

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. In several markets, patient access barriers remain when public reimbursement of medicines is restricted to only some of the approved uses.

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



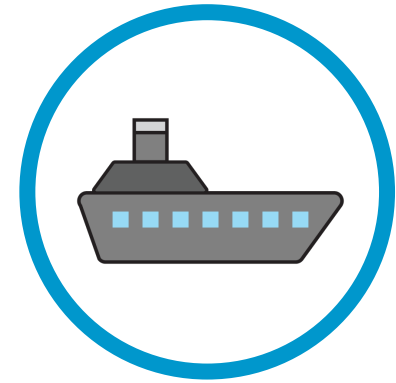
Strong intellectual property rights and enforcement



Science-based and globally-harmonized regulatory review



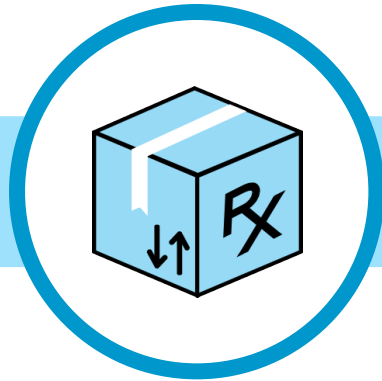
Transparent pricing and reimbursement that values innovation



Open and nondiscriminatory trade

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

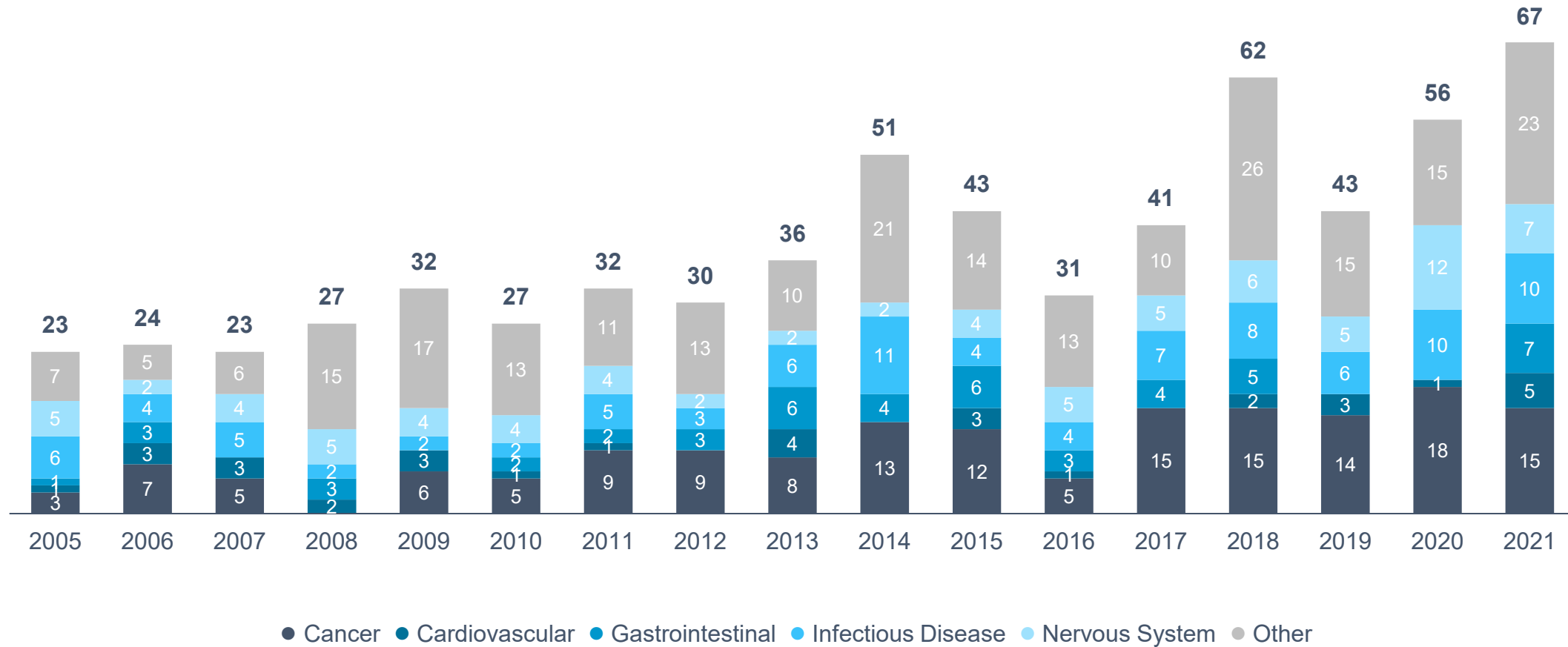
- Medicine is covered by public insurance
- At least some patients can use a public insurance plan to pay for the medicine
- Patients face access restrictions if the plan only covers some approved uses

Global Trends



A Record Number of New Medicines Launched in 2021

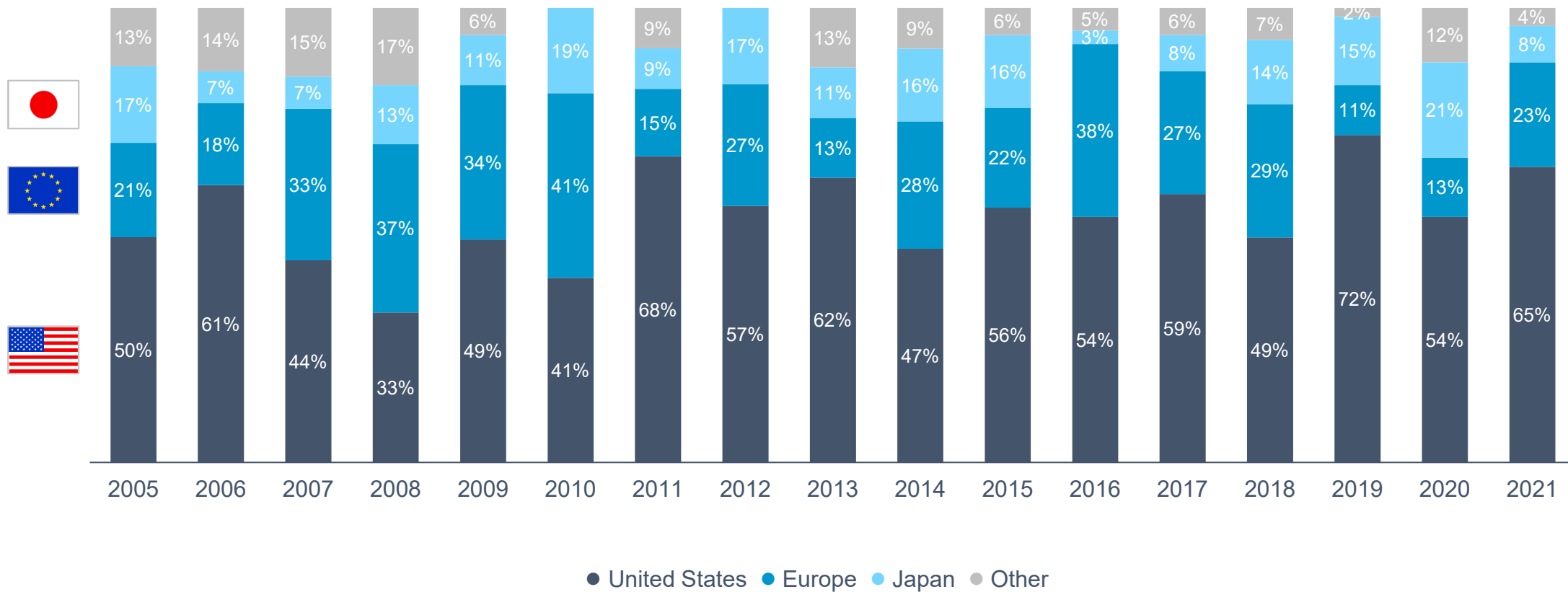
Number of New Medicines Launched Globally by Year and Therapy Area
(of all 648 new medicines launched from 2005 to end of 2021)



● Cancer ● Cardiovascular ● Gastrointestinal ● Infectious Disease ● Nervous System ● Other

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)



International Comparisons

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



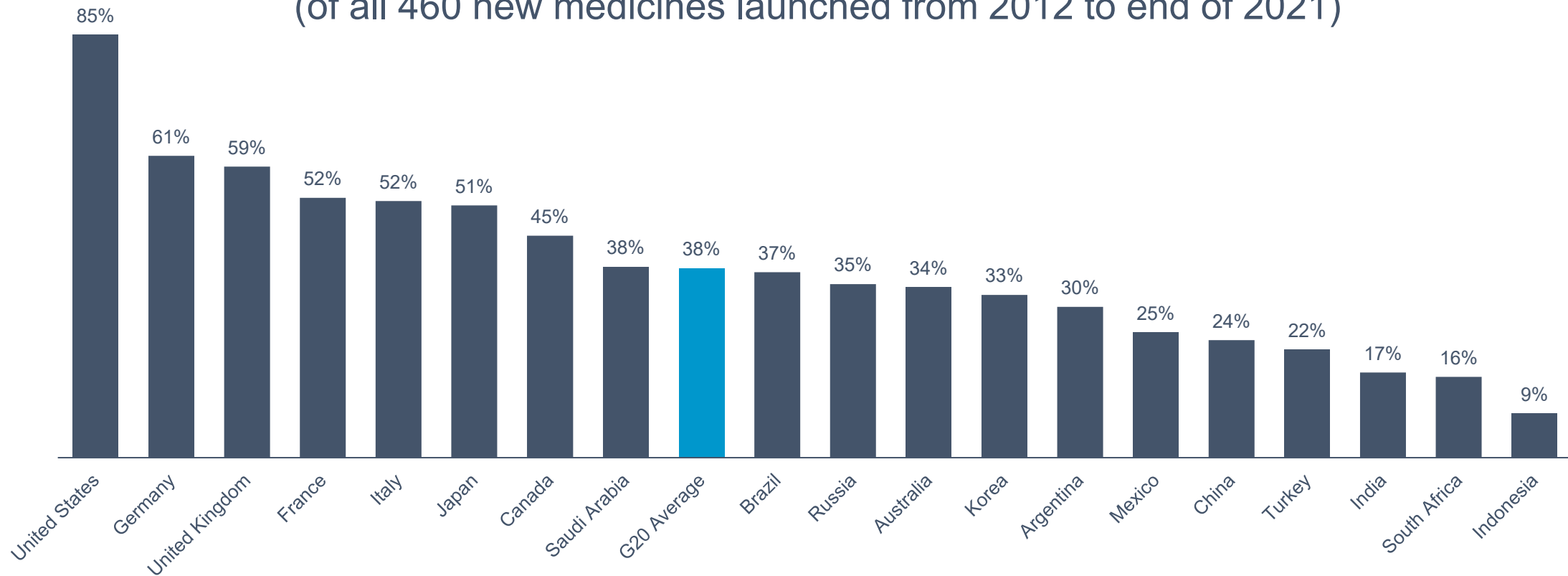
United States



European Union

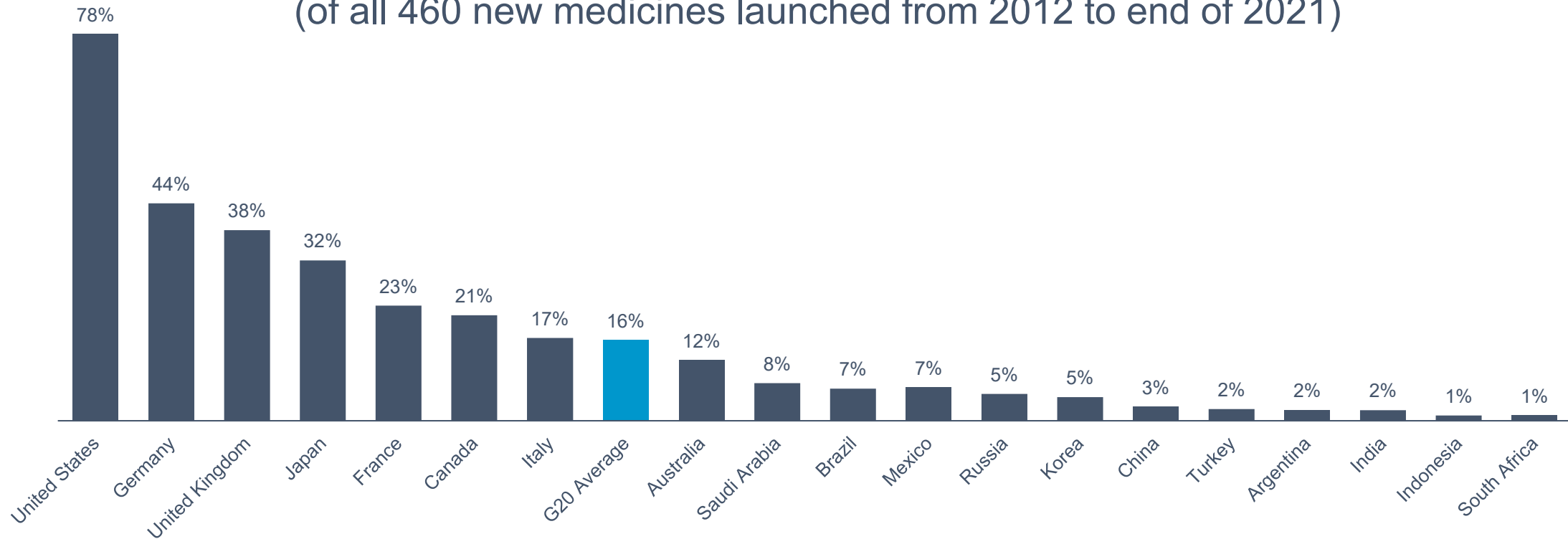
Launch of New Medicines Varies Significantly Across G20 Countries

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



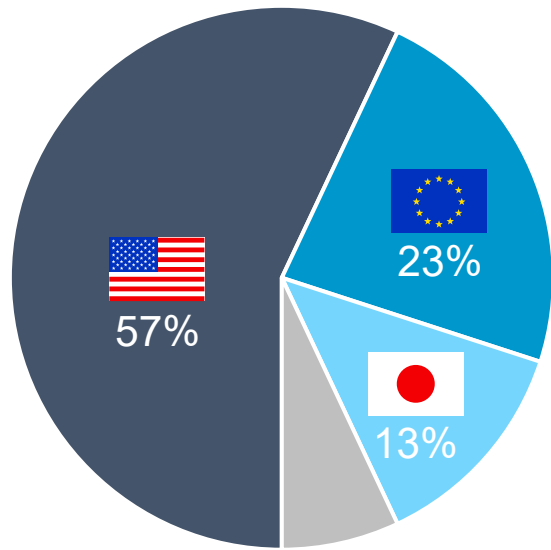
On Average, G20 Countries Have 16% of New Medicines Launched Within One Year of Global First Launch

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)



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)



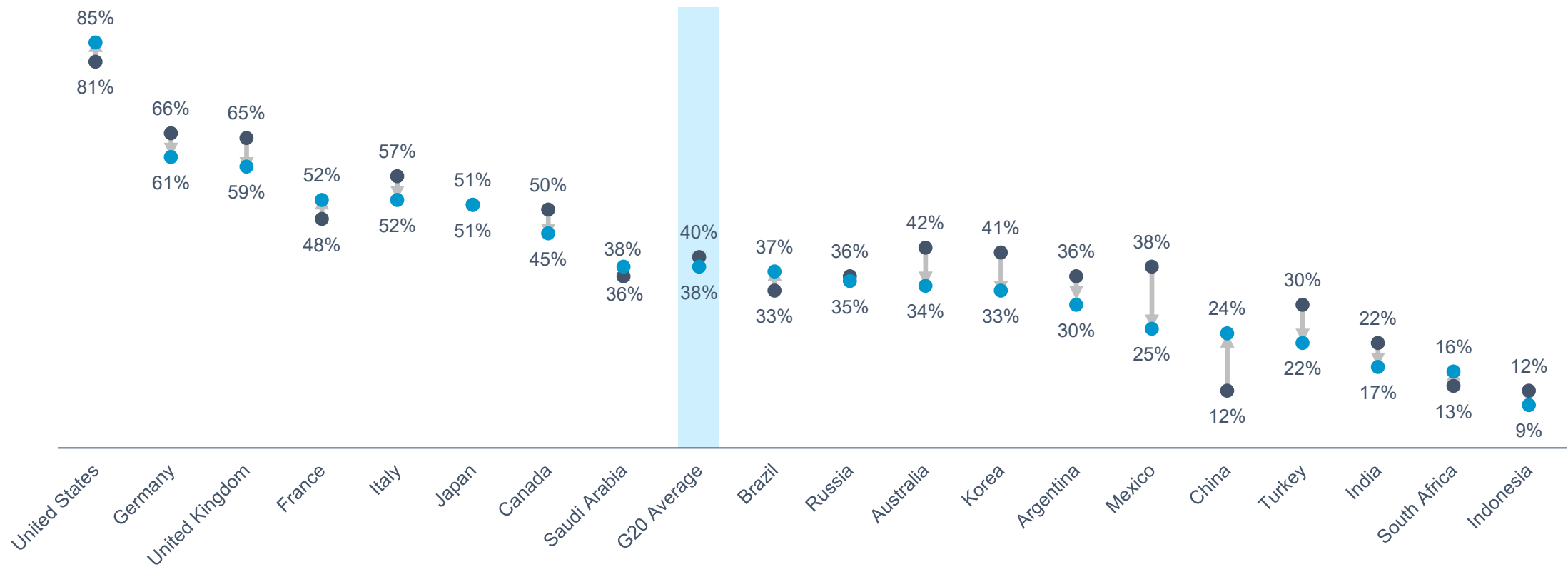
● United States ● Europe ● Japan ● Other

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



Launch of New Medicines Declined Over Time in Most G20 Countries

China Improved Most and Mexico Declined Most



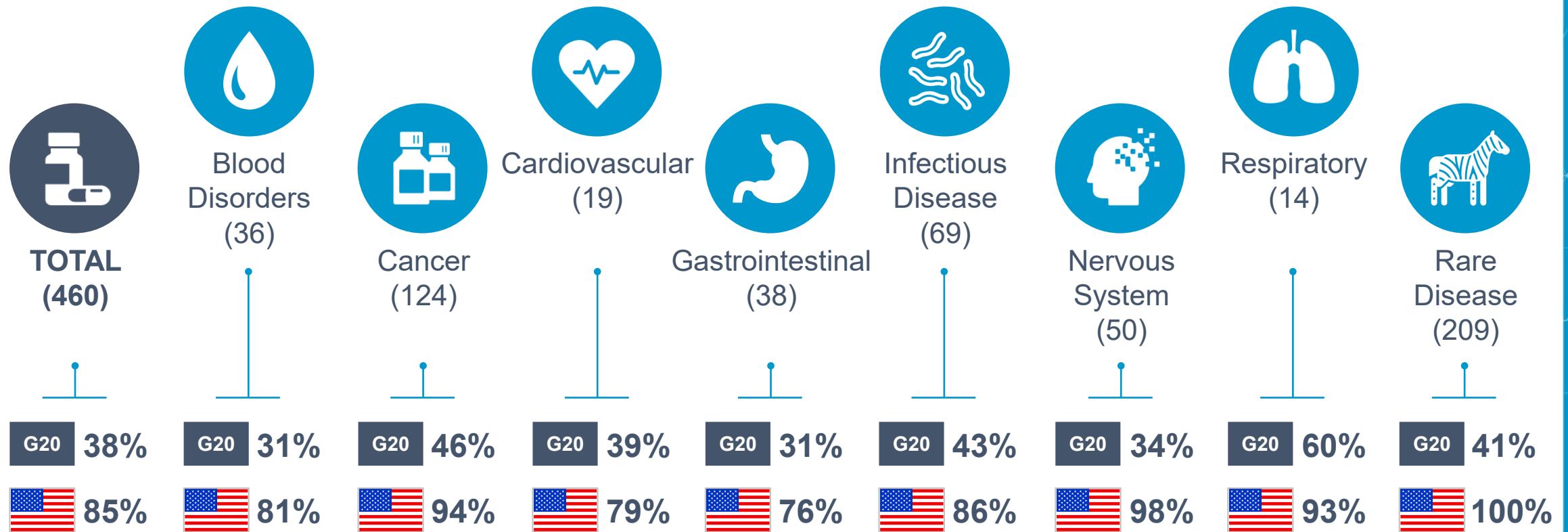
● New Medicines Launched Globally (2008 to 2017) as of 2017
 ● New Medicines Launched Globally (2012 to 2021) as of 2021



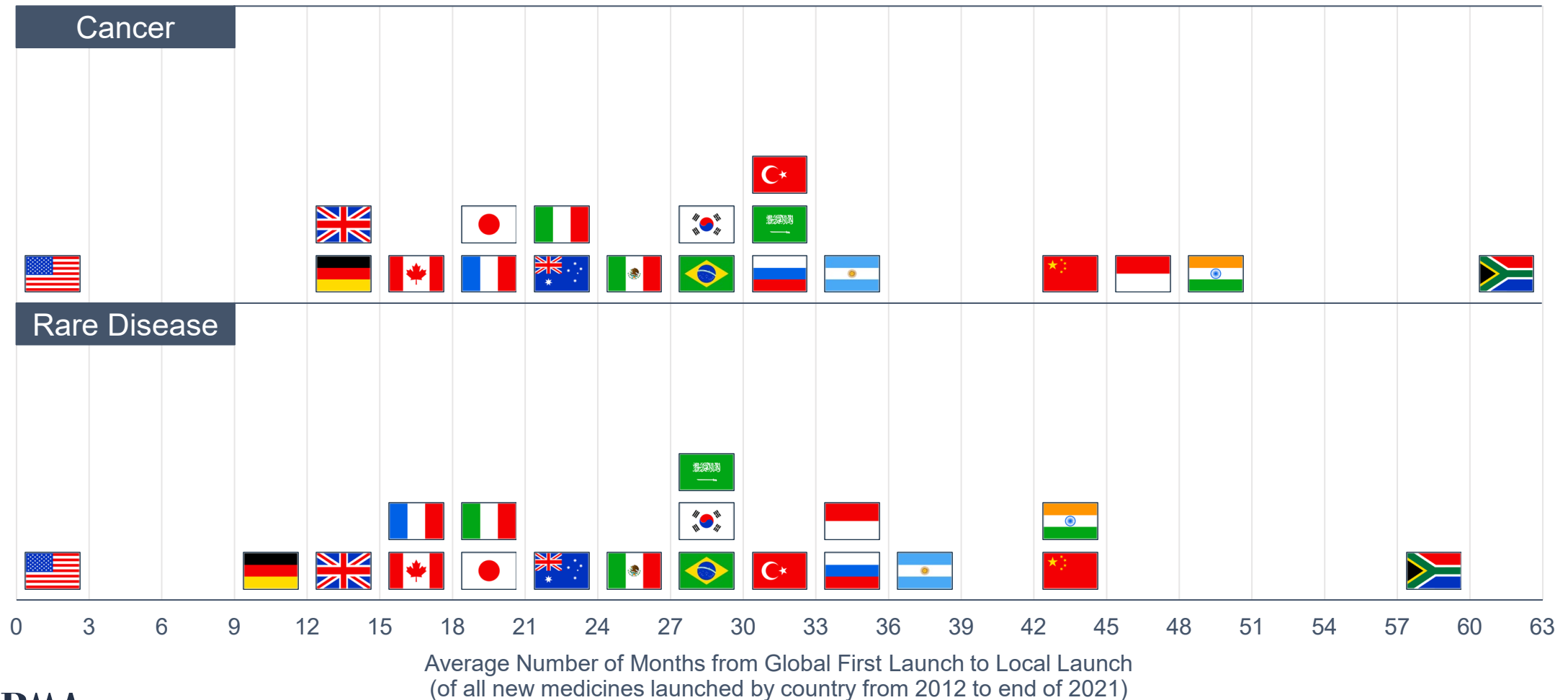
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data, October 2022.
 Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2005, and December 31, 2021.

Launch 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)

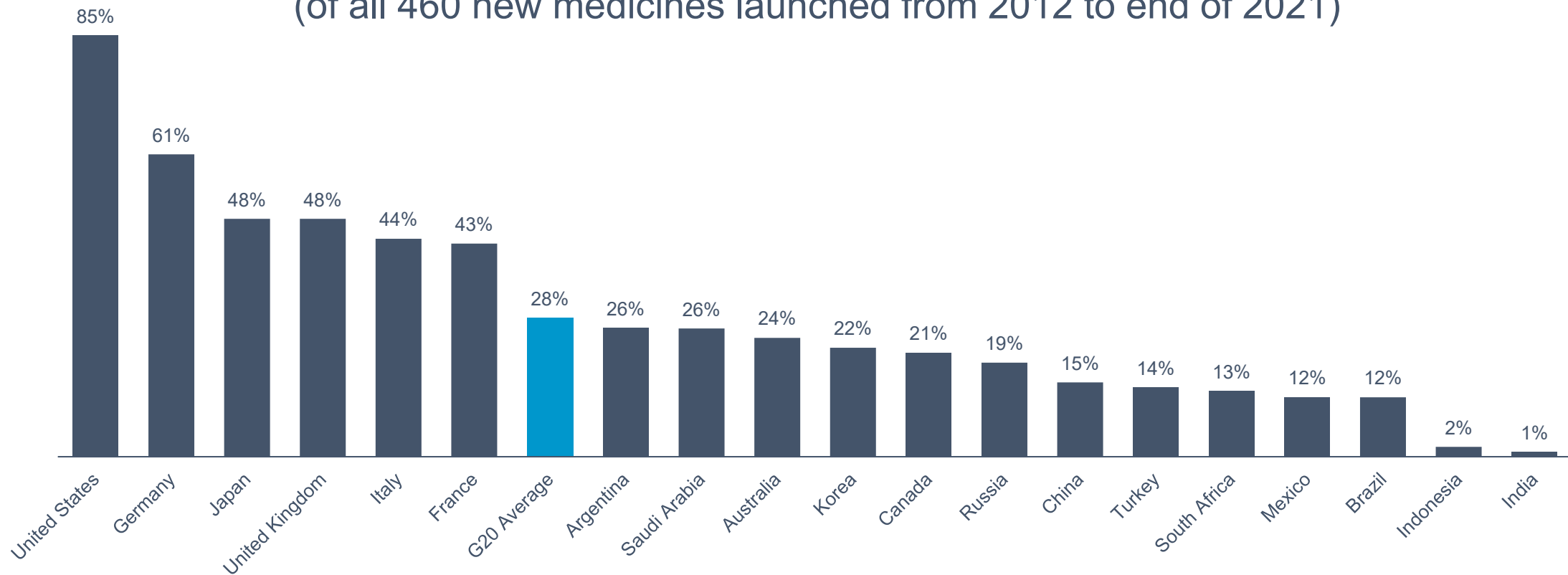


New Medicines For Cancer and Rare Diseases Launch Fastest in the United States Among G20 Countries



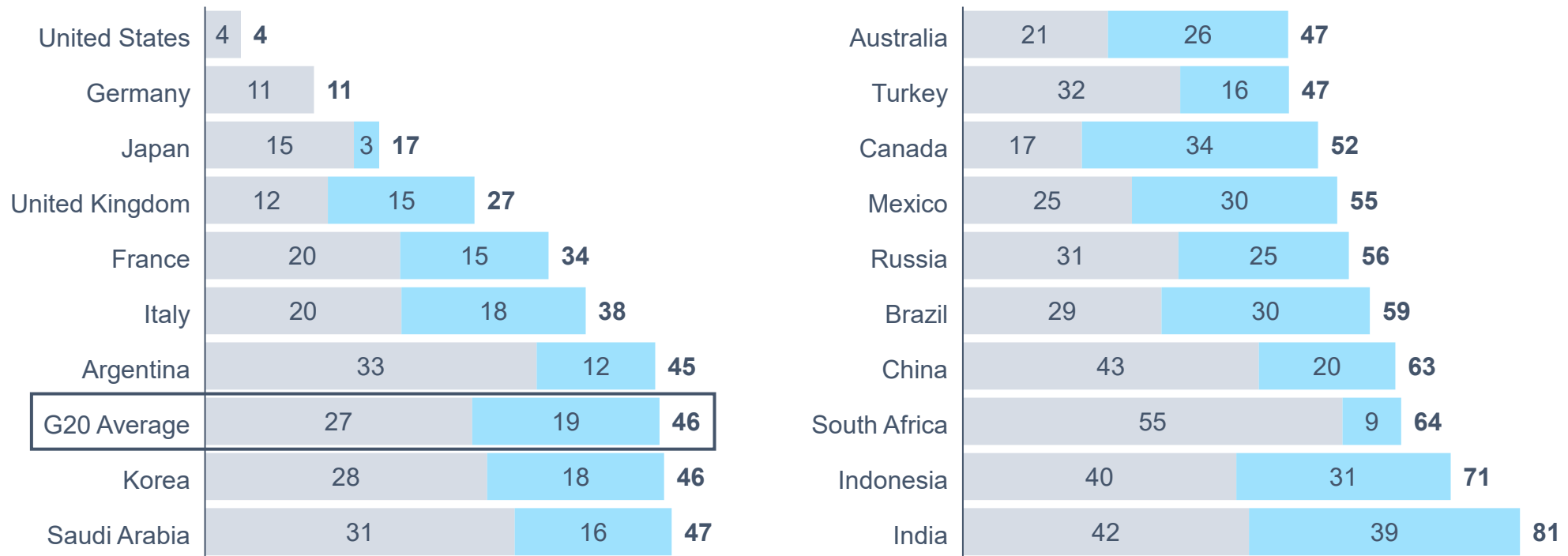
On Average, G20 Countries Have 28% of New Medicines Reimbursed by Public Insurance Plans

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



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

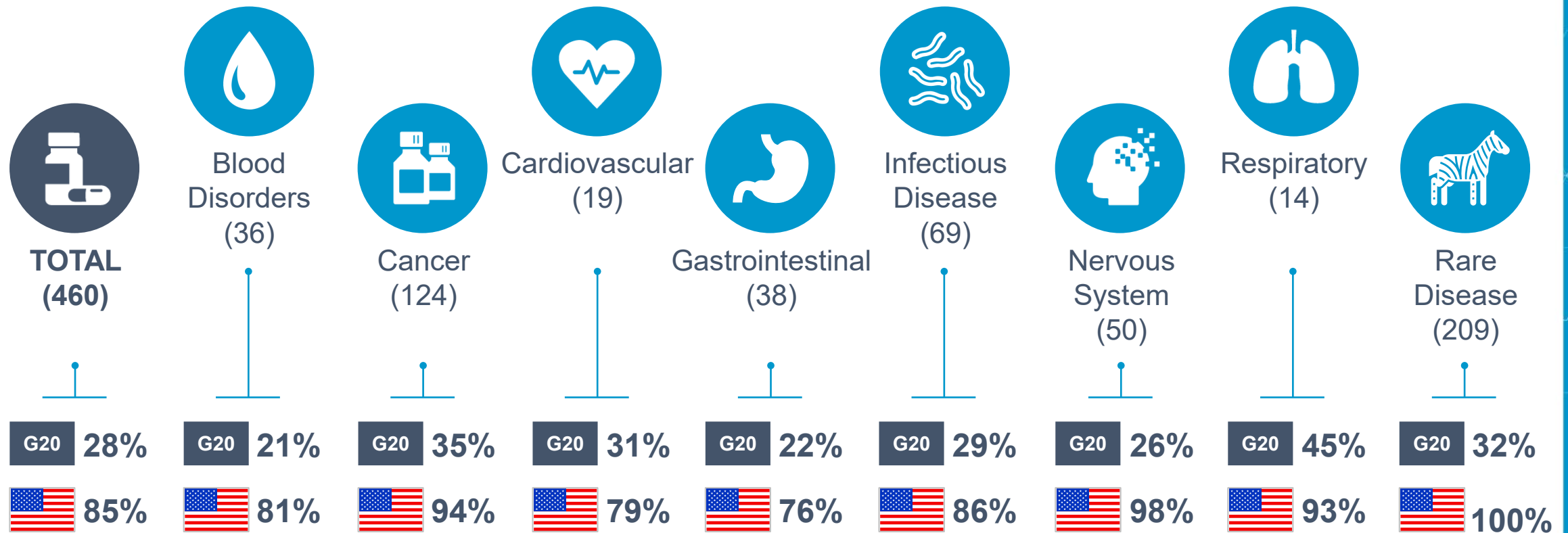
Number of Months from Global First Launch to Public Reimbursement by G20 Country (of all new medicines launched and reimbursed by country from 2012 to end of 2021)



- Average Number of Months from Global First Launch to Local Launch
- Average Number of Months from Local Launch to Public Reimbursement

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)



Access to New Medicines in OECD Countries



Australia



Austria



Belgium



Canada



Chile



Colombia



Costa Rica



Czech Republic



Denmark



Estonia



Finland



France



Germany



Greece



Hungary



Iceland



Ireland



Israel



Italy



Japan



Korea



Latvia



Lithuania



Luxembourg



Mexico



Netherlands



New Zealand



Norway



Poland



Portugal



Slovakia



Slovenia



Spain



Sweden



Switzerland



Turkey



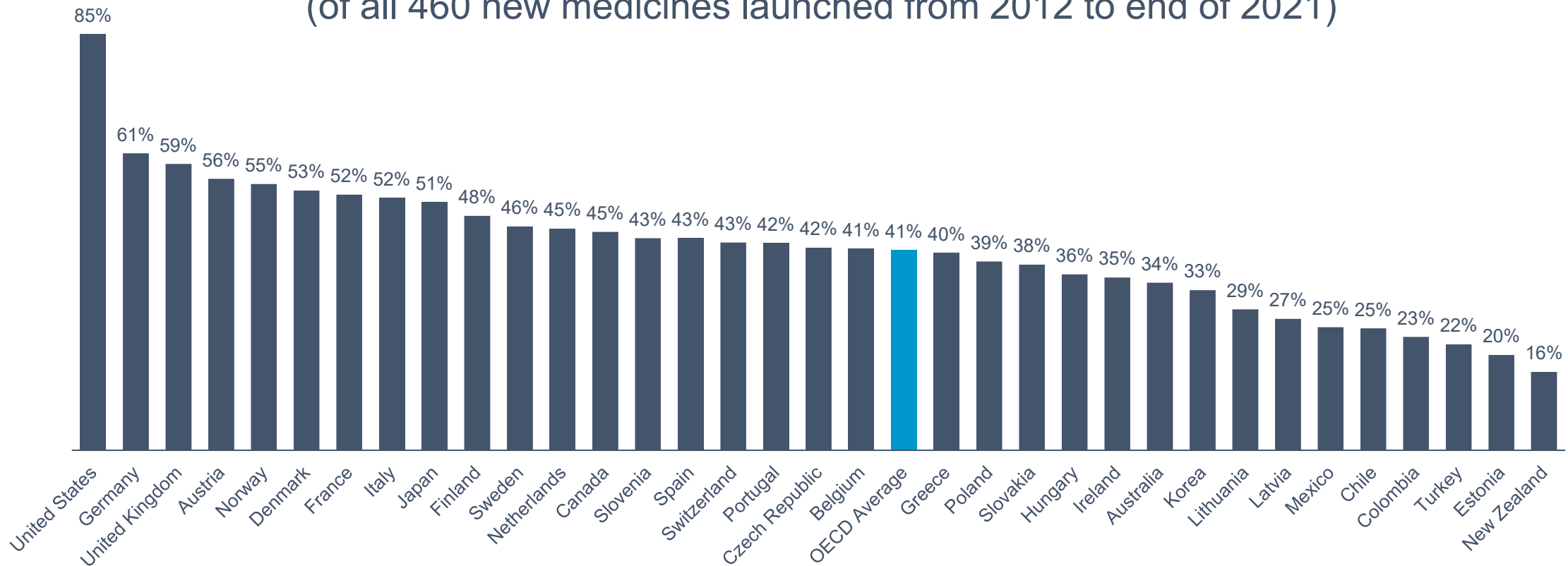
United Kingdom



United States

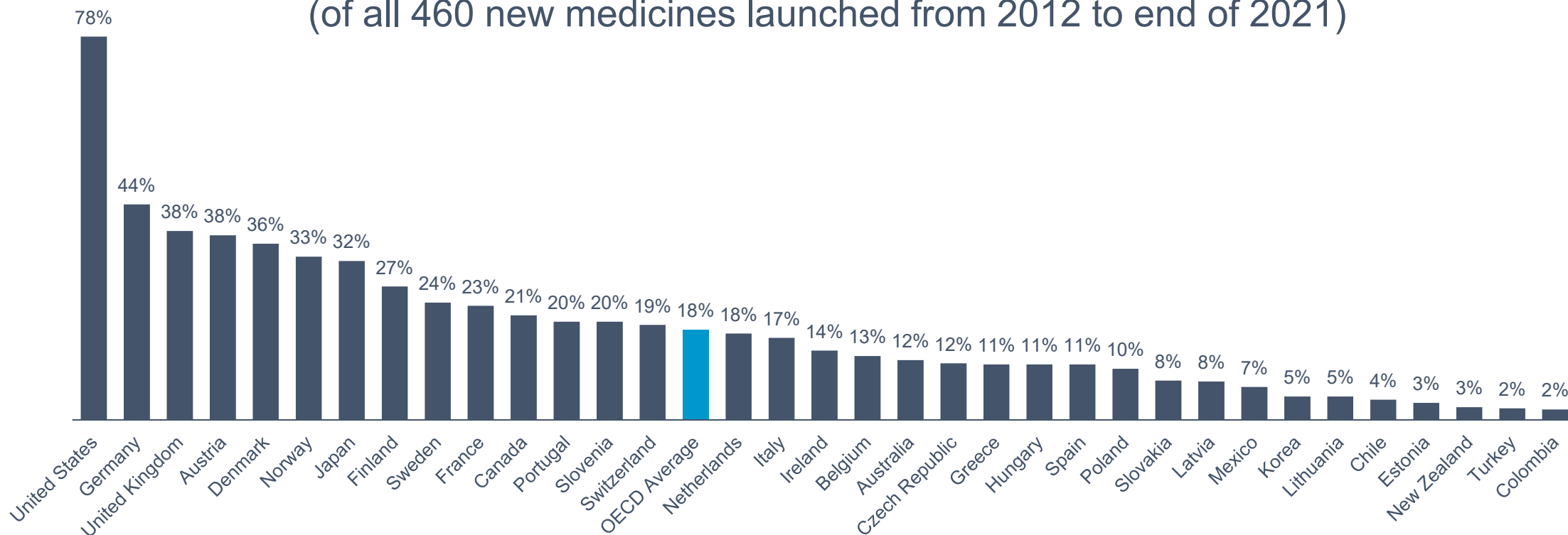
Launch of New Medicines Varies Significantly Across OECD Countries

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



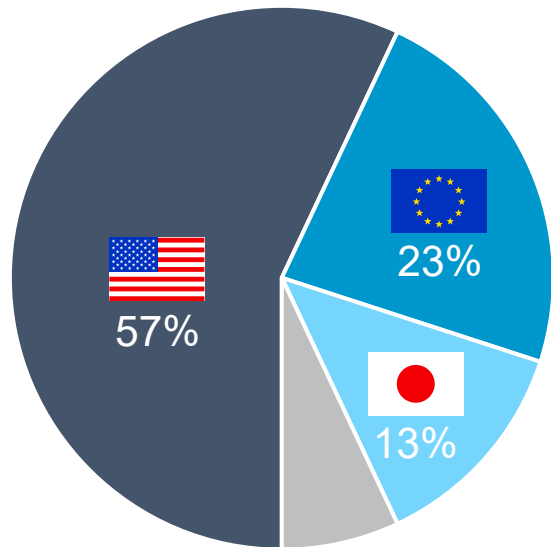
On Average, OECD Countries Have 18% of New Medicines Launched Within One Year of Global First Launch

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)



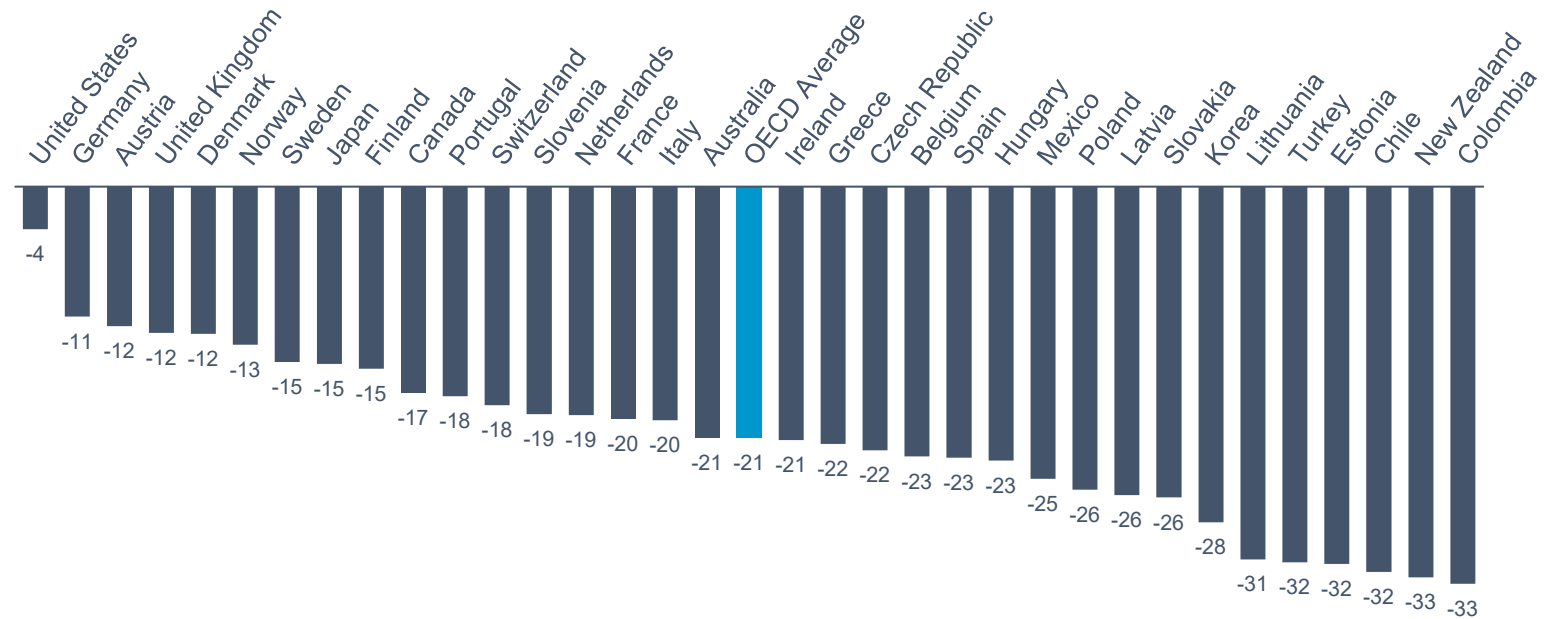
New Medicines Generally Launch First and Fastest in the United States Among OECD Countries

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



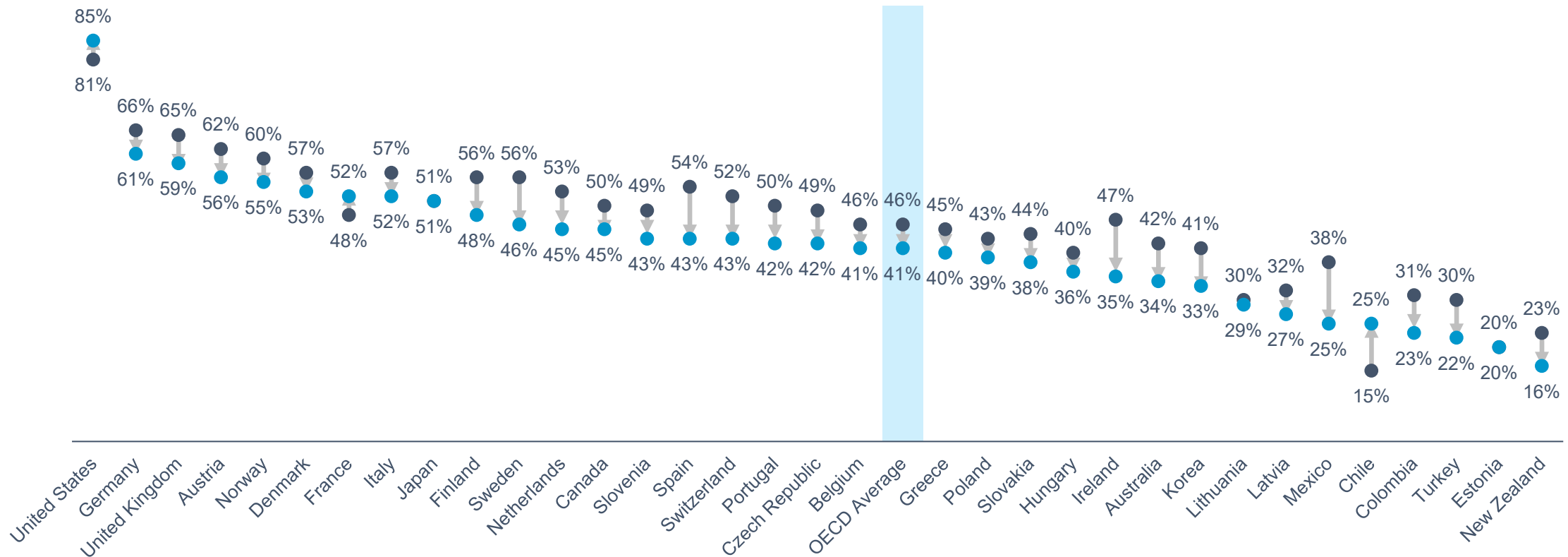
● United States ● Europe ● Japan ● Other

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



Launch of New Medicines Declined Over Time in Most OECD Countries

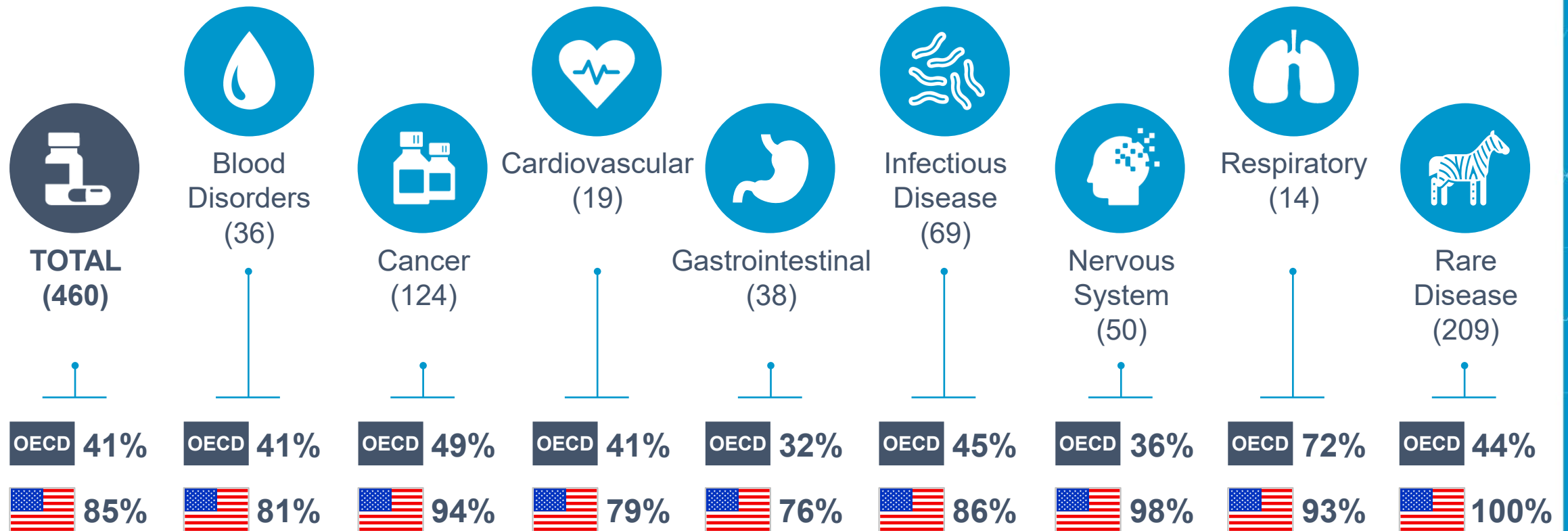
Chile Improved Most and Mexico Declined Most



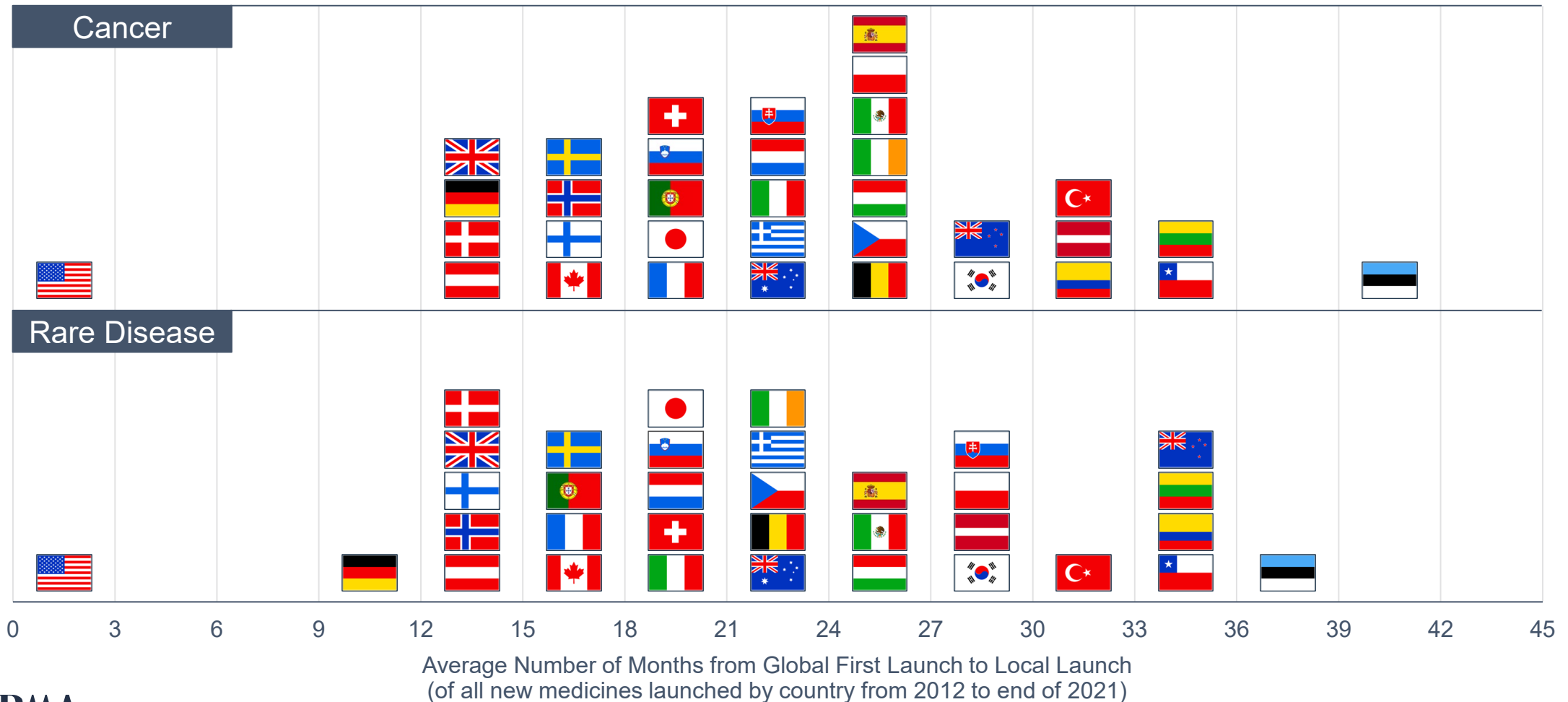
- New Medicines Launched Globally (2008 to 2017) as of 2017
- New Medicines Launched Globally (2012 to 2021) as of 2021

Launch 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)

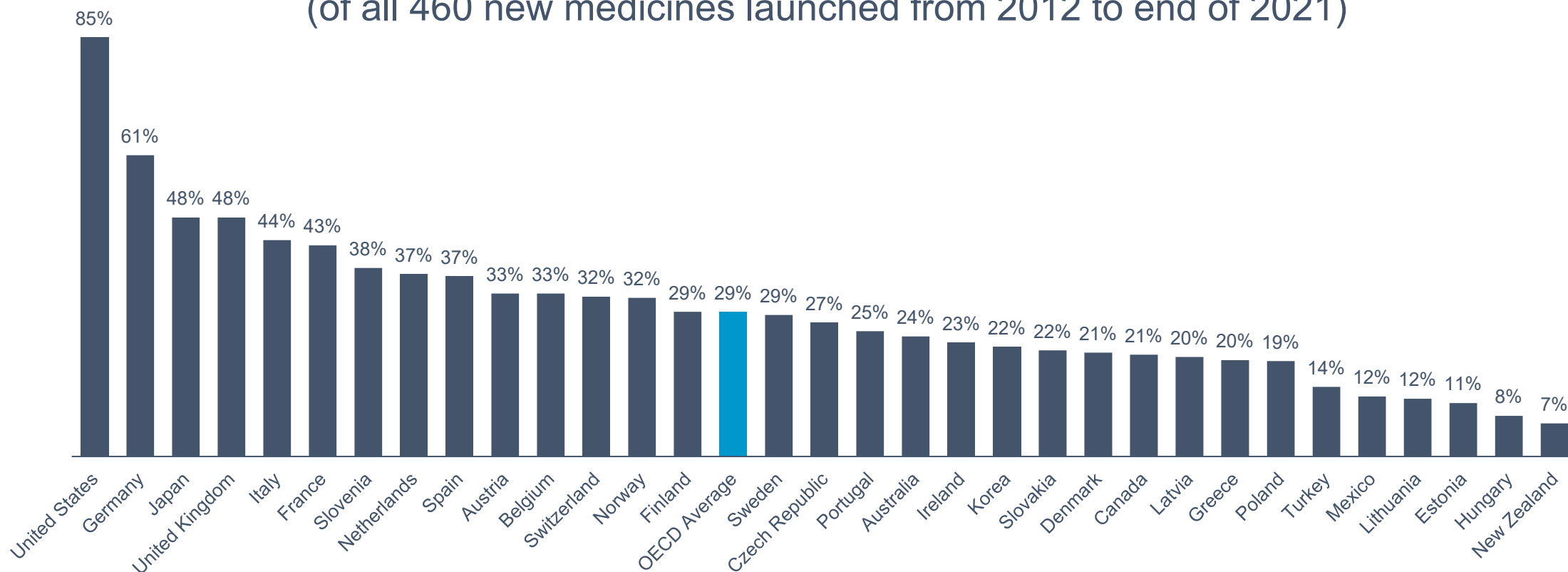


New Medicines For Cancer and Rare Diseases Launch Fastest in the United States Among OECD Countries



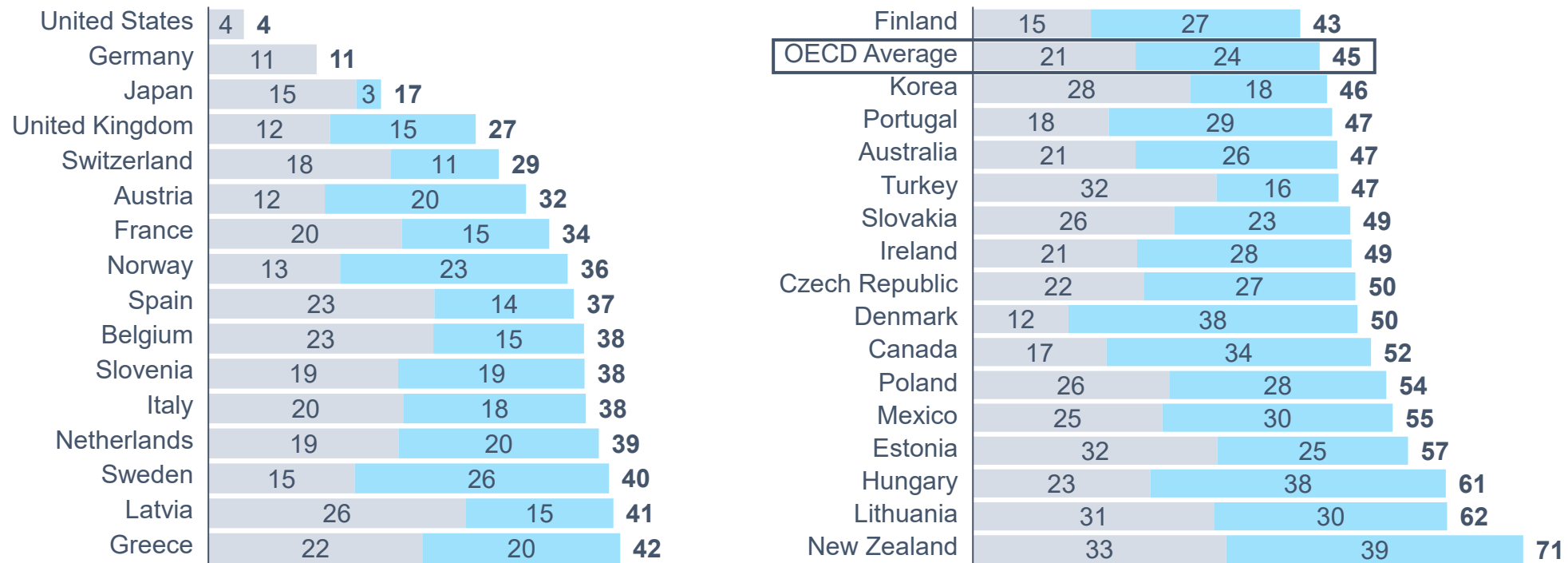
On Average, OECD Countries Have 29% of New Medicines Reimbursed by Public Insurance Plans

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



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

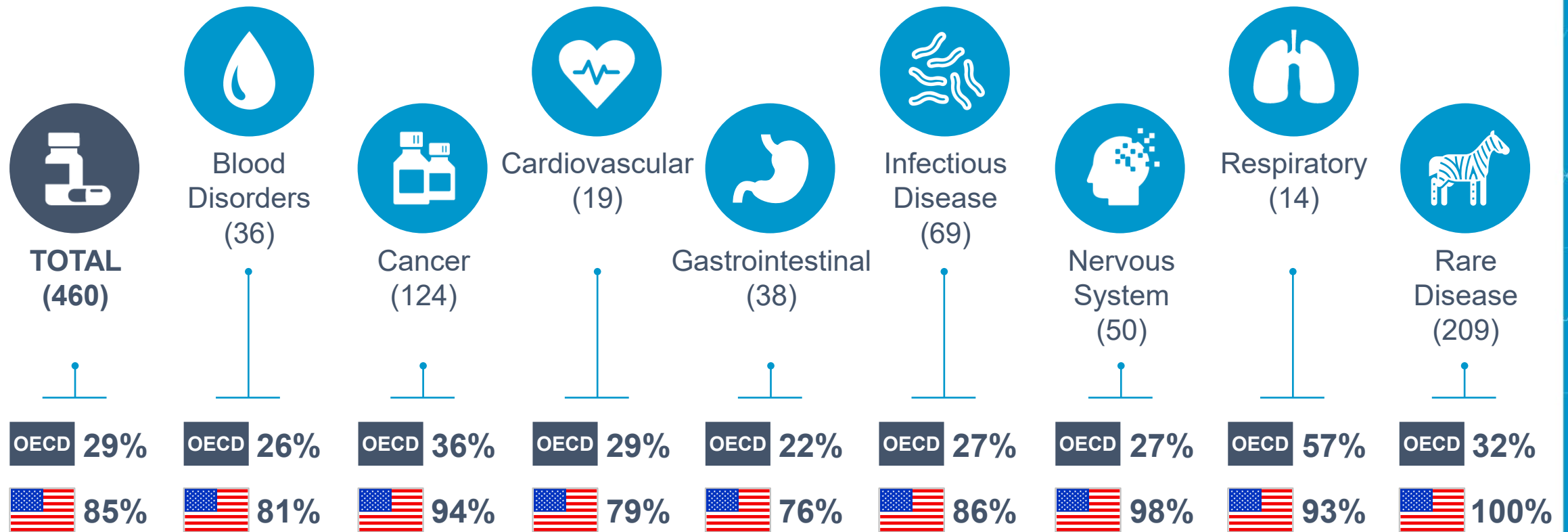
Number of Months from Global First Launch to Public Reimbursement by OECD Country (of all new medicines launched and reimbursed by country from 2012 to end of 2021)



- Average Number of Months from Global First Launch to Local Launch
- Average Number of Months from Local Launch to Public Reimbursement

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)



Access to New Medicines in the Americas



Argentina



Brazil



Canada



Chile



Colombia



Dominican Republic



Ecuador



Mexico



Peru



Uruguay



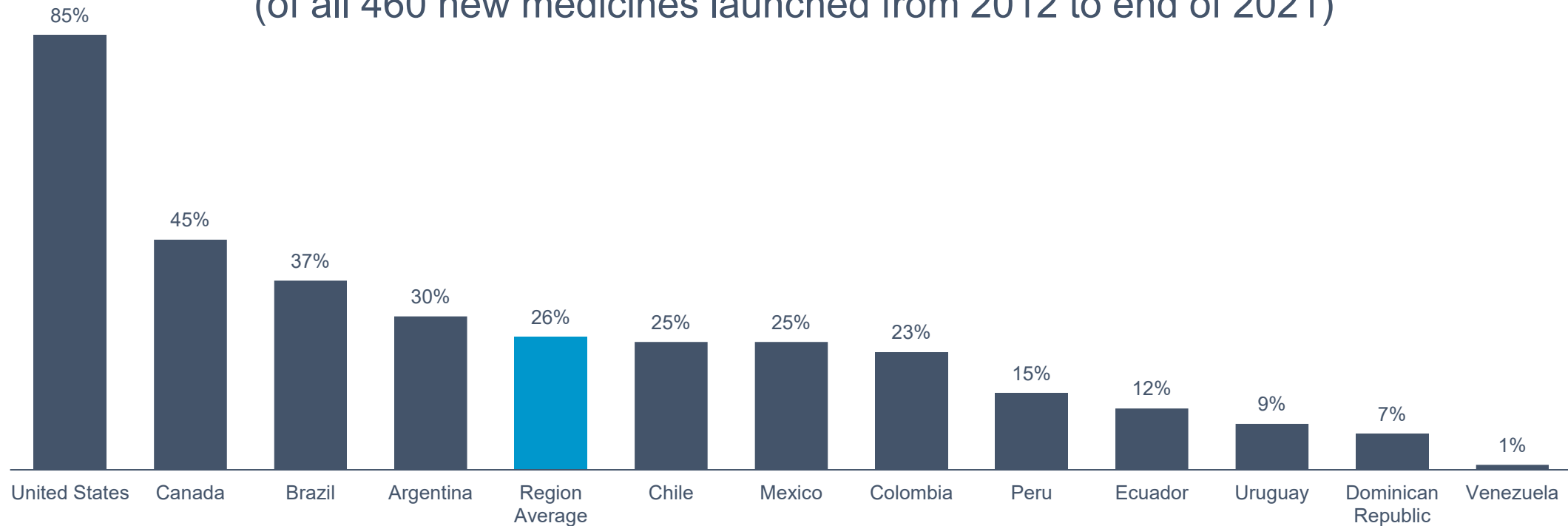
United States



Venezuela

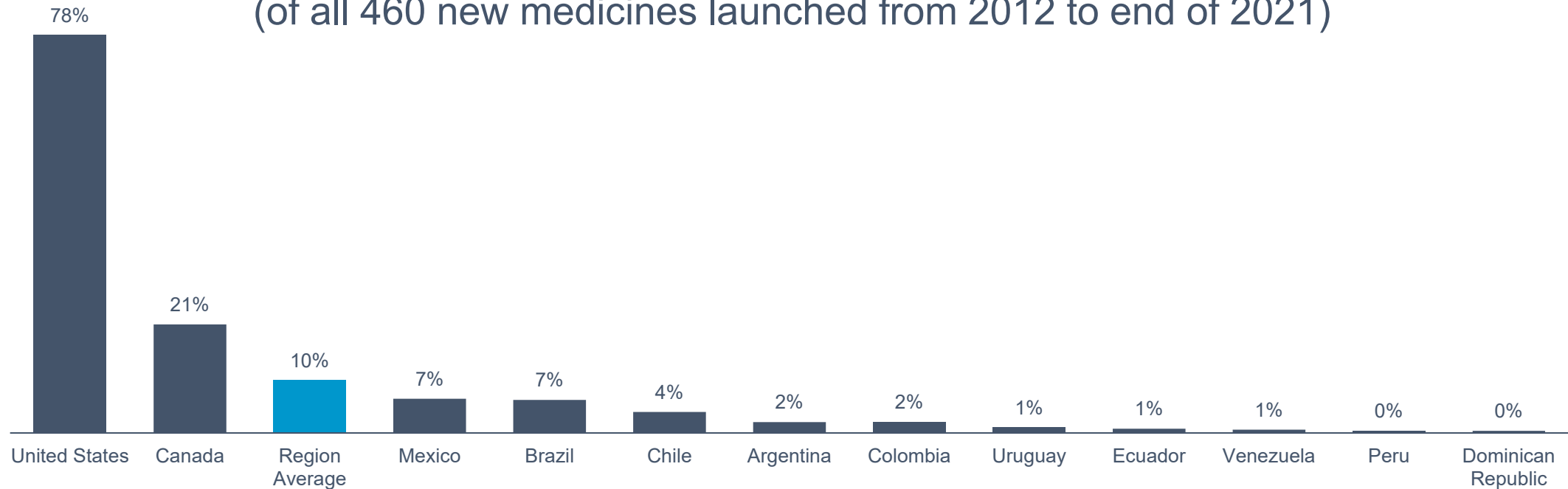
On Average, Countries in the Americas Have 26% of New Medicines Launch

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



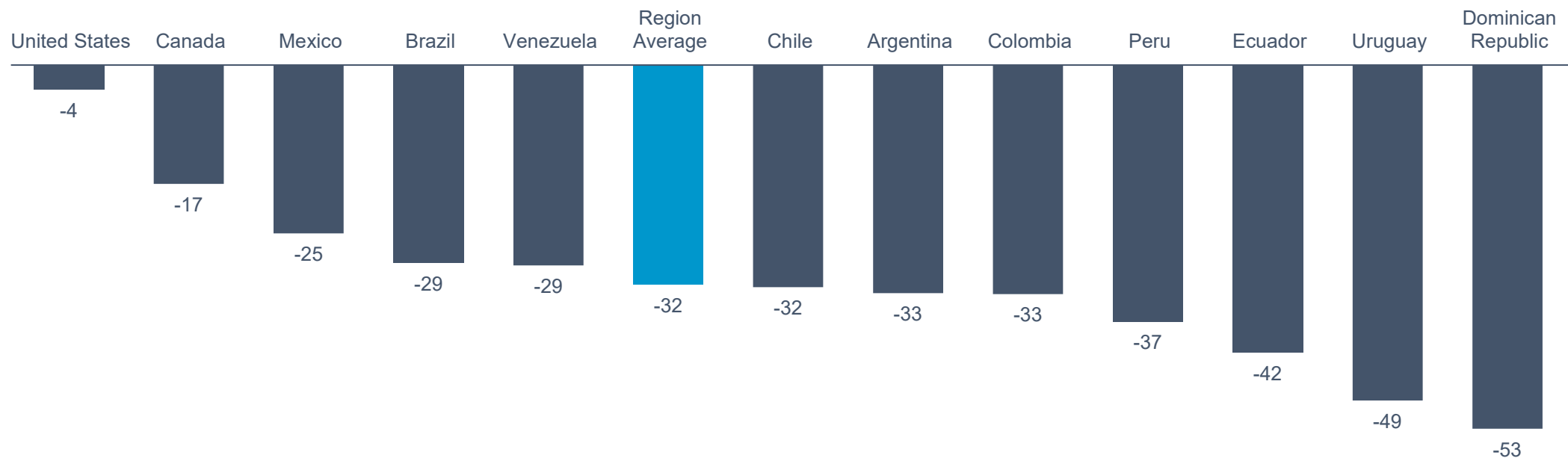
On Average, Countries in the Americas Have 10% of New Medicines Launch Within One Year of Global First Launch

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



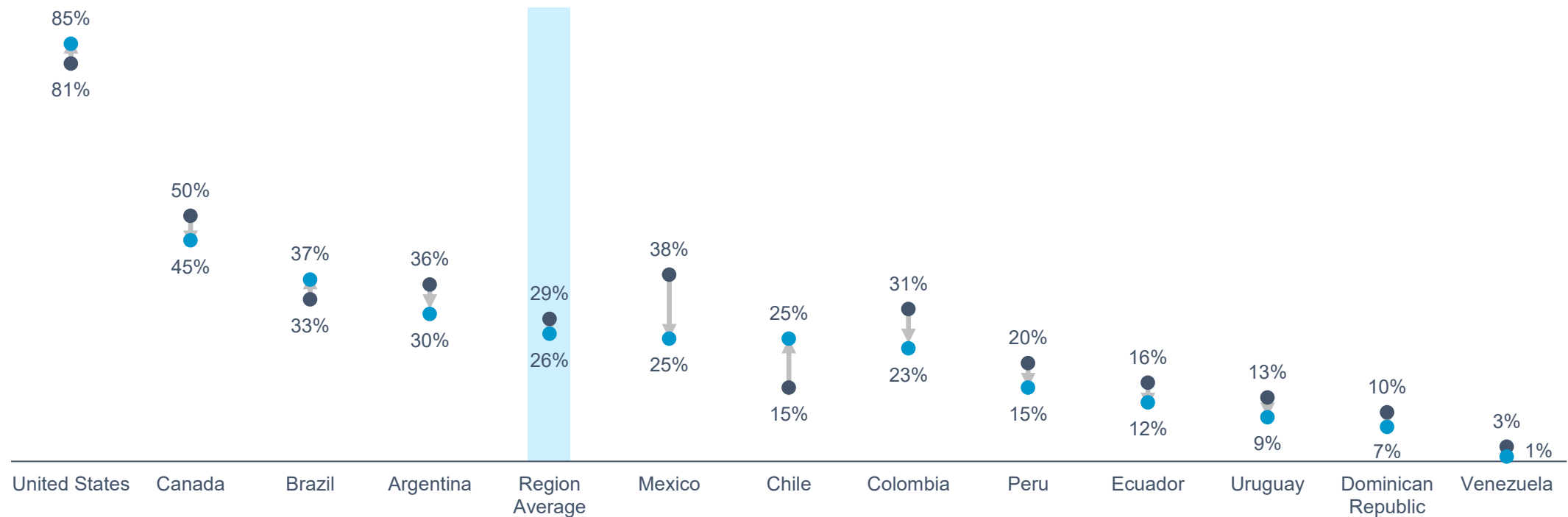
On Average, New Medicines Launch 32 Months After Global First Launch Among Countries in the Americas

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)



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

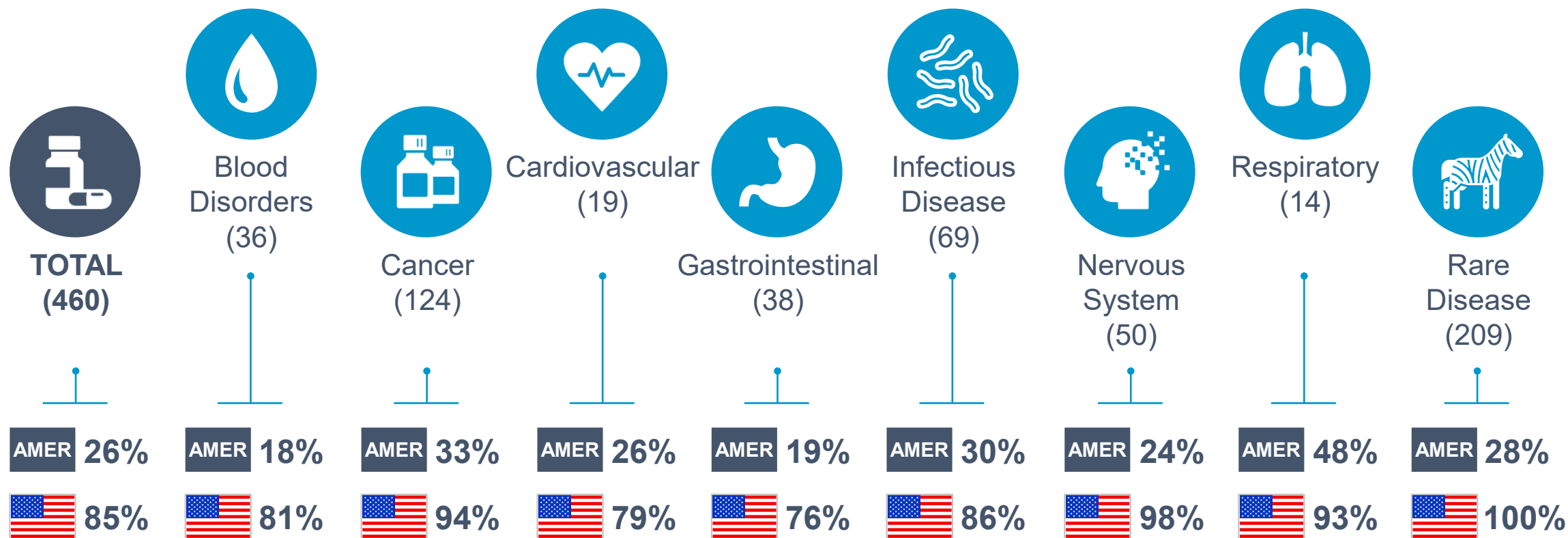
Chile Improved Most and Mexico Declined Most



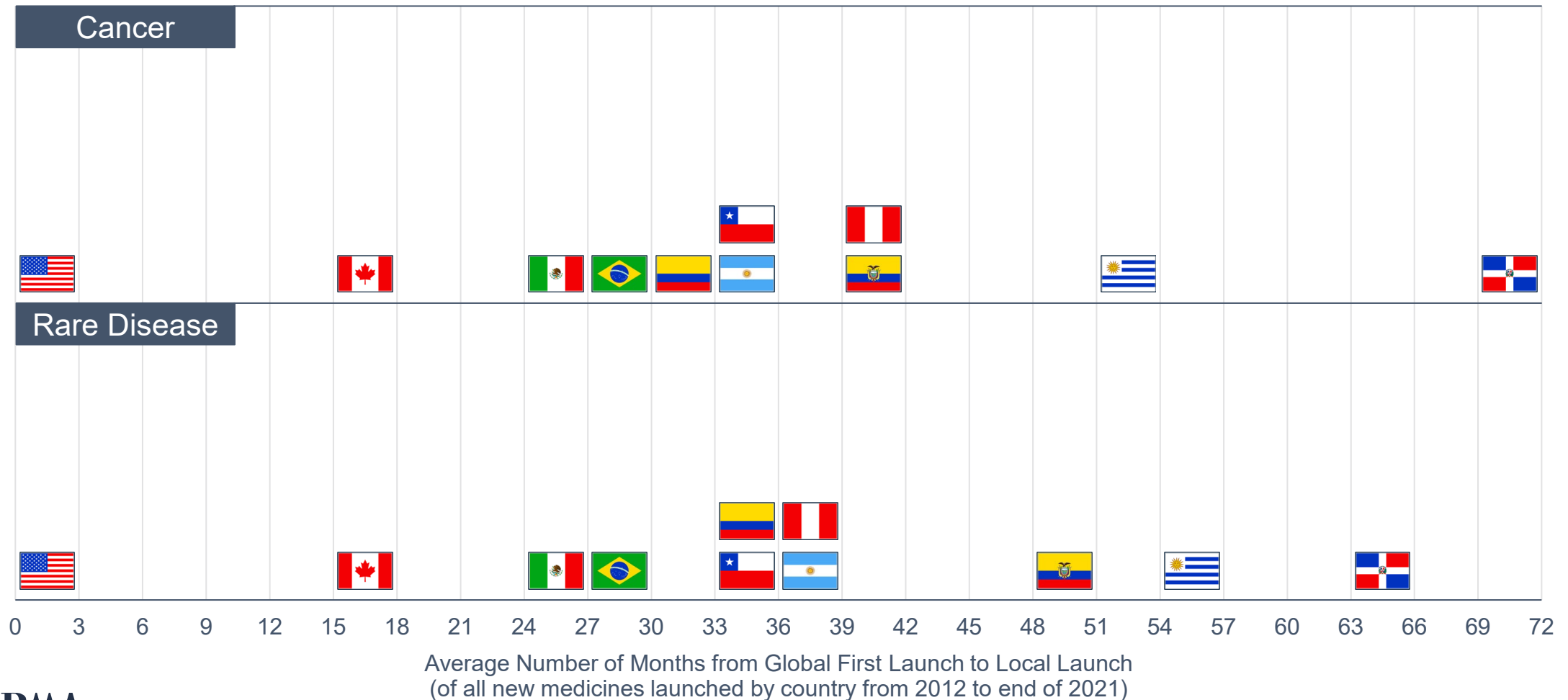
- New Medicines Launched Globally (2008 to 2017) as of 2017
- New Medicines Launched Globally (2012 to 2021) as of 2021

Launch 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)



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



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

Access to New Medicines in Asia-Pacific



Australia



Bangladesh



China



India



Indonesia



Japan



Kazakhstan



Korea



Malaysia



New Zealand



Pakistan



Philippines



Singapore



Sri Lanka



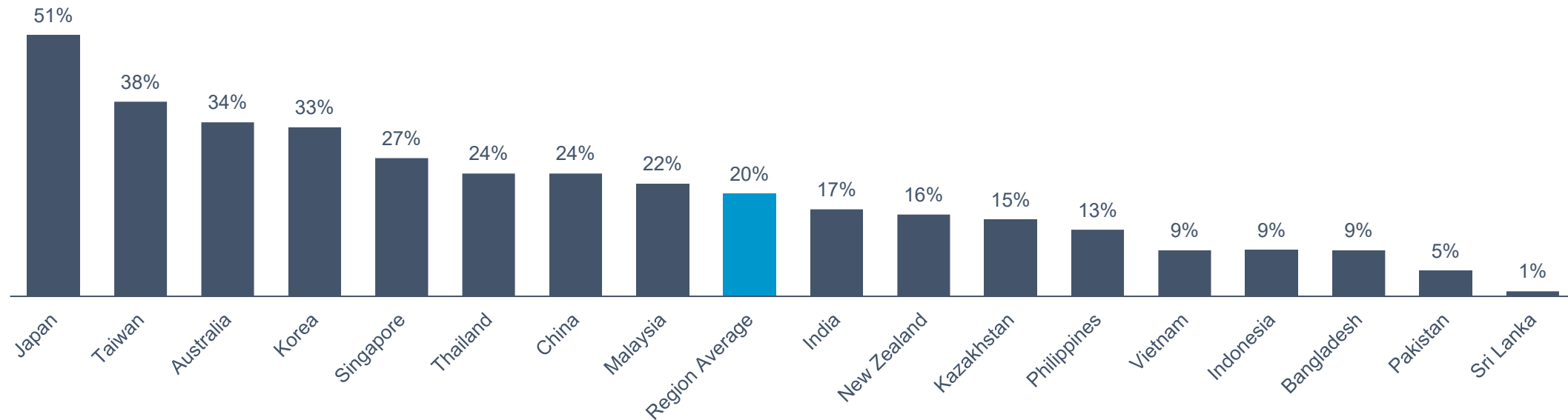
Thailand



Vietnam

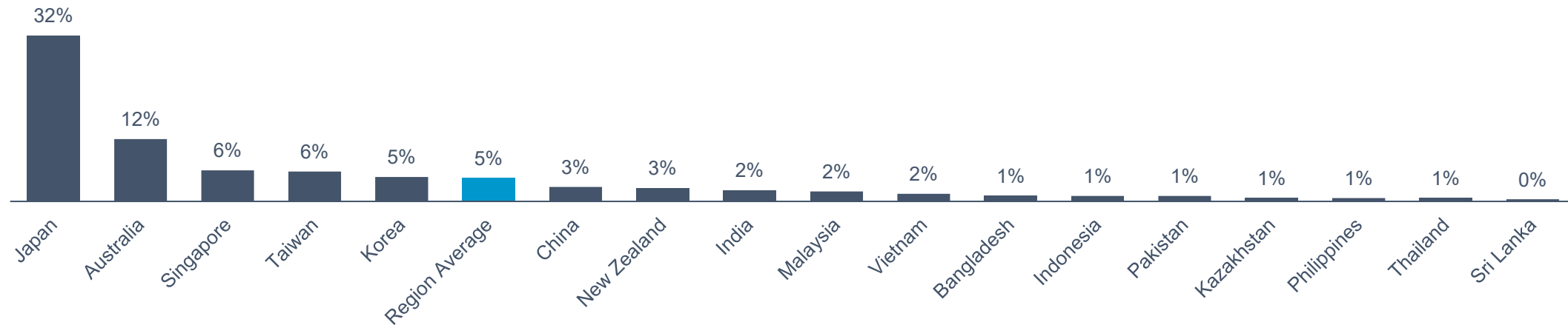
On Average, Asia-Pacific Markets Have 20% of New Medicines Launch

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



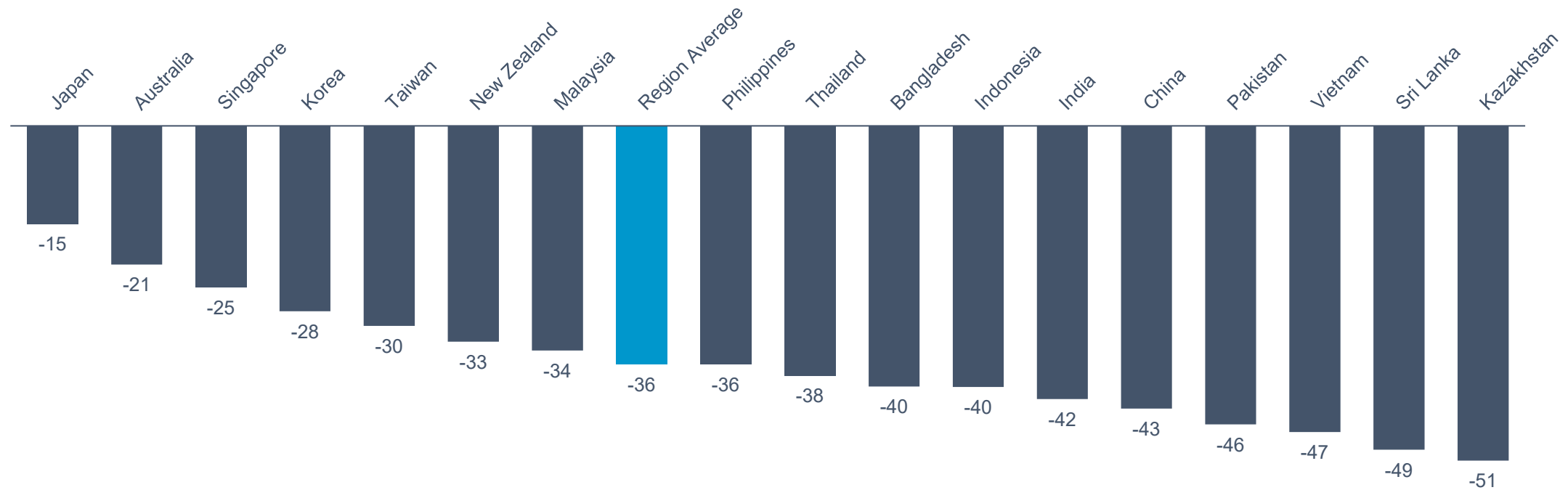
On Average, Asia-Pacific Markets Have 5% of New Medicines Launch Within One Year of Global First Launch

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)



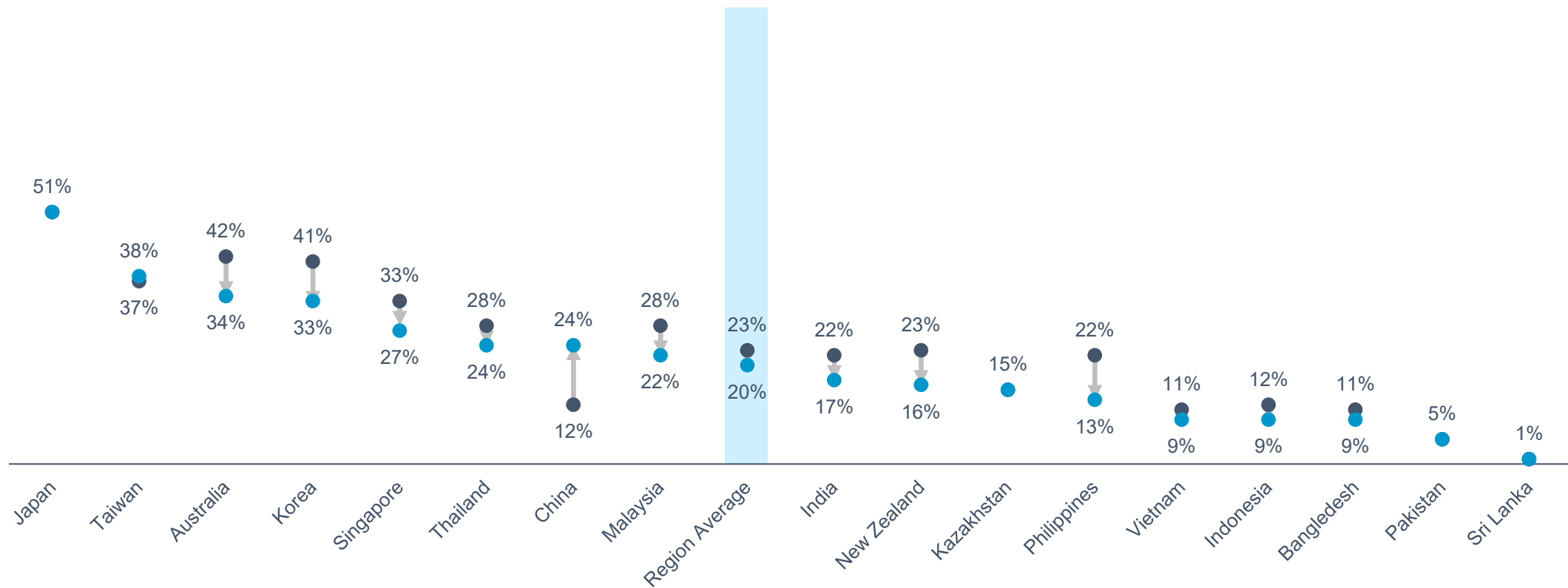
On Average, New Medicines Launch 36 Months After Global First Launch Among Asia-Pacific Markets

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)



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

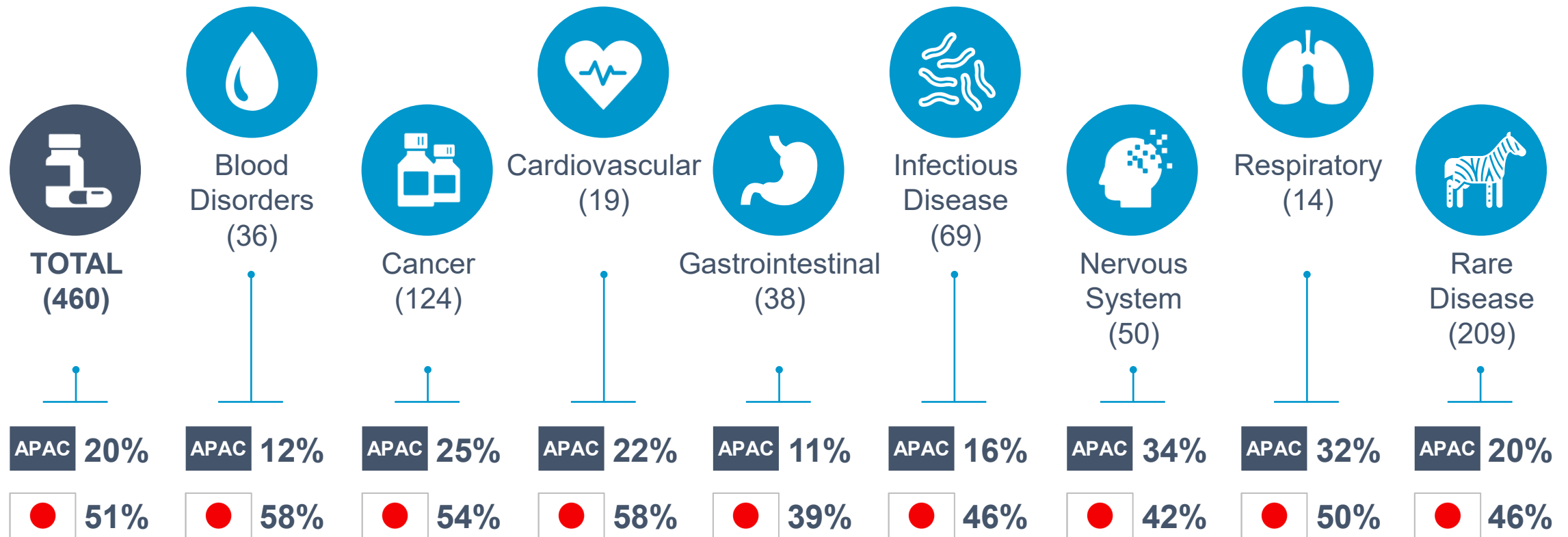
China Improved Most and Australia, Korea and the Philippines Declined Most



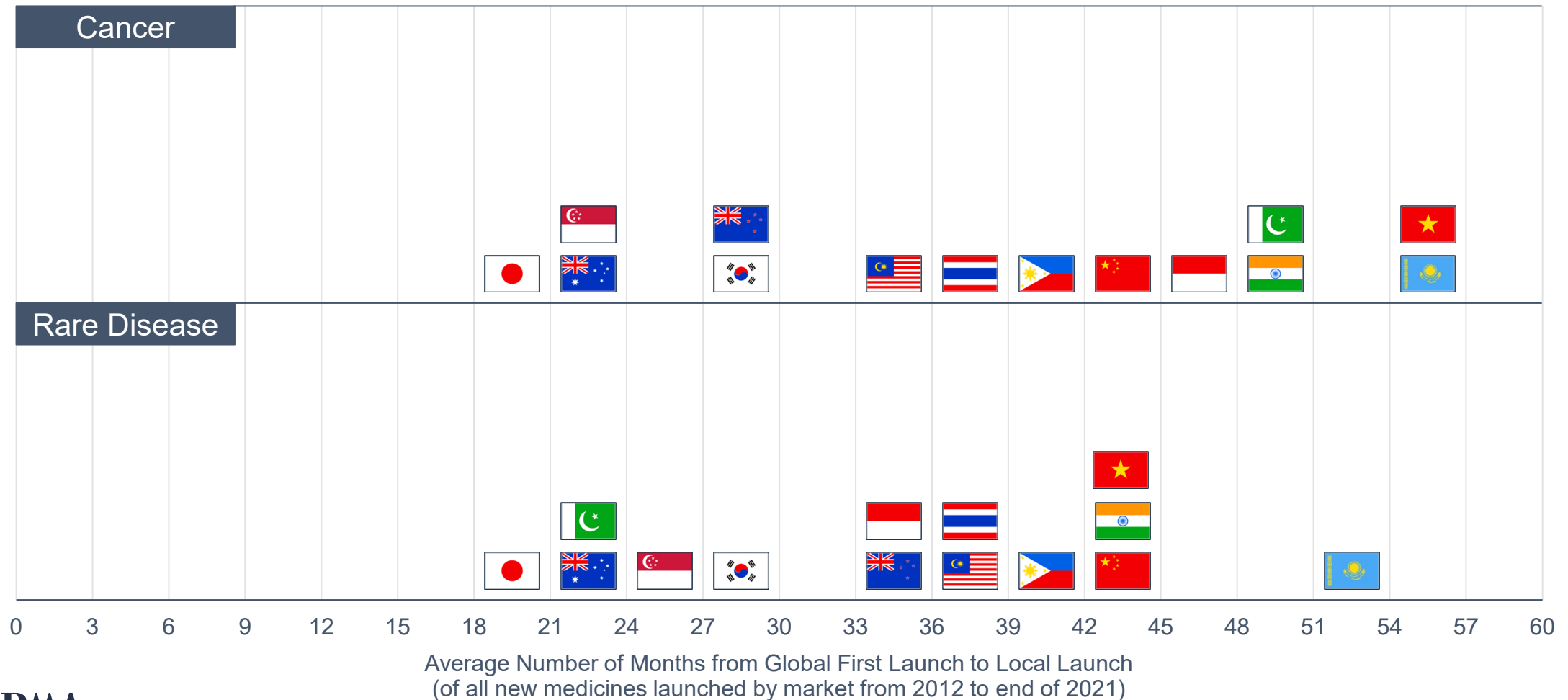
● New Medicines Launched Globally (2008 to 2017) as of 2017
 ● New Medicines Launched Globally (2012 to 2021) as of 2021

Launch 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)



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



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



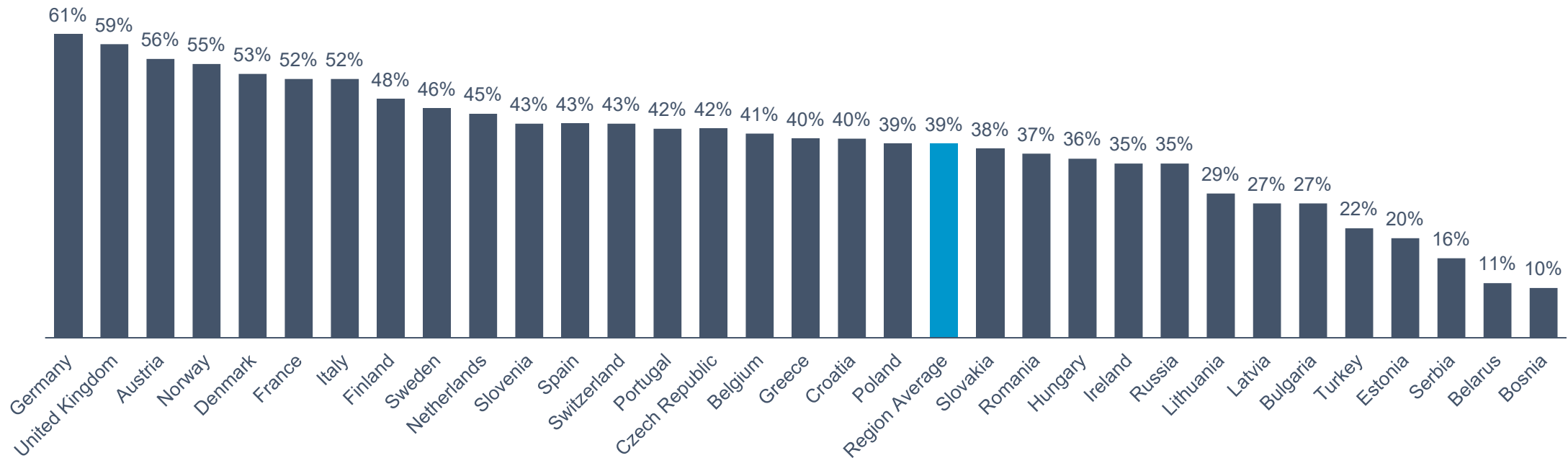
Turkey



United Kingdom

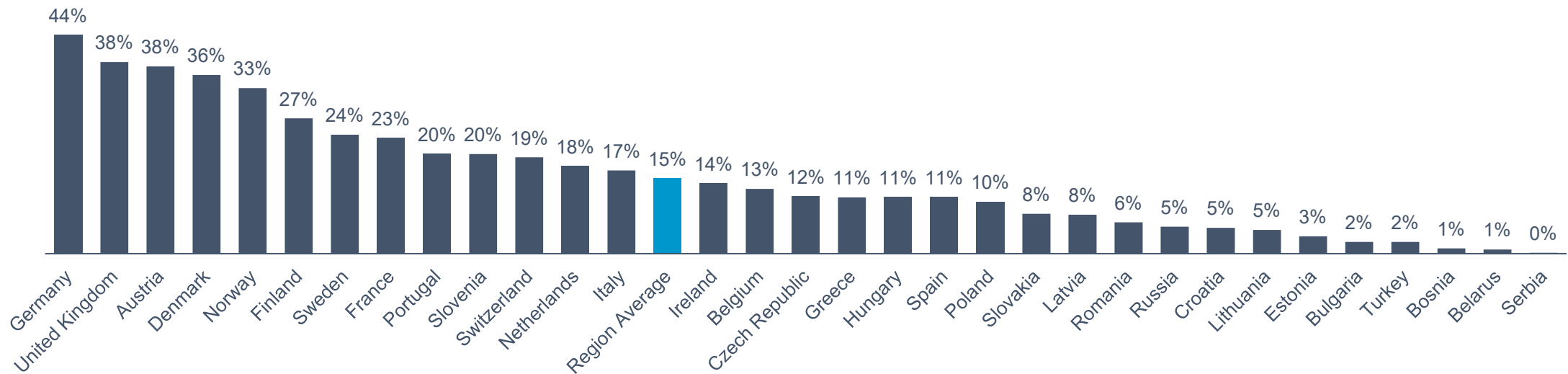
On Average, European Countries Have 39% of New Medicines Launch

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



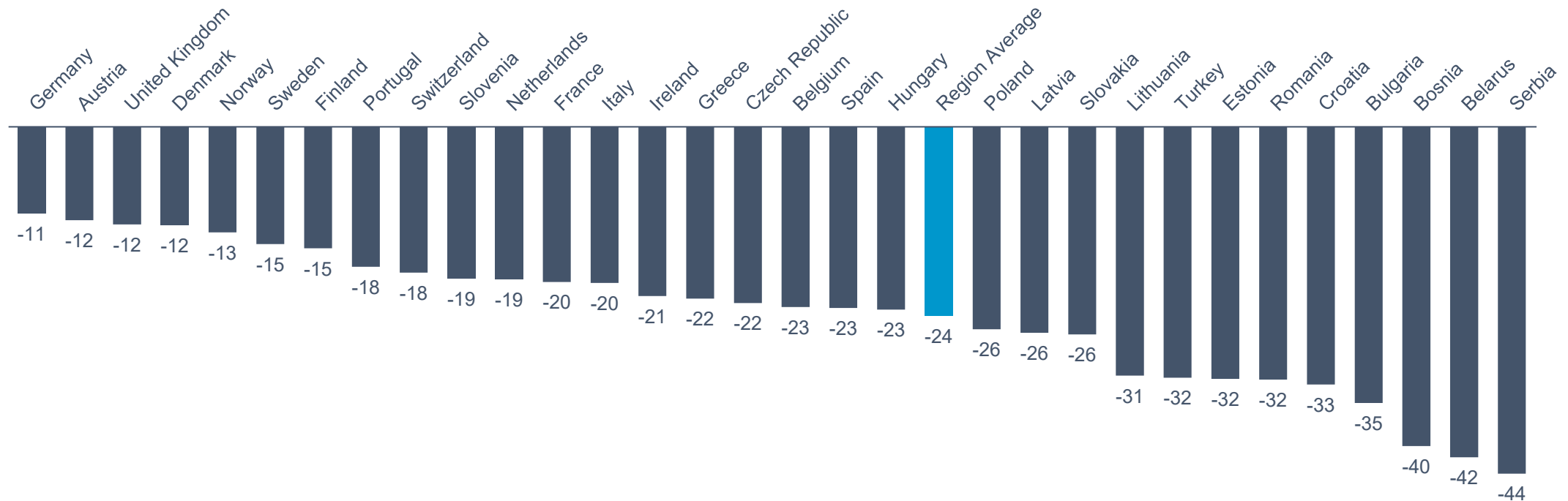
On Average, European Countries Have 15% of New Medicines Launch Within One Year of Global First Launch

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)



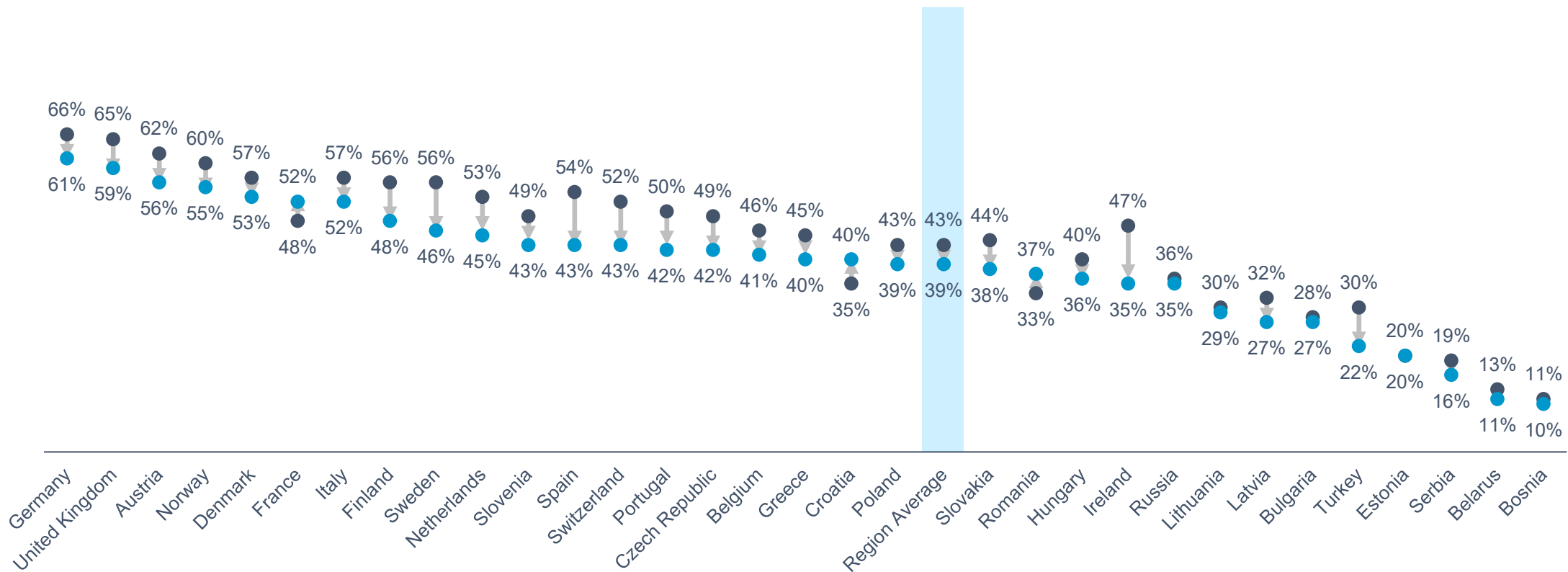
On Average, New Medicines Launch 24 Months After Global First Launch Among European Countries

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



Launch of New Medicines Declined Over Time in Most European Countries

Croatia Improved Most and Ireland, Spain and Sweden Declined Most



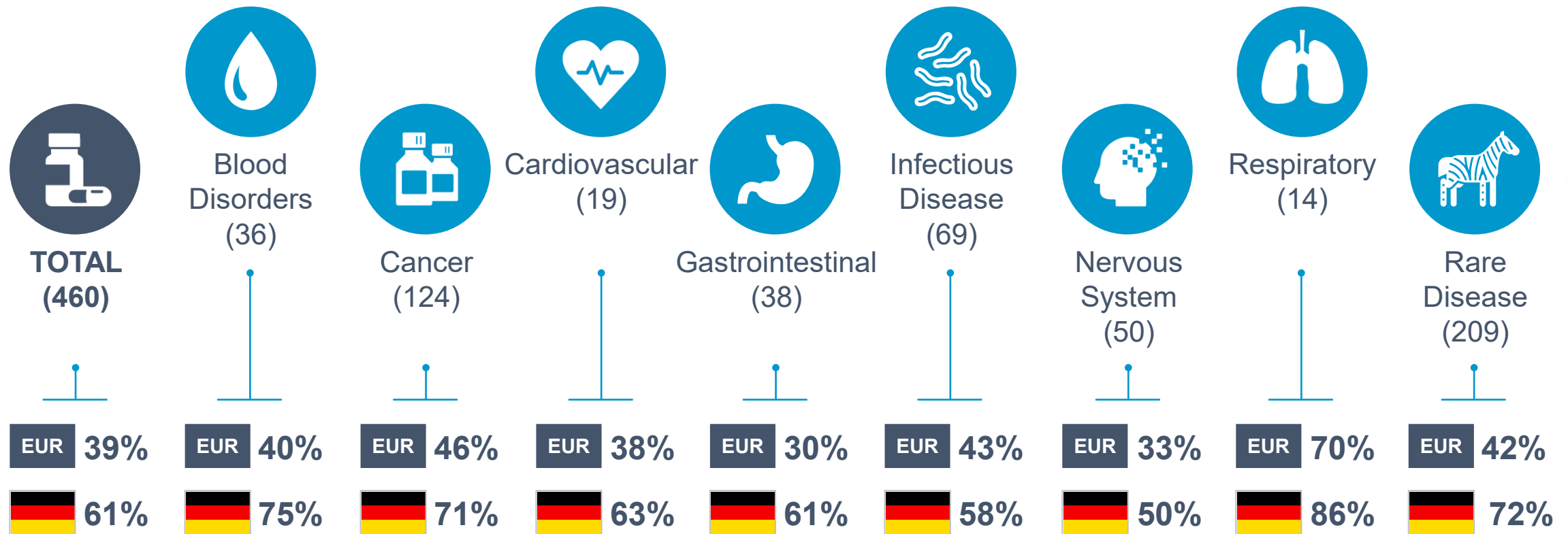
- New Medicines Launched Globally (2008 to 2017) as of 2017
- New Medicines Launched Globally (2012 to 2021) as of 2021



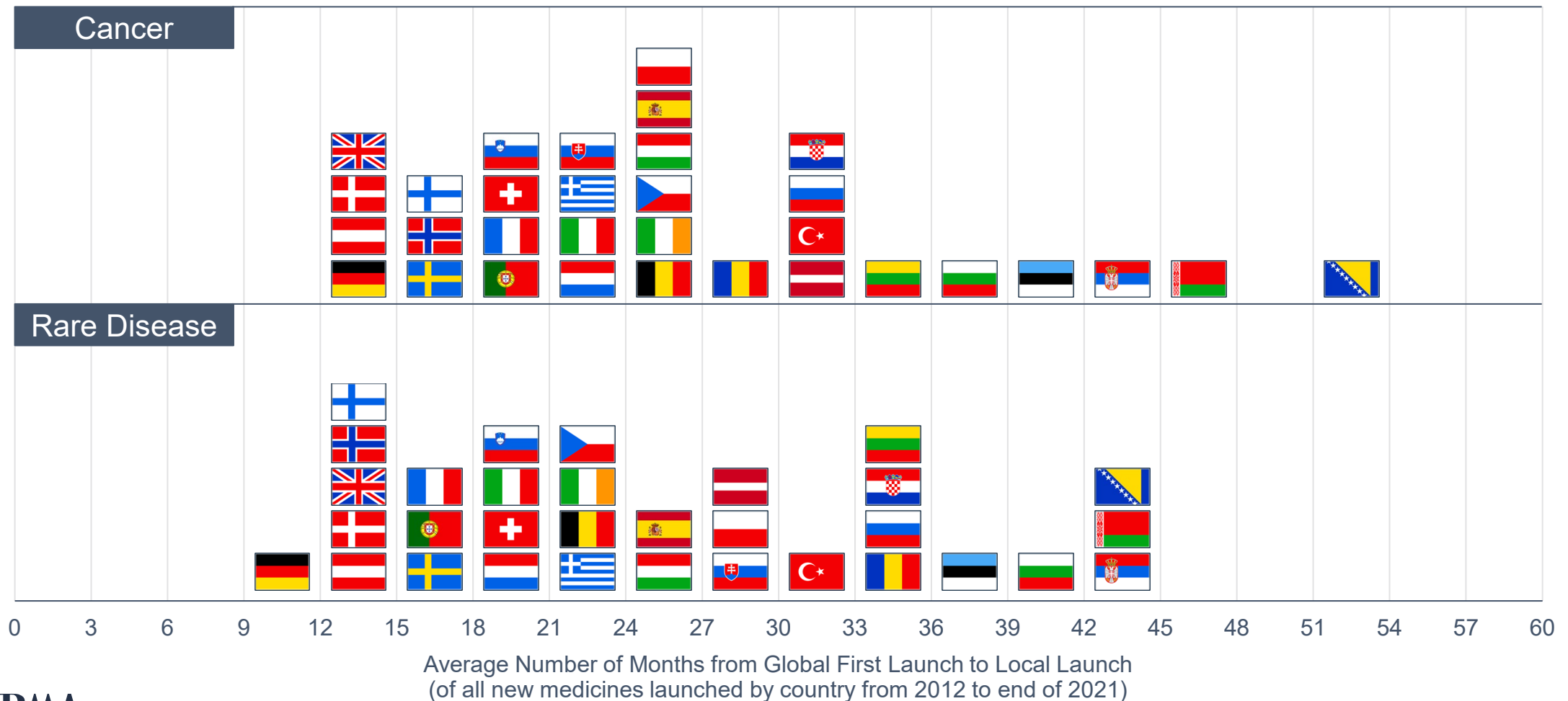
Source: PhRMA analysis of IQVIA MIDAS® and country regulatory data, October 2022.
 Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021. Data exclude: Iceland and Luxembourg.

Launch 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)



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



Access to New Medicines in the Middle East and Africa



Algeria



Egypt



Jordan



Kuwait



Lebanon



Morocco



Saudi Arabia



South Africa



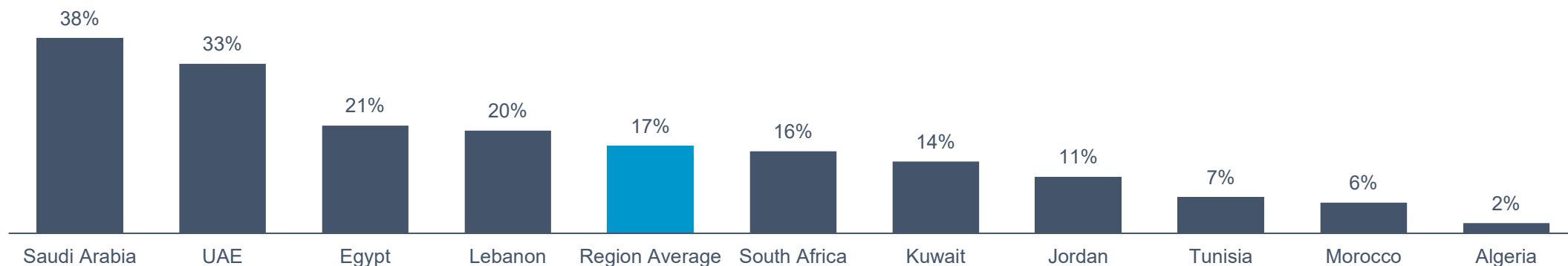
Tunisia



UAE

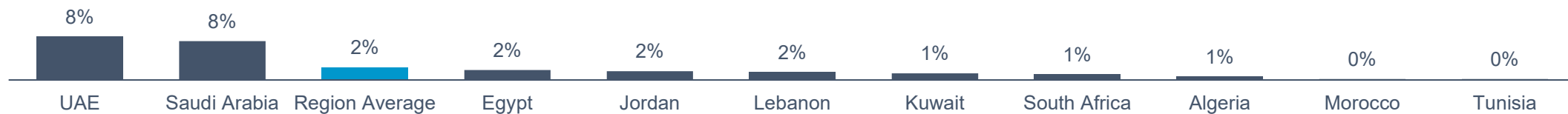
On Average, Middle East and Africa Countries Have 17% of New Medicines Launch

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



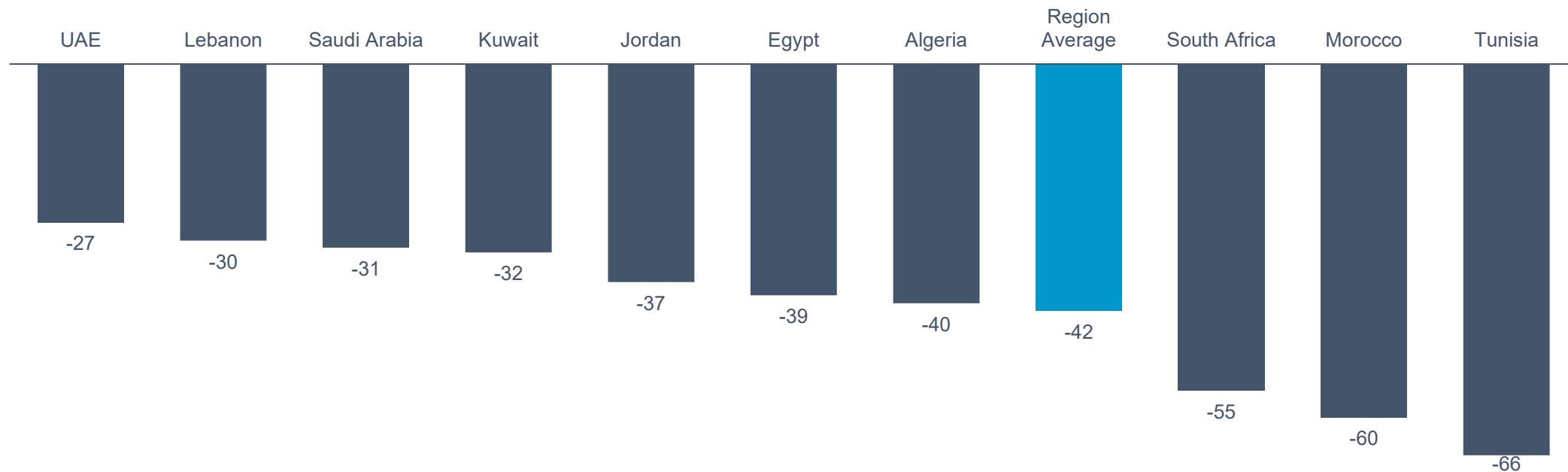
On Average, Middle East and Africa Countries Have 2% of New Medicines Launch Within One Year of Global First Launch

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)



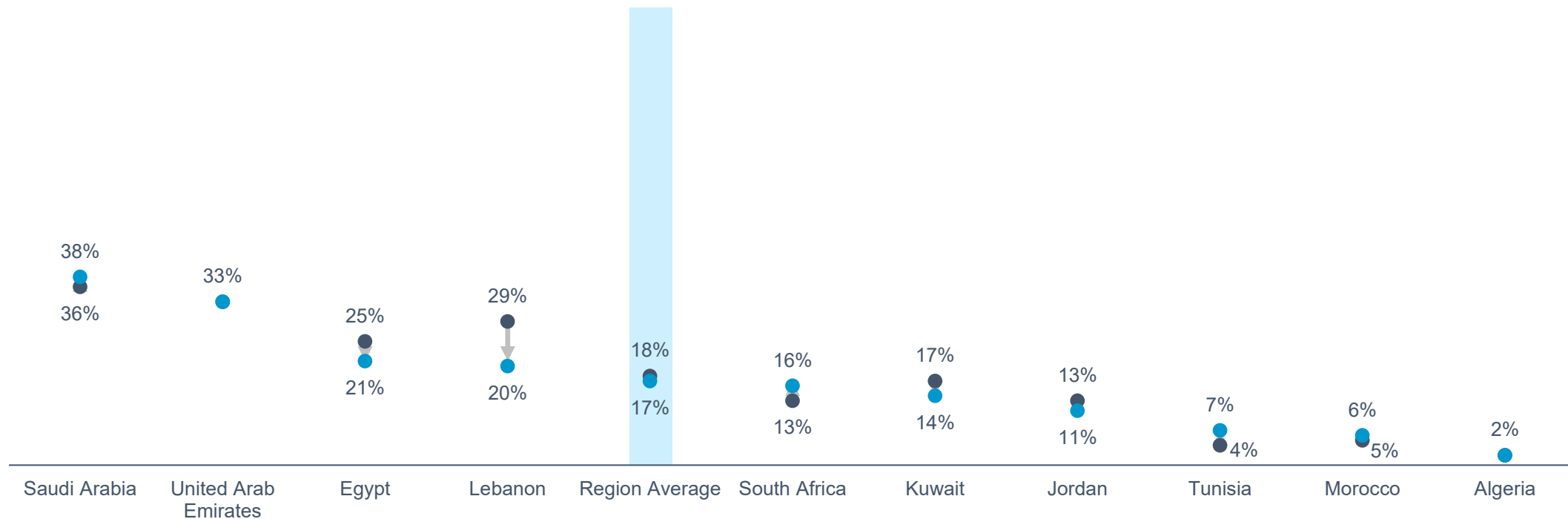
On Average, New Medicines Launch 42 Months After Global First Launch Among Middle East and Africa Countries

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)



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

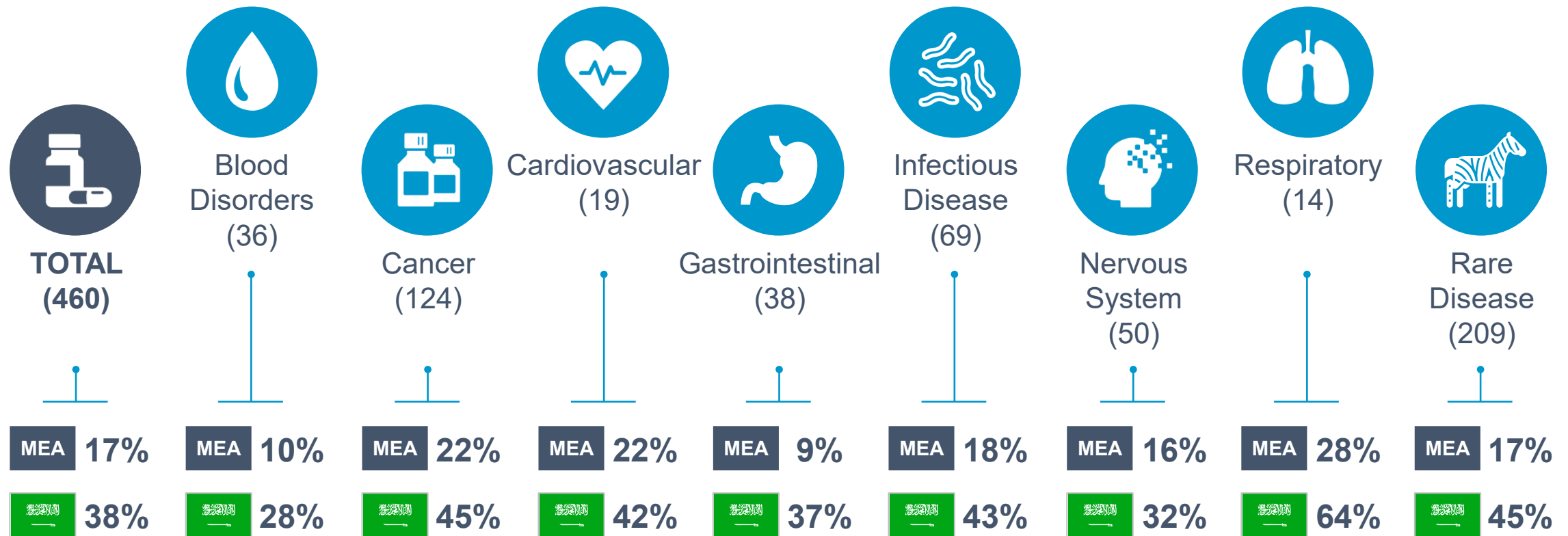
South Africa and Tunisia Improved Most and Lebanon Declined Most



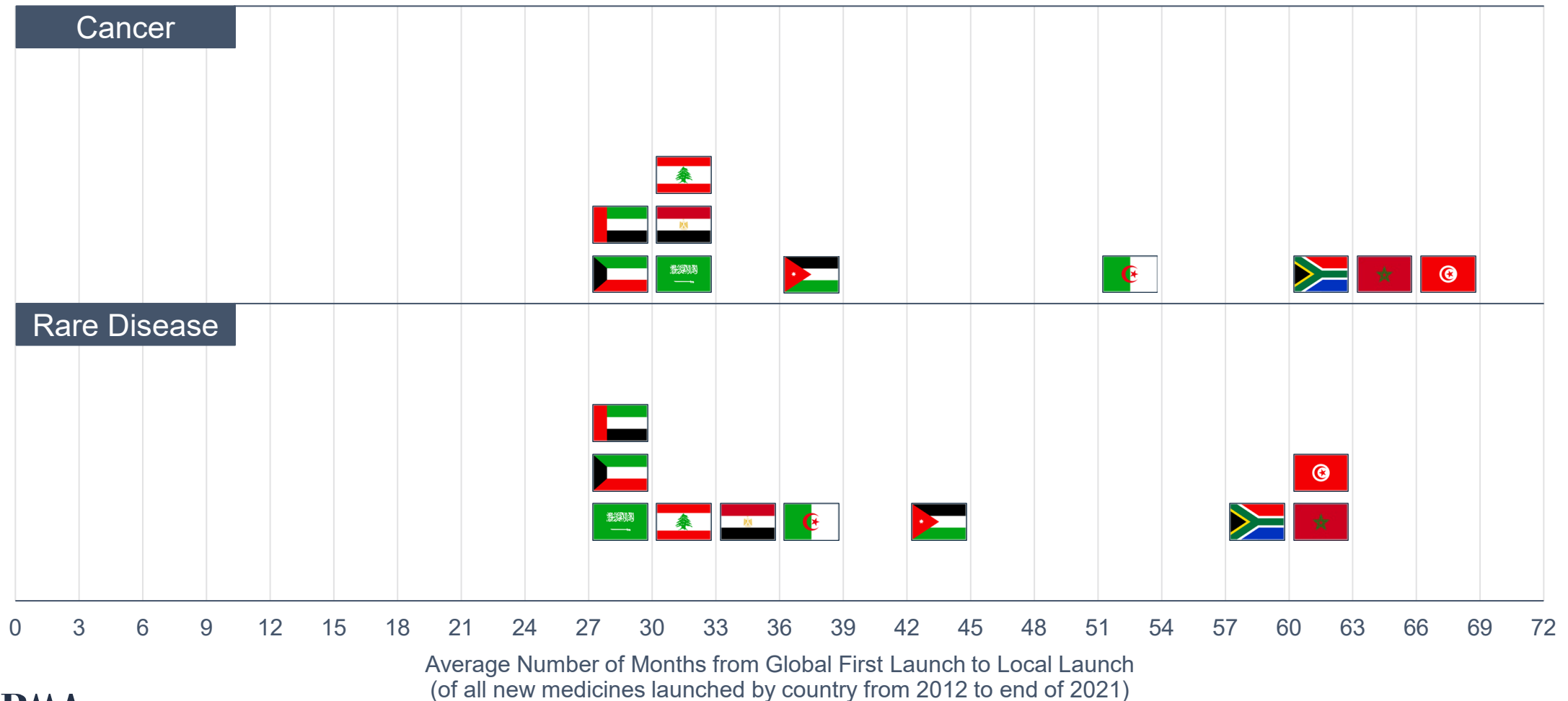
- New Medicines Launched Globally (2008 to 2017) as of 2017
- New Medicines Launched Globally (2012 to 2021) as of 2021

Launch 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)



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



Definitions and Methods

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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