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Assessment of Access to Medicines in Selected Countries in the Middle East and Africa

Final report

April 2019

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Project Objectives & Methodology

Under PhRMA sponsorship, we have assessed the level of access to new medicines in the Middle East and Africa vs. developed countries

Background

- Developed countries have largely achieved universal healthcare coverage, while many developing countries are implementing steps to increase coverage
- While the objective is the same, healthcare systems and practices differ across countries leading to different levels of access to medicines
- To understand which systems and policies can lead to better access, we must first evaluate how well countries do in terms of providing access to medicine for their populations

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Objectives

- In order to have a deeper understanding of how well countries perform in terms of providing access to medicines, IQVIA aims to:
  - Develop a high level assessment of the market access landscape in terms of registration, pricing and reimbursement in selected countries in MEA
  - Evaluate the performance against selected developed markets[1] on access to medicine according to agreed metrics

Geographical scope:

IQVIA conducted similar projects in other geographies, including Colombia and Australia, which have been shared with key stakeholders in respective markets and have been perceived positively

1 | Selected developed markets include US and EU5 (Germany, Italy, France, Spain and UK)

We have followed a three-phased approach to investigate high level access dynamics and analyse timings for agreed metrics in selected countries

Phase 1
High Level Overview of Market Access Landscape

Key activities

- Kick off project
- Develop a high level assessment of the market access process for in-scope countries
- Identify key trends, challenges and opportunities which might have an impact on market access timings

Deliverables

- High level assessment of market access dynamics and timelines per country including opportunities and challenges as well as key trends

Phase 2
Access to Medicines Assessment at Country Level

Key activities

- Identify NMEs launched in the US and EU5 from 2010-2018 Q1 (up to 200 NMEs)
- Align list of NMEs with the client
- For selected NMEs, analyse selected access indicators, i.e. registration, launch and reimbursement timings vs. developed countries[1]
- Depending on the data availability, assess the reasons for no launch decision

Deliverables

- Analysis of average timelines from registration to launch and reimbursement at country level (in contrast with FDA and EMA)

Phase 3
Cross-country Summary and Final Report

Key activities

- Compare MEA countries access to medicines and performance against selected access indicators
- Derive selected analysis per TAs, molecule types (small vs. biologic), etc (as feasible with the data available)

Deliverables

- Comparison of access to healthcare and medicines in developed countries'[1] vs in-scope countries' in Middle East and Africa
- Overall project report, encompassing all phases

1 | Selected developed markets include US and EU5 (Germany, Italy, France, Spain and UK)

Multiple sources have been leveraged, including IQVIA proprietary data assets as well as secondary data sources and primary market research

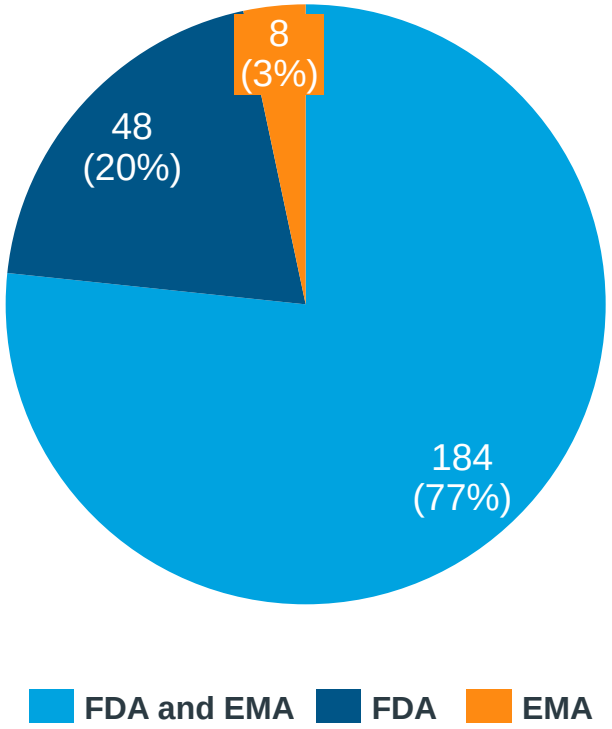
Proprietary IQVIA Health Data	• MIDAS and local databases will be utilized to identify the launch dates for selected NMEs in the regions
Secondary Data Sources	• Country specific secondary data sources will be utilized to estimate the registration and reimbursement dates for selected NMEs in the region
Primary Market Research[1]	• Targeted primary market research will be conducted to fill in gaps for registration and reimbursement timelines as needed
IQVIA Local Experts	• Local country experts will validate / sense check the information collected through different data sources
PhRMA members	• PhRMA members will validate the collected inputs and filling the missing information for their own products

Depending on the availability of publicly available information, we will utilize proxies for some of the countries for identification of registration and reimbursement timings

1 | Limited number of interviews / discussions with targeted stakeholders at country level (up to 15 interviews in total across all countries) will be conducted to fill in the information gaps

The evaluation of access in the selected MEA countries was grounded on the analysis of 240 NMEs

Number of NMEs registered by US FDA and EU EMA from 2010 – 2018
Universe: 240 NMEs



- New Molecular Entities (NMEs) registered in either US FDA or EU EMA between January 1st, 2010 and March 31st 2018 have been included into the analyses
- Combination products are included into the analyses if one of the molecules is NME
- Generics, biosimilars, OTC, herbal products, vaccines, radiology products, contrast agents and products used only for diagnostics are excluded

Key parameters have been defined to enable the comparison of access across countries

Indicator	Definition	Metric
Product Registration vs 1st reference FDA/EMA approval	• Defined as the timeline from NME 1st registration by FDA or EMA and sponsor company being granted authorization to commercialize the product	**Time to registration vs approval in 1st global reference :** The time elapsed between 1st registration in FDA or EMA and registration in the Region/Country
Product Local Registration	• Defined as the timeline between submission of registration dossier to the local authorities by the sponsor company and national market authorization being granted	**Time to local registration:** The time from MA dossier submission to approval (depending on data availability)
Product Launch	• Defined as the time when first sales are recorded for the product in the country	**Time to launch:** The time elapsed between registration in the Region/Country and launch in the Region/Country
Product Reimbursement	• Defined as the status in which the NME is granted access through public or private funding for a significant proportion of the country's population • In different countries it may be called "funding" or "reimbursement"	**Time to reimbursement:** The time elapsed between registration in the Region/Country and time for an NME to be granted reimbursement status in the Region/Country

Data sources included regulatory agencies, IQVIA proprietary information and external stakeholders in the 10 countries in scope

	South Africa	Morocco	Algeria	Tunisia	Egypt	Lebanon	Jordan	Saudi Arabia	Kuwait	UAE
Time to launch i.e. launch date	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets	IQVIA data assets
Time to registration* I.e. date of registration	Through SAHPRA and extensive desk research	Through PMR	Through MOH nomenclature	Through DPM	Through EDA and PMR	Through MoHP and PMR	Through JFDA	Through SFDA and PMR	Through PMR	Through PMR
Time to reimbursement	Indirect measure equal to launch date	Through PMR	Indirect measure Equal to registration date for hospital products	Through PMR	Through PMR	Through PMR	Indirect measure by checking presence on formulary and RDL	Through PMR	Through PMR	IQVIA data assets

Depending on the availability of publicly available information, are using proxies for some of the countries for identification of registration and reimbursement timings

Information available through secondary data sources

Information available through primary market research (PMR)

* Local registration submission dates are provided by Pharmaceutical companies through confidentiality agreements
Source: Secondary desk research, IQVIA expert insights

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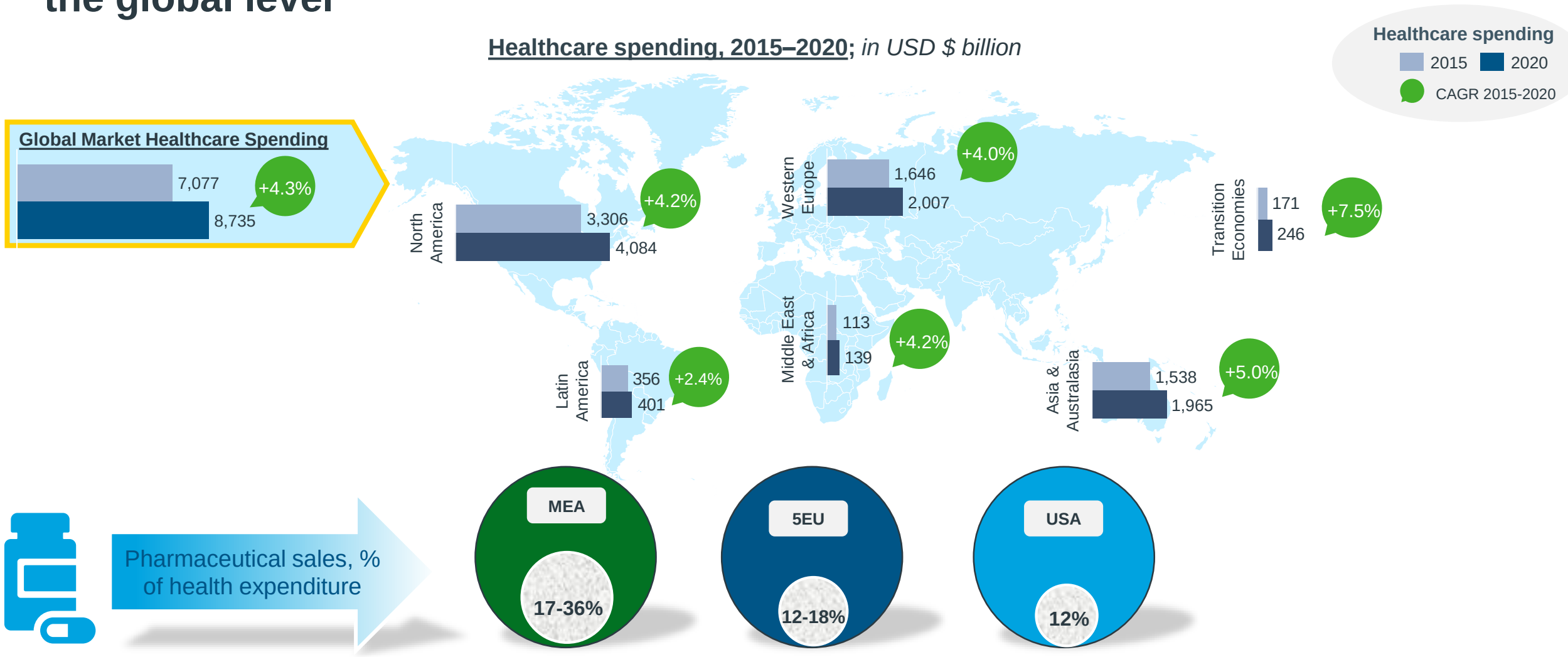
Market Access Dynamics in Middle East and Africa (MEA)

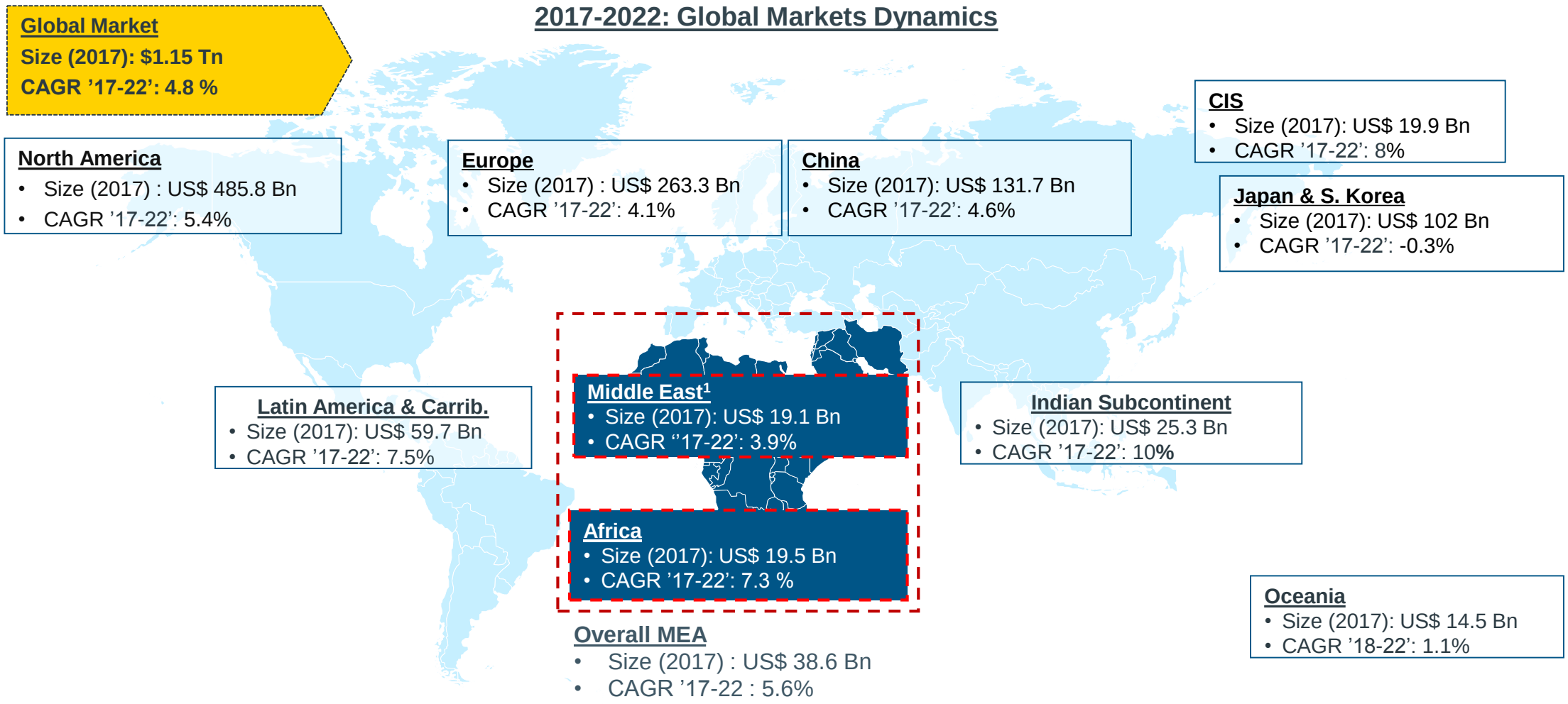
Healthcare is an important sector and takes a notable share of total GDP at the global level

Healthcare spending, 2015–2020; *in USD $ billion*



Source: World Industry Outlook, Healthcare and Pharmaceuticals, The Economic Intelligence Unit, June 2016, Deloitte - 2017 global health care sector outlook

By 2022, the global pharma market is expected to be $1.5 Tn; despite the economic slow down, MEA continues to grow at a moderate rate



Source: IQVIA Market Prognosis Q3 2018

PhRMA | Assessment of access to medicine timelines in selected countries in Middle East and Africa | Project Report | April 2019

The MEA market is shaped by a number of themes, including a maturing regulatory environment and expansion of healthcare coverage

Increase in healthcare demand

- Increasing and aging population
- Shift toward non communicable disease

Cost-related measures

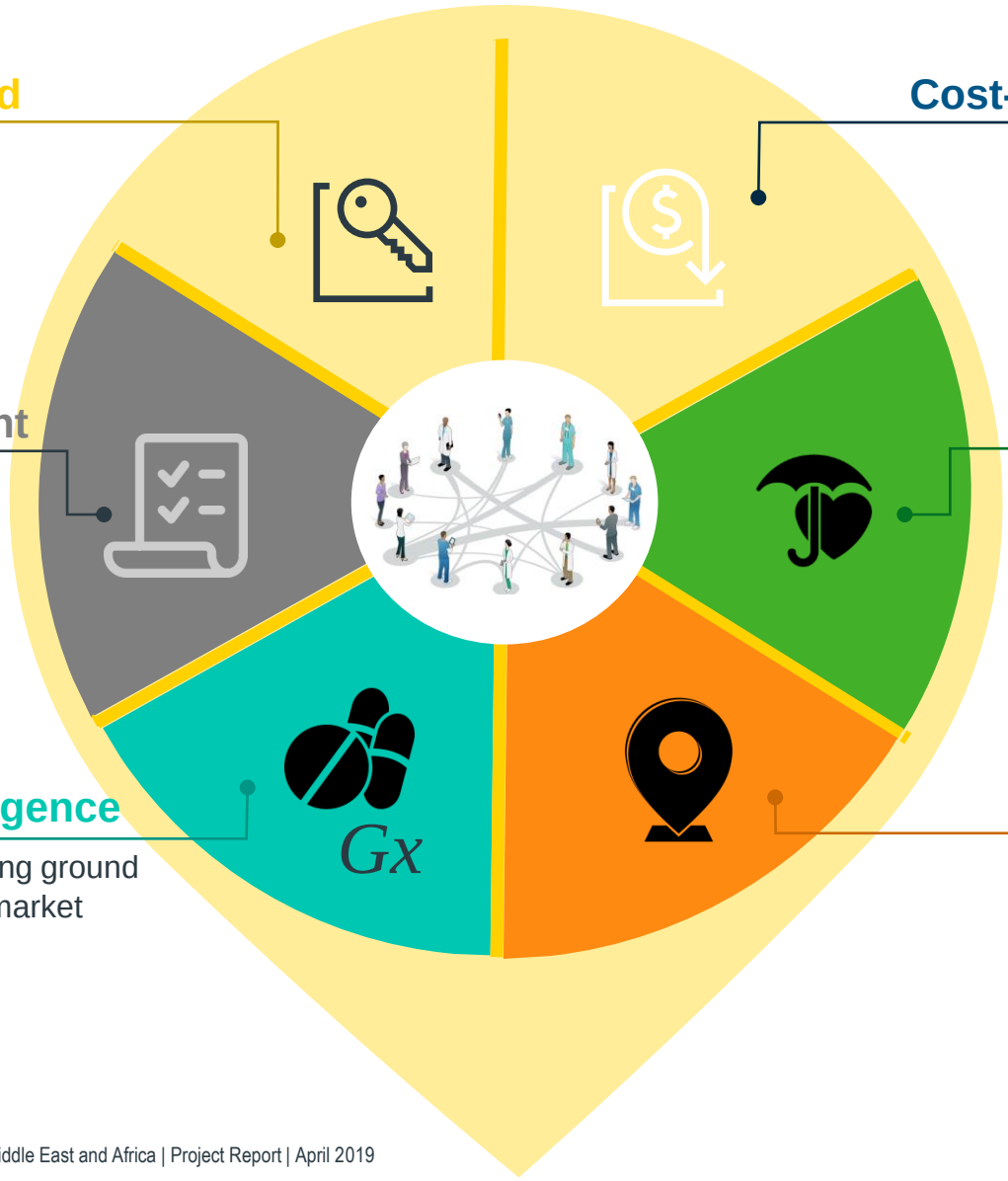
- Austerity measures / controls on spend
- Ad hoc price policies
- Restriction on number of reimbursed products

Maturing Regulatory Environment

- Increased use of Pharmacoeconomic modeling
- Streamlining stakeholders
- Change in regulatory bodies
- Consolidation of procurement process
- New abridged approval pathways

Expansion of healthcare coverage

- Innovative healthcare funding models
- Mandatory insurance coverage on the rise
- Private insurance expansion



Generics and Biosimilars emergence

- Generic prescribing and dispensing gaining ground
- Increase in number of biosimilars in the market

Localisation

- Govt. endorsements and benefits to promote local Mfg.
- Rising investment in local manufacturing
- Import restrictions

Source: Secondary research and IQVIA expertise

For innovative medicine, access to MEA market depends on multiple dimensions which are complex across countries

Registration

- Approval by local authorities is the required first step to launch a product, e.g., SFDA in KSA, MoH in UAE, Kuwait, Egypt

Pricing

- Pricing is another step that should be granted by regulators either before granting the registration or will undergo a national assessment after the registration

Reimbursement

- Reimbursement is a further step in market access, determining the conditions and patients for which reimbursement is permitted

Procurement

- Procurement is the purchasing process via national / local tenders or direct orders; it is the last step which can impact drug availability

Evidence-based decision-making
(HTA, RWE, Patient Registries, etc.)

Source: IQVIA expertise

For instance, the number of stakeholders involved and level of centralisation of decision-making varies significantly between countries

Source: Secondary research and IQVIA expertise

Registration timelines can go up to 5 years (or more) in countries like Algeria & South Africa, though most countries introduced a fast track path for innovation

Country	Official Timelines	Observed Timelines* (based on experience or feedback)		
		New drugs	Generics / Local products	Fast track
	• **290 working days** for new chemical entities (with 40% reduction for priority review) • **165 working days** for generics • **30 Working days** for products approved and marketed by BOTH FDA and EMA (verification process) • **60 W days** for products approved and marketed by EITHER FDA or EMA (abridged process)	• **16-20 months (standard)**	• **10-12 months** for generics • **6-8 months** for local products	• **9-10 months** for priority review • 6-8 Months for abridged/Verification review
	• **45 working days** for orphan and innovative medicines.	• **6-12 months (standard)**	• **6-8 months**	2-4 Months
	• **60 days** for technical approval (without pricing) for Orphan drugs, innovative products, and medicines that treat serious or life-threatening conditions and address unmet medical needs	• **12 months**	• **8-12 months**	• **4-6 months** for innovative drugs representing unmet medical need
	• **180 days** • **60 days for NMEs and new biologics registered by US FDA and EMA (fast track)** • **90 days** for NMEs and new biologics registered by US FDA or EMA (fast track)	• **18 months for small molecules** • **24 months for biologicals**	8-12 Months for 1st and 2nd generics 24-36 Months for generics coming after	**3-5 months**
	• **No official timelines**	• **6-9 months**	6-12 months; no clear differentiation between imported and local generics	Not available
	• **105 days** • **30 days for NMEs and new biologics registered by US FDA and EMA** (verification process) • **60 days** for NMEs and new biologics registered by US FDA or EMA (abridged process)	**2-3 biologicals** **1-2 years small molecules**	• **1-2 years**	Still no experience in the abridged/verification (only 1 innovative product registered in 2018)
	• **120-150 days for a new drug** • **100-130 days for a generic.**	• **1.5 years; up to 5 years**	• **<12 months** for local Gx with previous version on market • **Up to 14 months** for local Gx with no previous version on market	Not available
	• **14 months** for new drugs • 13 months for generics	• **14 Months**	• **13 months**	• **6-8 Months (specific cases initiated by request from the MoH)**
	• **1 year (technical committee approval only)**	• **24-36 months**	• **Up to 1year** with incentives for locally manufactured products	• Priority review is possible if the product is of major public health interest/ tender request/ first local manufacturing.
	• **265 calendar days** for medicines on the Essential Drugs List (EDL) and NMEs that are considered essential for national health	**5.5 years**		

Source: Secondary research and IQVIA expertise

Still very much driven by cost consciousness, reimbursement decisions are taking additional time, up to 2 years

Country	Population split per Insurance type	Primary decision-makers focus for reimbursement	Reimbursement Process	Time for reimbursement approval* (based on experience or feedback)
	62% 38%	Pharmaco- economic analysis driven	• **Decentralized***	Up to 1 year
	65% 19% 16%	Cost conscious	• **Decentralized***	Up to 1.5 years
	84% 14% 2%	Pharmaco- economic analysis driven	• **Centralized****	Timeline to formal reimbursement is yet not transparent
	84% 3% 13%	Cost conscious	• **Centralized****	1-2 years
	92% 3% 5%	Clinically-driven/ Cost conscious	• **Decentralized***	Up to 6 months
	59% 32% 9%	Cost conscious	• **Decentralized***	9 to 15 months
	85% 15%	Cost conscious	• **Centralized****	1.5 to 2 years
	45% 45% 10%	Cost conscious	• **Centralized****	8 months
	99% 1%	Cost conscious	• **Centralized****	Not available
	84% 16%	Cost conscious	• **Decentralized* for private sector** • **Centralized** for the public sector**	Up to 1 year

* A decentralized procedure means that the reimbursement decision is made at regional or local level by subsequent decision-makers
**A centralized procedure means that the reimbursement decision is made at national level by 1 decision maker body

Public OOP Private Insurance / Non-profit institutions

>3 years 1-3 years <1 year

Source: Albilad Capital; Saudi Insurance Sector Report; March 2017; IQVIA Market Prognosis; HIO – Value in health journal; Secondary research and IQVIA expertise

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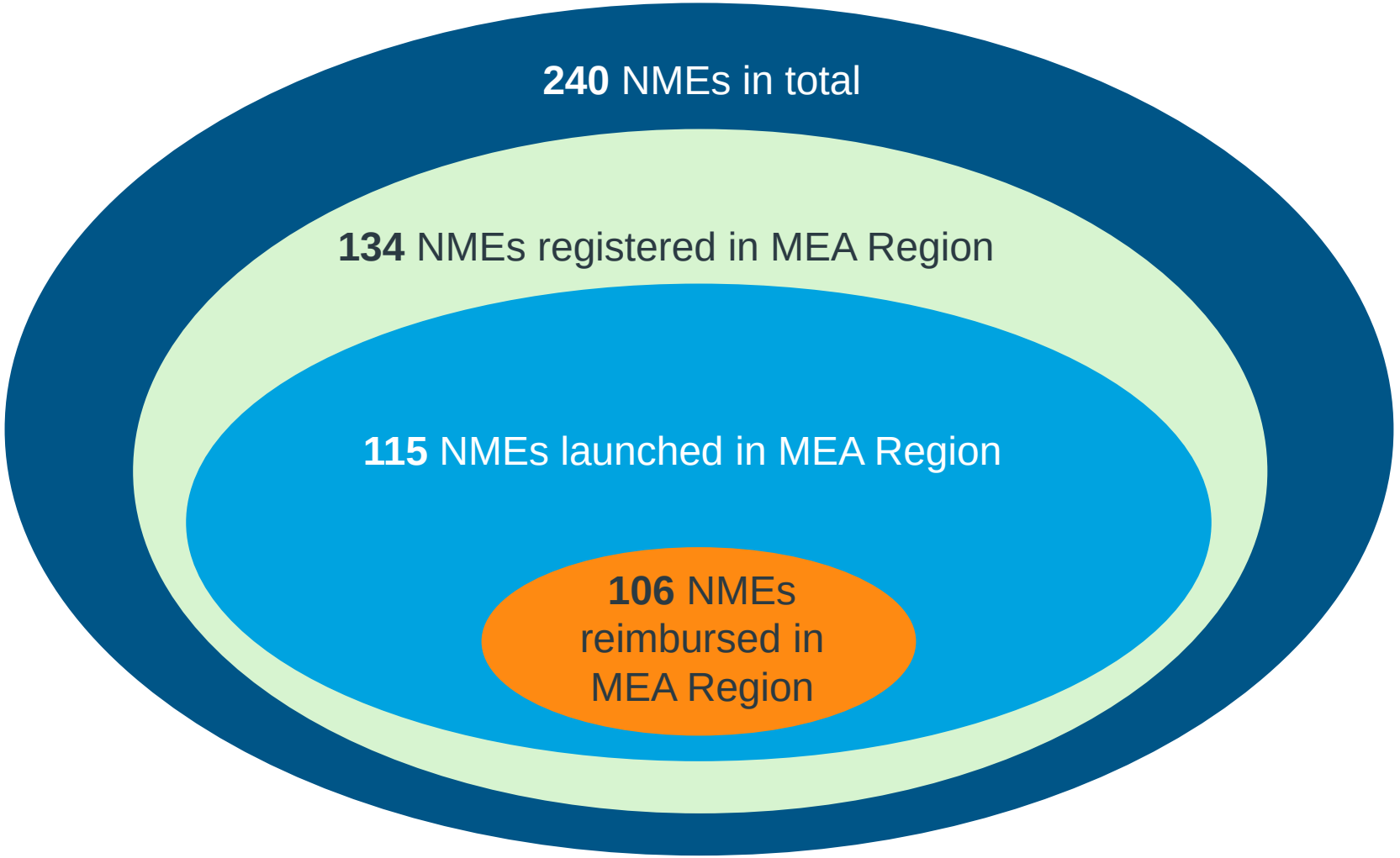
Cross-country Summary of Key Findings

Almost 45% of the 240 NME universe is not registered yet in the MEA region…



Key Highlights

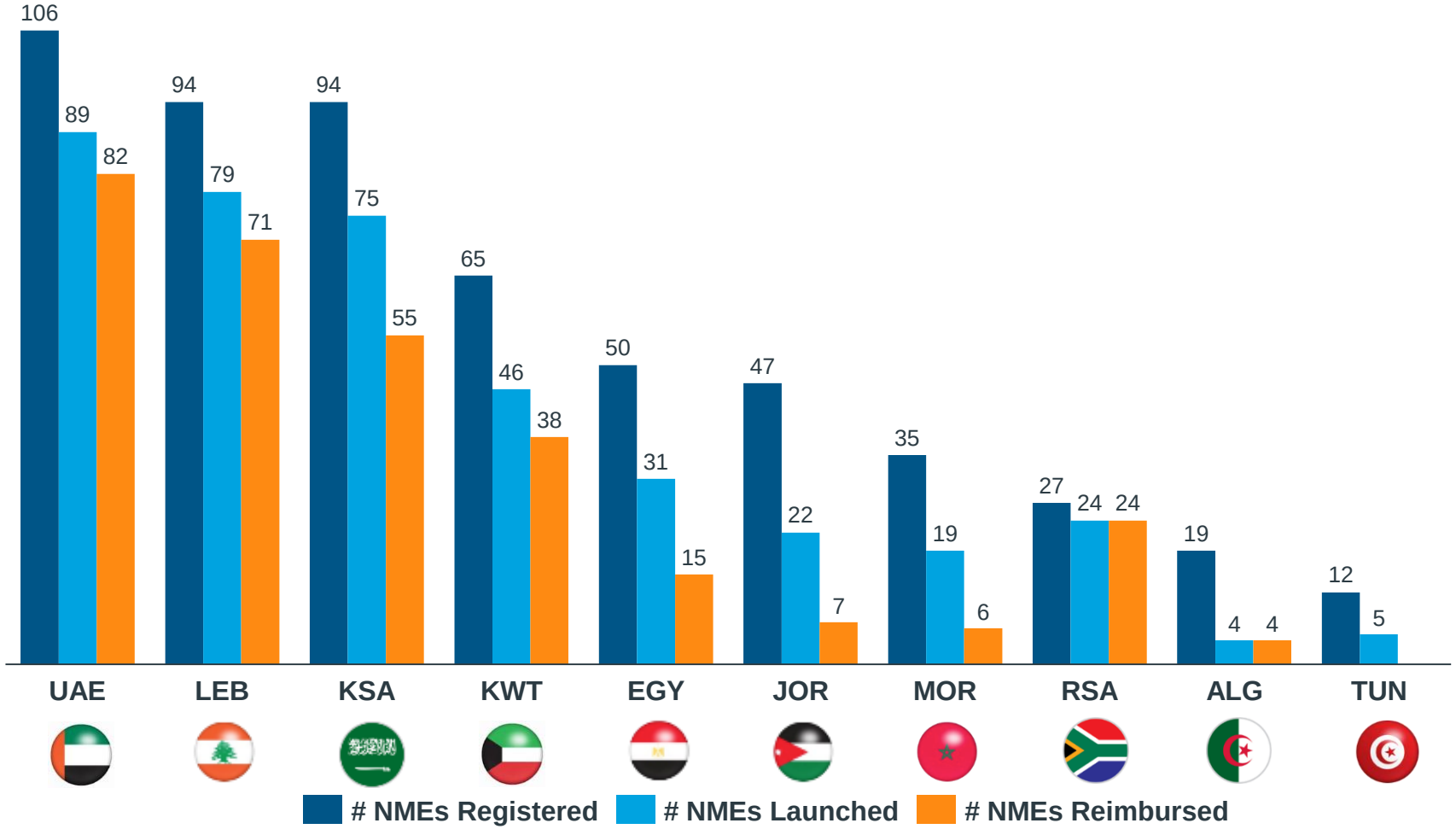
- 56% of the 240 NME universe are registered in the MEA region
- 14% of the registered molecules are not launched yet
- 92% of the launched products are reimbursed
- In addition to the registered products, there is also a number of NMEs available across the region on a name patient basis
  - Those molecules are not considered as registered, launched or reimbursed in any of the countries and are excluded from the analysis (Patient access is limited)

Note: Number of NMEs launched is based on IQVIA available data; NMEs available only in tenders in UAE and Jordan are not reflected in this analysis unless confirmed by the company

… it is even lower at a country level, the highest number of registered NMEs is in the UAE which is 106

Number of NMEs registered, launched and reimbursed per country in 2010 – 2018

Universe: 240 NMEs



Key Highlights

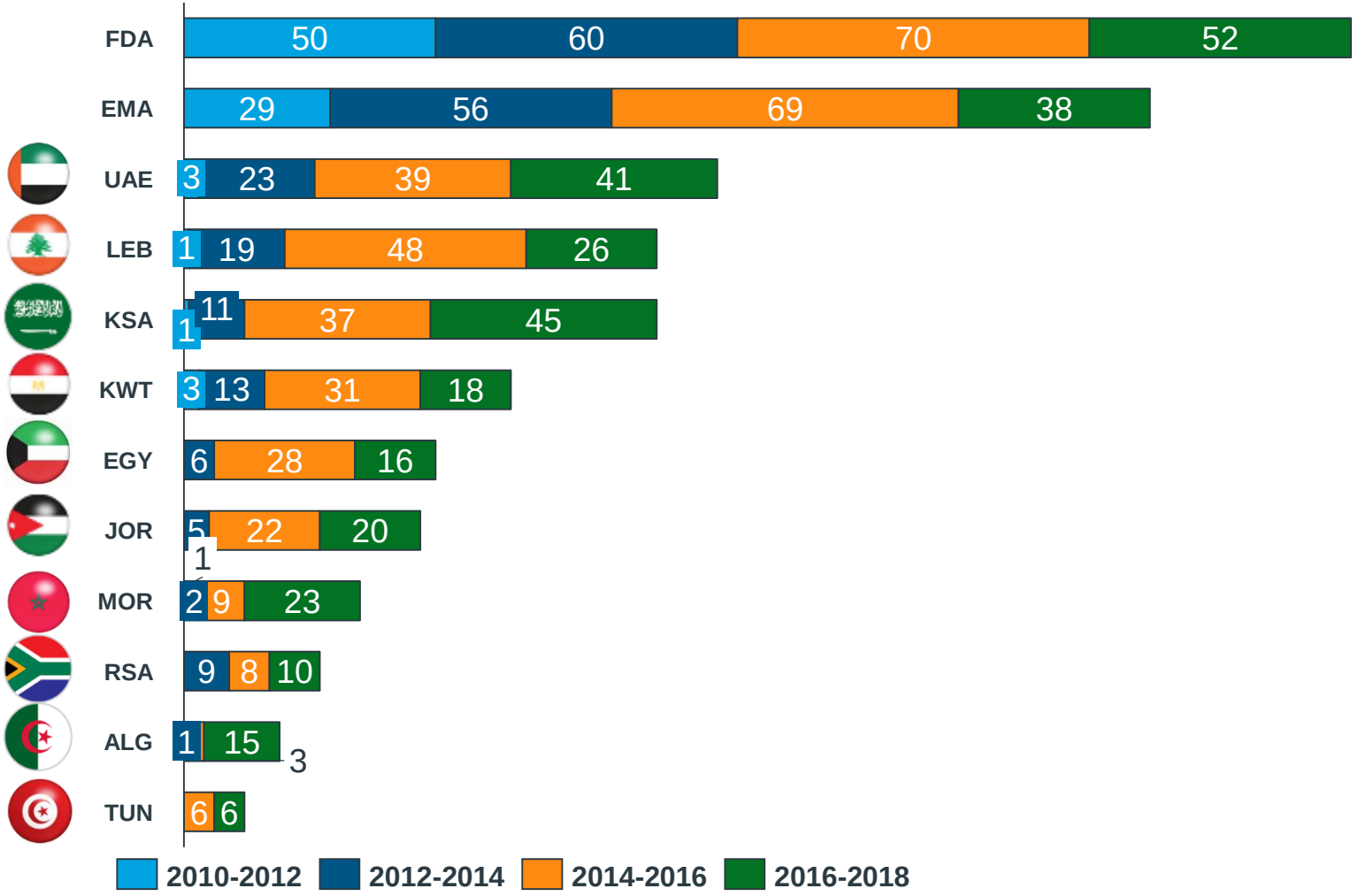
- The configuration of the market access landscape has a determinant impact on the number of available products per country
- The UAE has the maximum number of molecules registered in MEA followed by Lebanon and KSA
- Name-patient based programs are used more commonly in UAE, KSA and Kuwait as an early access mechanism
- The proportion of reimbursed NMEs is not correlated with the number of registered NMEs

Note: Number of NMEs launched is based on IQVIA available data; NMEs available only in tenders in UAE and Jordan are not reflected in this analysis unless confirmed by the company

In terms of time spread, the majority of NMEs have been registered between 2014 and 2018 in the EMA region…

Number of NMEs registered in 2010 – 2018

Universe: 240 NMEs



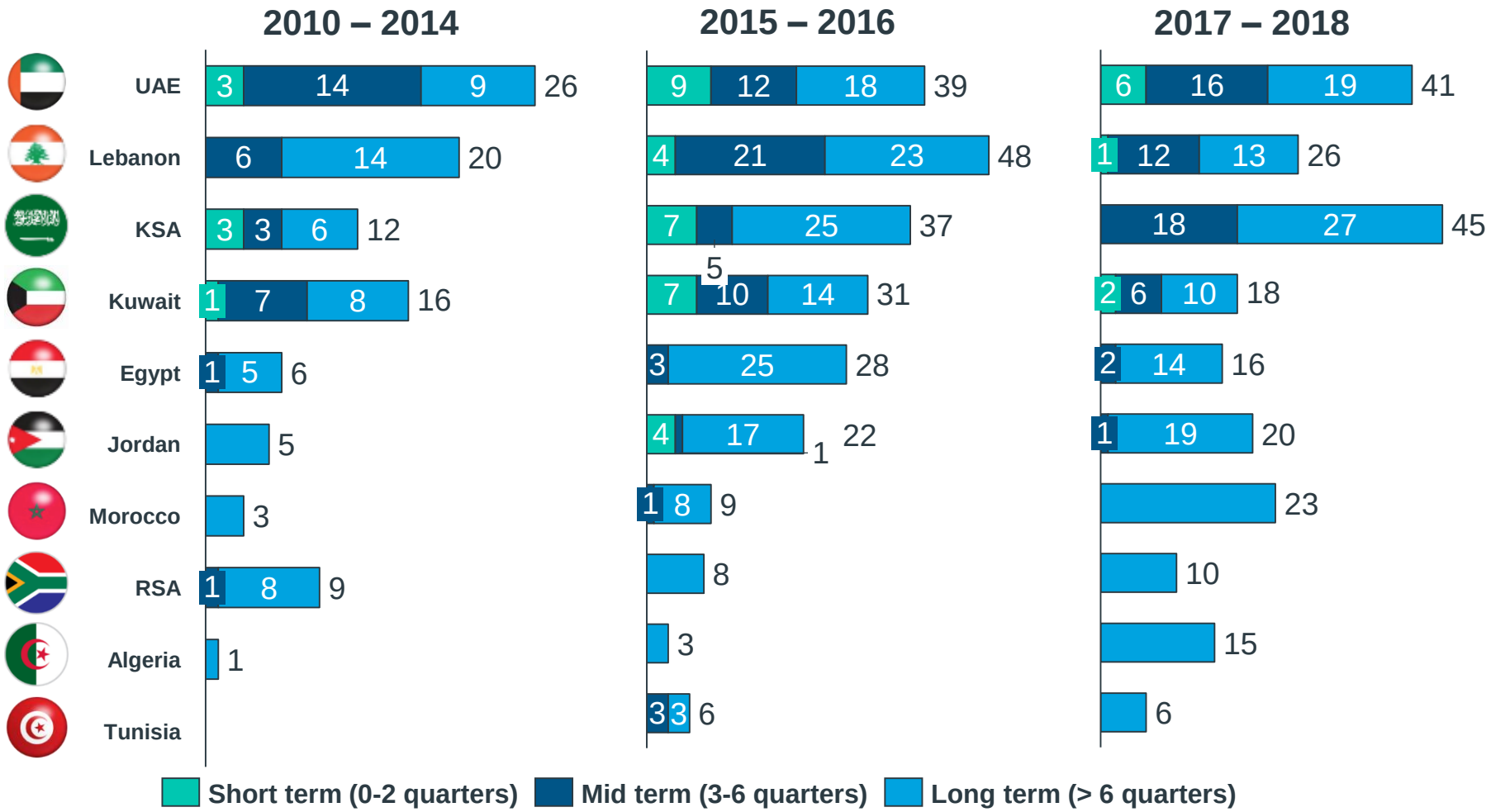
Key Highlights

- Regarding the registration timings in the region, the majority of NMEs have been available for the population only from 2014 onwards
- The UAE, Lebanon & Kuwait with shorter registration timelines are the only countries in the region where NMEs are introduced earlier to the market

Although the number of molecules registered has recently increased, the majority of them face longer registration timelines across the MEA since registration in EMA /FDA

Number of NMEs registered in 2010 – 2018

Universe: 240 NMEs



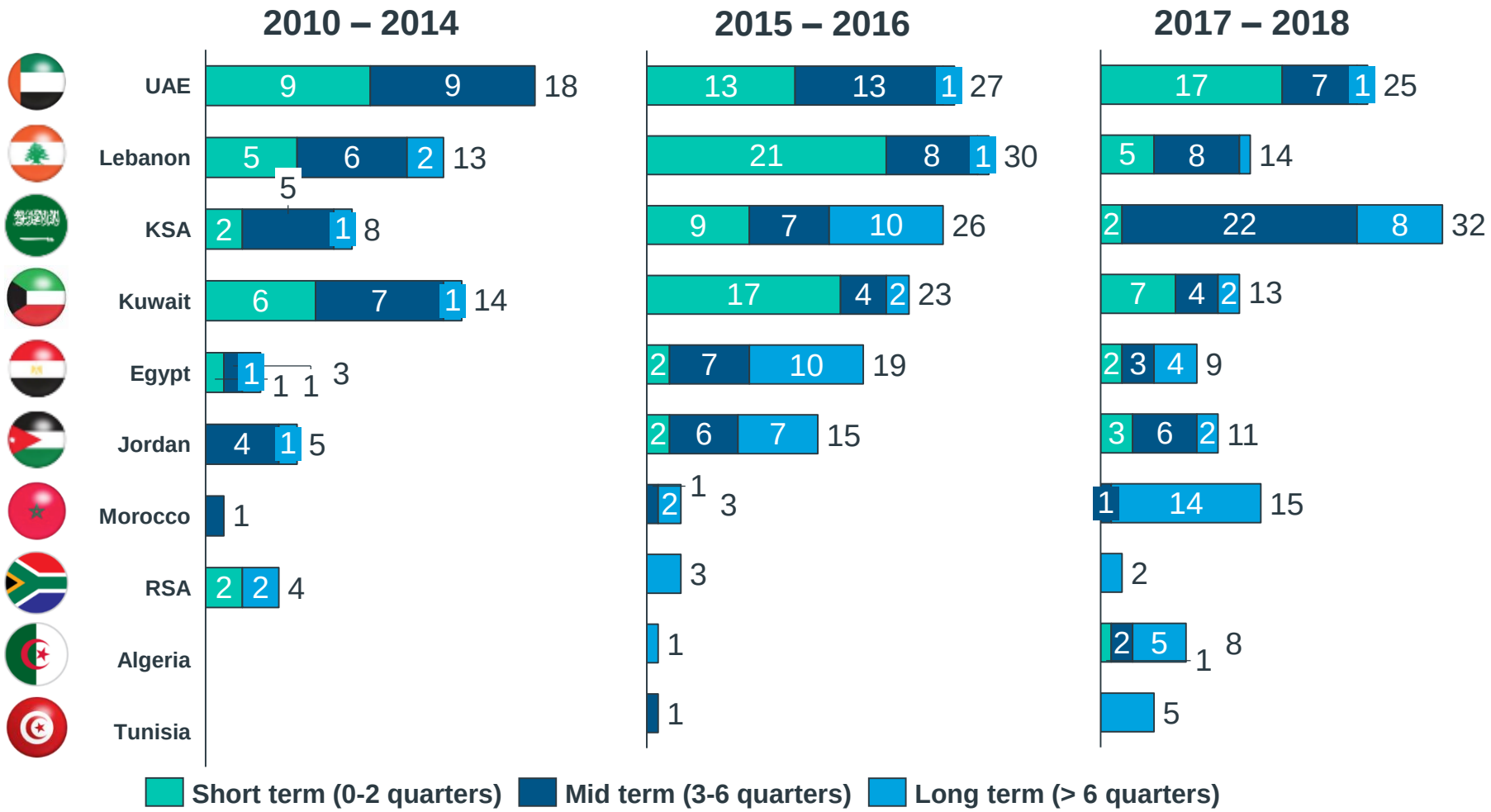
Key Highlights

- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- Registration timelines have been shorter in Middle East countries particularly in Lebanon, KSA and UAE
- NMEs, which have been granted a faster registration (< 6 months), are in prioritized therapy areas, such as oncology or anti-infectives /antivirals
- Registration timelines remain longer than 6 quarters in Algeria, Morocco, South Africa and Tunisia

Improvements in regulatory processes in certain countries are resulting in shorter local registration timelines since the actual submission date

Number of NMEs registered in 2010 – 2018 (Time to local registration in quarters)

Universe: 126 NMEs

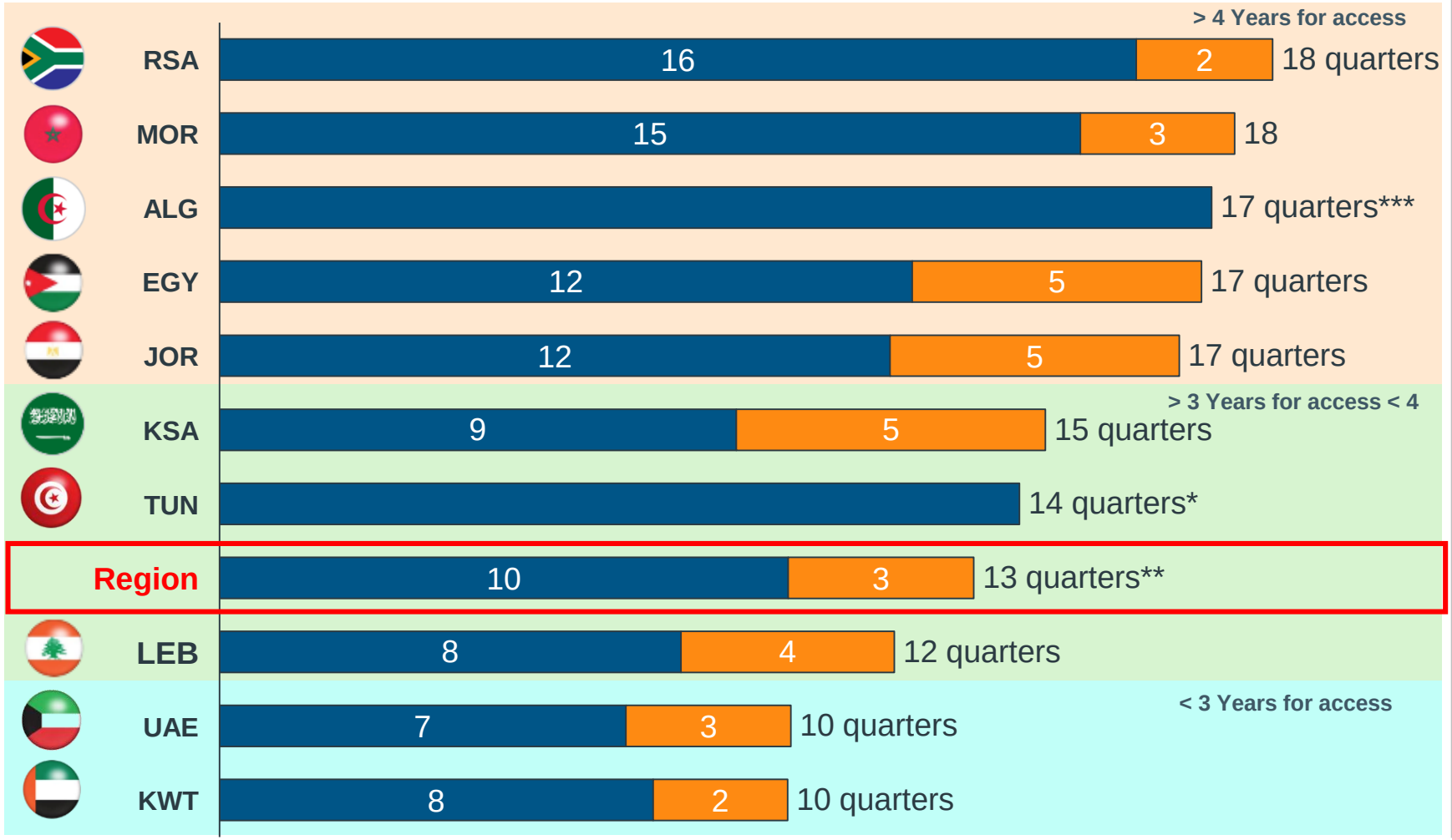


Key Highlights

- Time to register is the time elapsed between date of local dossier submission and registration in the region/country
- Local registration timelines have been shorter in Middle East countries, potentially driven by recent improvements in regulatory processes
- NMEs, which have been granted a faster registration (< 6 months), are in prioritized therapy areas, such as oncology or anti-infectives/ antivirals
- Local registration timelines remain longer than 6 quarters in Algeria, Morocco, South Africa and Tunisia

Average time to patient access to a NME has been 3.25 years in MEA region vs EMA/FDA approval; with faster access in Middle East countries than in Africa

Average time to access (by quarters) in MEA in 2010 – 2018



Key Highlights

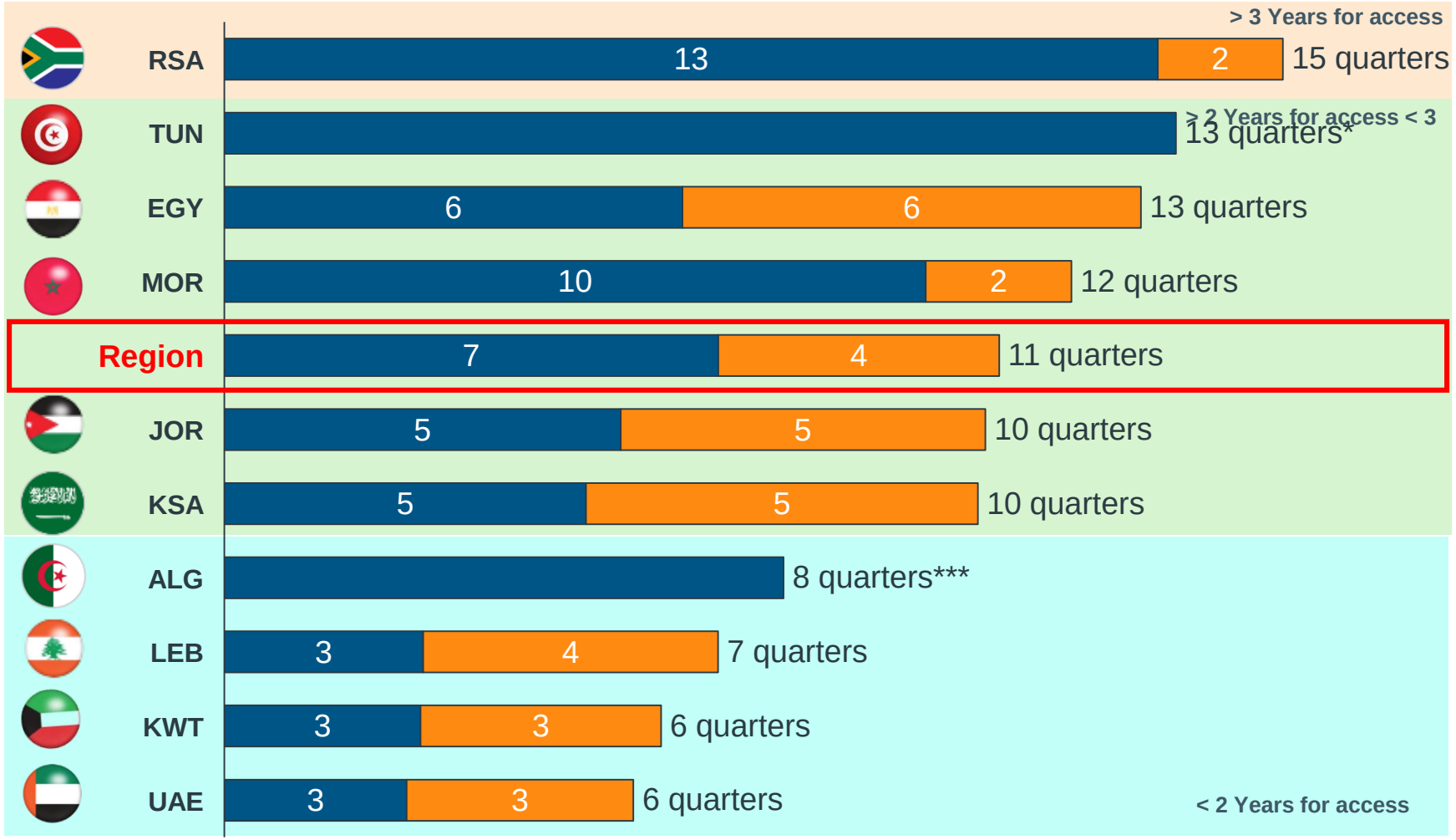
- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- UAE has the shortest time to access in the region with an average of 2.5 years; followed by Kuwait, Lebanon and Saudi Arabia
- Within countries in-scope, RSA and Algeria have the longest time to registration
  - For Algeria it could be explained by the fact that the registration process includes the pricing negotiation which can be prolonged for “expensive” products
  - For RSA, the long time to registration is explained by the backlog in SAHPRA

* None of the molecules are reimbursed Tunisia ***Launched molecules in Algeria are reimbursed in the same quarter as registration
** Countries with lower time to access have the highest number of NMEs registered

Time to registration
Time to reimbursement

However, when we remove the time elapsed from the FDA/EMA approval until the actual submission of the file locally, time to access decreases to 2.75 years

Average time to access (by quarters) in MEA in 2010-2018 – based on 126 NMEs



* None of the molecules are reimbursed Tunisia ***Launched molecules in Algeria are reimbursed in the same quarter as registration
** Countries with lower time to access have the highest number of NMEs registered

Time to local registration
Time to reimbursement

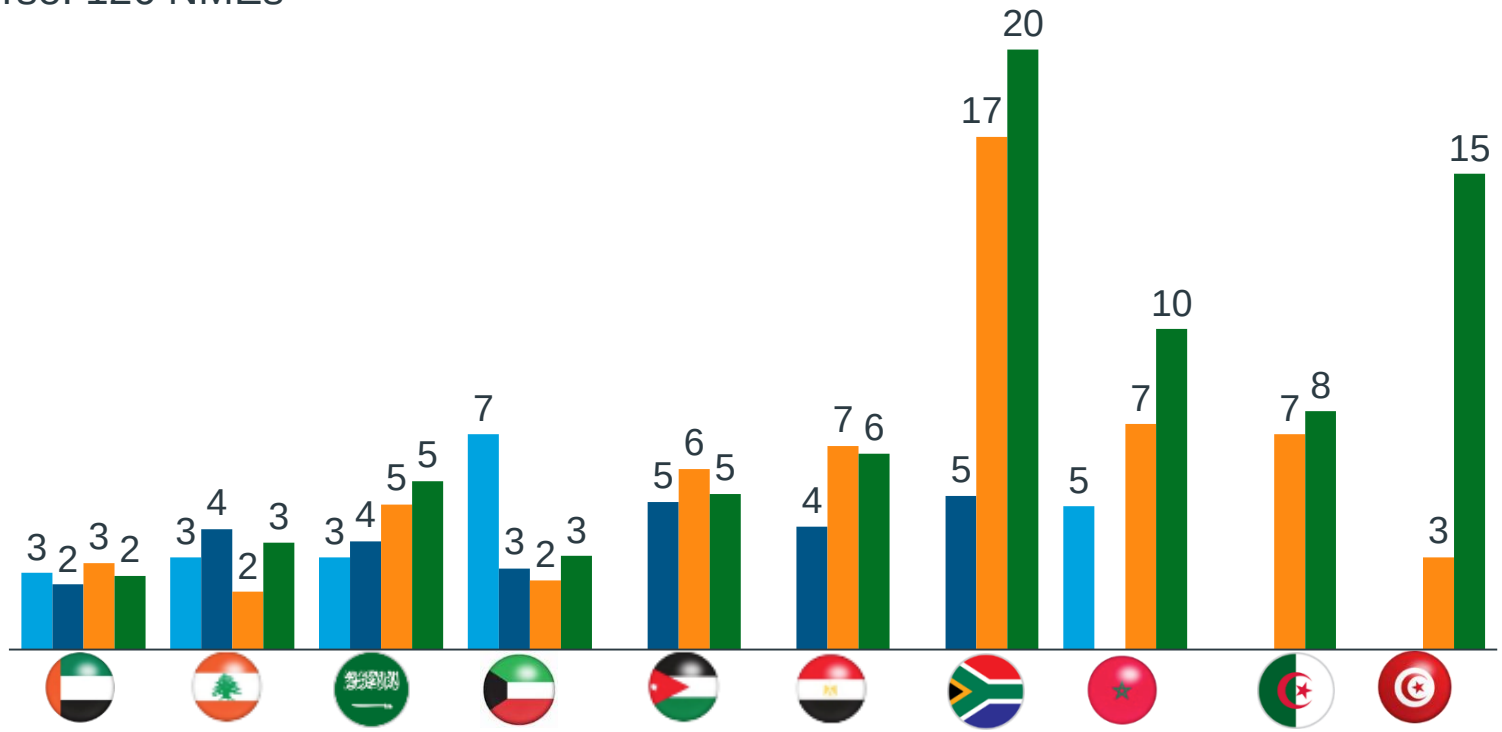
Key Highlights

- Time to local registration is the time elapsed between dossier submission to approval by local authorities
- The delay of actual submission of the file after the EMA/FDA approval is linked to several factors such as company decision, fulfillment of requirements and appointment limitations
- Kuwait, UAE and Lebanon have the shortest time to access in the region with less than 1.8 years
- Since none of the 126 products of the sub sample is reimbursed in Tunisia, time to access looks deceptively lower
- Reimbursement process is increasing the time to access in KSA, Jordan and Egypt

Timelines for registration since local dossier submission remained relatively short in the Middle East while increasing in Africa over the years …

Average time to local registration (quarters), NMEs registered in 2010 – 2018

Universe: 126 NMEs



# NMEs										
2010-2012	2	1	1	2				1		
2012-2014	16	12	7	12	5	3	4			
2014-2016	27	30	26	23	15	19	3	3	1	1
2016-2018	25	14	32	13	11	9	2	15	8	5

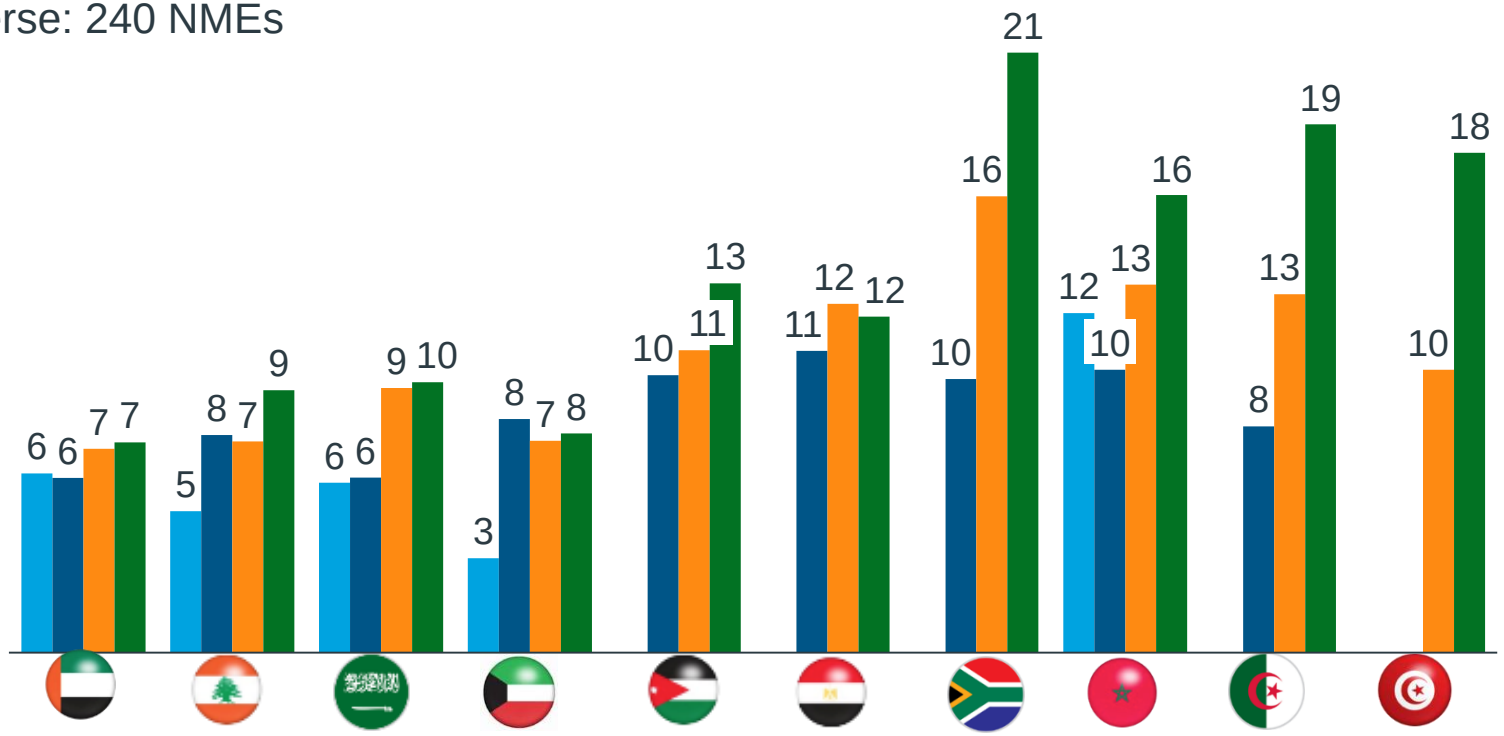
Key Highlights

- Time to local registration is the time elapsed between dossier submission to approval by local authorities
- Average registration timelines are less than one year (even less than 2 quarters for a few NMEs) in UAE, Lebanon, KSA and Kuwait;
  - Faster registration is observed more in priority therapy areas such as oncology
- Registration timelines remain longer for Algeria, Morocco, and Tunisia, however, they became shorter than RSA

However, the overall timelines for registration since EMA/FDA approval have increased in all the countries

Average time to registration (quarters), NMEs registered in 2010 – 2018

Universe: 240 NMEs



# NMEs										
2010-2012	3	1	1	3				1		
2012-2014	23	19	11	13	5	6	9	2	1	
2014-2016	39	48	37	31	22	28	8	9	3	6
2016-2018	41	26	45	18	20	16	10	23	15	6

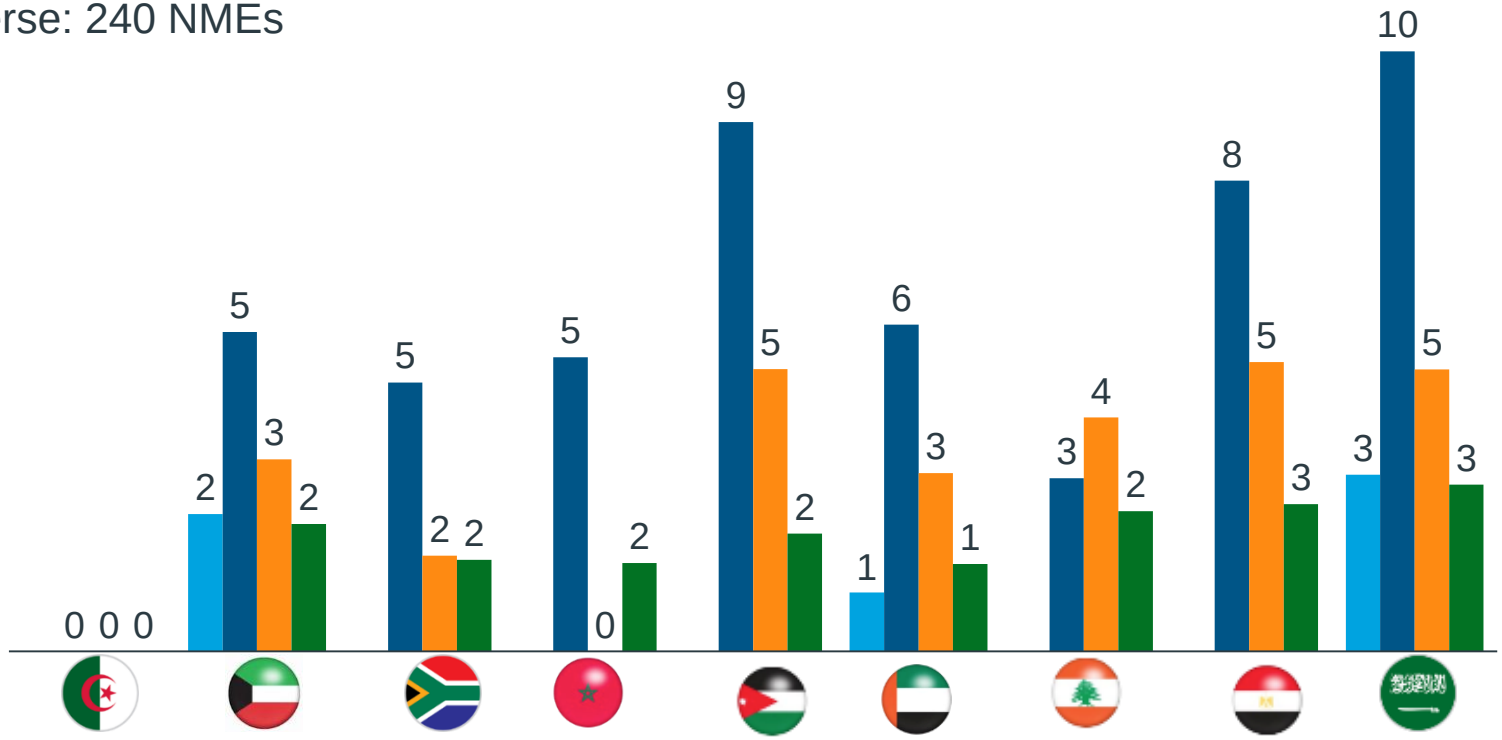
Key Highlights

- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- Registration timelines increased in the recent years in all the countries
- Registration timelines remain longer for Algeria, RSA, Morocco, and Tunisia compared to the other countries

On the other hand, registered NMEs are being reimbursed in a shorter time in recent years across the region

Average time to reimbursement (quarters), NMEs registered in 2010 – 2018

Universe: 240 NMEs



# NMEs									
2010-2012		3				2	1*		1
2012-2014	1	8	7	2	1	18	18	1	10
2014-2016	2	21	8		5	35	39	12	30
2016-2018	1	6	9	4	1	30	13	2	14
% of NMEs reimbursed to registered	21%	58%	89%	17%	15%	77%	76%	30%	59%

*Only one product has been registered within that time period; it has been excluded from the analysis due to being an outlier

Note: None of the NMEs launched in Tunisia are reimbursed. All the NMEs launched in Algeria & RSA are reimbursed

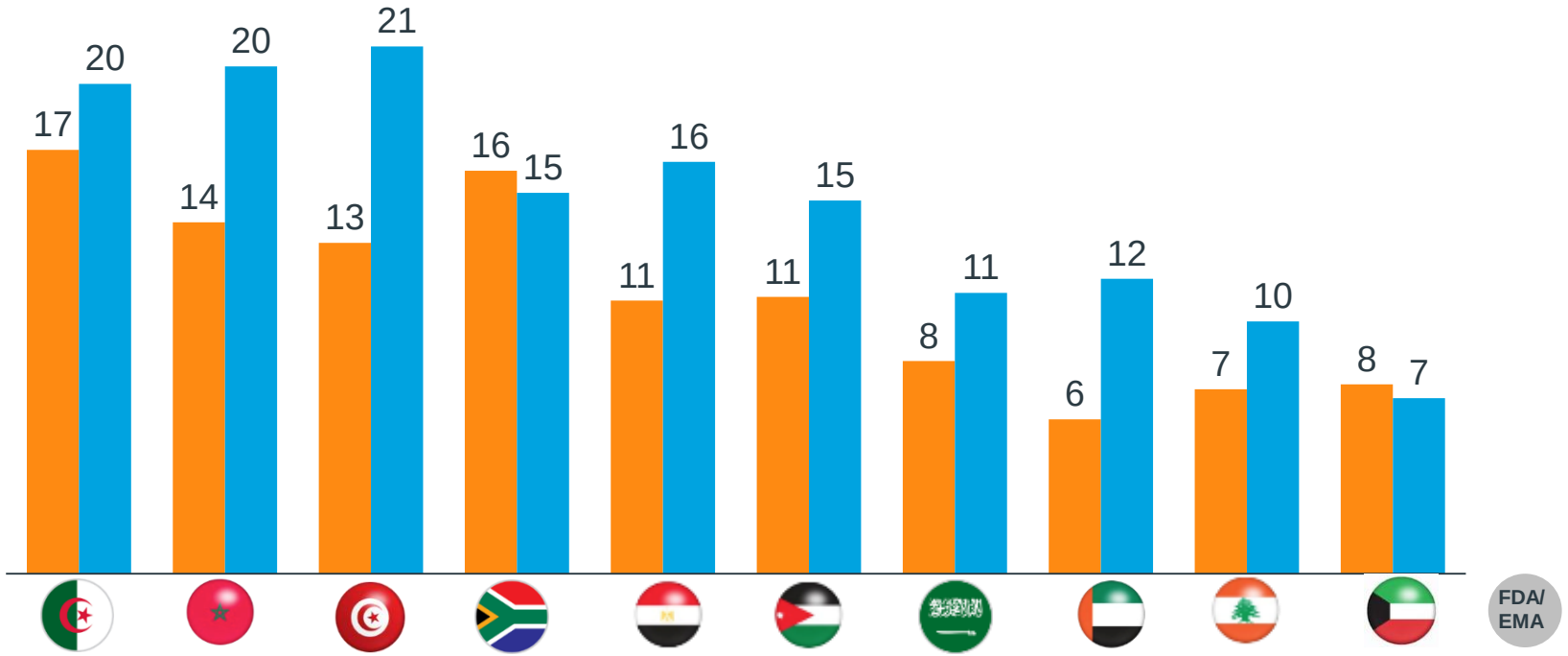
Key Highlights

- Time to reimbursement is the time elapsed between registration in the country and time for an NME to be granted reimbursement status in the country [refer to definition on slide #7]
- The reimbursement timeline has decreased in the recent years in all the countries
- Proportion of reimbursed products vs registration are considerably low in Morocco, Algeria, Jordan and Egypt

The top 20 MNCs seem to register innovative medicine faster, possibly due to their local presence and engagement with key stakeholders

Average time to registration (quarters), Top 20 MNCs vs others

Universe: 240 NMEs



# NMEs											
Top 20 MNCs	17	30	11	21	40	40	78	88	72	5	120
Others	2	5	1	6	10	7	16	18	22	65	120

Key Highlights

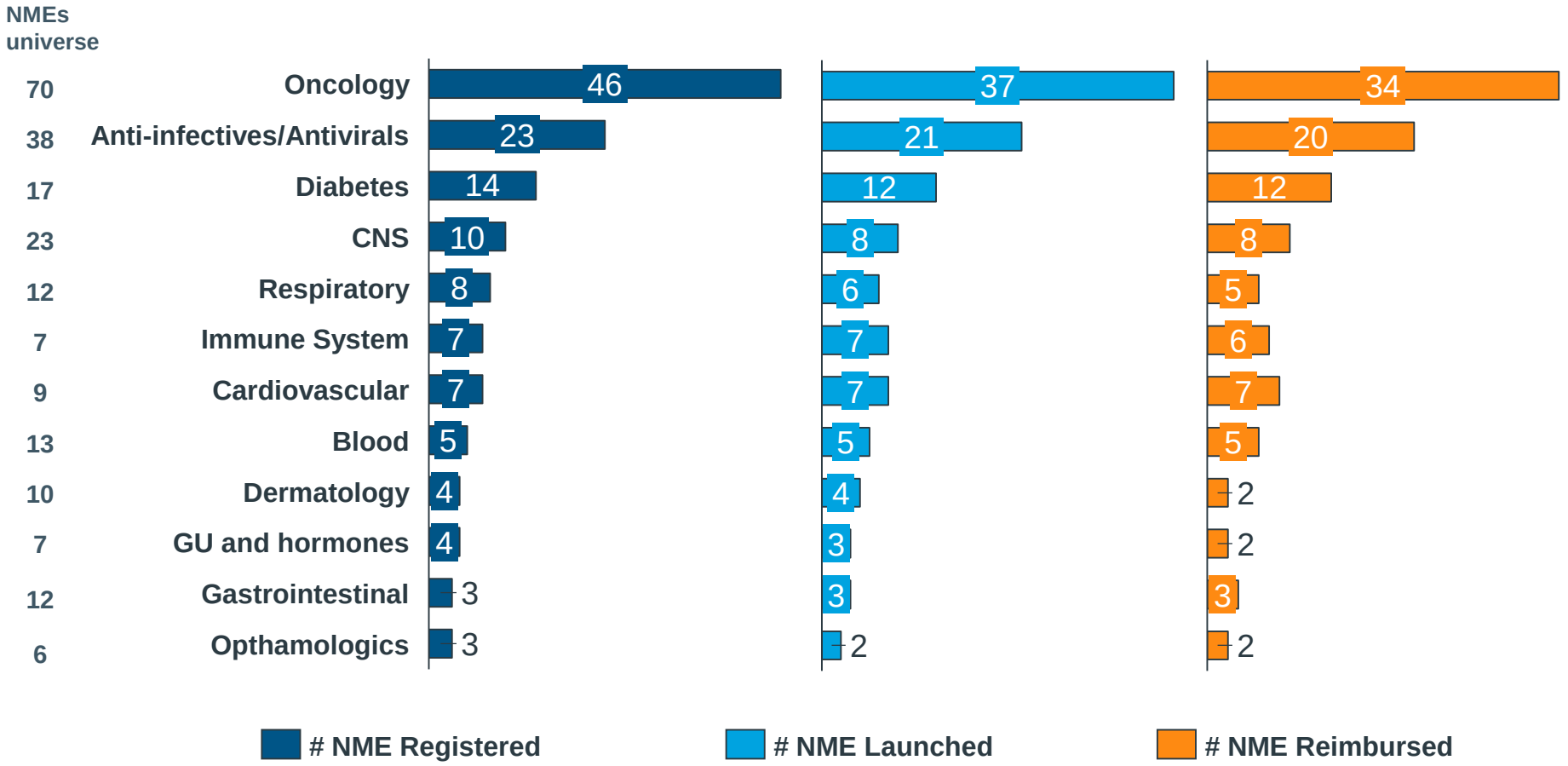
- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- Similar to the overall market trends, average time for registration for MNCs is the highest in Algeria followed by Morocco and Tunisia

Note: Top 20 MNCs are selected based on global sales

Aligned with country healthcare policy priorities, a higher number of NMEs are registered in oncology, anti-infectives / antivirals and diabetes TAs

Number of NMEs registered, launched and reimbursed in MEA by therapeutic area in 2010 – 2018

Universe: 240 NMEs

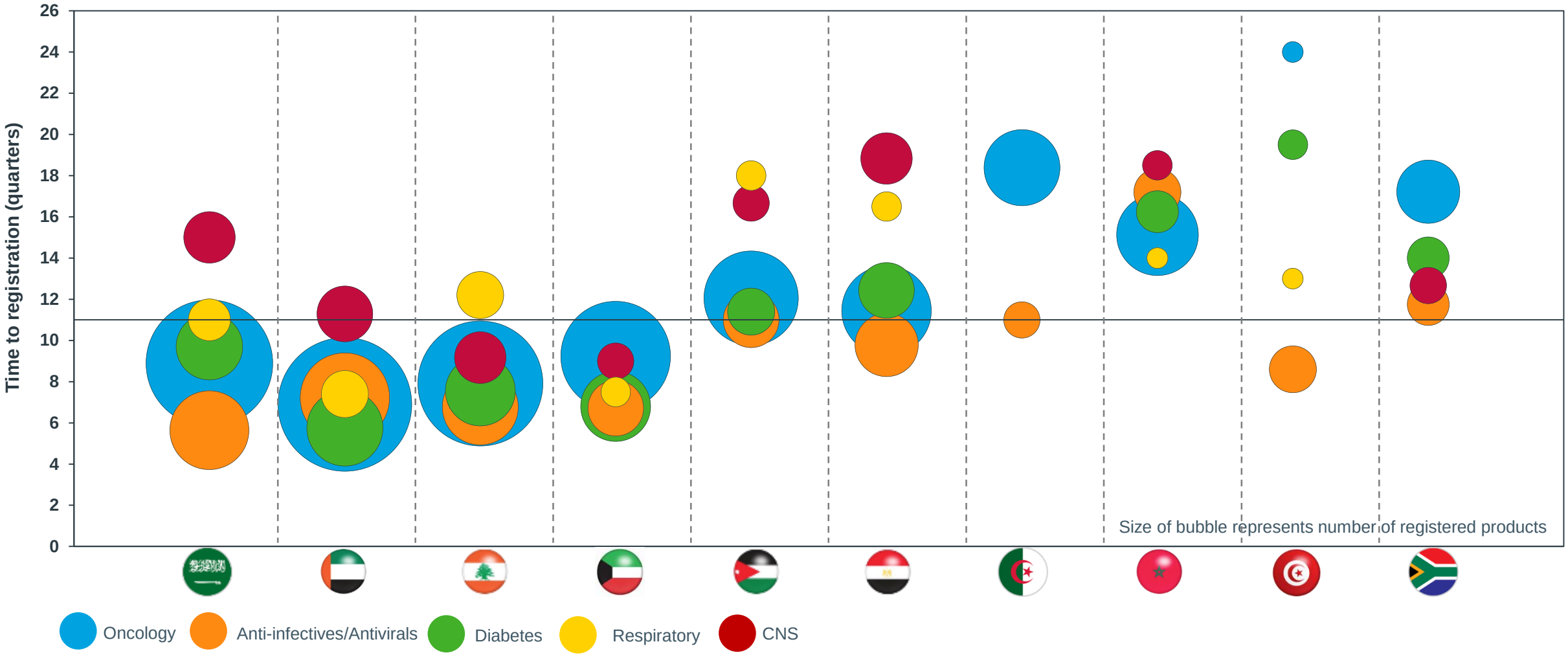


Key Highlights

- Number of available NMEs diverge significantly by therapeutic area with oncology being a priority in the region
- Higher number of registrations are for oncology, however, almost 34% of the NMEs are not available in the region
- 74% of the oncology NMEs are reimbursed in the region
- Similarly, anti-infectives/ antivirals and diabetes are among the focus therapy areas due to regional dynamics and this has been also reflected by the higher number of NMEs registered

Note: Number of NMEs launched is based on IQVIA available data; NMEs available only in tenders in UAE and Jordan are not reflected in this analysis unless confirmed by the company
None of the musculoskeletal and metabolic products are registered in the region

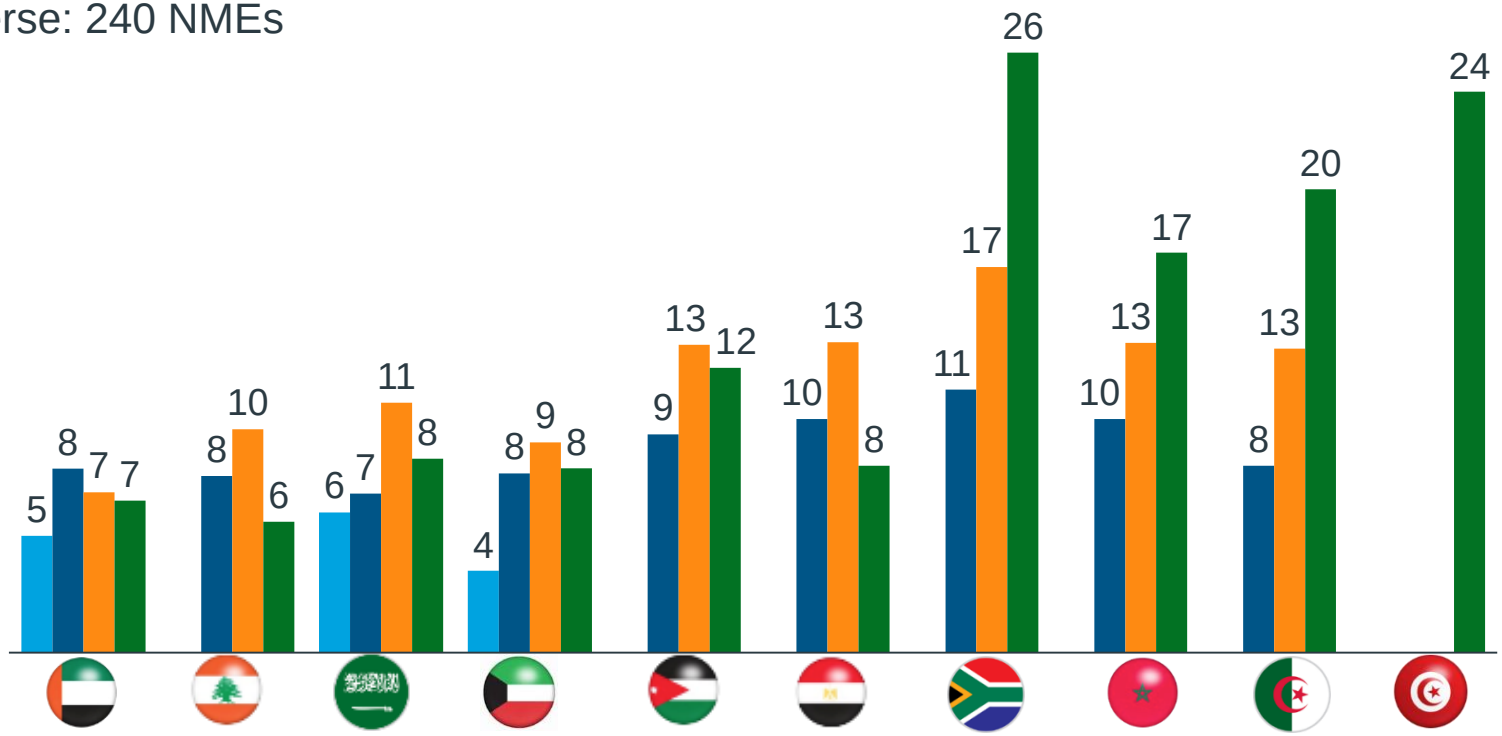
Key therapy areas are consistently prioritized in KSA, UAE and Lebanon



Inline with given priorities, Oncology registration timelines have decreased in ME countries, however, registration is taking even longer in Africa…

Average time to registration (quarters),Oncology NMEs registered in 2010 – 2018

Universe: 240 NMEs



# NMEs										
2010-2012	1		1	2						
2012-2014	8	9	5	3	3	2	4	2	1	
2014-2016	14	16	13	12	6	11	2	4	1	
2016-2018	17	10	17	10	11	5	3	9	11	1

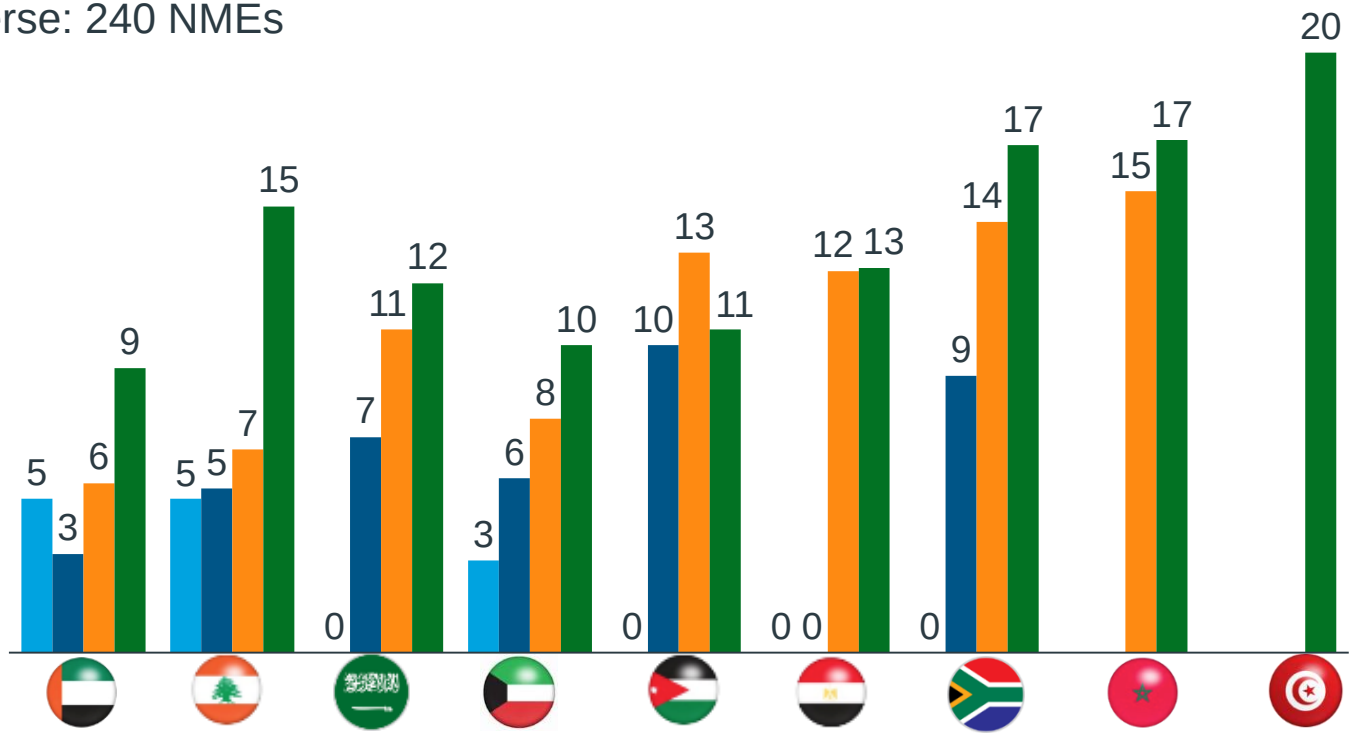
Key Highlights

- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- Along with the decrease in registration timelines, number of registered oncology products increased in recent years in UAE, KSA and Egypt
- On the contrary, average registration timelines for oncology products increased in African countries
- A similar trend is observed for anti-infectives / antivirals therapy area in countries in-scope

… whereas registration timelines for diabetes NMEs have increased over the years across MEA countries

Average time to registration (quarters), Diabetes NMEs registered in 2010 – 2018

Universe: 240 NMEs



# NMEs									
2010-2012	1	1		1					
2012-2014	5	3	1	3	1		1		
2014-2016	2	5	4	5	2	5	1	1	
2016-2018	5	2	5	2	2	2	2	3	2

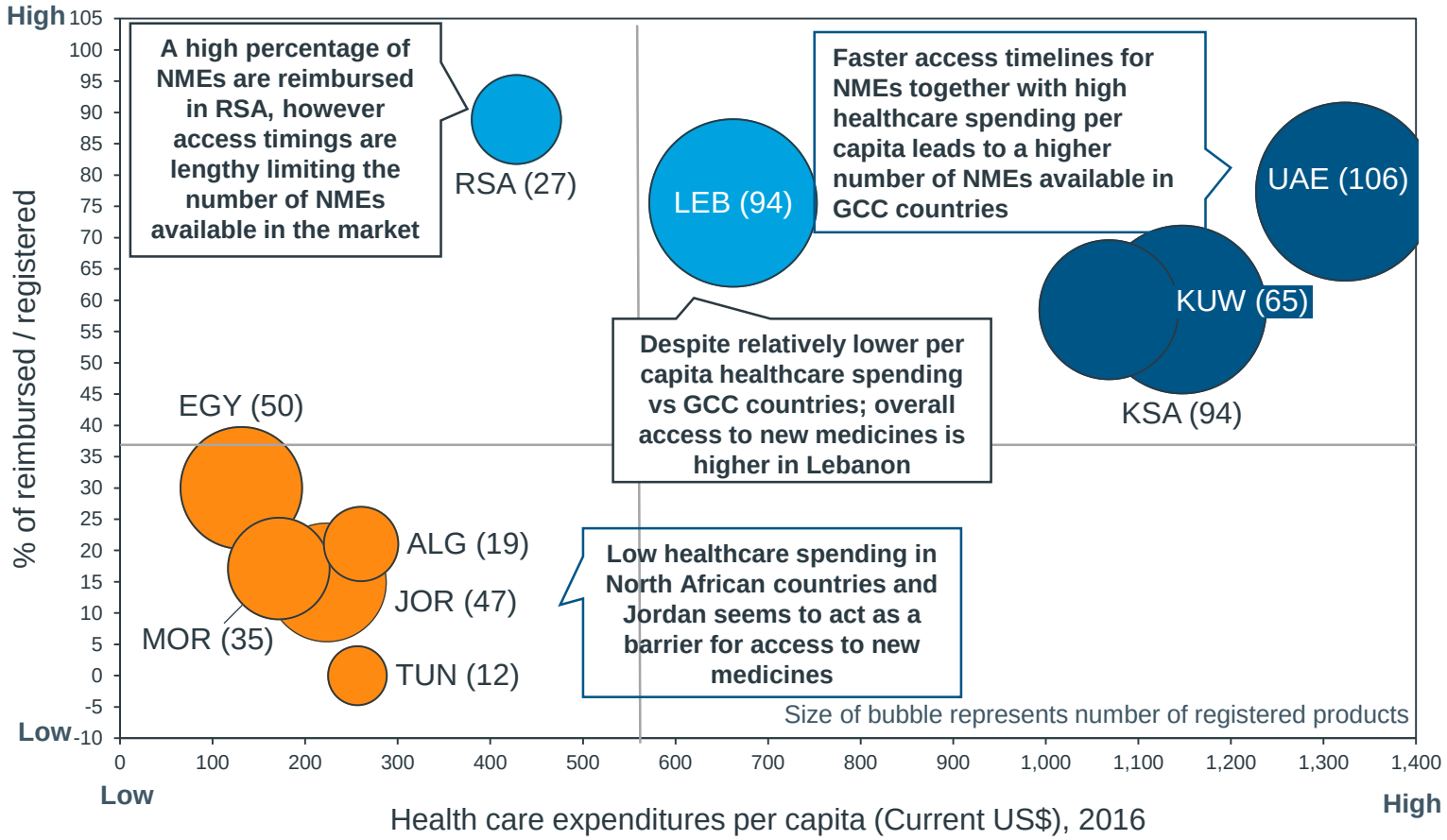
Key Highlights

- Time to register is the time elapsed between 1st registration in FDA or EMA and registration in the region/country
- Aligned with the overall view, registration timelines for diabetes NMEs increased in countries in-scope, with relatively fewer NMEs launched in recent years
- A similar trend is observed for CNS and respiratory therapy areas in countries in-scope
- One of the underlying reasons might be the availability of existing alternatives for these therapy areas in the country

Note: None of Diabetes products are registered in the Algeria

Overall there is a high level of correlation between the % of NMEs reimbursed vs registered and healthcare spending in MEA region, with the exception of RSA

Proportion of NMEs reimbursed vs. Healthcare expenditure per capita



Key Highlights

- GCC countries offer the better healthcare coverage system with high healthcare spending per capita correlated with high percentage of NMEs reimbursed; however the coverage is limited to nationals and expats with high income
- The RSA reimburses a high percentage of new drugs while their healthcare spending per capita is below region average

In summary…

- **The moderately growing** MEA pharmaceuticals market is shaped by a number of themes, including an **enhanced regulatory environment with accelerated timelines** and **expansion of healthcare coverage**
- **Almost half of the 240 NMEs** analyzed in this project are **not registered** in the MEA region; on the other hand, the number of **registered products increased significantly** in the Middle East recently while the picture didn't change much in Africa
    - Regulatory improvements are leading to **more and faster registration** of innovations, especially in UAE, Lebanon, KSA and Kuwait
- In the MEA region**, average time to access** to a NME has been **3.5 years** since **EMA/FDA approval** and **2.75 years** since **local submission**
    - One year average difference between EMA/FDA approval and local submission can be attributed to companies decision-making, fulfillment of local administrative requirements and appointment availability
    - The remaining 2.5 years are driven by multiple factors such as readiness/quality of the dossier, resources driving the process as well as the level of bureaucracy
    - **Average registration timelines since local submission** is **less than one year** (even less than 2 quarters for a few NMEs) in UAE, Lebanon, KSA, Kuwait and Jordan; faster registration is observed more in priority therapy areas such as oncology
- Possibly due to their local presence and engagement with key stakeholders, **top 20 MNCs seem to register innovative medicine faster**
- Aligned with country **healthcare policy priorities**, higher number of NMEs are registered in **oncology**, **anti-infectives**/ **antivirals** and **diabetes** therapy areas
    - While we observe shortening timelines for oncology and anti-virals, timelines increased for diabetes, respiratory and CNS
    - We observe implications **of the recent regulatory reforms** (**abridged / verification procedures, fast track procedures, priority review)** especially for the healthcare policy priority areas
- The impact of delays in access to new medicines should be considered in light of the value of innovation to patients, healthcare systems and society, as recently documented in a report by Prof. Frank Lichtenberg Columbia University examining 9 of 10 countries examined in this report

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Assessment of access to new medicines in selected countries in Middle East and Africa

Project report - APPENDIX

December 2018

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Appendix

Access to innovation has also been assessed for the therapeutic areas included on the table below

Therapeutic areas are categorized with anatomical therapeutic chemical (ATC) codes

ATC Code	Therapeutic Area	Description
J1, J4, J5, J6	Anti-infective/Antiviral	Antibacterial drugs, Antimycobacterials, Antiviral drugs, Immune sera and immunoglobulins
L1, L2	Oncology	Antineoplastic drugs, Endocrine therapy
R3, R7	Respiratory	Drugs for obstructive airway diseases, Other respiratory system products
S1	Ophthalmologic	Ophthalmological drugs
A10	Diabetes	Drugs used in diabetes
B1, B2	Blood	Antithrombotic agents, Antihemorrhagic drugs
C2, C9, C10	Cardiovascular	Antihypertensive drugs, Antihemorrhagic drugs, Lipid modifying agents
L3, L4	Immune System	Immunostimulants drugs, Immunosuppressants drugs
G2, G3, G4, H1, H4, H5	GU and hormones	Other gynecological drugs, Sex hormones and modulators of the genital system, Urological drugs, Pituitary and hypothalamic hormones and analogues, Pancreatic hormones
N3, N4, N5, N6, N7,	CNS	Antiepileptic drugs, Antiparkinson drugs, Psycholeptics drugs, Psychoanaleptics, Other nervous system drugs
D1, D2, D5, D8, D10,	Dermatology	Antifungals for dermatological use, Emollients and protectants, Antipsoriatic drugs, Antiseptics and disinfectants drugs, Acne drugs,
A16	Metabolic	Other alimentary tract and metabolism products
M1, M4, M5	Musculoskeletal	Anti-inflammatory and antirheumatic drugs, Antigout preparations, Drugs affecting bone structure and mineralization
A2, A3, A4, A5, A6, A7, A8	Gastrointestinal	Drugs for acid related disorders, Drugs for functional gastrointestinal disorders, Antiemetics and antinauseants, Drugs for constipation, Antidiarrheals, intestinal anti-inflammatory/anti-infective agents, Antiobesity preparations, excluding diet products, Bile and liver therapy
V3	Other	All other therapeutic products

New molecular entities included in the project (1/5)

#	Molecule Name
1	ABIRATERONE ACETATE
2	ACLIDINIUM BROMIDE
3	AFATINIB
4	AFLIBERCEPT
5	AFLIBERCEPT
6	ALBIGLUTIDE
7	ALBUTREPENONACOG ALFA
8	ALECTINIB HYDROCHLORIDE
9	ALIROCUMAB
10	APIXABAN
11	APREMILAST
12	ATEZOLIZUMAB
13	AVANAFIL
14	AVELUMAB
15	AVIBACTAM SODIUM#CEFTAZIDIME
16	AXITINIB
17	AZILSARTAN MEDOXOMIL
18	BEDAQUILINE FUMARATE
19	BELATACEPT
20	BELIMUMAB
21	BENRALIZUMAB
22	BEZLOTOXUMAB
23	BLINATUMOMAB
24	BOSUTINIB
25	BRENTUXIMAB VEDOTIN
26	BRIVARACETAM
27	CABOZANTINIB
28	CANAGLIFLOZIN
29	CANAGLIFLOZIN#METFORMIN HYDROCHLORIDE
30	CARFILZOMIB

#	Molecule Name
31	CEFTAROLINE FOSAMIL
32	CEFTOLOZANE SULFATE#TAZOBACTAM SODIUM
33	CERITINIB
34	CERLIPONASE ALFA
35	COBIMETINIB HEMIFUMARATE
36	CRIZOTINIB
37	DABRAFENIB MESYLATE
38	DACLATASVIR DIHYDROCHLORIDE
39	DALBAVANCIN
40	DAPAGLIFLOZIN
41	DAPAGLIFLOZIN#METFORMIN
42	DARATUMUMAB
43	DARUNAVIR#COBICISTAT
44	DIMETHYL FUMARATE
45	DINUTUXIMAB
46	DOLUTEGRAVIR
47	DULAGLUTIDE
48	DUPILUMAB
49	EDOXABAN
50	EFMOROCTOCOG ALFA
51	EFTRENONACOG ALFA
52	ELBASVIR#GRAZOPREVIR
53	ELIGLUSTAT
54	ELOTUZUMAB
55	ELUXADOLINE
56	ELVITEGRAVIR#COBICISTAT#EMTRICITABINE#TENOFOVIR ALAFENAMIDE
57	ELVITEGRAVIR#COBICISTAT#EMTRICITABINE#TENOFOVIR DISOPROXIL FUMARATE
58	EMICIZUMAB
59	EMPAGLIFLOZIN
60	EMPAGLIFLOZIN#METFORMIN

New molecular entities included in the project (2/5)

#	Molecule Name
61	EMTRICITABINE#RILPIVIRINE HYDROCHLORIDE#TENOFOVIR ALAFENAMIDE
62	EMTRICITABINE#RILPIVIRINE HYDROCHLORIDE#TENOFOVIR DISOPROXIL FUMARATE
63	EMTRICITABINE#TENOFOVIR ALAFENAMIDE
64	ENZALUTAMIDE
65	ETELCALCETIDE HYDROCHLORIDE
66	EVOLOCUMAB
67	RETIGABINE
68	FIDAXOMICIN
69	GLECAPREVIR#PIBRENTASVIR
70	GUSELKUMAB
71	IBRUTINIB
72	IDARUCIZUMAB
73	IDELALISIB
74	INGENOL MEBUTATE
75	INOTUZUMAB OZOGAMICIN
76	INSULIN DEGLUDEC
77	INSULIN DEGLUDEC#LIRAGLUTIDE
78	INSULIN GLARGINE#LIXISENATIDE
79	IPILIMUMAB
80	ISAVUCONAZOLE
81	IVACAFTOR
82	IXAZOMIB CITRATE
83	IXEKIZUMAB
84	LEDISPAVIR 90 MG#SOFOSBUVIR 400 MG
85	LENVATINIB MESYLATE
86	LESINURAD
87	LETERMOVIR
88	LINACLOTIDE
89	LINAGLIPTIN
90	LIXISENATIDE

#	Molecule Name
91	LUMACAFTOR#IVACAFTOR
92	LURASIDONE
93	MACITENTAN
94	MEPOLIZUMAB
95	MIDOSTAURIN
96	MIRABEGRON
97	NALOXEGOL
98	NECITUMUMAB
99	NETUPITANT#PALONOSETRON HYDROCHLORIDE
100	NINTEDANIB
101	NIRAPARIB TOSYLATE MONOHYDRATE
102	NIVOLUMAB
103	NUSINERSEN SODIUM
104	OBETICHOLIC ACID
105	OBINUTUZUMAB
106	OCRELIZUMAB
107	OCRIPLASMIN
108	OLAPARIB
109	OLARATUMAB
110	OMBITASVIR#PARITAPREVIR#RITONAVIR
111	OSIMERTINIB MESYLATE
112	OSPEMIFENE
113	PALBOCICLIB
114	PANOBINOSTAT LACTATE ANHYDROUS
115	PASIREOTIDE
116	PATIROMER SORBITEX CALCIUM
117	PEGINTERFERON BETA-1A
118	PEMBROLIZUMAB
119	PERAMPANEL
120	PERTUZUMAB

New molecular entities included in the project (3/5)

#	Molecule Name
121	POMALIDOMIDE
122	PONATINIB
123	RAMUCIRUMAB
124	RECOMBINANT HUMAN N-ACETYLGALACTOSAMINE-6-SULFATASE (RHGALNS)
125	REGORAFENIB
126	RESLIZUMAB
127	RIBOCICLIB SUCCINATE
128	RILPIVIRINE HYDROCHLORIDE
129	RIOCIGUAT
130	ROLAPITANT
131	RUXOLITINIB
132	SACUBITRIL#VALSARTAN
133	SAFINAMIDE METHANESULFONATE
134	SARILUMAB
135	SAXAGLIPTIN#DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE
136	SEBELIPASE ALFA
137	SECUKINUMAB
138	SELEXIPAG
139	SILTUXIMAB
140	SIMOCTOCOG ALFA
141	SOFOSBUVIR
142	SOFOSBUVIR#VELPATASVIR
143	SOFOSBUVIR#VELPATASVIR#VOXILAPREVI
144	SONIDEGIB DIPHOSPHATE
145	TASIMELTEON
146	TEDIZOLID
147	TELOTRISTAT ETIPRATE
148	TERIFLUNOMIDE
149	TOFACITINIB
150	TRAMETINIB

#	Molecule Name
151	TRASTUZUMAB EMTANSINE
152	TRIFLURIDINE#TIPIRACIL HYDROCHLORIDE
153	TUROCTOCOG ALFA
154	VANDETANIB
155	VEDOLIZUMAB
156	VEMURAFENIB
157	VENETOCLAX
158	VILANTEROL TRIFENATATE#UMECLIDINIUM BROMIDE
159	VISMODEGIB
160	VORTIOXETINE
161	DASABUVIR + OMBITASVIR + PARITAPREVIR + RITONAVIR
162	ABEMACICLIB
163	ACALABRUTINIB
164	ARIPIPRAZOLE LAUROXIL
165	ASFOTASE ALFA
166	BELINOSTAT
167	BOCEPREVIR
168	BREXPIPRAZOLE
169	BRIGATINIB
170	CARIPRAZINE
171	COPANLISIB
172	CROFELEMER
173	DELAFLOXACIN
174	DURVALUMAB
175	EFINACONAZOLE
176	ENASIDENIB
177	ETEPLIRSEN
178	FLIBANSERIN
179	GABAPENTIN ENACARBIL
180	GLUCARPIDASE

New molecular entities included in the project (4/5)

#	Molecule Name
181	LIFITEGRAST OPHTHALMIC SOLUTION
182	LORCASERIN HYDROCHLORIDE
183	LUCINACTANT
184	METRELEPTIN
185	MIPOMERSEN SODIUM
186	NALDEMEDINE
187	OLODATEROL
188	ORITAVANCIN
189	OZENOXACIN
190	PIMAVANSERIN
191	PLECANATIDE
192	SIMEPREVIR
193	SUVOREXANT
194	TALIGLUCERASE ALFA
195	TAVABOROLE
196	VILAZODONE
197	VORAPAXAR
198	AFAMELANOTIDE
199	ATALUREN
200	BARICITINIB
201	COBICISTAT
202	DASABUVIR
203	DELAMANID
204	GLYCEROL PHENYLBUTYRATE
205	LIPEGFILGRASTIM
206	LONOCTOCOG ALFA
207	MIGALASTAT
208	PITOLISANT
209	PIXANTRONE DIMALEATE
210	SUSOCTOCOG ALFA

#	Molecule Name
211	TAFAMIDIS
212	TALIMOGENE LAHERPAREPVEC
213	TENOFOVIR ALAFENAMIDE
214	FORODESINE
215	SUCROFERRIC OXYHYDROXIDE
216	LUSUTROMBOPAG
217	TIOTROPIUM OLODATEROL
218	OMARIGLIPTIN
219	VONOPRAZAN
220	RIPASUDIL
221	VANIPREVIR
222	TRELAGLIPTIN
223	TOPIROXOSTAT
224	LUSEOGLIFLOZIN
225	TOFOGLIFLOZIN
226	ACOTIAMIDE
227	ISTRADEFYLLINE
228	IGURATIMOD
229	ANAGLIPTIN
230	BIXALOMER
231	MOGAMULIZUMAB
232	AMENAMEVIR
233	APALUTAMIDE
234	ASUNAPREVIR, BECLABUVIR, DACLATASVIR
235	AXICABTAGENE CILOLEUCEL
236	BALOXAVIR MARBOXIL
237	BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMIDE
238	BUROSUMAB-TWZA
239	CRISABOROLE
240	DEUTETRABENAZINE

New molecular entities included in the project (5/5)

#	Molecule Name
241	ERTUGLIFLOZIN
242	ESKATA
243	IBALIZUMAB
244	LATANOPROSTENE
245	LJPC 501
246	NERATINIB
247	NETARSUDIL
248	RUCAPARIB
249	SEMAGLUTIDE
250	TEZACAFTOR
251	TISAGENLECLEUCEL
252	TIVOZANIB
253	VALBENAZINE
254	VORETIGENE NEPARVOVEC
255	ELVITEGRAVIR
256	OMBITASVIR

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