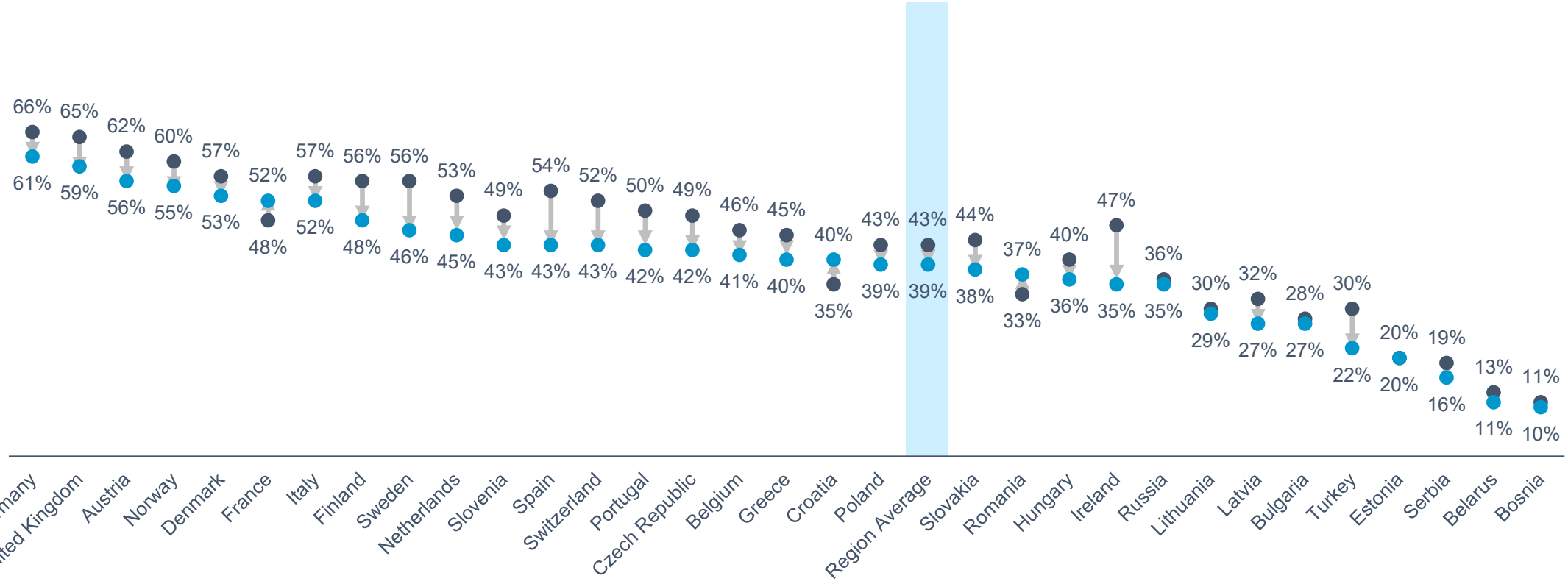


PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

Availability of New Medicines Declined Over Time in Most European Countries

Croatia Improved Most and Ireland, Spain and Sweden Declined Most



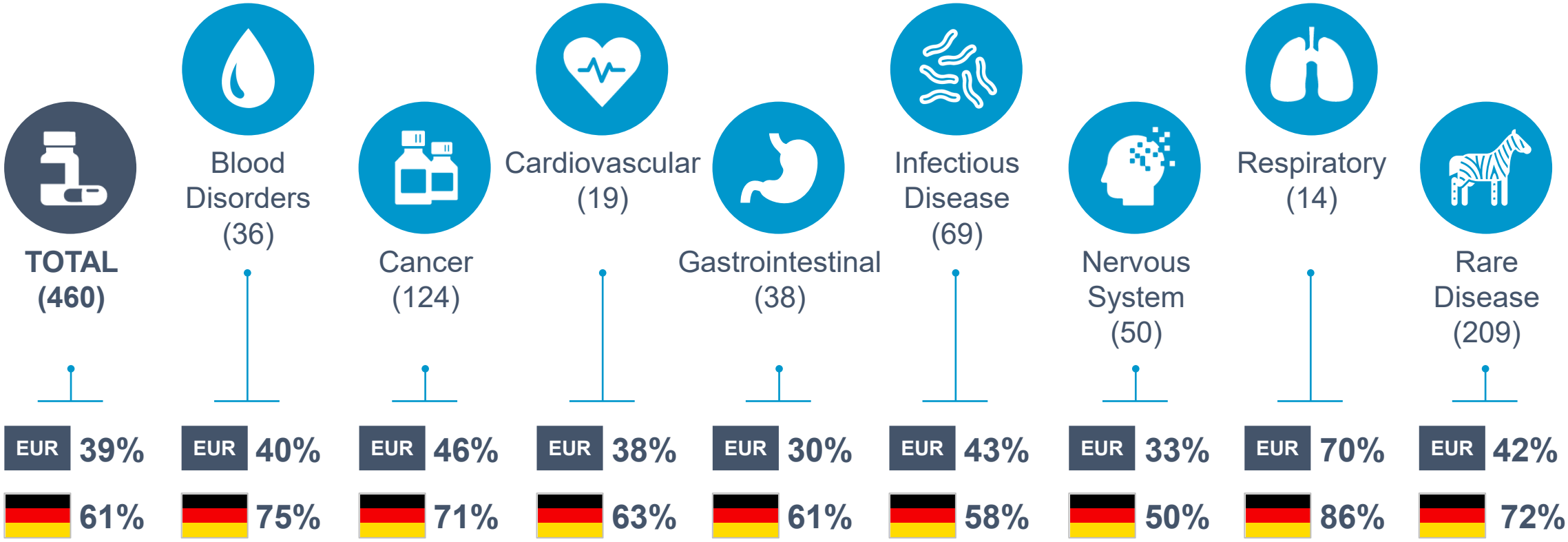
PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

Europe
Launched

Availability of New Medicines in European Countries by Therapy Area

Average vs. Leading Regional Country Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)

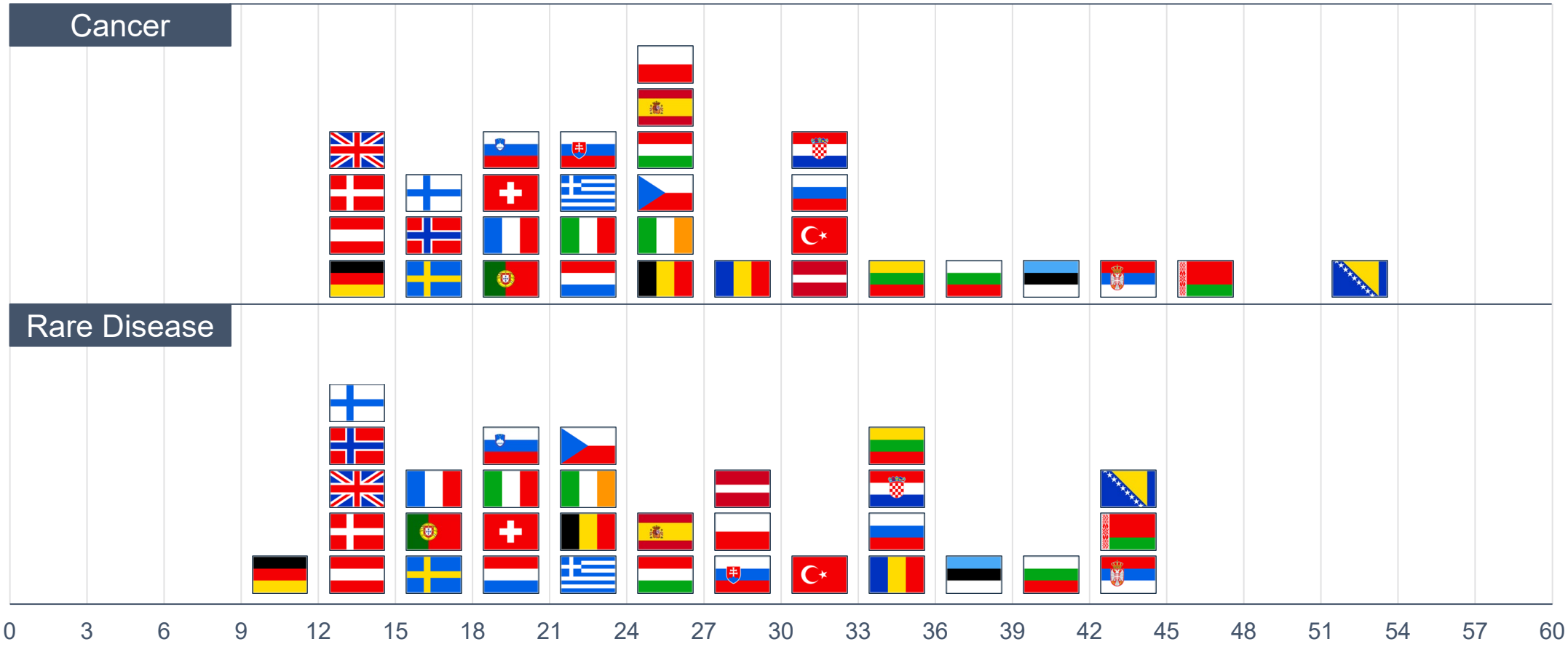


PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg. Therapy areas are mutually exclusive except for rare disease.

Europe
Launched

New Medicines For Cancer and Rare Diseases Launch Fastest in Germany Among European Countries



PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

Europe
Launched

Access to New Medicines in the Middle East and Africa

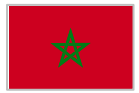

Algeria


Egypt


Jordan


Kuwait


Lebanon


Morocco


Saudi Arabia


South Africa


Tunisia


UAE

PhRMA
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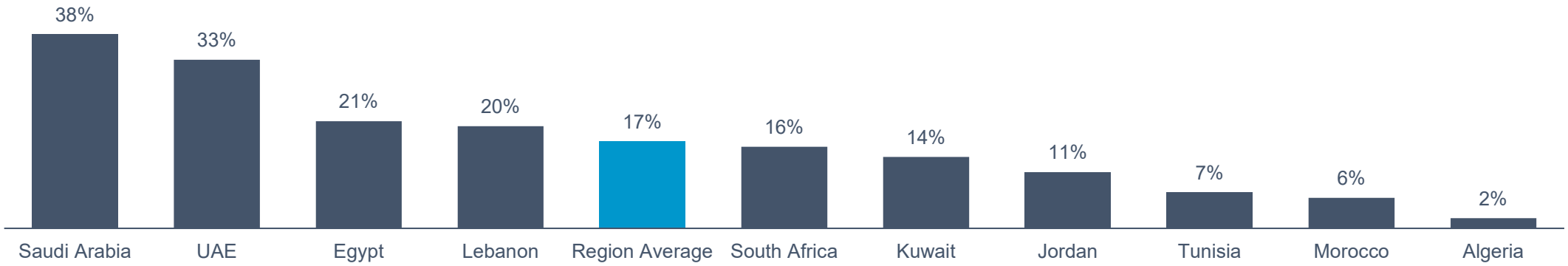
On Average, Middle East and Africa Countries Have 17% of New Medicines Available

Percentage of New Medicines Launched by Middle East and Africa Country (of all 460 new medicines launched from 2012 to end of 2021)

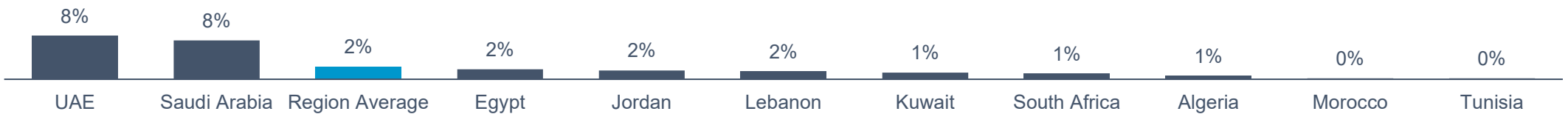


PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

On Average, Middle East and Africa Countries Have 2% of New Medicines Available Within One Year of Global First Launch

Percentage of New Medicines Launched Within One Year of Global First Launch by Middle East and Africa Country (of all 460 new medicines launched from 2012 to end of 2021)



PhRMA
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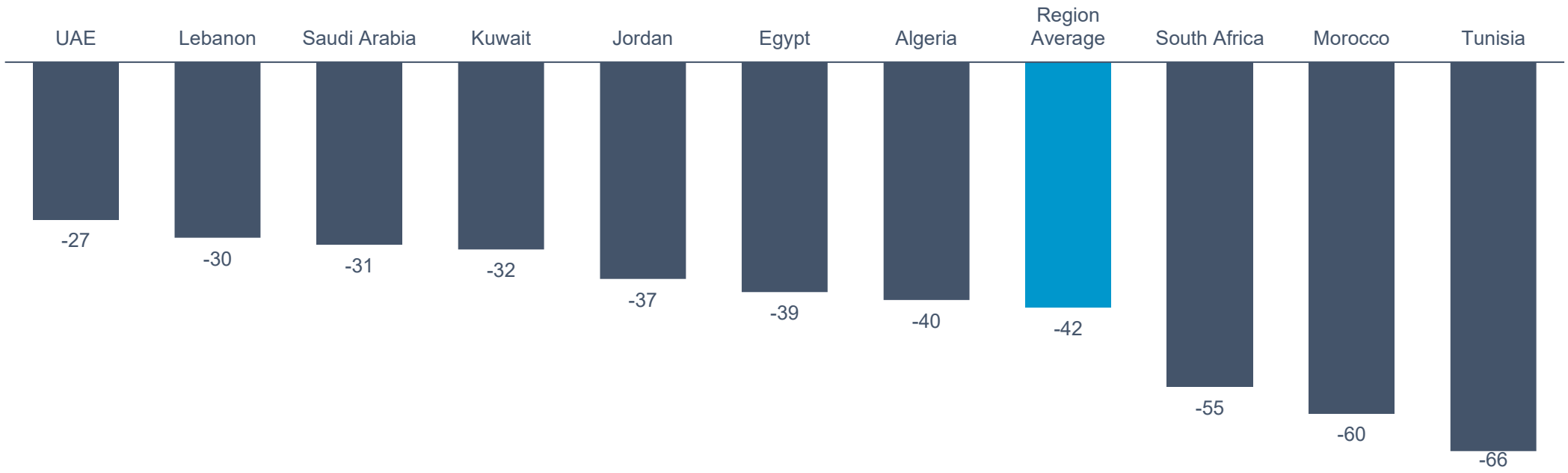
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

On Average, New Medicines Launch 42 Months After Global First Launch Among Middle East and Africa Countries

Average Months from Global First Launch to Local Launch by Middle East and Africa Country (of new medicines launched in a country from 2012 to end of 2021)



PhRMA
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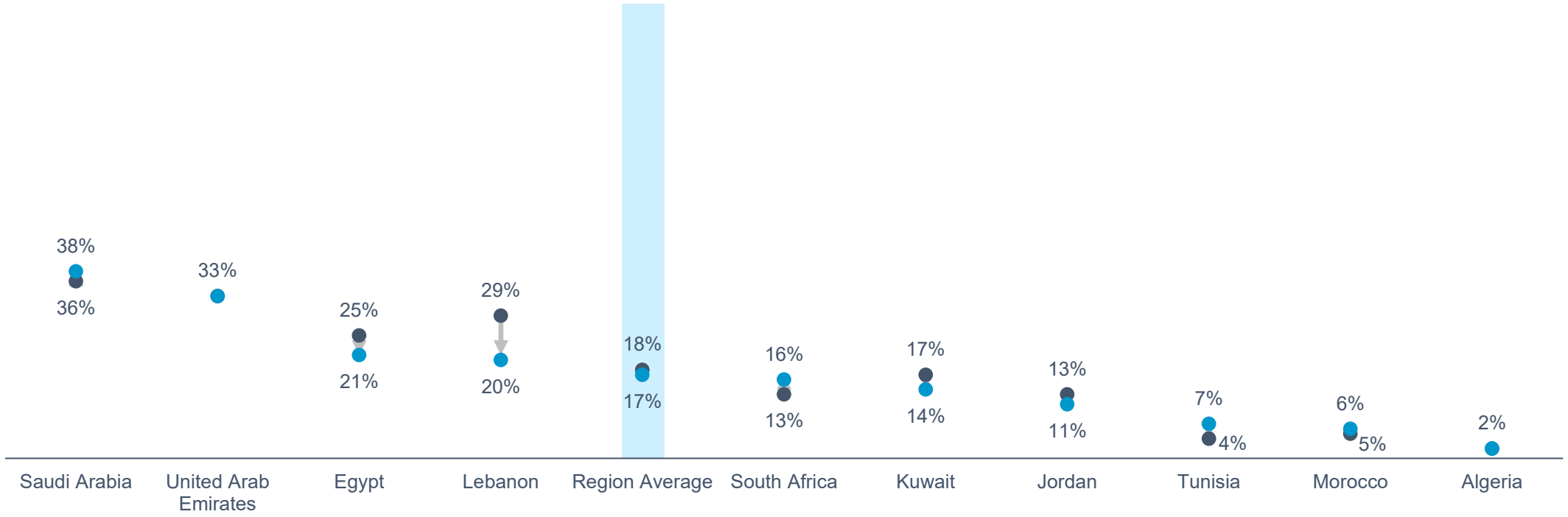
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

MEA
Launched

Availability of New Medicines Declined Over Time in Most Middle East and Africa Countries

South Africa and Tunisia Improved Most and Lebanon Declined Most



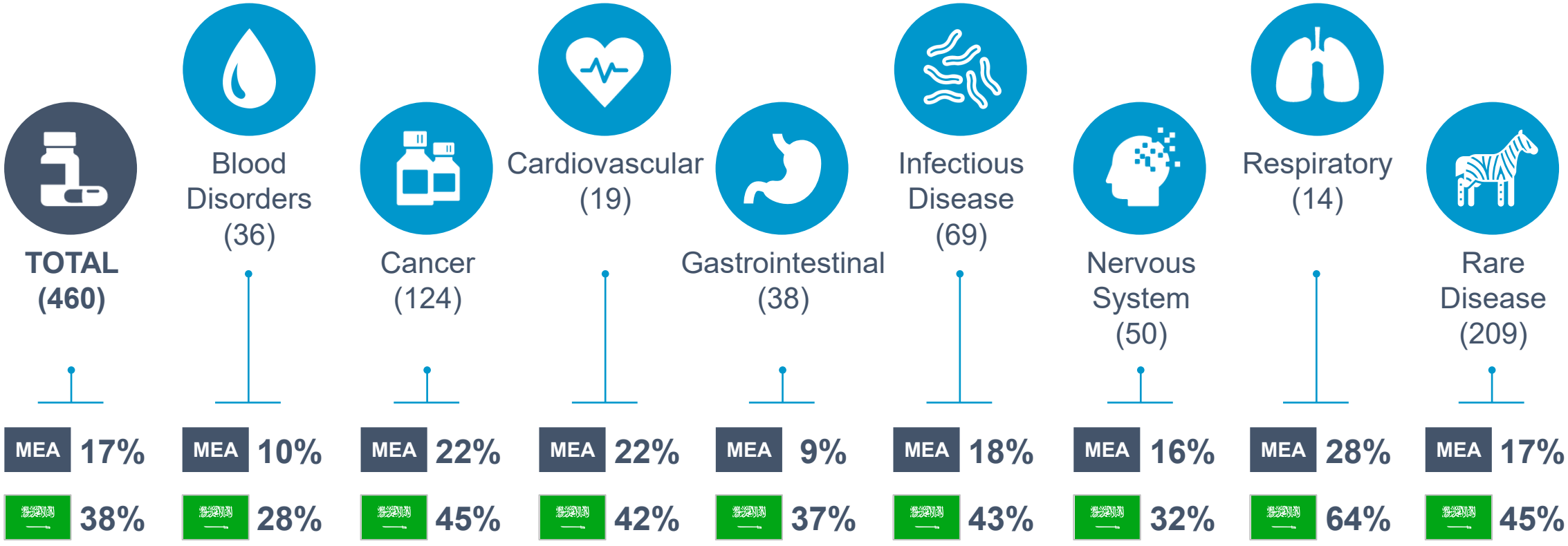
PhRMA
RESEARCH • PROGRESS • HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021.

MEA
Launched

Availability of New Medicines in Middle East and Africa Countries by Therapy Area

Average vs. Leading Regional Country Percentage of New Medicines Launched (of all 460 new medicines launched from 2012 to end of 2021)



PhRMA
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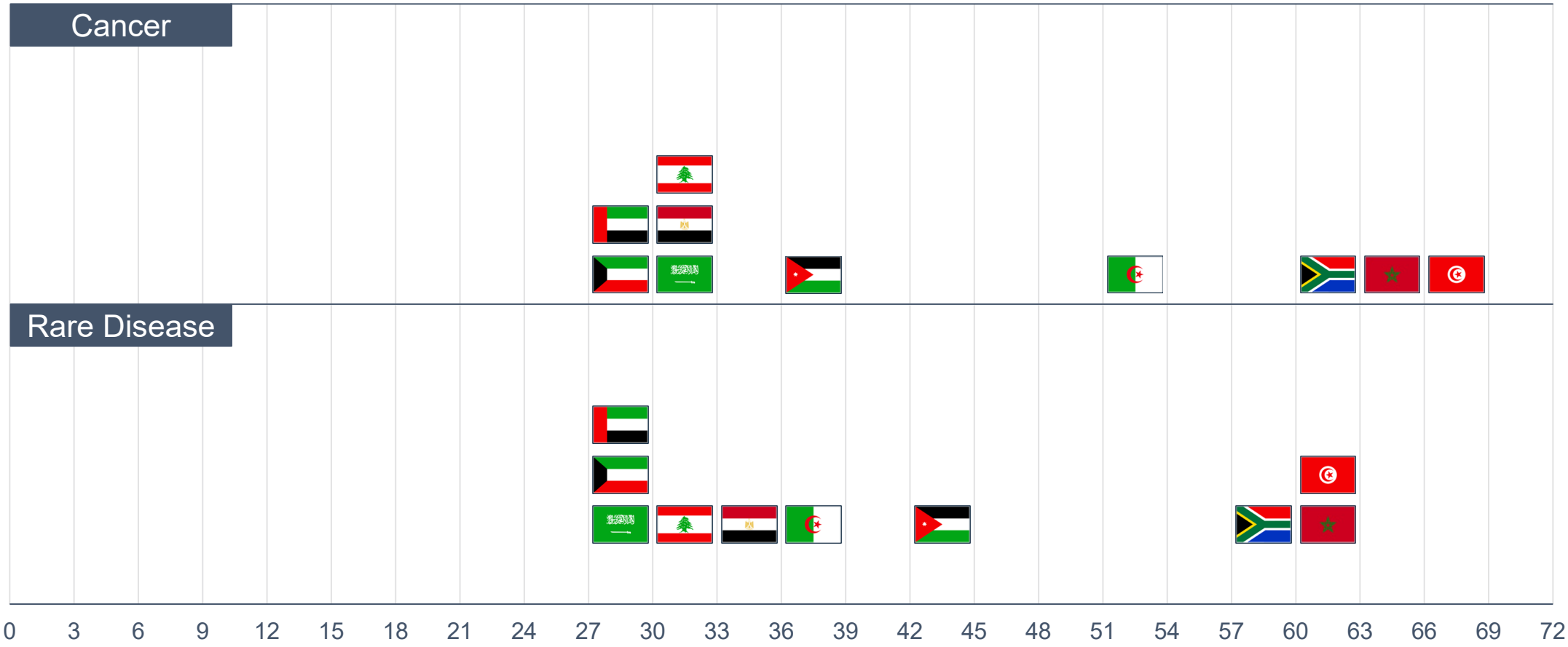
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Therapy areas are mutually exclusive except for rare disease.

MEA
Launched

New Medicines For Cancer and Rare Diseases Launch Fastest in UAE or Saudi Arabia Among Middle East and Africa Countries



PhRMA
RESEARCH + PROGRESS + HOPE

Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data. October 2022.
Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

MEA
Launched

Definitions and Methods

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Definitions and Methods

New Medicines in this report refers to all new active substances approved by the United States Food and Drug Administration, European Medicines Agency and/or Japan Pharmaceuticals and Medical Devices Agency and first launched in any country between January 1, 2012, and December 31, 2021. A new active substance is a chemical or biological substance not previously used in any other authorized medicine. During this time period, 460 new medicines launched in at least one of the 72 markets included in this report.

Launch Dates reflect when new medicines first become available for sale regardless of payer in each country. Launch dates are identified using a variety of data sources, including IQVIA MIDAS®, NAVLIN Price & Access Data and country regulatory data.

Public Reimbursement Dates reflect when new medicines first become covered by a public insurance plan, regardless of whether coverage is restricted to a subset of potential patients. For countries with a small private market, public reimbursement dates indicate when much of the population is first able to access new medicines. Public reimbursement dates for new medicines are identified using public formularies and lists, NAVLIN Price & Access Data and country regulatory data.

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