POLICY ELEMENT	IMPLEMENTATION STATUS (MAY 2022)			COMMENTS
	Implemented	In progress	Planned	
Regulatory and Institutional Arrangements				
The SHC will work with all sectors to monitor the implementation of the policy, evaluate its impact, and revise it as necessary.	☐	☑	☐	Indicators under development
For each specific area of policy implementation, a lead institution will be mandated to develop implementation strategies.	☐	☑	☐	Further assent needed to formalise roles for some institutions
Saudi Health Council: Oversee the development of the national medicine policy, in consultation with all concerned sectors. Ensure the policy's timely adoption.	☑	☐	☐	
Saudi Health Council: Collate and analyze medicines data to guide the monitoring and revision of the medicine policy.	☐	☐	☑	Need Saudi Health Council board approval
SFDA: Organize and manage the processes of registration, renewal and variations of pharmaceutical preparations (human, veterinary and herbal).	☑	☐	☐	
SFDA: License the processes of manufacturing, importing, exporting, distributing, promoting and advertising of medicines.	☑	☐	☐	
SFDA: Inspect pharmaceutical manufacturing sites.	☑	☐	☐	
SFDA: Assess the safety, efficacy and quality of pharmaceutical preparations and issue marketing authorization.	☑	☐	☐	
SFDA: Take on responsibility for Pharmaceutical pricing, pricing review, and evaluation of economic and clinical comparison studies in treatment groups.	☑	☐	☐	
SFDA: Monitor Narcotic drugs, psychotropic substances and controlled preparations and ensure compliance with relevant regulations and procedures.	☑	☐	☐	
SFDA: Develop and manage policies, regulations and guidelines for pharmaceutical preparations	☑	☐	☐	
SFDA: Conduct post-marketing surveillance of pharmaceuticals and ADR monitoring (Pharmacovigilance).	☑	☐	☐	
SFDA: Secure pharmaceutical product supply in the Saudi market and monitor and address supply shortages.	☑	☐	☐	
SFDA: Track medicines throughout the supply chain (RASD) to reduce fraud and ensure their safety and availability	☑	☐	☐	
SFDA: Regulate and approve clinical trials on medicines in Saudi Arabia	☑	☐	☐	
Ministry of Health: Oversee the development of clinical guidelines in all major therapeutic areas.	☑	☐	☐	
Ministry of Health: Develop, monitor, and enforce regulations to promote cost-efficient prescribing and dispensing, including international nonproprietary name (INN) substitution.	☐	☑	☐	Indicators under development
Center for Health Technology Assessment: Undertake HTA assessment of new technologies to inform reimbursement decision-making either for public or private payers	☐	☐	☑	Capacity building and governance structures needed

Center for Health Technology Assessment: Establish and revise guidelines, and update HTA country method	☐	☐	☑	Capacity building and governance structures needed
Center for Health Technology Assessment: Establish guidelines for managed entry agreement between payers and manufacturers.	☐	☑	☐	Capacity building and governance structures needed
National Unified Procurement Company: Plan demand for the public sector.	☑	☐	☐	
National Unified Procurement Company: Procure medicines for the public sector, considering policies on local content.	☑	☐	☐	
National Unified Procurement Company: Manage the public sector supply chain.	☑	☐	☐	
National Unified Procurement Company: Undertake “market making” for low-profit medicines.	☐	☐	☑	Further study needed to select these medicine and incentives
National Unified Procurement Company: Maintain framework contracts for procurement and distribution of medicines in emergencies and disasters.	☐	☑	☐	List of medicines may be expanded
National Unified Procurement Company: Maintain the national stockpile of medicines.	☑	☐	☐	
Public payer: Develop reimbursement formularies.	☐	☐	☑	Reimbusement policy not yet finalised
Public payer: Develop regulations to promote cost-efficient prescribing, including INN prescriptions, for reimbursement.	☐	☐	☑	Reimbusement policy not yet finalised
Public payer: 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 Disaster Council: Ensure that lead organizations integrate disaster preparedness into their respective roles.	☑	☐	☐	
National Disaster Council: Coordinate work of those organizations in the event of a disaster, including by maintaining a rapid data exchange platform and command center.	☑	☐	☐	
National Disaster Council: Lead public communication related to medicines in the event of a disaster.	☑	☐	☐	
Selection of Medicines				
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.	☐	☑	☐	Essential Medicine List exists; broader national formulary under development
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, and will considering costs, benefits, and relative value of different therapies, along with treatment and procurement guidelines.	☐	☐	☑	Requires finalisation of reimbursement policies, and development of governance structures.

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.	☐	☐	☑	Capacity building and governance structures needed
Appropriate Use of Medicines				
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.	☐	☑	☐	Completed for many conditions
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.	☐	☐	☑	Further research and curriculum development needed
Pricing of Medicines				
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	☐	☐	☐	
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.	☑	☐	☐	
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.	☑	☐	☐	
Procurement and Supply of Medicines	☐	☐	☐	
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.	☐	☑	☐	
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	☐	☐	☐	
There is an explicit strategy for development of the biopharmaceutical industry in KSA under the National Industrial Development Center (NIDC)	☐	☑	☐	Implementation guidelines under development
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.	☐	☐	☑	Will be implemented as necessary, following developments in the domestic pharmaceutical sector.
Pharmaceutical Security and Emergency Response	☐	☐	☐	
The National Disaster Council is responsible for budgeting, planning, and coordinating all activities aimed at securing and rapidly mobilizing medical supplies in cases of emergencies or national disasters.	☐	☐	☑	Research needed to finalise list of priority supplies; governance mechanisms need further development
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 Disaster Council.	☐	☑	☐	
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.	☐	☑	☐	
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.	☐	☐	☑	National Committee must be formalised before this can be fully implemented
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.	☑	☐	☐	

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.	☑	☐	☐	
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.	☐	☐	☑	Research to identify the appropriate mix of skills needed before curricula can be developed
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.	☐	☐	☑	Research to identify the appropriate mix of skills needed before appropriate regulations can be developed
SFDA: Saud Food and Drug Authority				