2020

POLICY PAPER

Kingdom of Saudi Arabia

A Medicine Policy to Support Vision 2030

General Directorate for National Health Economics and Policy
Saudi Health Council, Kingdom of Saudi Arabia

وزارة الصحة
Ministry of Health

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

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Abbreviations

AUD	Australian dollar
CAD	Canadian dollar
CCHI	Council of Cooperative Health Insurance
DALY	disability-adjusted life year
DRG	diagnosis-related group
EU	European Union
GCC	Gulf Cooperation Council
GHC	Gulf Health Council
GHE	Government Health Expenditure
HEU	Health Economics Unit
HTA(s)	health technology assessment(s)
ILO	international nonproprietary name
INN	International Non-proprietary Names
JPY	Japanese yen
KSA	Kingdom of Saudi Arabia
LCGPA	Local Content and Government Procurement Authority
MOH	Ministry of Health
NIDLP	National Industrial Development and Logistics Program
NTP	National Transformation Program
NUPCO	National Unified Procurement Company
OECD	Organisation for Economic Co-operation and Development
OOP	out of pocket
PHAP	Public Health Assurance Purchaser
PPI	proton pump inhibitor
PPS	Pharmaceutical Procurement Services
PTC(s)	Pharmaceutical and therapeutic committee(s)
RAS	Reimbursable Advisory Services
SCFHS	Saudi Commission for Health Specialties
SFDA	Saudi Food and Drug Authority
SHC	Saudi Health Council
UK	United Kingdom of Great Britain and Northern Ireland
US	United States of America
US$	United States dollar
VHA	Veterans Health Administration

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Executive Summary

Introduction

In 2016, the Kingdom of Saudi Arabia (KSA) set a course toward transforming the nation by 2030. A radically reformed health sector will form a core pillar that supports this wider social and economic transformation. Medicines—pharmaceuticals, vaccines, biologics, and consumables—along with diagnostics and medical equipment sit at the center of any health system. Therefore, a variety of actors, led by the Saudi Health Council (SHC) the Ministry of Health (MOH) and the Saudi Food and Drug Authority (SFDA), have come together to renew the National Medicine Policy so that it supports the transformation of the health sector. The pharmaceutical market in Saudi Arabia is the largest and most sophisticated in the Middle East and North Africa region, valued at some US$8.2 billion in 2019. Historically, the market has been fragmented, including among the many state agencies active in the health sector. Currently, the majority of medicines provided to Saudi citizens served by various health services are paid for by government entities that run those services, while expatriates are covered by mandatory private health insurance (provided by their employers) and are generally treated in the private sector. However, the most recent data suggest that retail sales still account for 44 percent of medicine in terms of value. The current system is weighted toward secondary- and tertiary-level curative care; until recently only limited attention has been paid to minimizing costs while maximizing health outcomes. The National Transformation Program (NTP) aims, over time, to achieve better and more equitable health outcomes while reducing pressure on public finances. This medicine policy supports those aims by laying out the medium- and long-term strategies of KSA in relation to medicines, thus providing direction to public and private actors on both the demand and the supply side of the market. This document presents the major issues that were discussed during the development of the policy, examining current national practice in the light of international practices and experience. A detailed accounting of the evidence informing policy choices expressed in the updated medicine policy are presented in Part I of this policy note; the new National Medicine Policy itself is presented in Part II. The current policy will be implemented in a highly dynamic environment and must therefore allow for flexibility. It will be followed by the implementation of regulations, closely monitored, and adapted as necessary over time.

Regulatory and Institutional Arrangements

Medicine policy cuts across a number of areas of government and must be implemented by a large number of institutions, so coordination and clear lines of accountability are essential to successful implementation. International experience suggests that a clear demarcation of

roles is especially important between the medicine regulator, which is responsible for ensuring the quality of pharmaceutical products, and the Ministry of Health (MOH), often responsible for many aspects of the selection, procurement, and prescription of medicines. KSA has an autonomous regulatory agency, the SFDA, which ensures the efficacy, quality, and safety of registered medicinal products. The hospitals and retail pharmacies through which these medicines reach patients are regulated by the MOH. Increasingly, procurement is carried out through the National Unified Procurement Company (NUPCO). Several other institutions are also involved in product selection, procurement, and financing. The new Medicine Policy clarifies the roles of each of these actors, mandating a lead institution to develop strategies for each area of policy implementation.

Selection of Medicines

Medicine selection procedures aim to guarantee the broadest possible access to well-established, quality-assured therapies (including through controlling costs), while also ensuring timely access to new therapies that are proven safe and effective (by providing a market sufficiently profitable to attract manufacturers). Budgets can be extended by selecting products that deliver the greatest health benefits for the lowest cost among the many alternative products typically found in a market.

Rapid authorization of products in the domestic market makes them quickly available to patients; in some cases, keeping products affordable requires the use of compulsory licensing and other recognized exceptions to standard intellectual property regimes. Rapid authorization of safe and effective generic equivalents to innovator products can also be a powerful tool in increasing access to affordable medicines. Reducing duplicative market authorization procedures speeds up market entry. Duplication can be reduced through joint assessment and mutual recognition (a procedure used by KSA through the Gulf Cooperation Council) or tiered risk-based assessment, which provides abridged review for products already approved by other stringent regulators.

Once products have been authorized, they can be reviewed for cost-effectiveness and included in essential medicine lists and national or institutional formularies, which cut costs by guiding physicians in prescribing the most cost-effective alternatives. The SFDA publishes a list of essential medicines by molecule name and provides therapeutic alternatives it considers safe and effective. The new National Medicine Policy envisages a single national formulary listing medicines selected for coverage throughout the publicly funded health system.

Increasingly, new treatments are subjected to health technology assessments (HTAs), a priority setting analysis that explicitly considers both the costs and the benefits of a medicine. HTAs are often performed by semi-independent bodies insulated from the pressure of industry, politicians, and patient groups. Analytic methods vary depending on the goal, but commonly include cost-utility analysis or cost-effectiveness analysis. The latter looks at the incremental benefit of a new treatment compared with existing alternatives, and also weighs up secondary benefits such as a reduced need for follow-on surgery. Treatments that deliver benefits below a nationally agreed cost threshold per year of healthy life gained may be considered for insurance coverage or public funding. The new KSA Medicine Policy provides for systematic HTAs performed by the newly established Center for Health Technology Assessment.

Appropriate Use of Medicines

Policies to ensure the appropriate use of medicines support the equitable use of safe and cost-effective medicines, while protecting both patients' interests and public health. They aim to counter financial or cultural pressures to prescribe inefficiently. The policies include using

treatment guidelines; incentivizing the prescribing, dispensing, and consumption of generic medicines, including the introduction of tiered payments for branded drugs; and encouraging good practice among community pharmacists.

Historically, all of these approaches have been underused in KSA. In 2016, innovator medicines accounted for 62.7 percent of the prescription medicines consumed in KSA. This compares with under 20 percent in the United States, China, New Zealand, and many northern European countries. The new Medicine Policy will seek to capitalize on the considerable opportunity that exists actively to incentivize the procurement and prescription of generic medicines and to increase public demand for value-based medicine.

Pricing of Medicines

Cost-containing policies stretch resources to deliver medicines to a larger number of people, but if prices are pushed too low, manufacturers may withdraw from the market or compromise quality. Medicine pricing policies thus aim to ensure fair prices that strike a balance between availability and affordability.

KSA is a high-income country with a relatively high prevalence of rare genetic disorders and noncommunicable diseases for which new but expensive therapies are increasingly being developed. Many countries try to secure affordable access to these therapies through managed entry agreements that pay for expensive new therapies against clinical outcomes. The use of such agreements will require significant investment in patient registries and the sharing of data between different actors in the health sector.

For more common therapies, ceiling prices and reference pricing are more commonly used to control costs. KSA currently sets explicit limits on the price of new generic entrants to its market, while other products are benchmarked against prices in a large number of other countries. While this process has been instrumental in controlling costs at levels that are among the lowest in the region, it introduces some delays and can be streamlined. The SFDA also sets ceiling prices for all medicines. While this has little effect on medicines in the public sector, which are largely procured through NUPCO, it protects patients from excessive out-of-pocket spending.

Financing and Reimbursement of Medicines

Medicine financing and reimbursement policies aim to maximize the efficient use of funds. They should be considered together with decisions about investment in public health infrastructure and health promotion that constrain demand for curative care. Since diseases associated with consumption and sedentary lifestyles contribute disproportionately to the burden of disease in KSA, increased investment in health promotion should reduce the pressure on medicine budgets in the future.

Choices about reimbursement—for example, between fee-for-service models or those that pay by diagnosis-related group (DRG) or through capitation—affect choices about consumption of medicine made by both health care providers and patients. The health financing system in KSA is evolving rapidly; the use of DRGs coupled with reimbursement against clearly defined formularies could incentivize the use of more cost-effective medicines by providers. Tiered copayments may also increase patient demand for medicines that are more cost-effective and reduce unnecessary polypharmacy.

Industrial policies that favor the use of locally produced medicines promote domestic economic growth and can increase national resilience but may also result in an overall increase in expenditure compared with importing medicines from countries that benefit from economies of scale. These choices should be a factor in health financing policies.

Procurement, Supply, and Accessibility of Medicines

Procurement policies aim to avoid shortages and promote equity, securing an uninterrupted supply of quality-assured medicines sufficient to meet national demand, at affordable prices. Centralized mechanisms that consolidate demand generally achieve better prices. NUPCO is providing a centralized procurement mechanism to an expanding proportion of the health care providers in KSA, while developing flexible frameworks designed to minimize the administrative burden on hospitals and other end users of medicines.

As procurement becomes more highly centralized, it is important to maintain a diverse selection of manufacturers and distributors in order to ensure sustainability of supply. Similarly, as buying power is consolidated and prices drop, buyers must become increasingly attentive to ensuring that prices are sufficient to prevent market withdrawal and maintain adequate quality assurance.

The National Pharmaceutical Industry

Vision 2030 has identified the pharmaceutical and biotechnology cluster as a priority area for investment and growth. Procurement, pricing, and regulatory choices can have the secondary effect of supporting local research and manufacturing of medicines, for example, by incentivizing the procurement of locally produced products. Demand-side approaches, such as price premiums compared with imported alternatives, can eat into the health budget, with opportunity costs that affect other areas of health financing. However, they can also attract foreign investment that leads to technology transfer. Changes to the curriculum of schools of pharmacy may support this development by ensuring a ready supply of adequately trained pharmaceutical chemists willing to work in the industry.

Pharmaceutical Security and Emergency Response

Normal channels for producing, verifying, procuring, and distributing medicines are vulnerable in times of national crisis, when medicines may be most needed. A pharmaceutical security and emergency response policy aims to maintain robust systems that allow for the rapid procurement and delivery of medicines if disaster strikes. Such systems prioritize two things: flexibility and coordination. Flexibility is provided through the advance planning of rapid-response framework agreements that can be drawn on quickly as necessary, with a minimum of red tape. Coordination provides clear lines of accountability that take advantage of existing expertise but authorize deviation from their normal operating procedures to allow for more rapid action as necessary. In KSA, this role is performed by the National Risk Unit.

Data Systems

Good medicine policies are informed by the rapid and coherent analysis of data from numerous sources, some of it commercially or politically sensitive. Data policies aim to facilitate efficient collection and compilation of these data and to encourage their active and timely use in decision-making, while protecting the privacy of patients and other actors.

Recent technological advances, including data-matrix systems, standardized metadata, and common data exchange protocols, have made it far easier to collect and share data, but institutional barriers to data sharing remain in place. In KSA, the increasing integration of procurement and health financing systems and the growing use of electronic medical records and track-and-trace technology present growing opportunities for the effective sharing and use of data. However, norms of data sharing are not well established in the historically fragmented

health system. A strong political mandate to share information through a designated institution is likely to be necessary to realize the potential of the new data systems to contribute to HTAs, and to monitor the implementation of this policy.

Human Resources

Human resource policies aim to shape the mix of training, skills, opportunity, and motivation so that the needs of the developing pharmaceutical sector are appropriately filled. This is especially difficult to achieve at a time of rapid transformation because the academic and other systems that build skills will have been designed for a previous era, and they will be run by people shaped for that era.

While KSA's pharmacy schools produce around 1,500 graduates a year, most are fitted for work in clinical pharmacology. The emerging system will also need people skilled in pharmaco-economics, health systems planning, procurement, logistics and data management, industrial chemistry, and regulatory science. The predominance of expatriate workers in community pharmacies, by far the largest but also lowest-paid employment sector for pharmacists in KSA, is a particular concern, not least because the role of community pharmacists will certainly grow if plans outlined in the National Health Transformation Plan to dispense all outpatient medicines through community pharmacies are realized.

Coherent and forward-looking guidance for education and training curricula that meet the evolving needs of the pharmaceutical sector are needed.

1 INTRODUCTION

In 2016, the Kingdom of Saudi Arabia (KSA) set a course toward transforming the nation by 2030. A radically reformed health sector will form a core pillar supporting this wider social and economic transformation.

Medicines—pharmaceuticals, vaccines, biologics, and consumables—along with diagnostics and medical equipment sit at the center of any health system. The choices that are made about product selection, distribution, financing, and use are critical determinants for the smooth functioning of the health system. These determinants are themselves influenced by many other policy decisions, relating not only to health financing, but also to industry, trade, taxation, and institutional arrangements. A wide array of actors is involved in making the very choices and decisions by which they are also affected. These actors include pharmaceutical manufacturers, distributors, and retailers; public health officials; health insurers; hospital managers; physicians; pharmacists; and patients.

Current data systems do not allow for an accurate estimate of public spending on pharmaceuticals in Saudi Arabia, but market research reports valued the Saudi pharmaceutical market at US$8.2 billion in 2019; industry sources expect this value to rise to US$9.3 billion by 2021. This accounts for just over one-fifth of all health spending. While the majority of medicines are paid for by government entities and some are covered by private insurance, 2016 estimates put household spending on medicines at SAR 2.7 billion (US$713 million) (IQVIA 2019a: IQVIA 2019b; BMI Research 2017; World Bank 2018). Most recent data suggest that retail sales accounted for 44 percent of medicines in terms of value (and 60 percent in volume terms) in early 2019 (IQVIA 2019b). This high household expenditure was worrisome given that the demographic and epidemiological profile of the country suggests that the demand for treatment for managing chronic, noncommunicable diseases will increase over the coming decades. These diseases include cancers and other areas in which research investments are currently yielding results, providing the opportunity for treatment with innovative but often expensive biological therapies.

Because medicines are so central to good clinical practice, and because the sector involves many actors with sometimes conflicting interests, many countries find it useful to develop a national pharmaceutical (or health technology) policy. Indeed, the existence and implementation of such a policy is taken into account by the World Health Organization when it considers the maturity of a nation's medicine regulation landscape. A medicine policy aims to lay out the medium- and long-term goals of a country in relation to pharmaceuticals, thus providing direction to public and private actors on both the demand and the supply side of the market. The policy remains a steering document; the

principles it espouses are usually implemented through more detailed policy guidance that can be revised as necessary to ensure that the aims of the policy continue to be met.

KSA published a National Medicine Policy in 2004 and a policy implementation plan the following year, and drafted an update in 2013; the Saudi Health Council (SHC) approved this update in 2016. However, much has changed in the health sector since then. The government is therefore currently updating the draft policy to set the course for medicines in the country as it reforms its health sector in support of Vision 2030. The National Medicine Policy itself is provided at the end of this document, in Part II. The remainder of this document provides background and contextual information to inform and support policy choices expressed in the updated policy. It is structured around the major components of the National Medicine Policy. For each component, the document:

- Briefly describes the policy goals;
- Outlines considerations related to that goal, including interactions with other areas of policy, differences that often arise between various actors affected by the policy area, and trade-offs that must be evaluated;
- Gives an overview of recent and current developments in KSA, and reviews issues that may encourage or obstruct the successful implementation of various policy options in the country; and
- Describes the policy choices included in the current policy.

Many policy areas are interdependent; this document cross-references as appropriate.

1.1 Health Transformation

The duty of the state to ensure that all citizens of KSA have access to health care is enshrined in the country's laws (including Article 31 of the Basic Law of Governance, and Article 2 of the Health Law of Saudi Arabia) (KSA 1992, 2002 2002).

Currently, the majority of care for Saudi citizens is provided through services operated by a number of government entities, including the Ministries of Health and Defense and the National Guard. Expatriates are covered by mandatory private health insurance, provided by their employers, and are generally treated in the private sector.

The current system is weighted toward secondary- and tertiary-level curative care; until recently there has been only limited attention paid to minimizing costs while maximizing health outcomes. The National Transformation Program (NTP) aims, through a phased reform of this system, to change roles, responsibilities, and financing mechanisms to achieve better and more equitable health outcomes while reducing pressure on public finances (MOH, no date). Changes that have implications for medicine policy include:

- A shift in the role of the Ministry of Health (MOH) from a service provider to a commissioner and regulator;
- The expansion of the Public Health Assurance Purchaser (PHAP) system as a consolidated payer for health services;
- An increased focus on payment against health outcomes;
- The expansion of the National Unified Procurement Company (NUPCO) as a consolidated procurer of medicines;
- The vertical integration and corporatization of public health service providers and an increased role of private providers;
- The increased use of electronic patient records;

- The use of community pharmacies to dispense outpatient medicines; and
- The prioritization of the pharmaceutical sector in the national industrial policy.

The implications of these changes for medicine policy are discussed in greater detail in the sections that follow.

1.2 Overall Objectives of the Medicine Policy

The overall objective of any medicine policy is to provide citizens with sustainable and equitable access to safe, effective, and affordable medical products. The specific objectives of the policy of the KSA are:

- To ensure that citizens and residents of KSA have access to a continuous supply of medicines, quality-assured by the appropriate authorities;
- To ensure that those medicines are affordable and available to public health services and eligible individuals nationwide, regardless of income;
- To promote appropriate use of these medicines based on state-of-the-art therapeutic guidelines as well as good value for money;
- To encourage good pharmaceutical practice among public and private health services, pharmaceutical manufacturers, distributors, and pharmacists; and
- To support policy implementation through appropriate legal and regulatory structures and the provision of sufficient financial and human resources.

The current policy will be implemented in a highly dynamic environment and must therefore allow for flexibility and adaptation. It is critical that its implementation be closely monitored, and that both regulations for implementation and the policy itself are regularly reviewed using predefined metrics to ensure that the objectives listed above are being met.

1.3 Organization of Document

The remainder of this document is organized into two main parts: Part I provides background and contextual information to inform and support policy choices expressed in the updated policy. Part II is the National Medicine Policy itself.

PART I

Medicine Policy 2020 in Context

REGULATORY AND INSTITUTIONAL ARRANGEMENTS

2

2.1 Regulatory and Institutional Arrangements: Policy Goals

Medicine policy cuts across a number of areas of government and must be implemented by a large number of institutions. Regulations should aim to support the smooth functioning of the system as a whole. Policies governing institutional roles aim for a fair division of labor, with a clear definition of roles, responsibilities, and accountability, including for the enforcement of regulations.

2.2 Regulatory and Institutional Arrangements: Policy Considerations

The two main actors in the realm of medicine policy are typically the Ministry of Health (MOH) and the regulatory authority that oversees the medicine sector. The relationship between the two varies widely; in some countries they maintain total independence or are semi-autonomous, whereas in others, the regulator is situated within the MOH.

The demarcation of roles is not always clear. While the medicine regulator is clearly responsible for regulating the quality of pharmaceutical products, the MOH may be involved in regulating many aspects governing the purchase, prescribing, dispensing, and sale of those products. Other authorities, including ministries of industry, commerce, and environment, may also be involved in regulating the production of medicines.

Regulatory reach can vary by sector. In some countries, for example, the medicine regulator has limited authority to inspect private health service providers to ensure they are complying with good distribution and pharmacy practice. Turf wars between sectors and institutions are common. This can lead to high regulatory burden in some areas, while leaving gaps in others.

Lack of clarity about institutional accountability often means that existing regulations are not effectively enforced.

2.3 Regulatory and Institutional Arrangements: Status Quo and Implementation Issues

The Kingdom of Saudi Arabia (KSA) has a well-staffed regulatory agency, the Saudi Food and Drug Authority (SFDA), which regulates the pharmaceutical sector in the geographical area of Saudi Arabia. The SFDA is governed by a Board of Directors and is both institutionally and financially autonomous, reporting directly to the President of the Council of Ministers and having its own budget line. The role of the SFDA is to regulate access to the national pharmaceutical market; ensure the efficacy, quality, and safety of registered medicinal products; define and enforce professional standards for all establishments that produce, import, distribute, promote, and advertise pharmaceuticals; and educate health professionals and consumers about the rational and safe use of medical

products. The SFDA aims to achieve the highest international standards in regulatory practice and is an active member of international regulatory coordination bodies.

The establishments that sell pharmaceutical products on the community level (retail pharmacies) are regulated by the MOH and the SFDA. The MOH is responsible for licensing retail pharmacies and ensuring that pharmacy staff are licensed by the Saudi Commission for Health Specialties (SCFHS), while the SFDA is responsible for the products sold by retail pharmacies. The monitoring of retail pharmacies is the responsibility of pharmaceutical care units at health directorates in each Saudi region.

In practice, the division of labor and enforcement responsibilities is not always clear, according to the MOH, which notes that "The current Saudi health system is significantly fragmented, leaving various regulatory bodies with restricted, often overlapped, jurisdiction and authority" (MOH KSA 2018b). Scholars note that responsibility for enforcing regulations issued by the SFDA often lies with the MOH. The back and forth between the two can be "complex, lengthy, and bureaucratic," obstructing timely action that could prevent further violations, thus potentially endangering patients (Yazed S. Alruthia et al. 2018).

In a study in Jeddah, every one of 59 community pharmacies visited by researchers prominently displayed the regulatory license issued to them by the MOH, indicating that they meet standards for pharmacy practice. All 59 also dispensed prescription drugs without prescriptions to researchers posing as patients, suggesting that those standards are not regularly monitored or enforced (Al-Mohamadi et al. 2013).

2.4 Regulatory and Institutional Arrangements: National Policy

The Saudi Health Council (SHC) maintains overall responsibility for development of the cross-sectoral policy framework for medicines. The SHC will work with all sectors to monitor the implementation of the policy, evaluate its impact, and revise it as necessary.

For each specific area of policy implementation, a lead institution will be mandated to develop implementation strategies. In addition, specified institutions will support policy implementation or provide information to allow policy goals to be met effectively.

In the initial stages of policy implementation, lead roles are specified as follows:

Saudi Health Council

- Oversee the development of the national medicine policy, in consultation with all concerned sectors. Ensure the policy's timely adoption.
- Plan and mandate cross-sectoral data contribution that will allow for efficient monitoring and revision of the policy.
- Review data analysis and revise the policy as necessary, in consultation with all concerned institutions, on a predetermined schedule.
- Lead cross-sectoral consultation to define emerging policy needs and questions.
- Collate and analyze medicines data to guide the monitoring and revision of the medicine policy.

Saudi Food and Drug Authority

- Organize and manage the processes of registration, renewal and variations of pharmaceutical preparations (human, veterinary and herbal).
- License the processes of manufacturing, importing, exporting, distributing, promoting and advertising of medicines.
- Inspect pharmaceutical manufacturing sites.

- Assess the safety, efficacy and quality of pharmaceutical preparations and issue marketing authorization.
- Take on responsibility for Pharmaceutical pricing, pricing review, and evaluation of economic and clinical comparison studies in treatment groups.
- Monitor Narcotic drugs, psychotropic substances and controlled preparations and ensure compliance with relevant regulations and procedures.
- Develop and manage policies, regulations and guidelines for pharmaceutical preparations
- Conduct post-marketing surveillance of pharmaceuticals and ADR monitoring (Pharmacovigilance).
- Secure pharmaceutical product supply in the Saudi market and monitor and address supply shortages.
- Track medicines throughout the supply chain (RASD) to reduce fraud and ensure their safety and availability
- Regulate and approve clinical trials on medicines in Saudi Arabia

Ministry of Health

- Oversee the development of clinical guidelines in all major therapeutic areas.
- Develop, monitor, and enforce regulations to promote cost-efficient prescribing and dispensing, including international nonproprietary name (INN) substitution.

Center for Health Technology Assessment

- Undertake HTA assessment of new technologies to inform reimbursement decision-making either for public or private payers
- Establish and revise guidelines, and update HTA country method
- Establish guidelines for managed entry agreement between payers and manufacturers.

National Unified Procurement Company

- Plan demand for the public sector.
- Procure medicines for the public sector, considering policies on local content.
- Manage the public sector supply chain.
- Undertake “market making” for low-profit medicines.
- Maintain framework contracts for procurement and distribution of medicines in emergencies and disasters.
- Maintain the national stockpile of medicines.

Public payer

- Develop reimbursement formularies.
- Develop regulations to promote cost-efficient prescribing, including INN prescriptions, for reimbursement.
- Negotiate reimbursement prices for high-value medicines.

Private payers

- Develop reimbursement formularies, based on guidance and governance by the Council of Cooperative Health Insurance (CCHI).

Academic institutions and Saudi Commission for Health specialities

- Take responsibility for curriculum development, workforce licensing, training and continued education and professional development.

National Risk Unit

- Ensure that lead organizations integrate disaster preparedness into their respective roles, as described above.
- Coordinate work of those organizations in the event of a disaster, including by maintaining a rapid data exchange platform and command center.
- Lead public communication related to medicines in the event of a disaster.

SELECTION OF MEDICINES

3

3.1 Selection of Medicines: Policy Goals

Policies governing the selection of medicines stand at the heart of any broader pharmaceutical strategy. In all but the most resource-constrained markets, medicine selection procedures aim to guarantee the broadest possible access to well-established, quality-assured therapies, while also ensuring timely access to new therapies that are proven safe and effective.

3.2 Selection of Medicines: Policy Considerations

The selection of medicines is inextricably linked to their pricing and their appropriate use. Because no country has unlimited resources, the two core goals of selection policies—universal access to established therapies and timely access to innovative products—are in some ways at odds with one another. Money spent on (usually expensive) innovative drugs is money that cannot be spent on more established medicines. Policy makers therefore have to consider mechanisms to achieve an equitable balance between the two.

Mechanisms to control prices, perhaps the most important lever in maximizing equitable access to medicines, are discussed in Section 5. However, budgets can also be extended by seeking efficiencies in product selection and procurement, for example by limiting fragmentation in supply (approaches include the use of market authorization procedures, formularies, and health technology assessments, or HTAs), or HTAs as well as by pooling demand from different buyers in the health sector.

Many health conditions can be treated in more than one way, and among the variety of treatments available, many exactly or broadly equivalent products are often offered. They may differ in dosage form, packaging, branding, and price, and in practice they sometimes also differ in quality.

Market authorization

When choosing medicines, cost considerations should always be secondary to two other factors: safety and efficacy. In most countries, it is the responsibility of the medicine regulator to ensure that every medicine on the national market has undergone stringent testing to prove that it effectively treats the conditions for which it is indicated, and that any potential side effects are well described and contained at acceptable levels. Most regulators check that these conditions are met before issuing a certificate allowing the product to be sold on the national market. Market authorization is in most cases a prerequisite for further selection processes, such as inclusion in a national or institutional formulary or in other reimbursement lists.

In some cases, manufacturers do not seek to register products in a market because the cost of registration outweighs likely profits, or because registration could threaten profits in other markets, for example through parallel exports. The use of compulsory licensing or other flexibilities allowed in the case of public health need under the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights rules can greatly reduce prices and increase access in such cases (Smith, Correa, and Oh 2009). The use of these flexibilities tends to be deeply resented by research-based companies and can sometimes result in withdrawal of other branded products from markets deemed to be insufficiently protective of patent rights. (Ooms and Hanefeld 2019). Policies designed to maximize market entry for high-cost innovator products are discussed in Section 5 on pricing.

Market authorization can be time-consuming and expensive; it currently involves a great deal of duplication as authorities in different countries review the same documentation for identical treatments. Especially in countries with limited capacity to review large numbers of applications, lengthy national authorization procedures can deprive patients of access to new therapies, while also depriving health systems of access to cheaper alternatives as products come off patent. The cost of preparing dossiers, in terms of both time and money, can also dissuade companies from seeking entry to smaller or less-profitable markets, again depriving those markets of access to particular therapies.

Public health officials and patient advocates often seek workarounds for these problems, for example by seeking waivers for medicines of public health importance, or by promoting "compassionate use" programs that allow individuals to import unlicensed products to meet their own needs. These responses tend to undermine equity as well as the ability of the national regulator to ensure quality throughout the supply chain. Furthermore, they obstruct pharmacovigilance and product recall procedures, and provide an easy entry point for substandard and falsified medicines (WHO 2017b).

In recent years, several approaches have emerged to uphold the integrity of market authorization procedures as a guarantor of quality while reducing the burden on regulators and industry. These include:

Joint assessment and mutual recognition: Many regions, including the Gulf Cooperation Council (GCC), have developed procedures through which national regulators share the burden of dossier review and product authorization. The largest of these is the European Union (EU), which has been operating a joint review process for new medicines since 1998. Once a medicine has been judged to be safe and effective by the centralized review process, it is eligible to register in all EU markets without further review. This greatly reduces the paperwork for pharmaceutical companies and tends to bring products to the market more quickly. This is especially beneficial for the smaller markets in the group, because companies may otherwise not have bothered to submit products for regulatory review in those countries.

Joint assessment reduces the workload for individual national regulators. In some systems, it has led to specialized divisions of labor, with different national authorities taking the lead on product types in which they have particular expertise. However, there is danger that a joint assessment is only as strong as the weakest of its members. All partners must have confidence in one another's technical capacity, standards, and review procedures if these harmonized approaches are to succeed.

Risk-based assessment: Many national regulators, including those of Australia, Canada, and Singapore, adopt a tiered approach to product review and market authorization. They reserve full review procedures for new products, as well as those with complex safety profiles, including narrow therapeutic indices. Full review is also likely for nationally produced medicines, and sometimes for products that meet important

needs in relation to the nation's disease profile. Other products, including generics and other well-established medicines, may be authorized following an abridged review. This abridged review focuses more on quality than safety and efficacy profiles, which have passed detailed review by other national agencies, or a simple verification process to ensure that submitted products are identical to those approved elsewhere (Alsager, Hashan, and Walker 2015).

Prequalification: Since 2001, some products of global health importance have undergone rigorous prequalification procedures, monitored by the World Health Organization (WHO). Until recently, prequalification was available only for vaccines and for medicines and point-of-care diagnostics for HIV, tuberculosis, malaria, and reproductive health products. The success of the program has led to its gradual expansion; prequalification of biosimilar medicines for cancer has been piloted, and insulin was added to WHO's list in late 2019 (WHO 2017a; Fletcher 2019).

Essential medicines lists and formularies

Even after potentially ineffective or poor-quality drugs have been weeded out by the regulator, a bewildering number of quality-assured products remain on offer for most conditions. National health systems, insurers, hospitals, and other buyers can benefit from limiting this variety and choosing a small number of products to achieve each therapeutic goal. Clinical guidelines that take into account efficacy, safety, and the relative costs and benefits of a treatment can be used to decide which products should take precedence on a limited list.

In general, these choices are expressed at the national level through a national list of essential medicines, which lists medicines considered the most important in the national context by therapeutic area, dosage form, and strength. Essential medicines lists, which guide purchases in the public system, do not usually list manufacturers or brands, and instead use international nonproprietary names (INNs). They commonly go hand in hand with disease-specific treatment guidelines, discussed in Section 4.

Purchasers of medicines in both the public and the private sectors often issue a more detailed list, or formulary, which provides more information about each product, for example listing side effects, drug interactions, or reimbursement status. These formularies generally take one of three forms:

1. Indicative—a simple aid to decision-making for physicians;

2. Compulsory (or "closed")—only listed products will be reimbursed, unless prescribing physicians seek special authorization for alternatives; or

3. Tiered—physicians may offer a variety of products, but they will have different implications for patients in terms of reimbursement.

Until the late 1990s, decentralized Veterans Health Administration (VHA) facilities in the United States used a number of different formularies. In 1997, the VHA introduced a single, nationwide closed formulary for a number of common conditions. This consolidated the market and allowed for more aggressive price negotiations with manufacturers of the selected drugs. An analysis of spending on five of the drugs in question showed that the shift to a unified national formulary cut prices per pill by between 13 percent and 36 percent over a six month period, saving an estimated US$82.4 million (Huskamp, Epstein, and Blumenthal 2003).

Most countries and insurers take relative costs and benefits into account when deciding which products to list on a formulary. Failure to do so can have consequences for prices. In Indonesia, for example, committees of physicians decide which products to include on the national formulary without regard for cost; they are listed by INN name. Once a product is listed on the

formulary, the national health insurance system is required by law to reimburse for the product. Despite the very large potential market represented by the insurer's 223 million beneficiaries, this requirement has greatly restricted the ability of the MOH to negotiate down the price of listed products where there are only limited potential suppliers, including most of those that are on-patent (Ursu and Rabovskaja 2017).

Most closed formularies favor quality-assured generics if they are available (see Section 4). The pharmaceutical industry is generally uncomfortable with any mechanism that restricts product choice, arguing that the quality of care may suffer if patients do not have access to a full range of options. However, limited systematic research on the clinical outcomes of closed formularies finds no increase in morbidity, mortality, or other adverse events (Huskamp, Epstein, and Blumenthal 2003).

Physicians sometimes also resent what they perceive to be an intrusion on their expertise and autonomy; this is one reason that it is important to involve specialist medical associations in the selection process for essential medicines lists and formularies.

Besides facilitating negotiations that lower prices, formularies that restrict the number of alternative therapies can facilitate quality assurance, supply planning, stock management, pharmacovigilance, and other forms of data collection, while reducing the scope for errors in prescription and dispensing. Tiered formularies also shape physician and patient behavior, encouraging use of more cost-effective medicines.

Therapeutic equivalence

Publications that list accepted therapeutic equivalents are less restrictive than formularies. They provide information about patent status of innovator drugs and list all the licensed equivalents to those medicines that are judged to be safe and effective. They can help institutions (including hospitals and private payers) make decisions about the most cost-effective approach to treatment. The best-known of these publications is the US Food and Drug Administration's *"Approved Drug Products with Therapeutic Equivalence Evaluations*" (commonly known as the *Orange Book*).

Health technology assessment

HTAs are a form of analysis that take both costs and benefits of a medicine or intervention explicitly into consideration to inform choices about care. HTAs are being increasingly used by countries aiming to achieve or sustain universal health coverage. These assessments are used to guide the selection of new products as well as to prioritize the use and financing of existing interventions. The analysis takes into account the incremental benefit of the treatment compared with existing alternatives in terms of reduction in mortality, morbidity, and adverse effects. Depending on the perspective informing the HTA (for example, does it prioritize patient or social welfare, or overall benefits for taxpayers?) secondary benefits, such as a reduced need for follow-on surgery or higher order therapy, may also be considered. These incremental benefits are set against the incremental cost of the medicine, including the facilities and personnel needed to administer it successfully. The outcome of the analysis is most often expressed in terms of the cost of each disability-adjusted life year (DALY) saved by the treatment. Decisions about the relative costs and benefits vary between assessment bodies in part because of their varied perspectives; cultural perceptions of value are also at play (Horscroft et al. 2017).

Most countries that routinely use HTAs in selecting products for use in public systems have established a threshold price level below which a product is considered to provide "value for money." The WHO stresses that countries must choose their threshold taking local factors into account. As a broad guide, however, the organization suggests that this threshold be set below

three times a country's per capita gross domestic product per DALY saved (Bertram et al. 2016). However, the process of agreeing on this level and ensuring that it is applied equitably to all conditions, regardless of their cause or whom they affect, can be controversial. Where sufficient data and expertise exist, HTAs can also be performed at the hospital level.

The biggest challenges to the successful use of HTAs at any level are the availability of cost and clinical data; the willingness to share those data; the availability of expertise in health economics; and the political will to insulate analysis and decision-making from pressure put forth by the industry, patient groups, physicians, hospital administrators, or other interest-seeking stakeholders.

Many countries have established independent or quasi-independent bodies, insulated from political pressure, to perform HTA. Examples include Australia's Pharmaceutical Benefits Advisory Committee; the Medicare Services Advisory Committee in the United States; the Pharmaceutical Management Agency in New Zealand; the National Institute for Health and Clinical Excellence in England and Wales; and the Institute for Quality and Efficiency in Health Care in Germany (Al-Jazairi, Al-Qadheeb, and Ajlan 2011).

3.3 Selection of medicines: Status quo and implementation issues

Market authorization

Pharmaceutical manufacturers wishing to sell a medicine in Saudi Arabia must seek a market authorization from the Saudi Food and Drug Authority (SFDA) for each proposed formulation and dosage of the medicine. The SFDA is widely recognized as being the strongest medicine regulator in the region. It is both diligent and relatively stringent in its assessment procedures and provides transparent guidance across a range of regulatory requirements. For example, in 2010 the country became the first in the region to provide a clear route for the authorization of biosimilar medicines. This regulatory clarity has helped to attract market entrants, reducing the cost of biological medicines in KSA (Kanavos et al. 2018).

Until recently, the SFDA carried out full assessments on most products, resulting in backlogs, which in turn led to slow market entry for new products. Consequences included treatment-seeking overseas, often at considerable costs to the state, as well as increased pressure for work-around solutions. In March 2019, for example, the SFDA issued a draft guidance on the importation of unregistered products through a compassionate use program (SFDA 2019b). In May 2020, however, the SFDA published revised guidance allowing for the rapid registration of new chemical or biological entities that have been approved by regulators in the United States and/or the European Union in the previous two years (SFDA 2020). Medicines produced in the United States, the United Kingdom, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, the Netherlands, Austria, or Singapore, and approved by both the US and the EU regulator within the past two years, can apply for registration following verification of documentation. Medicines registered by just one of the two qualify for abridged registration. These processes are valid for new chemical entities and biological products; they exclude generic medicines and biosimilars, blood products, vaccines, and what the agency refers to as "advanced therapy medicinal products." The SFDA aims to register products that meet all requirements for verification within 30 working days, while abridged registration should take no longer than 60 working days.

The SFDA is unusual in that it requires a Certificate of Pharmaceutical Product and pricing information to be filed at the time of dossier submission, along with laboratory analysis that often duplicates analysis that has taken place elsewhere. The price information, which requires verification by embassies of KSA, and the product testing, are required even for registrations

submitted under the verification and abridged procedures. However, the laboratory analysis requirement is waived if the product is registered in a GCC country with an accredited medicine testing laboratory (Al-Rubaie, Walker, and Salek 2014; Hashan et al. 2016). These requirements add to the regulatory burden for companies seeking registration and may slow market entry, even for products fast-tracked by virtue of previous registration in the United States and/or European Union.

Manufacturers based in India and other low- and middle-income countries voice concern that guidelines requiring that a product be marketed in at least two countries with stringent regulatory authorities before it can be submitted for consideration by the SFDA are discriminatory. This is particularly the case in light of what they see as relatively lax conditions applied under GCC rules to the import of products from other manufacturers in the Gulf region (BMI Research 2017).

Since 1999, KSA has been an active member of the GCC's Centralized Registration Committee, which aims to provide harmonized evaluation and registration of medicines throughout the GCC. When a manufacturer applies for registration through the body, the dossier is evaluated by regulators from two member states, chosen in alphabetical rotation. If the dossier is approved, the product is automatically eligible to receive market authorization in all member states (Al-Rubaie, Salek, and Walker 2015).

In theory, this should reduce the burden of market entry for both regulators and manufacturers. In practice, however, that is not always the case. In recent years, the SFDA has evaluated all GCC applications in parallel with the other designated regulators, adding not only to their own workload but also to the time taken for approval by the regional body. Manufacturers say that approval through the GCC does not always guarantee them access to all regional markets. Some manufacturers thus prefer to concentrate their resources on seeking authorization in the biggest or most profitable markets, where they often have close working relationships with regulators (Al-Rubaie, Salek, and Walker 2015; Al-Rubaie, Walker, and Salek 2014; Alsager, Hashan, and Walker 2015).

In terms of using market authorization as a tool to promote access, the SFDA has a strong record. This creates tensions with the industry—a regional comparison by market analyst BMI rated Saudi Arabia 11th of 14 countries in the Middle East and North Africa in terms of respect for patents in 2018. Similarly, in 2019 the United States listed the country on its "Special 301" watch list of intellectual property violators, providing specific examples of what it considered to be breaches of patent protection through the licensing or procurement by public bodies of generic alternatives to on-patent medicines (BMI Research 2018; Office of the United States Trade Representative 2019).

Essential medicines list and formularies

The SFDA publishes and regularly updates an essential medicines list, which references priority medicines by INN. This list is compiled by choosing products that are included in the WHO essential medicines list, are included on the MOH vaccination schedule, or are first-line treatments for diseases considered epidemic in KSA. It also provides therapeutic alternatives registered as safe and effective by SFDA (SFDA 2019c). In its analysis of challenges to be addressed by health transformation, the MOH nonetheless cites "lack of treatment options in the desired hospitals" as one of the challenges (MOH 2018a).

The MOH published a national formulary in 2012, but until recently no national formulary was used consistently across publicly funded subsectors of the health system. Many hospitals and medical cities had their own formularies, and analysts point to inconsistencies even within a single subsector. Decisions about which products to list on hospital formularies

lay with pharmaceutical and therapeutic committees (PTCs) and there was little consistency in either the make-up of these committees or the procedures for considering evidence (World Bank 2018). Health economists are generally underrepresented on these decision-making committees.

In January 2020, the MOH published the national formulary as a Smartphone app. A press release from the MOH suggests that it is constantly updated with changes to the formulary, and contains information for both physicians and the general public (MOH 2020). However, pharmacists in KSA report that it is currently available only to physicians working for the ministry. It is unclear to what extent its use will be enforced across sectors.

The various health sectors deal with different patterns of disease and may have different therapeutic needs. Eventual enforcement of a rationalized formulary across the various sectors is probably desirable, although it is likely to excite some resistance from senior members of PTCs in larger hospitals. The health transformation plan envisages an ever-greater role for the Public Health Assurance Purchaser (PHAP). Though implementation will be phased, the eventual goal may be to assume the role of a single payer in the public health sector. If that happens, the case for active enforcement of a unified public sector formulary based in part on systematic use of HTAs will be strong.

Information on product selection in the private sector is limited. The Council of Cooperative Health Insurance (CCHI), which regulates private sector insurers, stipulates a minimum package of benefits for scheme members but gives limited guidance over product selection. In a survey of 16 private insurers published in 2013, fewer than half followed the guidance in the CCHI's model policy. Others accepted medicines selected by service providers, while in-house doctors, pharmacists, or committees made at least some decisions at nine companies (Bawazir et al. 2013). While companies did not necessarily prioritize drugs on the nation's essential medicines list, most ensured that all covered medicines had national market authorizations.

In practice, a significant proportion of care in private hospitals is still paid for out of pocket (OOP), and hospital pharmacies may in some cases become a profit center, disincentivizing the use of price-limiting formularies. In many private hospitals, a significant proportion of prescribing decisions are made by expatriate physicians (BMI Research 2017). Conversion training and certification procedures may thus need to underline the importance of complying with any policies related to prescription practices that aim to protect patients from excessive OOP spending.

Health technology assessment

The SFDA requires cost data to be submitted with applications for market authorization and takes likely costs and benefits into account in its decision-making. However, full health technology assessment is neither required nor commonly performed at the national level in KSA. In September 2017, the Saudi Health Council (SHC) approved the establishment of a national committee under its supervision to study the issue of high price of some medicines for Hepatitis C, blood diseases, and cancer (SHC 2017), and there is a clear intention to expand the use of HTAs.

The primary obstacles to the greater use of HTAs at present is the lack of reliable data on which to base estimates of costs (and costs averted) (Al-Jazairi, Al-Qadheeb, and Ajlan 2011; Al-Omar et al. 2019). The data constraints are greater in the public than in the private sector. National expertise in health economics is limited, and in pharmaco-economics it is still more limited. This is in part the result of a tight focus on clinical pharmacy training in the country's medical education sector (see Section 11 on Human Resources). Although the government

has put value-based health care at the center of its transformation strategy (MOH, no date), value-based decision-making is not yet well embedded at any level of the health system, and health economists are not routinely included in decisions around the selection of medicines.

Successfully implementing purchasing decisions made on the basis of HTA requires the flexibility to redistribute money between budget lines and even departments, within a hospital and beyond. An apparently budget-busting medicine prescribed in primary care to reduce the risk of stroke might, for example, yield considerable savings by averting the cost of surgery at a tertiary hospital. Such trade-offs are difficult to achieve in practice in the current Saudi health financing landscape, where there is little interaction between budget lines even within the same hospital (Al-Jazairi, Al-Qadheeb, and Ajlan 2011). However, as the national health system transitions through a cluster phase and reconfigures around geographically defined, vertically integrated accountable care organizations, this sort of systemwide analysis will become both more necessary and more feasible.

All of these limitations are recognized within health policy circles in KSA; policy makers also recognize that duplicating existing HTA efforts in other high-income countries is undesirable. However, KSA faces issues related to demography, climate, culture, and epidemiology that are uncommon among other high-income countries. Its health sector and society are also both exceptionally dynamic. There is thus a clear need for locally specialized expertise in horizon scanning and HTA (Al-Omar et al. 2019). In early 2020, MOH officials reported that the government had decided to establish a Center for Health Technology Assessment, and that recruitment was ongoing.

3.4 Selection of Medicines: National Policy

Medicines available to patients in KSA should have a marketing authorization from the SFDA, issued once the product has satisfied the criteria for safety, efficacy, and quality.

The responsible authorities will develop/maintain a national list of medicines, including essential medicines, based on INN.

A national reimbursement formulary will list medicines selected for coverage through public funding. This will provide guidance across all sectors of the public health system.

In selecting medicines for inclusion in the reimbursement formulary, experts will take an inclusive approach, considering costs, benefits, and relative value of different therapies, along with treatment guidelines and guidelines issued by the Saudi Local Content and Government Procurement Authority.

The Center for Health Technology Assessment will develop medium-term demand forecasts for emerging therapies, based on changing epidemiology and health utilization patterns. It will coordinate horizon scanning for new products, and assess costs and benefits using established HTA procedures. These assessments will be based on cost and outcome data from public and private providers, in accordance with a mandate established by the responsible authorities.

APPROPRIATE USE OF MEDICINES

4

4.1 Appropriate Use of Medicines: Policy Goals

A medicines formulary, developed on the basis of the safety and cost-effectiveness of listed products, is the platform on which appropriate use of medicines is built. However, safe, cost-effective products still have to be prescribed, dispensed, and consumed appropriately. A number of other policies can thus be used to support the likelihood that the use of safe and cost-effective medicines is maximized across a population in a way that is equitable, while allowing physicians to act in the best interests of patients.

Policies to ensure the appropriate use of medicines also aim to protect patients from adverse effects, —for example, adverse drug interactions—while safeguarding public health by reducing threats posed by excessive or inappropriate use of medicines, such as the spread of drug-resistant infections.

4.2 Appropriate Use of Medicines: Policy Considerations

Section 3 considered the selection of medicines at higher institutional levels. In practice, many decisions about medicines are made at the interface between patients and physicians or pharmacists, where medicines are prescribed, dispensed, and bought. In these interactions, many different factors and interests are at play.

The inequality of access to information is often stressed; doctors, who do the prescribing, have the upper hand in terms of knowledge. Their choice of medication may be influenced by scientific evidence or therapeutic experience, but habit, personal perception, and financial self-interest may also play a part. Pharmacists have varying degrees of freedom to influence or alter choices made by doctors, depending on the country. Community pharmacies in many countries are subject to strong commercial pressure to dispense irrationally. Patients, for their part, are not voiceless, often demanding a particular treatment or brand even when it is not clinically indicated, quality-assured, or the most cost-effective option (Kaplan et al. 2012).

Beyond market authorization and the use of formularies, the major policy approaches to increasing the use of safe and cost-effective medicines include using treatment guidelines; mandating or incentivizing the prescribing, dispensing, and consumption of generic medicines; and encouraging good practice among community pharmacists (Ferrario et al. 2020).

Treatment guidelines

Many global health organizations, national authorities, and specialist medical associations

publish guidelines that aim to guide doctors, pharmacists, dispensers, and other health care staff in the treatment of specific conditions. These are generally developed after broad consultation with a wide range of experts (increasingly including patient groups) and include guidelines on choice of medicines, selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The recent WHO guidelines on medications for diabetes provide an example (WHO 2018).

For well-established conditions, existing treatment guidelines often need only minimal adaptation to serve in a particular country or hospital setting. The extent to which the use of treatment guidelines is enforced varies widely. Where consistency of care is prized above physician autonomy, treatment guidelines are an important tool for nudging prescribers—and sometimes also pharmacists—toward the most appropriate use of medicines.

Generic promotion policies

Quality-assured generic medicines or biosimilars deliver the same therapeutic benefits as innovator brands, often at much lower costs. In Europe, measures to increase the rational use of generics and biosimilars have greatly impacted medicine budgets. Although the volume of proton pump inhibitors (PPIs) reimbursed in Scotland between 2001 and 2010 increased threefold, total spending on the drugs was 59 percent lower in 2010 than it had been at the start of the period. Near-identical savings were achieved by the Netherlands, which, like Scotland, implemented a range of measures to increase prescription of generic medicines (Godman et al. 2014).

Objective: Assess the influence of multiple supply- and demand-side initiatives across Europe for established medicines to enhance prescribing efficiency before a decision to prescribe a particular medicine is made. Subsequently, utilize the findings to suggest potential future initiatives that countries could consider.

Method: An analysis of different methodologies involving cross-national and single-country retrospective observational studies on reimbursed use and expenditure of PPIs, statins, and renin-angiotensin inhibitor drugs among European countries.

Results: The nature and intensity of the various initiatives appreciably influence prescribing behavior and expenditure—for a case in point, see the earlier discussion about expenditures for PPIs in Scotland and the Netherlands. A similar picture was seen with prescribing restrictions, where a study looking at cost differences in private sector settings in 17 countries with less-developed health financing systems found costs savings of 9 to 89 percent (Cameron et al. 2012). A 2008 study in public sector hospitals in China calculated that a switch to generic substitutes for just four branded medicines could save US$86 million, representing 65 percent of the costs (IQVIA 2019).

Many countries have introduced a suite of measures on both the supply side and the demand side to increase the use of generic and biosimilar medicines. Data from the Organisation for Economic Co-operation and Development (OECD) and market research sources indicate that in the United States, United Kingdom, Germany, France, China, and New Zealand more than four-fifths of reimbursed medicines by volume are generic (OECD 2018; IQVIA 2019a).

However, these rates of generic use were not always easily achieved. For therapies developed within the last decade or two, doctors, pharmacists, and patients tend to have more experience with patented drugs, for the simple reason that for the years the patent is in effect, no equivalent generic or biosimilar drug is available. This shapes habits and perceptions on all sides. In addition, where medicines are paid for out of pocket (OOP), selling branded medicines tends to be more profitable than selling a generic

equivalent, disincentivizing the prescription or sale of generic medicines.

Countries keen to increase the use of quality-assured medicines without increasing spending on medicines adopt various policies to incentivize the use of generic medicines. These include:

Promotion of generic prescribing: Some health authorities and hospitals require physicians to use only international nonproprietary names (INNs) when writing prescriptions. France, Greece, Jordan, The Netherlands, Oman, Portugal, Qatar, Spain, Sweden, and United Arab Emirates are among the nations that mandate the use of INN in prescriptions, while in the United Kingdom it is strongly encouraged (Panteli et al. 2016). In Japan it is incentivized financially; physicians are paid JPY 70 (around US$0.70) if all medicines prescribed to outpatients are prescribed using an INN or generic name, and JPY 50 (US$0.50) if at least one is. The use of electronic prescription software, integrating therapeutic guidelines with recommended INN-based medications, can greatly reduce the use of brand names in prescriptions.

Generic substitution: Even where physicians continue to prescribe by brand, pharmacists can dispense generic equivalents. In some jurisdictions, including Jordan, this is mandated unless specifically prohibited by the prescriber; in others it is permitted, although sometimes with the consent of either the physician or the patient. A few countries do not allow generic substitution when a branded drug is prescribed. These tend to be places where INN prescribing is already mandated or strongly encouraged unless the physician has specific reasons for prescribing a branded medicine.

Evidence from the United States suggests that while physicians usually consent to substitution, seeking patient consent is associated with a 25 percent fall in successful substitutions of generic for branded medicines, compared with jurisdictions where patient consent is not required (Shrank et al. 2010).

Australia and Japan have provided pharmacists with financial incentives for substitution. In Australia, pharmacists were paid AUD 1.50 (in August 2010) each time they dispensed a lower-cost substitute for a premium medicine. As of 2020, pharmacists in Japan are paid a bonus (on a sliding scale) if the share of generic medicines sold in their pharmacies is over 75 percent in a three-month period. This has risen from a bonus threshold of just 30 percent in an earlier iteration of the regulations, reflecting the extent to which the incentives have contributed to establishing new norms. Currently, if the proportion of generics falls under 20 percent in a three-month period, the pharmacy forfeits part of its dispensing fee. The country calculated that its generic substitution policy reduced state spending on medicines by approximately JPY 1.3 trillion a year (Hassali et al. 2014). The policies contributed to increasing the share of generic medicines from 46 percent of the Japanese market by volume in 2013 to 73 percent by 2018. The trend is expected to continue, exceeding 80 percent by 2020 (IQVIA 2019a).

Generic substitution policies can generate savings quite rapidly. A 2006 study estimated that the Canadian province of British Columbia saved CAD 2.9 million within nine months of enforcing generic substitution for PPIs (Schneeweiss et al. 2006).

Generic substitution is facilitated by the provision of clear national guidelines or lists of medicines that are considered effective substitutes. Australia, Finland, Sweden, the United Kingdom, and the United States are among the countries that publish therapeutic equivalent lists (Hassali et al. 2014).

Tiered pricing: One of the obstacles to increasing demand for generics is objections from patients, who are more familiar with brand names and who may distrust the quality of generics from local or lesser-known manufacturers. While encouraging use of generics can reduce OOP spending on medication, the primary purpose of generics policies is to protect public budgets

and contain costs for insurers. Some countries therefore provide patients with the option to choose branded drugs, on the condition that they contribute to the cost.

Sweden, which mandates prescribing by INN, allows patients to choose branded alternatives so long as the patient pays the difference between the generic and the branded price. In the United States, insurers often vary the copayment depending on the status of the drug. One study showed that copayments averaged US$7 for a generic drug, US$37 for a drug on the insurer's formulary of branded medicines, and US$75 for branded medicines that were not favored by the insurer (Hassali et al. 2014).

Physician and patient education: Allowing patients to pay more for branded medicines does little to overcome their core distrust of generic medicines, a distrust they very often share with doctors, especially in markets where innovator pharmaceutical companies have historically had strong links with physicians' associations. Close to half of a sample of over 500 physicians who participated in a study in the United States said they were distrustful of the quality of generic drugs, close to a quarter also doubted their efficacy, and close to a third preferred to avoid generic medicines for their own care (Shrank et al. 2011). All of these negative perceptions were significantly more common among older physicians.

Physicians' attitudes, as well as their financial incentives, can interact with patient distrust of generic medicines, which is often more pronounced for medicines that are made domestically. Ironically, efforts to avoid generic medicines can actually expose patients to genuinely poor-quality medicines, in the form of falsified products. An example comes from Indonesia. Although there is a steady supply of domestically produced, WHO-prequalified vaccines, which are available to patients at no cost, patient demand for expensive imported vaccines is high. Some doctors are happy to encourage patient demand for "better quality" alternatives because charging patients for imported vaccines generates substantial extra income. Unfortunately, medicine falsifiers are also happy to meet the demand. In 2016, over 1,000 children were injected with non-sterile, fake "vaccines" by doctors in private hospitals (Pisani et al. 2019).

In light of negative perceptions around generic quality, some countries have tried to educate prescribers, pharmacists, patients, and the general public about the benefits of generic medicines in terms of increasing equitable access to care across the health system, as well as increasing their knowledge about quality assurance procedures for generic medicines. In some countries, pharmacy chains focusing primarily on the provision of quality-assured generic medicines are gaining market share.

Most of the evidence suggests that multiple, concurrent policies are more effective in driving up the use of generics than any single approach (Godman et al. 2014; Kaplan et al. 2012).

4.3 Appropriate Use of Medicines: Status Quo and Implementation Issues

Treatment guidelines

The Ministry of Health (MOH) provides national standard treatment guidelines for many conditions; these are aligned with the national essential medicines list. In 2014, the MOH's Saudi Center for Evidence-Based Healthcare published a manual outlining procedures for the development of clinical practice guidelines; guidelines had been developed in at least 10 areas by 2017 (The Saudi Center for Evidence-Based Health Care 2014; Alrasheedy et al. 2017). These guidelines provide information on potential pharmacological treatment, including discussions of medicines not currently registered by the Saudi Food and Drug Authority (SFDA) (for example: *Saudi Guidelines on the Prevention and Management of Obesity, 1st Edition* 2016, 34). A Smartphone app released by the MOH in

January 2020 listing medicines on the national formulary is said to integrate treatment guidance (MOH 2020).

Use of clinical practice guidelines appears to be patchy. In a 2011 survey of 29 hospitals in Riyadh, half of which were private, two-thirds reported using treatment guidelines (M. S. Alsultan et al. 2012). Therapeutic guidelines for subsets of the population, such as older patients, may lead to poor prescription practices among general practitioners, in particular. One study at a large family and community medicine clinic in Riyadh found that over 60 percent of patients aged over 65 were taking potentially inappropriate medicines (Alturki et al. 2020).

Generics policy

In 2016, innovator medicines accounted for 62.7 percent of the prescription medicines consumed in KSA, and 54.5 percent of the total drug market. This proportion is much higher than that in many other countries at similar income levels. The vast majority of the innovator drugs were imported, mostly from the United States, Switzerland, Germany, and France (BMI Research 2017).

High consumption of originator and other branded medicines is supported by the practice of physicians of prescribing by brand, a habit based at least in part on a distrust of generic alternatives (Salhia et al. 2015). There are currently no national regulations or guidelines governing prescription practices. While health authorities and hospitals are increasingly trying to use prescribing guidelines to encourage greater use of INNs when writing prescriptions, physicians often remain resistant (M. S. Alsultan et al. 2012; World Bank 2018). Research suggests that cost control does not figure prominently in either the training or the consciousness of physicians or pharmacists (Alkhuzaee et al. 2016). In one study, fewer than half of 178 hospital-based doctors expressed an awareness of the cost benefits of generic medicines; researchers suggest this may be because generous state provision means the costs are not felt by patients (Salhia et al. 2015). In a 2010 study of pharmacists in 27 hospitals in Riyadh, only seven of them reported any training related to the costs of medications for prescribers—although 16 hospitals did require approval for prescribing non-formulary products (M. S. Alsultan et al. 2012).

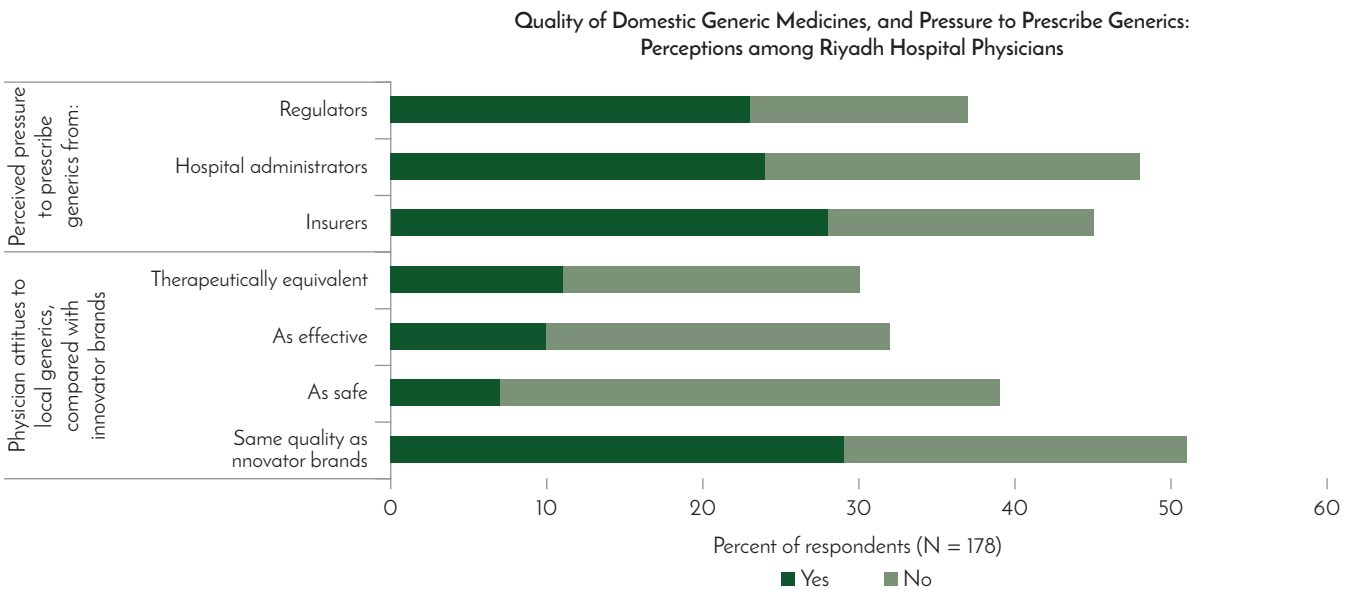
This relative disdain for generic medicines may be reflected in hospital procurement practices: hospitals appear to pay particular attention to keeping branded products in stock. In a study of 120 pharmacists in Riyadh hospitals, two-thirds reported that generics were more commonly out of stock than originator medicines. The proportion was higher in MOH hospitals and medical cities than in other non-MOH hospitals (Yazed Sulaiman Alruthia, AlKofide, et al. 2017).

Physicians, for their part, report little pressure to prescribe lower-cost medications. Figure 1, taken from a study of physicians at one public and one private hospital in Riyadh, summarizes doctors' attitudes to both the quality of generic medicines, and the pressure to prescribe them.

Attitudes toward domestic generics are particularly worrisome. Though most physicians surveyed by Salhia and colleagues were not overly concerned that locally made generics were unsafe, they were less sure about efficacy. Fewer than one physician in three believed that domestic generics meet the same quality standards as originator brands, and fewer than one in five thought they were therapeutically equivalent (Khan et al. 2016; A. S. Alsultan and Hakeam 2018).

Recent recalls of domestically produced generics tend to confirm their prejudices (see Section 8 on domestic manufacturing). These attitudes stress the importance of production audits to ensure good manufacturing practice, strong post-market surveillance, and judicious communication in order to maintain physician and public confidence in safe and cost-effective generic medicines.

FIGURE 1 **ATTITUDE TOWARD GENERIC MEDICINES AMONG PHYSICIANS IN RIYADH, AND PERCEIVED PRESSURE TO PRESCRIBE GENERICS**



Source: Salhia et al., 2015.

Therapeutic substitution

Article No. 23 of the Health Professions Act allows pharmacists to perform generic substitution, except for drugs with a narrow therapeutic index. Though they do not have to seek approval from prescribers, they must get consent from patients (a provision that in other contexts greatly reduces the use of substitution). While there does not yet appear to be a formal Orange Book type list of approved therapeutic equivalents (Alhawassi et al. 2018; Alrasheedy et al. 2017), is a well-defined pharmaceutical pricing policy, and the medicine prices are strictly controlled. The Saudi pharmaceutical market is the largest market in the Middle East and Africa, the 2020 Essential Medicines List does list both national and WHO-endorsed equivalents for a number of products (SFDA 2018).

Awareness and use of these legal provisions appear to be low. Just seven of 27 hospital pharmacies surveyed in Riyadh reported substituting generic for branded medicines, while in a study of 121 community pharmacists in three regions, fewer that two-thirds even knew that they were permitted to substitute generic medicines without consulting the prescriber (M. S. Alsultan et al. 2012). This is not entirely surprising, given that over 90 percent of community pharmacists are expatriates, and therapeutic substitution may not be emphasized in the conversion exams they must take to practice in KSA (see Section 11 on Human Resources). In addition, many pharmacists themselves doubted the quality of generic medicines.

Tiered pricing

Because the cost of medicines in the reimbursed sector is generally covered, with no copayments required, there are currently no formal mechanisms for tiered pricing in KSA. However, an informal tiered pricing system operates through OOP payments.

Long waiting times and perceived low quality of services and medicines in the public sector means that many people eligible for free treatment in the public sector choose instead to seek treatment, and buy medicines, from private sources (Moradi-Lakeh et al. 2016). Community pharmacists are financially incentivized to sell more expensive medicines. Many Saudi customers, in any case, express a preference for brands when buying medicines without a prescription. Where they do not, pharmacists will usually propose branded medicines. The result is that patients are effectively paying high prices for therapies that they could have received for free. Though the impact on public finances is minimal, this undermines national goals of equity, financial protection, and rational use of resources.

Many studies underline the potential for irrational use of medicines in the current system. Patients often access services in more than one of the nation's subsystems and because patient records are not shared, duplicate and sometimes conflicting prescriptions are common. One study of over 17,000 adult hospital outpatients found that 47 percent were taking five or more medicines concurrently, excluding any that they had been prescribed in other settings or acquired over the counter (Balkhi et al. 2017). Authors attributed the high level of polypharmacy in part to the fact that medicines were provided free of charge, lowering barriers to overuse. If successful, current efforts to increase the use of electronic records, described in Section 10, should reduce this risk.

Mystery patient studies underline the ease with which prescription medicines can be acquired over the counter in community pharmacies, including well-known chain pharmacies. In a 2011 study in Jeddah, pharmacists in 59 community pharmacies and one hospital pharmacy all gave out antihypertensives without prescription; all except the hospital also sold antibiotics; while just four of 38 pharmacists refused to sell antipsychotics without a prescription. A similar willingness to sell medicines without prescriptions was recorded in a nationwide study of 150 community pharmacies. On average across six regions and ten drugs, 63 percent of pharmacists gave out drugs without prescriptions. Worryingly for those concerned with the spread of antimicrobial resistance, 57 percent were happy to sell the broad spectrum antibiotic Ciprofloxacin on demand (Al-Mohamadi et al. 2013; Alshammari et al. 2017). Questioned later in the study about their practices, some pharmacists mentioned that they were not aware of any clear guidance on which medicines they were allowed to sell over the counter.

While guidance does exist, including through the registration processes of the SFDA, there is a clear mismatch between regulation and implementation. This may be in part because of a division of labor among regulators—while the SFDA regulates the prescription status of products, pharmacies are licensed by the MOH. Academics note that it is unclear who bears the responsibility for monitoring compliance with pharmacy regulations in different settings (Al-Mohamadi et al. 2013).

4.4 Appropriate Use of Medicines: National Policy

The MOH, working inclusively with professional and expert bodies, will continue to provide updated national clinical practice guidelines based on the latest peer-reviewed evidence, including locally specific evidence where epidemiologically warranted. These guidelines, which include recommendations for medicines' use, may be adapted to meet the needs of different public and private sectors.

The responsible authorities will expand efforts to encourage and incentivize the prescribing, dispensing, and use of quality-assured generic or biosimilar medicines where appropriate. They will introduce measures to incentivize INN-based prescription, develop clear guidance on therapeutic substitutes, and consider media and education campaigns targeting patients, prescribing physicians, and pharmacists as appropriate.

Education in value-based prescribing and dispensing will be strengthened in national curricula, and policies and regulations related to appropriate use of medicines will be emphasized in conversion courses and examinations for expatriate pharmacists.

5 PRICING OF MEDICINES

5.1 Pricing of Medicines: Policy Goals

In most countries, policies that contain or lower the price of medicines aim to increase the number of people who can access safe and effective therapies for a given level of public funding. However, very low prices can reduce the availability of products in a market and undermine investment in manufacturing and distribution, thus threatening product quality. Policies that govern or shape the price of medicines therefore aim to ensure fair prices that strike a balance between availability and affordability (Moon et al. 2020).

5.2 Pricing of Medicines: Policy Considerations

Countries at all levels of income employ a wide array of policy measures for price setting. These may include:

- ***Ceiling prices***: usually based on reported manufacturing and distribution costs and fair profit;
- ***Internal reference pricing***: often used for pricing generics, prices are set at a fraction of the price of therapeutically similar products already on the market;
- ***External reference pricing***: prices are set relative to those paid for the same product in other markets;
- ***Value-based pricing***: prices are set relative to benefits projected in a health technology assessment; and
- ***Managed entry agreements*****:** usually applied to expensive innovative therapies made by a single manufacturer, these are negotiated agreements that can limit spending, for example, by paying against clinical outcomes.

Each has strengths and weaknesses. The effect of external reference pricing depends heavily on the choice of comparator countries and the way exchange rates are handled in price calculations. In general, it has the capacity to drive significant price reductions over quite short periods. In higher-income markets, value-based pricing is gaining popularity for novel and expensive therapies (Ferrario et al. 2020; Kanavos et al. 2018).

While institutional responsibility for price setting varies, it is most often performed by an independent committee linked with the Ministry of Health (MOH) or public payer.

Ensuring availability

Most medicines are made by companies whose principle aim is to maximize profits for shareholders while staying viable in the long term. Many of these companies, including almost all of those which make innovative products, are highly globalized. When deciding where to invest or to register products, they therefore

take into account a nation's size, wealth, relative profitability, and the ease of securing sales.

In wealthier nations, there is often strong pressure from physicians and patient groups for access to new treatments, which in this time of rapid drug discovery include genetic, biological, and targeted therapies. With the help of the sales force and lobbyists of pharmaceutical firms, this pressure sometimes builds before there is a strong enough evidence base for therapeutic effectiveness, let alone cost-effectiveness. Governments are increasingly obliged to develop mechanisms that support rapid access while protecting their budgets. Managed entry agreements, which take many forms but which tend to work best when negotiated at a national level, are an increasingly common tool for achieving this goal. However, to work effectively, they require rigorous use of patient registries or other strong systems for collecting, sharing, and analyzing data on costs and therapeutic outcomes (Vogler et al. 2017).

Low prices relative to similar markets may dissuade companies from seeking to register products quickly, or at all, not onlym because profits are likely to be low but also because low prices in countries that are benchmarked by their peers may set a precedent that affects returns in other markets. Evidence from Algeria, Romania, and Turkey suggests that cost control measures have undermined the willingness of companies to bring products to market, thus restricting the therapeutic options available to patients. Cost control measures that lead to large price reductions, especially if they are sudden, can also lead to the withdrawal of products that are already registered. In the three years after Romania effectively capped prices at the EU minimum while charging producers a claw-back tax, for example, manufacturers withdrew around 2,000 of 6,200 products, leading to nationwide shortages of many important medicines (QuintilesIMS 2017).

Participation in trading blocs or agreements may also create vulnerabilities, because distributors buy in the lowest-priced markets for resale at higher prices elsewhere in the bloc, thus sweeping bare the shelves of pharmacies in cheaper markets.

Uncertain profits (often the result of low or fluctuating demand and price) affect the market for medicines globally as well as nationally. Certain essential medicines are difficult to buy anywhere, not because they are difficult to make, but because the demand is limited and therefore manufacturers have little incentive to continue making them. Ensuring the supply of such medicines requires a collaboration with manufacturers, ensuring them of predictable demand and stable price, over a period long enough to justify the required investment. Governments, as well as multilateral organizations, can work together to aggregate demand and ensure fair pricing, thus creating incentives for continued supply. These initiatives are sometimes referred to as *market shaping*.

Ensuring quality

Quality assurance costs money for all pharmaceutical producers, whether innovator or generic. Since profit margins are generally very slim on low-value, high-volume generics, quality assurance tends to represent a higher proportion of manufacturing and distribution costs than it does on high-end products. In addition, most generics manufacturers are currently highly dependent on raw materials made in China or India. Producers in other countries are thus also exposed to currency risks, which can add to production costs. When prices fall, already slim margins are squeezed yet further. The risk of cost-cutting rises and the risk of substandard production, packaging, or product handling rises with it (Pisani et al. 2019).

Efforts to control costs, for example by setting ceiling prices based on production costs, must therefore take into account the not insubstantial costs of continuous quality assurance.

5.3 Pricing of Medicines: Status Quo and Implementation Issues

The Saudi Food and Drug Authority (SFDA) is unusual among medicine regulators internationally, in that it sets the retail price of medicines as part of the market authorization process, using a mixture of internal and external reference pricing. Briefly:

New chemical entities, innovator products, and biosimilars: Companies must submit pricing certificates, verified by the Saudi Embassy, showing the price of its product in the country of origin and in other countries where it is marketed, from a basket of 30 reference countries. Added to this price is 2 percent for shipping, as well as profit margins of 10–15 percent for wholesalers and 10–20 percent for retailers (Alhomaidan et al. 2016). A year after the registration of the first generic equivalent, the originator price may be lowered by 20–30 percent.

Generics: Both external and internal reference systems are used. Companies must, at the time of application, submit price data from 30 other countries,[1] verified by the Saudi Embassy in each country. The SFDA also benchmarks against prices of existing products. The first generic is priced at 70 percent of the originator price, unless it is domestically produced, in which case its price may not exceed 65 percent of the originator price. The price of two subsequent entrants are reduced by a further 10 percent each. The price of the fourth generic entrant becomes the highest allowable for all successors (Kanavos et al. 2018).

The submission of verified pricing data can be time-consuming. This, as well as an industry perception that cost controls may be eroding profit margins in the Saudi market, may in recent years have accounted for the relatively long period between the time a new drug is submitted anywhere in the world, and the manufacturer's application for market approval in Saudi Arabia (Al-Rubaie, Salek, and Walker 2015; BMI Research 2018). Figure 2 compares the registration process for new active substances in the Saudi market between 2011–2013 with market entry in Australia, Canada, and Singapore. The most notable difference was the time between approval anywhere in the world and submission of the dossier for registration in the local market. In Canada, submissions were received an average of two weeks after first approval globally. Singapore and Australia received applications in under three months. By contrast, companies took an average of one year and five months to apply for registration in Saudi Arabia (Hashan et al. 2016).

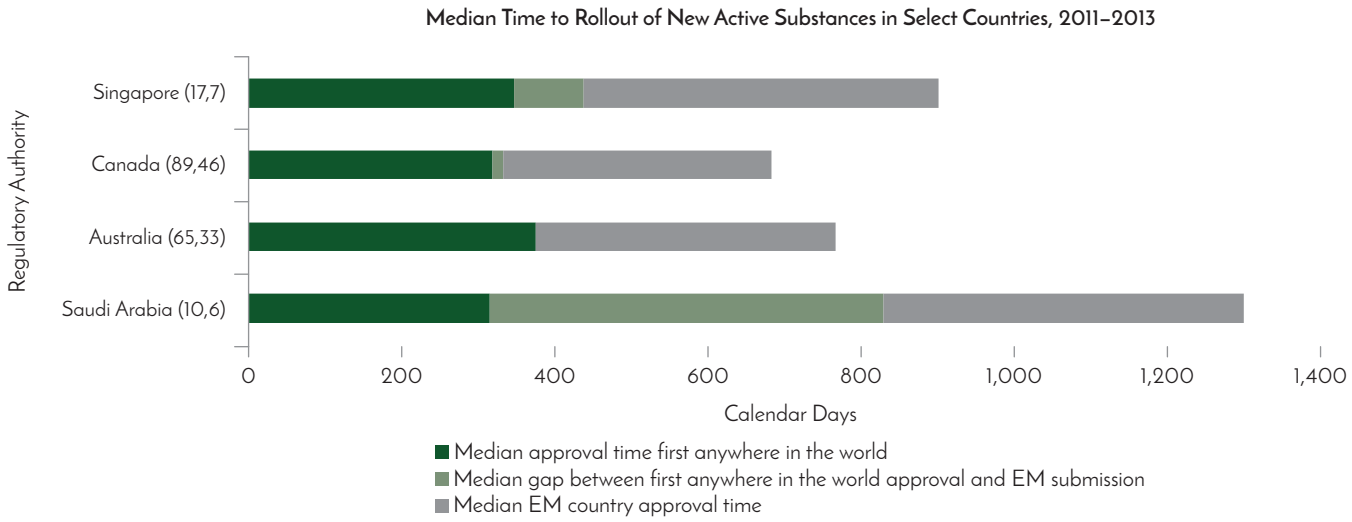
The SFDA has brought in new procedures to cut registration times and has reflected its determination to do so in its own performance targets. However, it appears to have retained the time-consuming price information and verification requirements even for registrations submitted under the verification and abridged procedures (KSA 2019).

This information may be important for price setting, and prices set by the SFDA are doubtless important in capping out-of-pocket (OOP) spending on medicines bought in community or even hospital pharmacies. However, they have little effect on public budgets, since most public sector procurement occurs through bulk purchasing, which undercuts the price ceilings set by the SFDA (World Bank 2018).

Market research reports aimed at multinational pharmaceutical companies regularly stress the Saudi government's progress in implementing cost-containment measures, which compares overall spending on domestic and imported pharmaceuticals in KSA and three other

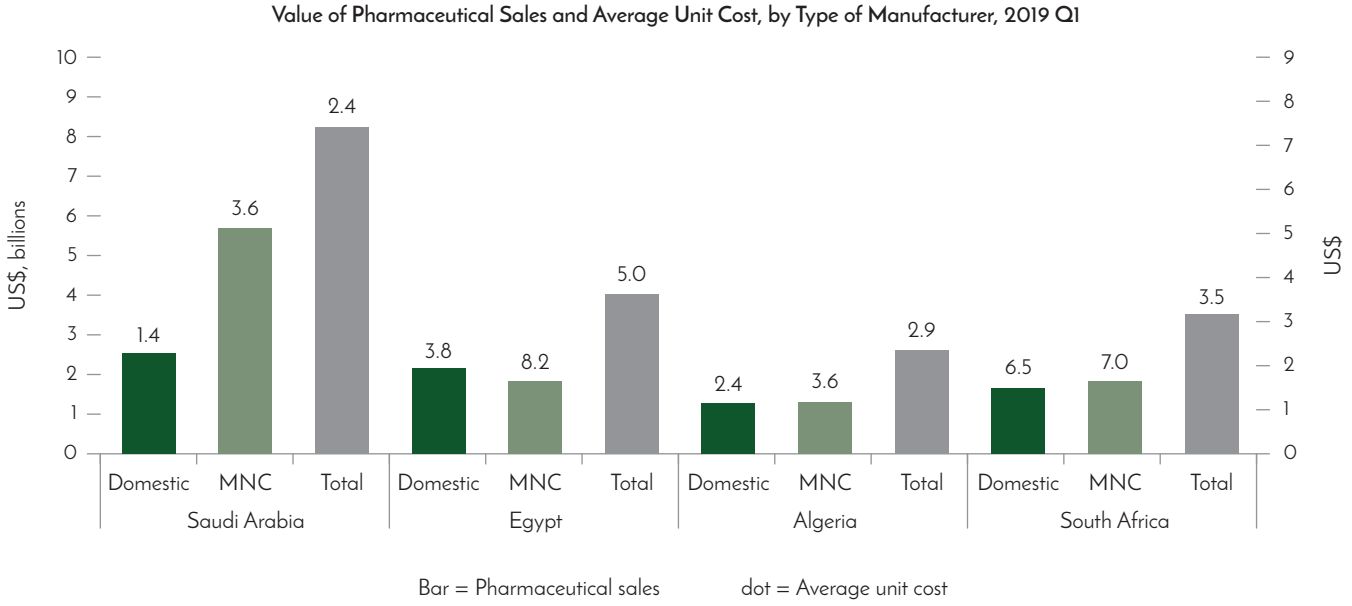
[1] As of 2018, these countries were: Algeria, Argentina, Australia, Bahrain, Belgium, Canada, Cyprus, Denmark, Egypt, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Jordan, Kuwait, Lebanon, the Netherlands, New Zealand, Oman, Portugal, the Republic of Korea, Spain, Sweden, Switzerland, Turkey, the United Arab Emirates, and the United Kingdom.

FIGURE 2 MEDIAN TIME TO ROLLOUT OF NEW THERAPIES, VARIOUS COUNTRIES



Source: Hashan et al. 2016.
Notes: EM = Emerging markets. Numbers in brackets next to country name (n1,n2) are the number of new active substances and number of companies, respectively. New active substances in this analysis includes those with first anywhere in the world submission, first anywhere in the world approval, application submission, and application approval dates. Only Australia and Canada data are provided from the public domain and from the agency. Singapore company data show approval time for all review types but the majority of the applications underwent abridged review.

FIGURE 3 SPENDING ON PHARMACEUTICALS AND AVERAGE UNIT COST VARIOUS MARKETS



Data source: IQVIA MEA market report, 13th edition; author's analysis.
Note: MNC = multinational corporation.

markets, suggests that the cost control measures are indeed relatively effective. In terms of average unit cost, KSA now pays less than half as much as Egypt, the second largest market in the region, for both imported and domestically manufactured medicines. Of the large markets, only Algeria matches the prices KSA achieves for medicines from multinational suppliers, possibly in part because of a different product mix.

It is worth noting that the cost per counting unit (the smallest unit in which a medicine is manufactured, typically a pill or vial) achieved in KSA fell between 2018 and 2019 (from US$4.1 to US$3.5 per unit for products from multinational manufacturers and US$1.5 to US$1.4 for local products). This was a period in which the National Unified Procurement Company (NUPCO) expanded its procurement activities.

5.4 Pricing of Medicines: National Policy

The SFDA regulates retail prices for all medicines in order to limit OOP spending on medicines. This regulation will occur in ways that do not unduly delay market entry for new medicines.

FINANCING AND REIMBURSEMENT OF MEDICINES

6

6.1 Financing and Reimbursement of Medicines: Policy Goals

Financing policies for medicine aim to ensure that public and private funds are used as efficiently as possible in the procurement and distribution of medicines. Reimbursement policies aim to protect families from excessive spending on health while incentivizing efficient use of medicines across all sectors and minimizing the bureaucratic and administrative burden on patients and service providers.

6.2 Financing and Reimbursement of Medicines: Policy Considerations

Demand forecasting

Financing requirements for medicines are determined in large part by other health, social, and industrial investment policies. In general, the greater the investment in policies that promote healthy environments and lifestyles, the less investment is needed for curative care, including medicines. Demand planning, the bedrock of well-planned health financing policies, involves a clear understanding of the likely effect of these investment choices on disease profiles, as well as on medicine costs.

Demand is itself shaped by reimbursement models, including the way benefits packages are defined and paid for; these factors significantly affect health-seeking behavior as well as prescribing and dispensing habits.

Shaping provider behavior

Many health systems reimburse hospitals in "bundles," paying a set price for a package of services and goods, usually defined as a diagnosis-related group (DRG). Payment by DRG includes the cost of medicines used to treat the condition in question. This should incentivize the efficient use of resources, since service providers can keep or repurpose any money that they save on medication or other aspects of service provision. In practice, however, it sometimes leads to under-treatment. Where hospitals or other service providers procure their own pharmaceuticals, it can also open the door to the purchase of low-cost medicines that sometimes turn out to be substandard or falsified (Pisani et al. 2019).

The other major approach to reimbursement is fee-for-service, in which service providers are reimbursed for each service they perform or commodity they use. This system clearly reduces the incentive to use the most cost-effective medications. However it is worth noting that DRG-based reimbursement is not a foolproof way to reduce costs, either, since in profit-maximizing institutions, physicians, and hospital administrators quickly become adept at "up-coding" to maximize what they can charge for each case (Rosenthal 2018).

The two systems tend to lead to the collection of different types of data, which has implications for medicine policy more broadly. Fee-for-service systems generally reimburse against prescriptions. When electronic records are used, as is almost always the case in these systems, this results in an extremely detailed database of pharmaceutical use. It allows for effective implementation of track-and-trace systems (see Section 10 on Data Systems) and provides critical information for demand planning and health technology assessment (HTA).

DRG-based systems (together with capitation systems used in primary health care) are less burdensome administratively than those that require bills for and reimburse against every service and medicine provided. However, their successful implementation is by no means simple, even in countries such as Thailand, which has a strong record in public health and hospital management (Pongpirul et al. 2011). Unless they are specifically designed to capture information on pharmaceutical use, DRG- and capitation-based systems preclude particular policy choices. It is, for example, difficult to reconcile the use of these systems in health financing with a drug delivery system that aims to deliver reimbursed outpatient medicines through community pharmacies.

Shaping patient behavior

As is clear from the discussion of appropriate use of medicines in Section 4, patients participate actively in deciding on their own care, including what medicines they consume. Their choices are shaped by perceptions around need and product quality, but also by factors relating to cost and out-of-pocket spending.

In private insurance markets, patients may choose their insurer based on the benefits they offer. In public markets, they may wish to increase their own contributions in order to access specific services or medicines. In both cases, tiered copayments, described above, are an effective way of allowing beneficiaries (and physicians) flexibility to access premium services without undermining the equitable provision of access to core services for all those covered. Reviews of the impact of copayments for medicines indicate that requiring beneficiaries to contribute to the cost of medicines lowers spending as well as consumption (Huskamp, Epstein, and Blumenthal 2003). It is likely that such a requirement also avoids wasteful dispensing of medicines that are not consumed, and that may be disposed of dangerously.

6.3 Financing and Reimbursement of Medicines: Status Quo and Implementation Issues

Vision 2030 encompasses a radical reimagining of health financing in KSA; the current situation is thus extremely dynamic. There is a clear intention to increase the role of the private sector, as well as an insurance-based model for health financing. It is expected that the dispensing of medicines will be decoupled from prescribing in primary and outpatient care, increasing the role for community pharmacists.

Private health insurance has been compulsory since 2007 for all private sector employees, including all expatriates not in government service. At the start of 2020, over 3.6 million Saudi nationals and 7.6 million expatriates were covered by 26 private insurers (CCHI, no date). The Council of Cooperative Health Insurance (CCHI), which regulates the sector, specifies a minimum package of benefits, but it does not give clear details about which medicines should be covered.

The public sector does not currently implement clearly defined packages of benefits. Medicines are free at the point of dispensation for patients accessing public sector services in Saudi Arabia, as well as for insured patients in the private sector.

Demand forecasting

The disease profile in the country is dominated by diseases related to behavioral risks, principally related to eating, smoking, and sedentary lifestyles, although traffic accidents also take a high toll (IHME 2015). The most effective way to reduce demand for treatment related to these conditions involves changing diets and other behaviors, as well as taking measures to improve road safety. High levels of consanguinity may also contribute to unusually high rates of genetic disorders for which treatment options are limited but expensive (Ahmad and Chanoine 2017; AlGhamdi, AlKhars, and AlAnazi 2019; Alqadi et al. 2018). Investment in early detection programs, with the option of preventative therapy where indicated, might reduce the need for more expensive interventions later on.

Currently, health service provision is heavily weighted toward curative care and uptake of preventative services is poor. A survey of close to 12,000 households conducted in 2013 found that while almost three-quarters of adults had visited a health facility in the previous two years because of ill health or injury, only 23 percent of them had accessed facility-based health promotion or preventative services over the same time period (El Bcheraoui et al. 2015). The same survey tested all participants for hypertension, and close to half of participants also provided blood for the diagnosis of other conditions. Of those diagnosed with hypertension, diabetes, and hypercholesterolemia during the survey, 57 percent, 44 percent, and 65 percent respectively did not know of their condition.

Meanwhile, entry points for effective prevention are ignored. In a records review of the use of statins at a major government hospital, Alsaggabi (2019) found that only 22 percent of 300 patients were given any advice on diet, and 16 percent on increasing activity. Inevitably, underinvestment in prevention will increase demand for pharmaceuticals, and thus will increase the overall financial provision necessary.

Major changes in the workforce will affect demand for medicines in the medium and longer term. Vision 2030 continues existing efforts to reduce dependence on expatriate labor. This will increase the proportion of the working population that will retire in-country (since most expatriate workers leave KSA before retirement age) and hence will require health care later in life, when consumption of medicines is highest. Meanwhile, female participation in the workforce is expected to increase, from 22 percent in 2018 (compared with an average of 44 percent in all high-income countries). Such increases are generally accompanied by a decrease in fertility, reducing demand for some services in the short term and many other services in the longer term as populations shrink.

At the moment, no institution is tasked with bringing together all the data that would be needed for accurate demand forecasting, the basis for robust planning for health financing in the short, medium, or long term.

Shaping provider behavior

Provider behavior will be shaped in part by reimbursement policies. It will be important to ensure that the reimbursement methods chosen are consistent with the efficient implementation of other policy choices. For example, any capitation- or DRG-based financing system for outpatient care may require the systematic collection of prescription data to allow for reimbursement of medicines dispensed through pharmacies. Planners may also wish to consider the potential impact on the bottom line and sustainability of community pharmacies occasioned by switching their role from selling (mostly branded) medicines to supplying (largely generic) reimbursed medicines.

Performance-based reimbursement is already in use in many of the 5,202 private health care providers contracted by the nation's 26 private health insurers. Although training programs are in place, capacity to make full use of these

systems remains limited. A 2014 study of six private health care providers in the Eastern Province found that even accredited facilities made very limited use of DRG or other disease coding mechanisms, preferring to use charge-masters (Bah et al. 2015).

Shaping patient behavior

The provision of free medicines (with no copayments), together with registration of patients in multiple sectors of the health system and the minimal use of transferable electronic patient records, have resulted in high rates of polypharmacy. A study of prescriptions filled by over 17,000 outpatients in a single pharmacy showed that 66 percent of older adults were taking five or more medicines a day, compared with 39 percent of older adults in a similar setting in Italy (Balkhi et al. 2017; Slabaugh et al. 2010). This may also contribute to high levels of wastage, with patients not taking the dispensed medicines. In a 2013 household survey of approximately 11,000 adults, close to two-thirds of those taking medicines for a chronic condition reported non-adherence, largely because they were "feeling better" (Moradi-Lakeh et al. 2016).

Policies that encourage patients to travel for treatment by covering the cost of overseas treatment will probably increase overall costs to the insurer, creating opportunity costs for investment in medicines at home. In 2017, the Saudi government paid for over 2,400 patients to travel abroad for treatment, over half of them to the United States, the world's most expensive medical destination (MOH 2018a). Treating these patients at home may save money overall, but it is also likely to increase demand for more expensive, innovator therapies in home markets.

6.4 Financing and Reimbursement of Medicines: National Policy

The responsible authorities will ensure that provisions for public financing of medicines are based on the latest data-based demand forecasts made by all public sectors based on the reimbursement formulary.

The National Unified Procurement Company (NUPCO) will manage the reimbursement of prescription medicines through community pharmacies, prescribed by public providers.

Reimbursement mechanisms, including those in schemes regulated by the CCHI, will seek to maximize the use of cost-effective medicines, including by referring to formularies and defined benefits packages as appropriate. These mechanisms may include the introduction of co-payments without prejudicing the ability of lower-income populations to access effective, quality-assured medicines.

Negotiations to increase access to expensive, single-source medicines through managed entry agreements will be led by purchasing bodies at the national level, informed by data provided by all sectors, and in collaboration with the Center for Health Technology Assessment.

PROCUREMENT, SUPPLY, AND ACCESSIBILITY OF MEDICINES

7

7.1 Procurement and Supply of Medicines: Policy Goals

Shortages of medicines, including those at the local level, threaten lives and create opportunities for purveyors of falsified medicines. Procurement policies, which work in close conjunction with policies on pricing, aim to secure an uninterrupted supply of quality-assured medicines sufficient to meet national demand, and to do so at affordable prices. Policies governing supply aim to ensure that the procured items are equitably distributed in ways that maintain quality and avoid localized shortages.

7.2 Procurement and Supply of Medicines: Policy Considerations

Many procurement mechanisms are in operation around the world. Most aim at least in part to achieve low prices, but they may also focus on tackling problems of market size, market fragmentation, or seasonality of demand. Procurement policies can also incentivize production of particular products, support national industrial development, and contribute to reducing corruption. Common mechanisms include:

Centralized procurement: A single procurement agency buys medicines, usually on behalf of a single payer such as a national insurer or national health service.

National or international pooled procurement: A single entity buys medicines on behalf of a large number of users. The entity could buy on behalf of several countries (as is the case with the Gulf Cooperation Council [GCC]'s, Group Purchasing Programme, or the Pharmaceutical Procurement Services, which operates in the Organisation of Eastern Caribbean States). International pooled procurement initiatives are also operated on behalf of global health bodies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria. At a national level, such mechanisms are also sometimes used to reduce fragmentation caused by administrative decentralization: examples include China, Malaysia, and Mexico.

Outsourced procurement: National authorities contract with a specialist procurement agency such as Crown Agents or SGS Group Management SA to deliver procurement services. This method is used principally by governments attempting to overcome challenges of limited capacity and endemic corruption.

Within each of these mechanisms, there are also several options for tendering and contracting. These include direct purchase, framework agreements, restricted tenders (often including some element of prequalification) and open tenders. Contracts may be awarded to single or multiple winners.

In general, procurement of larger volumes of a more limited number of medicines leads to

lower prices; for this reason, centralized and pooled procurement models are growing in popularity. However, these models can be politically challenging to implement because they often replace more fragmented systems, which by definition encompass a large number of vested interests. Deciding on the appropriate level of aggregation in national procurement is thus more a political than a technical decision.

Where centralized or pooled procurement is chosen, a further important policy decision involves the institutional responsibility for medicines procurement. The two most common choices in the public sector are the Ministry of Health (MOH) or the national procurement agency. While the latter is more likely to have the expertise to successfully run large and complex tenders or negotiations, professional procurement staff rarely include those with sector expertise that would help avoid life-threatening consequences of poor procurement choices. In Indonesia, for example, the national procurement agency in 2014 introduced a system for medicines based on the system it uses to procure office furniture or cars. Tenders to provide particular medicines to a market of over 200 million people for two years went to the lowest single bidder with a valid market authorization. This sparked a "race to the bottom," threatening product quality and greatly increasing the risk of stock-outs when the single winner was unable to fulfill production targets (Ursu and Rabovskaja 2017).

On the supply side, policies may be introduced to reduce the complexity of the supply chain, for example by restricting the number of actors involved in importing, distributing, and retailing medicines. Policies that increase or mandate transparency, such as requiring the use of track-and-trace technology, can be instrumental in monitoring equitable distribution of medicines and in flagging impending shortages.

Finally, distributors and retailers of medicines must have a stake in ensuring that patients have access to adequate supplies. This may mean paying premiums for delivery of medicines to remote or low-density markets, or incentivizing community pharmacists to stock slow-moving items. In addition, payment delays that cause cash-flow difficulties for distributors or pharmacists must be avoided. Where public purchasers are slow to pay, pharmacists sometimes cease providing services to public sector clients entirely.

7.3 Procurement and Supply of Medicines: Status Quo and Implementation Issues

Saudi Arabia participates in regional pooled procurement through the Gulf Cooperation Council's (GCC's) Group Purchasing Programme, which is headquartered in Riyadh.

Leading public sector procurement at the national level is the National Unified Procurement Company (NUPCO), established in 2009. The agency is mandated to manage all public procurement of pharmaceuticals, supplies, and medical technology. In its early years, its clients were dominated by the establishments run by the MOH. In recent years, other sectors have significantly increased the proportion of medications procured through the agency. As it consolidates demand, NUPCO should be in an increasingly strong position to negotiate fair prices, including managed entry agreements for new therapies. In the long term, private sector providers might also benefit from NUPCO's negotiating power by joining in pooled tenders for essential medicines and other products prioritized in a national formulary.

NUPCO also offers distribution services as well as a platform linking public hospitals with community pharmacies. When fully functional, this may resolve some of the implementation challenges raised in Section 6 on reimbursement.

Alternative procurement channels include the GCC's Gulf Joint Procurement Programme and procurement direct from manufacturers. Import distribution is controlled exclusively by Saudi Arabian firms.

Industry analysts note that many government tenders in KSA are open only to local medicine suppliers and are biased toward drug companies with the strongest local representation, not least because they are announced with very short lead times (BMI Research 2018).

Shortages

Although the recent consolidation of public procurement may have improved the situation nationally, medicine shortages remain common at the local level in both the public and the private sectors, as well as at community pharmacies. In a 2017 study of hospitals in Riyadh, 42 percent of pharmacists at MOH-affiliated medical cities reported daily medicine shortages in their hospitals, as did around 15 percent of those in other public hospitals. A majority of respondents in all hospitals said that shortages compromised quality of care at their workplace. Reasons for the shortages include poor use of data in demand planning, inventory management, and selection of suppliers (Yazed Sulaiman Alruthia, AlKofide, et al. 2017; Yazed S. Alruthia et al. 2018).

A survey of 240 community pharmacies in four regions of KSA attempted to establish the availability of 28 commonly prescribed psychotropic medicines. Fifteen of these medicines were unavailable in over half of the pharmacies visited.

Articles 23 of the Law on Pharmaceutical Establishments and Preparations requires community pharmacies to make products available regardless of price or demand, and Article 24 engages the MOH in providing a list of those products. At the time of the research, pharmacists were unaware of such a list (Yazed Sulaiman Alruthia, Mansy, et al. 2017; Government of Saudi Arabia 2004). However, the Saudi Food and Drug Authority (SFDA) has since begun to publish a list of shortages on its website (https://beta.sfda.gov.sa/en/list_shortage_drugs). In late February 2020, the agency gave details of 139 products that are currently experiencing shortage or stock-outs in the local market, including details of the manufacturer and the importing/distributing agent. It is worth noting that shortages can actually be a consequence of overconsolidated demand, because if an auction fails, it may take some time to put in place alternative procurement mechanisms. The final results of NUPCO's June 2019 tender for vaccines and pharmaceuticals show that, of the 421 products tendered, 118 received no quotes and a further 123 were canceled or not awarded (NUPCO 2019).

Interestingly, during the period in 2016 in which surveys indicated shortages of psychotropic medicines were the norm, the SFDA received no reports of shortages. This may be because the stock-outs were in fact a matter of commercial choice. The primary reason given for the absence of psychotropics from pharmacy shelves was that these were slow-moving products with low profit margins. This underlines the importance of considering the commercial interests of pharmacists when planning procurement and supply systems. Community pharmacists may need to be incentivized to stock some items, for example through mechanisms that replace expired doses of low-demand items.

An additional challenge will arise as telemedicine becomes more common. While telemedicine will facilitate the provision of health services in areas that are more remote, there is a risk that it will also increase demand for medicines in areas that are currently poorly supplied through community pharmacies. While the current policy does not explicitly address provisions for dispensing medicines prescribed through telemedicine, this area must be closely monitored and policies developed as appropriate.

7.4 Procurement and Supply of Medicines: National Policy

NUPCO will procure reimbursable medicines provided through public sector institutions, considering procurement policies and guidelines issued by the Saudi Local Content and Government Procurement Authority (LCGPA).

For medicines dispensed by public facilities, NUPCO will organize procurement through an e-procurement platform that allows for transparent bidding or auctions, leading to framework contracts with suppliers. Under these contracts, decentralized budget holders can order directly from the supplier (manufacturer or distributor).

Consolidated purchasers will use their purchasing power in a way that secures a functioning market and a secure supply, for example by splitting contracts between two or more manufacturers to avoid oligopoly or monopoly situations.

The government of KSA will work with other governments and multilateral organizations in support of market-shaping initiatives that ensure a stable supply of medicines with limited global availability.

NUPCO will operate under a set of defined quantitative performance parameters and issue a yearly public report on progress toward achieving these parameters.

As a condition of granting market authorization or certifying importers and distributors for good practice, the SFDA will require the proactive reporting of anticipated disruptions to supply of registered medicines.

The responsible authorities will ensure that stocks of essential medicines are available nationwide and rapidly accessible at the patient level.

THE NATIONAL PHARMACEUTICAL INDUSTRY

8

8.1 Pharmaceutical Industry: Policy Goals

While medicine policy principally aims to secure an uninterrupted supply of quality-assured medicines at fair prices, procurement, pricing, and regulatory choices can have the secondary effect of supporting local research and manufacturing of medicines, and thus economic growth.

8.2 Pharmaceutical Industry: Policy Considerations

The issue of pharmaceutical production is dealt with in greater detail in documents laying out policy options for industrial development. Here, some of the issues most closely linked with other parts of the medicine policy are briefly considered.

Pharmaceutical production is broadly divided into three camps: research and innovation, production of innovative medicines, and production of generic medicines. Different qualities secure dominance in each of these fields. Research and innovation is dominated by companies and countries with access to the most developed intellectual capital base. High levels of technical competence are required for production of innovative medicines, while assured supply of active ingredients and the capacity to produce at very high volume confers an advantage for generic producers.

Building or attracting these qualities where they are absent requires significant financial investments and may also take time. Governments wishing to promote local production may provide fiscal or financial incentives that support investment (for example tax breaks, free use of land or utilities, and so on) as well as guaranteeing a market for domestically produced goods. The public sector in the Russian Federation, for example, will reimburse medicines on the national essential medicines list only if they are produced domestically (A.T. Kearney 2016). While this option is available only to countries with very well-established domestic industries, many less drastic forms of preferential purchasing are possible. In most cases, however, countries must, for a period, be prepared to pay more for domestically produced medicines than they would for imported products of the same quality. Where domestically produced generics replace imported innovator brands, they may nonetheless represent a cost saving, although this is not always the case (Anggriani 2018).

The cost impact and financing implications of policies to promote domestic pharmaceutical production will depend on choices made. In general, supply-side approaches such as the subsidization of costs of production or tax breaks will be financed out of the general budget, whereas demand-side approaches, such as price premiums compared with imported alternatives, will eat into the health budget, with opportunity costs that affect other areas of health financing.

Decisions to promote and protect local pharmaceutical production are usually made at the highest political level. Political support for manufacturers can sometimes undermine the ability of national regulators to impose strict standards for quality assurance in production or distribution, thus threatening product quality, and, ultimately, patient health. This dynamic is aggravated in cases where domestic manufacturers are simultaneously under strong pressure to support political commitments to provide affordable health care to all citizens, because they are often expected to provide medicines at relatively low prices. The cost-cutting that results can lead to substandard production, which is not picked up because of relatively lenient regulation (Pisani et al. 2019).

Besides potentially raising costs and/or undermining quality, protectionist medicine policies can act as obstacles to market entry for products made elsewhere, sometimes reducing choice or access to therapies.

8.3 Pharmaceutical Industry: Status Quo and Implementation Issues

Vision 2030 has identified the pharmaceutical and biotechnology cluster as a priority area for investment and growth, and the National Industrial Development and Logistics Program (NIDLP) lays out an explicit strategy for development of the biopharmaceutical industry in KSA.

The 27 domestic pharmaceutical manufacturers registered in KSA currently concentrate on the production of generic medicines, and account for 15 to 18 percent of the national market; the realization of Vision 2030 would see this rise to 40 percent. To encourage new investment in the sector, KSA provides local companies with interest-free investment capital as well as subsidized access to land and utilities (BMI Research 2017).

The country also provides demand-side incentives. Products manufactured locally (and in other Gulf Cooperation Council, or GCC, countries) are approved in an average of 134 days, compared with 346 days for equivalent existing active ingredient products manufactured in other countries. Locally manufactured second-brand products are awarded the same price as the innovator brand, while many public sector tenders are restricted to, or otherwise favor, domestically produced products (Alrasheedy et al. 2017; Al-Rubaie, Salek, and Walker 2015; Khan et al. 2016; SFDA 2012).

Foreign-owned companies have recently increased their investment in manufacturing within the country—for example, new investments have been announced by Merck Sharp & Dohme, Sanofi, and AbbVie. While some foreign partnerships are restricted to secondary packaging of medicines made elsewhere, others involve the production under the license of branded products for both the domestic market and export (A.T. Kearney 2016; BMI Research 2018; IQVIA 2019b).

Plans to further expand the sector may be constrained by limited technical expertise. As detailed in Section 11 on Human Resources, Saudi schools of pharmacy remain focused on clinical pharmacy and somewhat neglect the skills most needed by industry. In a survey of over 90 percent of final-year students in the Pharmacy program at King Saud University, 83 percent said they had no practical training related to industry, 17 percent felt that they had the knowledge and the skills to work in the pharmaceutical industry after graduation, and just 8.2 percent chose industry as their top career choice (Bin Saleh et al. 2015).

The Saudi Food and Drug Authority (SFDA) regularly inspects production sites throughout KSA; compliance with current good manufacturing practice appears high, and several production sites have received good manufacturing practice certification from the European Medicines Agency (European Medicines Agency 2019). The agency's actions signal its determination to ensure the quality of locally produced medicines. For example, in 2018, the SFDA investigated

physician reports of lack of therapeutic efficacy of two locally manufactured generic clopidogrel products. Having established lack of bioequivalence with the reference product (Plavix), the agency withdrew market authorization. More recently, the agency announced the recall of all aspirin marketed under the brand "Jusprin 81mg," made by Gulf Pharmaceutical Industries/ Julphar, because of unspecified quality defects (A. S. Alsultan and Hakeam 2018; SFDA 2019a).

8.4 The National Pharmaceutical Industry: National Policy

There is an explicit strategy for development of the biopharmaceutical industry in KSA under the National Industrial Development and Logistics Program NIDLP. By leveraging the existing ecosystem, the industry is in a good position to serve national and regional clients.

The Local Content and Government Procurement Authority (LCGPA) will set policies stimulating technology transfer and guiding government purchasing of all goods including pharmaceuticals, aiming at increasing the market share of locally manufactured pharmaceuticals.

Fiscal authorities will take into account policies to incentivize domestic production and sourcing when calculating budgets, aiming to ensure that they are neutral in terms of public financing for health.

PHARMACEUTICAL SECURITY AND EMERGENCY RESPONSE

9

9.1 Pharmaceutical Security and Emergency Response: Policy Goals

In times of national crisis, such as in the wake of a natural disaster, a major industrial accident, or in the event of a hostile attack, medicines are often urgently needed. And yet it is at exactly these times that the normal channels for producing, verifying, procuring, and distributing medicines break down. A pharmaceutical security and emergency response policy aims to maintain up-to-date and robust systems and easily accessible resources that will allow for the rapid procurement and delivery of medicines if disaster strikes.

9.2 Pharmaceutical Security and Emergency Response: Policy Considerations

The nature of disasters is that they are rarely predictable. It is therefore difficult to plan ahead; we cannot know which medicines will be needed, or where they must be delivered. In addition, medicines have a relatively short shelf-life and must be correctly stored. Excessive stockpiling is therefore likely to be wasteful. On the other hand, medicine procurement cycles tend to be rather long—far too long to allow for a rapid response on a business-as-usual model.

Deviating from business as usual, however, carries its own risks. Bypassing normal procedures of quality assurance can open the door to substandard medicines, while stepping out of the regulated supply chain in response to emergencies is often associated with the introduction of falsified products (WHO 2017c). It is therefore important to "plan for the unplanned," for example, by developing financing instruments and framework procurement contracts (including with international organizations that may be less incapacitated by a localized disaster) that can be triggered in the event of an emergency.

Disaster response is best carried out by the institutions that already have expertise in the relevant functions. However, they will often have to deviate from their normal operating procedures to allow for more rapid action. It is therefore common to have emergency plans in place, and a small number of staff trained and authorized to act quickly once an emergency has been declared. Since an unusually high level of coordination among different agencies and sectors is often required,—often in a situation where communication in rendered difficult by disruptions to infrastructure—it is also common for those trained individuals to be mobilized by a specially designated national crisis response unit, which usually answers directly to the highest authorities.

9.3 Pharmaceutical Security and Emergency Response: Status Quo and Implementation Issues

There are not currently any formal pharmaceutical security plans in place in KSA. However, the National Risk Unit has been designated as the responsible body to coordinate responses of all sectors in the case of national disasters, natural and otherwise.

The National Unified Procurement Company (NUPCO) currently maintains a stockpile of essential medicines that can be quickly mobilized; the Saudi Health Council (SHC), the Saudi Food and Drug Authority (SDDA), the Ministry of Health (MOH), and other partners also plan to review a list of medicines most likely to be needed in emergencies, and to consider rapid financing instruments.

9.4 Pharmaceutical Security and Emergency Response: National Policy

The National Risk Unit is responsible for budgeting, planning, and coordinating all activities aimed at securing and rapidly mobilizing medical supplies in cases of emergencies or national disasters.

Those activities will be implemented by the relevant sectors. Disaster preparedness (such as maintenance of formularies and contracts allowing for rapid procurement) will be integrated into the routine activities of each sector. Each sector will also designate staff for training and mobilization in cases where an emergency response is mobilized by the National Risk Unit.

DATA SYSTEMS – MONITORING AND REVIEW

10

10.1 Data Systems – Monitoring and Review: Policy Goals

Appropriate analysis of data generated within the health system—as well as data from other sources, including those related to production costs, currency rates, trade, and industry—is a vital tool in maintaining a sufficient supply of necessary medicines that are safe and cost-effective. Data policies aim to facilitate efficient collection and compilation of these data and to encourage their active and timely use in decision-making, while protecting the privacy of patients and other actors.

Data systems also provide information that can indicate whether the National Medicine Policy is achieving its aims. Policy documents provide high-level guidance for the medium term. Especially in a highly dynamic environment, they aim to combine flexibility with a steady hand. Regular monitoring of implementation will allow for corrections to be made as appropriate, without requiring disruptive changes in direction.

10.2 Data Systems – Monitoring and Review: Policy Considerations

Reliable real-time data are essential for demand forecasting as well as for the efficient management of medical products in the supply chain and in diagnostic or therapeutic application. They are also needed for monitoring compliance with medicine policy. Data, at the necessary level of granularity, need to be easily accessible to decision-makers in managerial and clinical positions. While data systems by nature promote transparency, those related to medical records and pharmaceutical use must at the same time protect patient privacy.

Pressure for greater transparency around public procurement and pharmaceutical pricing is mounting globally, although price transparency is being met with fierce resistance from the pharmaceutical industry. Though norms are changing, there may be a case for continuing to treat some forms of data as confidential. However, this does not mean it they cannot be shared with trusted partners for purposes of national program planning and monitoring.

Recent technological advances, including barcoding and data-matrix systems, standardized metadata, and common data exchange protocols, have made it far easier to collect and share data. However, in many settings, technology has changed far more quickly than human or institutional culture. Vested interests—institutional, commercial, and personal—very often stand in the way of effective sharing of data. The more fragmented a health sector is, the more difficult it is to establish a successful data platform to facilitate management of patients or pharmaceuticals. Institutional and commercial rivalry in fragmented health systems explain the failure to implement planned pharmaceutical track-and-trace systems in China and the United States (Pisa and McCurdey 2019).

For manufacturers and importers, there are also cost and logistical implications associated with the implementation of data-matrix or other tracking systems. Where complying with national track-and-trace requirements is burdensome or expensive, companies may choose not to participate. This creates risks for smaller markets imposing country-specific regulations. However, these risks will diminish if countries coalesce around agreed global standards.

Full track-and-trace allows for transparent and efficient inventory management. It flags stock-outs and provides early warning of potential shortages, and allows for easy tracking of consumption patterns. Combined with electronic patient records and demographic data, it forms the core of demand planning. And while it does not provide information on the quality of medicines acquired from legitimate manufacturers or importers, it protects against the injection of falsified products into the national supply chain.

Turkey is so far the only country to successfully implement full track-and-trace through its pharmaceutical supply chain. The impetus for the program was the reduction of fraud in the national health insurance system. In 2007, four years into the implementation of the consolidated national system, this fraud was thought to be costing the state US$1 billion annually, enough to spark very strong political commitment to reform. The successful implementation of the system was dependent on a conjunction of the following factors: 1) a pharmaceutical market large enough to remain attractive to producers even after they invested in new packaging requirements; 2) control of 85 percent of that market by a single payer, who could thus call the shots; 3) near-universal reimbursement of medicines sold in pharmacies, meaning that consumers had no incentive to buy outside of the regulated supply chain; and 4) reimbursement of pharmacists based on prescriptions scanned, meaning that pharmacists were strongly incentivized to scan every sale (Pisa and McCurdey 2019).

While technology and data-sharing platforms offer a great deal, their actual utility is often undermined by a dire lack of investment in human beings. Even big data approaches offer little unless the data are interpreted and acted upon by humans trained to analyze the data, and unless there exist adequate communications mechanisms that allow their analysis to be translated into management and procurement decisions.

Data should also be used for the monitoring, regular review, and continuous improvement of procurement practices and medicine-related policies. Challenges in policy monitoring include the definition of appropriate, measurable indicators and the establishment of timeframes in which measurable changes can realistically expect to occur as a result of policy implementation. Perhaps the greatest challenge in an area that involves so many key institutions is the establishment of clear lines of accountability. In other words, when data systems identify problems or shortcomings, it should be clear whose job it is to rectify them.

Issues of causality are often raised, especially in the case of perverse or unexpected outcomes. It is not always easy to differentiate between the wrong policy and the right policy, poorly or insufficiently implemented. Where suspicion falls on poor implementation rather than misguided policy choices, evaluators should seek to understand the reasons for that poor implementation. These reasons may be political or structural; in this case, technical solutions alone will probably do little to improve the situation.

10.3 Data Systems – Monitoring and Review Status Quo and Implementation Issues

The various sectors of KSA's public health system do not currently share a common data platform. Indeed even within sectors, data use is poor, according to the Ministry of Health (MOH), which notes the challenge to quality of care posed by "lack of transparency and limited

documented information about patients, health practices, and costs" (MOH 2018a).

A 2014 study by Hasanain et al, found that only 14 of 27 hospitals in Riyadh used electronic patient records, while just 10 had computer-based data entry systems for ordering medicines. A separate study in a large specialist hospital in the city found that most pharmacists did not become aware of impending shortages until the shelf was completely emptied of a particular medicine. Reporting of shortages to the Saudi Food and Drug Authority (SFDA) is also far from complete, as discussed in Section 7 on procurement and supply (Yazed Sulaiman Alruthia, AlKofide, et al. 2017; Yazed Sulaiman Alruthia, Mansy, et al. 2017).

The National Transformation Program (NTP) aims to increase the use of individual electronic medical records to 70 percent by 2020 (MOH, no date). The use of GS1-based pharmaceutical tracking systems has been planned since at least 2014.

At a meeting on medicine shortages held in Riyadh in February 2018, stakeholders pointed to poor stock management as a continuing problem in KSA, suggesting that the technology was not yet meeting its goals (Yazed S. Alruthia et al. 2018). In late 2019, the SFDA issued detailed guidance on requirements for GS1 barcoding of products, including aggregation to pallet-level packaging (SFDA 2019c). With new, clear guidance and continuing implementation, the situation may thus be expected to improve.

In terms of monitoring the medicine policy, no clear indicators as yet exist. The choice of feasible indicators will depend very heavily on the scope and effective implementation of data systems. The schedule for monitoring and policy review will be determined by the speed of implementation of changes across the health and industrial sectors. It may be necessary to monitor the medicine policy on a modular basis.

10.4 Data Systems – Monitoring and Review: National Policy

The responsible authorities will mandate related sectors to share the information necessary for the effective monitoring of this medicine policy. They may also encourage the establishment or consolidation of registries and other data collection systems, for example to inform health technology assessments (HTAs) or improve monitoring of cost-effective use of medicines.

The Saudi Health Council (SHC) will establish an expert group that will be tasked with monitoring progress in implementing this policy, maintaining a stakeholder dialogue around the policy, and updating it on a regular basis. The monitoring group will also recommend specific actions needed to improve the implementation of the policy.

Led by the SFDA, the government will continue to implement a single system for tracing the passage of medicines through each point of the supply chain, from manufacturer or importer to point of dispensation. Implementation of the system may be phased, but it will eventually be mandatory for all transactions involving medicines in KSA.

The government will provide training and other support to facilitate the implementation of this electronic system throughout the supply chain. Data will be made available to all users at the level required for their own stock control, inventory management, procurement, and decision-making purposes. Access controls will be implemented to protect confidential information from unauthorized users.

The responsible authorities will ensure adequate human and other resources to ensure data are used to support national planning and procurement goals and will facilitate the sharing of data with bodies mandated to perform HTAs and to otherwise contribute to the implementation and monitoring of the national medicine policy.

11 HUMAN RESOURCES

11.1 Human Resources: Policy Goals

Policy and strategies are implemented by people, therefore strategic success depends employing enough people with the right training, skills, opportunity, and motivation to perform their roles fully. Human resource policies aim to shape this mix so that the needs of the developing pharmaceutical sector are appropriately filled in the short, medium, and long term.

11.2 Human Resources: Policy Considerations

In many countries, curricula for the training of health professionals are determined by academic institutions, often with input from senior members of professional associations. This ensures stability and allows for the incorporation of experience. However, since experience is by definition shaped by the past, it can also act as a brake on innovation. Where a country aims to transform its economy and professions, external guidance (for example from government planning departments) can help to ensure that curricula are developed to meet evolving as well as existing needs.

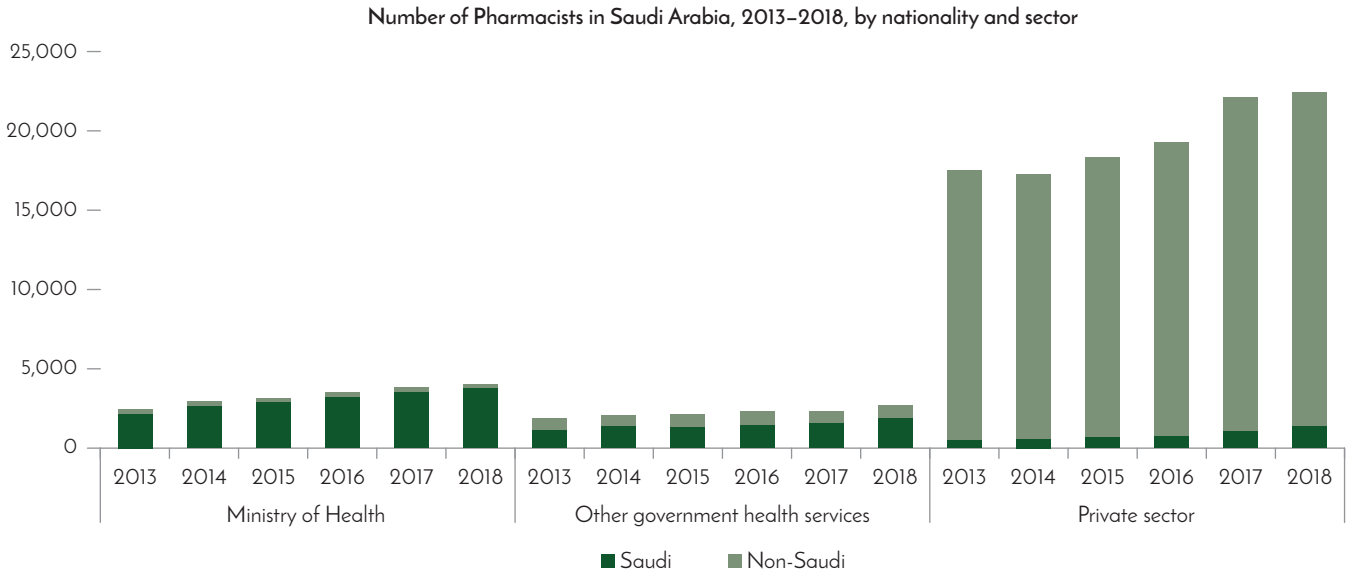
The skills most necessary to the successful implementation of a modern medicine policy include competence in pharmaco-economics, health systems planning, procurement, logistics and data management, industrial chemistry, clinical pharmacology, and regulatory science.

Human resource development is about more than education and skills training. However, because even the best trained people contribute little to the field if they have no opportunity or motivation to use their skills, policy makers must try to match skills with both needs and opportunities. This can be hard to achieve in a dynamic economy, where existing jobs (especially at a senior level) are often filled with people who were trained for a previous system.

11.3 Human Resources: Status Quo and Implementation Issues

There are currently 28 pharmacy schools in KSA, with around 1,500 annual graduates. The curricula in all of these schools are dominated by clinical pharmacology. Although some of the skills necessary in the evolving pharmaceutical sector may be acquired in other faculties, for example schools of economics or public health, the current system does seem to result in a mismatch between newly minted skills and emerging needs, with pharmaco-economists and industrial pharmacologists in particularly short supply (Bin Saleh et al. 2015). In 2017, just 11 percent of all pharmacists working in Saudi Arabia were employed in scientific offices, industry, and medical warehousing (MOH 2018b).

FIGURE 4 **PHARMACISTS EMPLOYED IN SAUDI ARABIA, BY NATIONALITY AND SECTOR**



Source: Kingdom of Saudi Arabia, Ministry of Health.

The mismatch between needs and motivation is greater still. In a 2018 survey of 411 pharmacy students, over half wished to practice in hospital pharmacies, with a further quarter aiming for posts in academic institutions. Fewer than 2 percent expressed any desire to work in a community pharmacy, in large part because they did not think such work would meet their salary expectations of SAR 12,000 a month (US$3,200). Students' expectations are sensible given that close to half of the respondents in another study of community pharmacists reported monthly salaries under SAR 5,000 (Alhomoud et al. 2019; Almaghaslah et al. 2019).

Currently, most Saudi pharmacists are indeed employed in hospital pharmacies, while, as Figure 4 shows, community pharmacies are overwhelmingly staffed by expatriates, despite provisions in the Law of Pharmaceutical Establishments and Preparations, which stipulates that pharmacies must be both owned and managed by Saudi nationals licensed to practice pharmacy.

Just over 1,000 expatriate pharmacists are currently employed in public sector hospital pharmacies—some 16 percent of the public sector total. That compares with over 21,000 employed in community pharmacies. The majority of these trained in Egypt, and almost all are men.

The role of community pharmacists will certainly grow if plans outlined in the National Health Transformation Plan to dispense all outpatient medicines through community pharmacies are realized. In order to achieve this goal, while simultaneously supporting the government's plans for Saudization of the workforce, policies may need to be adopted that make the sector more attractive to Saudi pharmacists, including the roughly 600 women who graduate each year from national pharmacy schools. In 2018, a conference on the future of the health workforce convened by the Saudi Commission for Health Specialties (SCFHS) recommended that female pharmacists be allowed to work in at least those community pharmacies that are located in malls (Almaghaslah et al. 2019).

Existing regulations requiring the employment of Saudi managers appear to have had little effect; it is possible that policies may wish to consider using positive incentives for the employment of Saudi citizens in community pharmacies.

As the discussion on prescribing practices in Section 4 on the Appropriate Use of Medicines made clear, the awareness of physicians about pharmaceutical policy is also rather low, with scant thought given to cost-effectiveness and little attention paid to the potential dangers of polypharmacy, while recordkeeping and data management are poor throughout the health system. As the country revises its plans for developing human resources for health, it will be important to ensure that information and education related to pharmaceuticals, including their cost-effective prescription and accurate recording and reporting of costs and adverse outcomes, are also embedded in the training of physicians, nurses, and health facility managers.

11.4 Human Resources: National Policy

The responsible authorities will develop guidance for education and training curricula that meet the evolving needs of the pharmaceutical sector and will support the introduction of such curricula.

Education and training across the medical and health sector will support medicine policy goals, including cost-effective use of medicines.

Employment regulations will consider the needs of the sector, including those shaped by the evolution of health service delivery, and will endeavor to incentivize the development and deployment of appropriate skills.

PART II

Medicine Policy 2020

Introduction

Policy for the medicines sector touches many parts of the health sector and overlaps with policies for other sectors, such as finance and industry.[2] This policy defines a high-level framework for legislation, regulation, and decision-making, and expresses general goals and principles for the sector. The policy aims to harmonize and coordinate the activities of the institutions in the sector, achieve maximum benefit for the population, and deliver value for the public and private funds spent on medicines.

The development of this guiding policy was coordinated by the Saudi Health Council (SHC), in consultation with the relevant stakeholders of the Saudi health sector. It aims to harmonize the work of the many institutions involved, considering the expertise and mandate of each. It also aims to avoid both contradictions and excessive duplication. A previous policy drafted by Saudi Food and Drug Authority (SFDA 2016) was used as an input into this document.

Specific strategies that allow for the implementation of the policy will be developed by each of the sectors. The SHC will provide support in helping sectors advocate for necessary resources, set realizable time frames, and prioritize policy implementation to focus first on areas that promise to deliver the largest impact, within a reasonably quick time frame. The SHC will also work with other institutions to monitor the ongoing implementation of the policy, anticipating and working to avoid or resolve potential obstacles, and reviewing and adjusting the policy as necessary.

Regulatory and Institutional Arrangements

The SHC maintains overall responsibility for development of the cross-sectoral policy framework for medicines. The SHC will work with all sectors to monitor the implementation of the policy, to evaluate its impact, and to revise it as necessary.

For each specific area of policy implementation, a lead institution will be mandated to develop implementation strategies. In addition, specified institutions will support policy implementation, or provide information to allow for policy goals to be met effectively.

In the initial stages of policy implementation, lead roles are specified as follows:

Saudi Health Council

- Oversee the development of the national medicine policy, in consultation with all

[2] The term *medicines* is used in this document to include pharmaceuticals, vaccines, biologics, and consumables used in treating patients. It does not include diagnostics or medical devices.

concerned sectors. Ensure the policy's timely adoption.

- Plan and mandate cross-sectoral data contribution that will allow for the efficient monitoring and revision of the policy.
- Review data analysis and revise policy as necessary, in consultation with all concerned institutions, on a predefined schedule.
- Lead cross-sectoral consultation to define emerging policy needs and questions.
- Collate and analyze medicines data on behalf of the SHC, to guide the monitoring and revision of the medicine policy.

Saudi Food and Drug Authority

- Organize and manage the processes of registration, renewal and variations of pharmaceutical preparations (human, veterinary and herbal).
- License the processes of manufacturing, importing, exporting, distributing, promoting and advertising of medicines.
- Inspect pharmaceutical manufacturing sites.
- Assess the safety, efficacy and quality of pharmaceutical preparations and issue marketing authorization.
- Take on responsibility for Pharmaceutical pricing, pricing review, and evaluation of economic and clinical comparison studies in treatment groups.
- Monitor Narcotic drugs, psychotropic substances and controlled preparations and ensure compliance with relevant regulations and procedures.
- Develop and manage policies, regulations and guidelines for pharmaceutical preparations.
- Conduct post-marketing surveillance of pharmaceuticals and ADR monitoring (Pharmacovigilance).
- Secure pharmaceutical product supply in the Saudi market and monitor and address supply shortages.
- Track medicines throughout the supply chain (RASD) to reduce fraud and ensure their safety and availability

Ministry of Health

- Oversee the development of clinical guidelines in all major therapeutic areas.
- Develop, monitor, and enforce regulations to promote cost-efficient prescribing and dispensing, including INN substitution.

Center for Health Technology Assessment

- Undertake HTA assessment of new technologies to inform reimbursement decision-making either for public or private payers
- Establish and revise guidelines, and update HTA country method
- Establish guidelines for managed entry agreement between payers and manufacturers.

National Unified Procurement Company

- Plan demand for the public sector.
- Procure medicines for the public sector, considering policies on local content.
- Manage the public sector supply chain.
- Undertake "market making" for low-profit medicines.
- Maintain framework contracts for procurement and distribution of medicines in emergencies and disasters.
- Maintain the national stockpile of medicines.

Public payer

- Develop reimbursement formularies.
- Develop regulations to promote cost-efficient prescribing, including INN prescriptions, for reimbursement.
- Negotiate reimbursement prices for high-value medicines.

Private payers

- Develop reimbursement formularies, based on guidance and governance by the Council of Cooperative Health Insurance (CCHI).

Academic institutions and Saudi Commission for Health Specialties

- Take responsibility for curriculum development, workforce licensing, training and continued education and professional development.

National Risk Unit

- Ensure that lead organizations integrate disaster preparedness into their respective roles, as described above.
- Coordinate work of those organizations in the event of a disaster, including by maintaining a rapid data exchange platform and command center.
- Lead public communication related to medicines in the event of a disaster.

Selection of Medicines

Medicines available to patients in the Kingdom of Saudi Arabia (KSA) should have a marketing authorization from the SFDA, issued once the product has satisfied the criteria for safety, efficacy, and quality.

The responsible authorities will develop/maintain a national list of medicines, including essential medicines, based on INN.

A national reimbursement formulary will list medicines selected for coverage through public funding. This will provide guidance across all sectors of the public health system.

In selecting medicines for inclusion in the reimbursement formulary, experts will take an inclusive approach, considering costs, benefits, and relative value of different therapies, along with treatment guidelines and guidelines issued by the Saudi Local Content and Government Procurement Authority (LCGPA).

The Center for Health Technology Assessment will develop medium-term demand forecasts for emerging therapies, based on changing epidemiology and health utilization patterns. It will coordinate horizon scanning for new products, and assess costs and benefits using established HTA procedures. These assessments will be based on cost and outcome data from public and private providers, in accordance with a mandate established by the responsible authorities.

Appropriate Use of Medicines

The Ministry of Health (MOH), working inclusively with professional and expert bodies, will continue to provide updated national clinical practice guidelines based on the latest peer-reviewed evidence, including locally specific evidence where epidemiologically warranted. These guidelines, which include recommendations for medicines use, may be adapted to meet the needs of different public and private sectors.

The responsible authorities will expand efforts to encourage and incentivize the prescribing, dispensing, and use of quality-assured generic or biosimilar medicines where appropriate. They will introduce measures to incentivize INN-based prescribing, develop clear guidance on therapeutic substitutes, and consider media and education campaigns targeting patients, prescribing physicians, and pharmacists as appropriate.

Education in value-based prescribing and dispensing will be strengthened in national curricula, and policies and regulations related to appropriate use of medicines will be emphasized in conversion courses and examinations for expatriate pharmacists.

Pricing of Medicines

The SFDA regulates retail prices for all medicines, in order to limit out-of-pocket spending on medicines. This regulation will occur in ways that do not unduly delay market entry for new medicines.

Financing and Reimbursement of Medicines

The responsible authorities will ensure that provisions for public financing of medicines are based on the latest data-based demand forecasts made by all public sectors based on the reimbursement formulary.

NUPCO will manage the reimbursement of prescription medicines through community pharmacies, prescribed by public providers.

Reimbursement mechanisms, including schemes regulated by the CCHI, will seek to maximize the use of cost-effective medicines, including reference to formularies and defined benefits packages as appropriate. These mechanisms may include the introduction of co-payments, without prejudicing the ability of lower-income populations to access effective, quality-assured medicines.

Negotiations to increase access to expensive, single-source medicines through managed entry agreements will be led by purchasing bodies at the national level, informed by data provided by all sectors, and in collaboration with the Center for Health Technology Assessment.

Procurement, Supply, and Accessibility of Medicines

NUPCO will procure reimbursable medicines provided through public sector institutions, considering procurement policies and guidelines issued by the Saudi LCGPA.

For medicines dispensed by public facilities, NUPCO will organize procurement through an e-procurement platform that allows for transparent bidding or auctions, leading to framework contracts with suppliers. Under these contracts, decentralized budget holders can order directly from the supplier (manufacturer or distributor).

Consolidated purchasers will use their purchasing power in a way that secures a functioning market and a secure supply, for example by splitting contracts between two or more manufacturers to avoid oligopoly or monopoly situations.

The government of KSA will work with other governments and multilateral organizations in support of market making initiatives that ensure a stable supply of medicines with limited global availability.

NUPCO will operate under a set of defined quantitative performance parameters and issue a yearly public report on progress toward achieving these parameters.

As a condition of granting market authorization or certifying importers and distributors for good practice, the SFDA will require the proactive reporting of anticipated disruptions to the supply of registered medicines.

NUPCO will ensure that stocks of essential medicines are available nationwide and rapidly accessible at the patient level.

The National Pharmaceutical Industry

There is an explicit strategy for development of the biopharmaceutical industry in KSA under the

National Industrial Development and Logistics Program (NIDLP). By leveraging the existing ecosystem, the industry is in a good position to serve national and regional clients.

The LCGPA will set policies stimulating technology transfer and guiding government purchasing of all goods including pharmaceuticals, aiming at increasing the market share of locally manufactured pharmaceuticals.

Fiscal authorities will take into account policies to incentivize domestic production and sourcing when calculating budgets, aiming to ensure that they are neutral in terms of public financing for health.

Pharmaceutical Security and Emergency Response

The National Risk Unit is responsible for budgeting, planning, and coordinating all activities aimed at securing and rapidly mobilizing medicines supplies in cases of emergencies or national disasters.

Those activities will be implemented by the relevant sectors. Disaster preparedness (such as maintenance of formularies and contracts allowing for rapid procurement) will be integrated into the routine activities of each sector. Each sector will also designate staff for training and mobilization in cases where an emergency response is mobilized by the National Risk Unit.

Data Systems – Monitoring and Review

The responsible authorities will mandate related sectors to share the information necessary for the effective monitoring of this medicine policy. They may also encourage the establishment or consolidation of registries and other data collection systems, for example to inform HTA or improve monitoring of cost-effective use of medicines.

The SHC will establish an expert group that will be tasked with monitoring progress in implementing this policy, maintaining a stakeholder dialogue around the policy, and updating it on a regular basis. The monitoring group will also recommend specific actions needed to improve the implementation of the policy.

Led by SFDA, the government will continue to implement a single system for tracing the passage of medicines through each point of the supply chain, from manufacturer or importer to point of dispensation. Implementation of the system may be phased, but it will eventually be mandatory for all transactions involving medicines in KSA.

The government will provide training and other support to facilitate the implementation of this electronic system throughout the supply chain. Data will be made available to all users at the level required for their own stock control, inventory management, procurement and decision-making purposes. Access controls will be implemented to protect confidential information from unauthorized users.

The responsible authorities will ensure adequate human and other resources to ensure data are used to support national planning and procurement goals and will facilitate the sharing of data with bodies mandated to perform health technology assessments (HTAs) and to otherwise contribute to the implementation and monitoring of the national medicine policy.

Human Resources

The responsible authorities will develop guidance for education and training curricula that meet the evolving needs of the pharmaceutical sector and will support the introduction of such curricula.

Education and training across the medical and health sector will support pharmaceutical policy goals, including cost-effective use of medicines.

Employment regulations will consider the needs of the sector, including those shaped by the evolution of health service delivery, and will endeavor to incentivize the development and deployment of appropriate skills.

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