

Governance of the pharmaceutical sector

A stylized graphic of a globe, composed of several overlapping, curved lines in shades of blue and grey, positioned in the lower-left quadrant of the slide.

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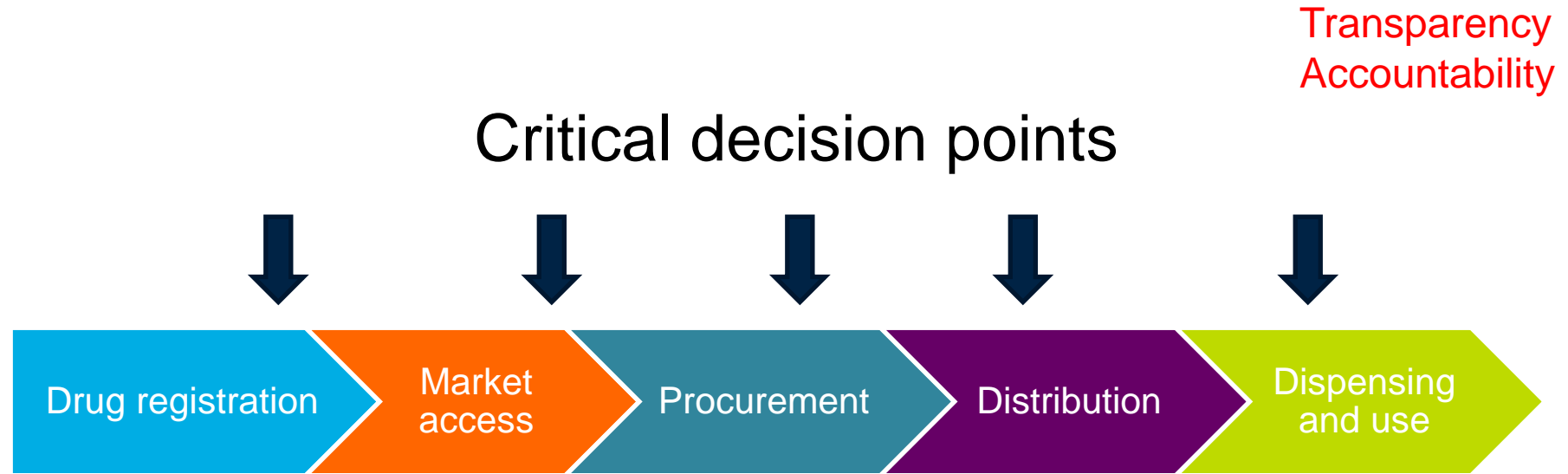
Governance definition

- The totality of ways in which a society organizes and collectively manages its affairs
- The sum of institutions, policies, rules, practices, norms, laws, procedures, initiatives...
- Go beyond governing and political authority
- More or less formal, more or less visible

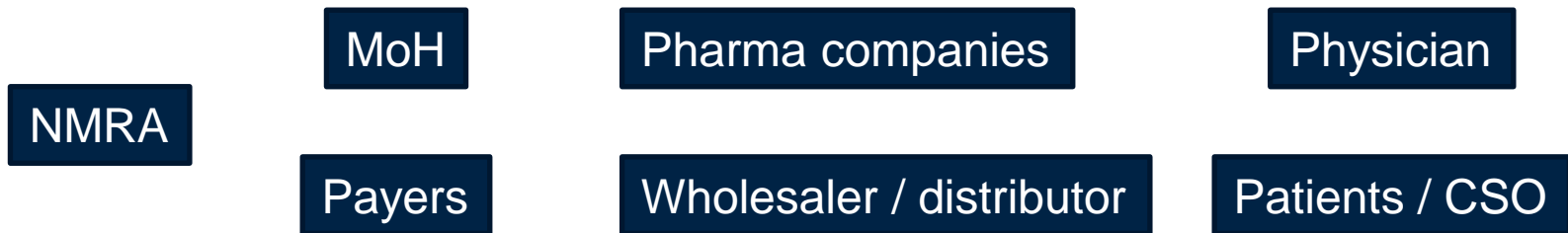
Governance in the pharmaceutical sector:

- Is complex and involves many stakeholders
- Deals with critical and high value input for health delivery systems
- Aims to manage a very lucrative business

The pharmaceutical value chain as a framework to assess governance



Various stakeholders



Medicines registration

- Need for transparent, effective and uniform laws for drug registration
- One potential source of market failure: disputable quality drugs registered, too long to approve, too few medicines approved....
- Critical role of National Medicines Regulatory Authorities (NMRAs)
- The balance between stringency and effectiveness is not easy to strike (e.g. Saudi FDA)

Market access (pricing and reimbursement)

- Generics pricing mechanisms
 - Price reductions set by government may not achieve the best value for money (e.g. 20 to 30% discount in UAE)
 - Subsequent price reductions for new entrants may limit competition
 - Different procedures are possible – make sound decisions, learn from peers
- Formulary inclusion
 - Critical step for many stakeholders and at risk of corrupt practices
 - Transparency is critical (criteria, selection committee membership and activities...) – example of Jordan Rational Drug List
- Pharmaceutical benefits in health insurances
 - Providing coverage for medicines
 - Controlling costs (payment, prescribing patterns, use)

Public procurement

- Highly formal procedures to prevent corruption and optimize value for money, sometimes at the expense of agility (which may put availability at risk)
- Transparency on supplier selection and bidding process required
- Technical expertise for prequalification activities may be required to compensate sometimes weak regulatory capabilities
- Preference for domestic manufacturers can limit the efficiency of the procurement process (e.g. Algeria)

Wholesale and distribution

- Develop information systems to ensure medicines are allocated, transported and stored adequately
 - Track and Trace systems (Turkey, Saudi Arabia...)
- Regulate wholesalers margin and value chain
 - Ensure affordability of medicines to patients
 - Avoid unnecessary wholesale-to-wholesale business
 - Regressive margins to favor generics medicines
- Regulatory oversight indispensable to ensure supply chain integrity but difficult to achieve
 - Limited resources of NMRAs
 - Vast and difficult geographies (e.g. Egypt)

Dispensing and use

- Promotion of rational use, respecting essential drug lists
 - E.g., antibiotic dispensing in Egypt
- Always a challenge to enforce drug outlets and point-of-sale regulation
 - Accredited outlets, pharmacy franchising as a solution to foster the formal market providing high quality medicines
 - Role of civil society organizations and citizens oversight
- Pharmacy benefit managers as third parties managing costs hence dispensing patterns and use

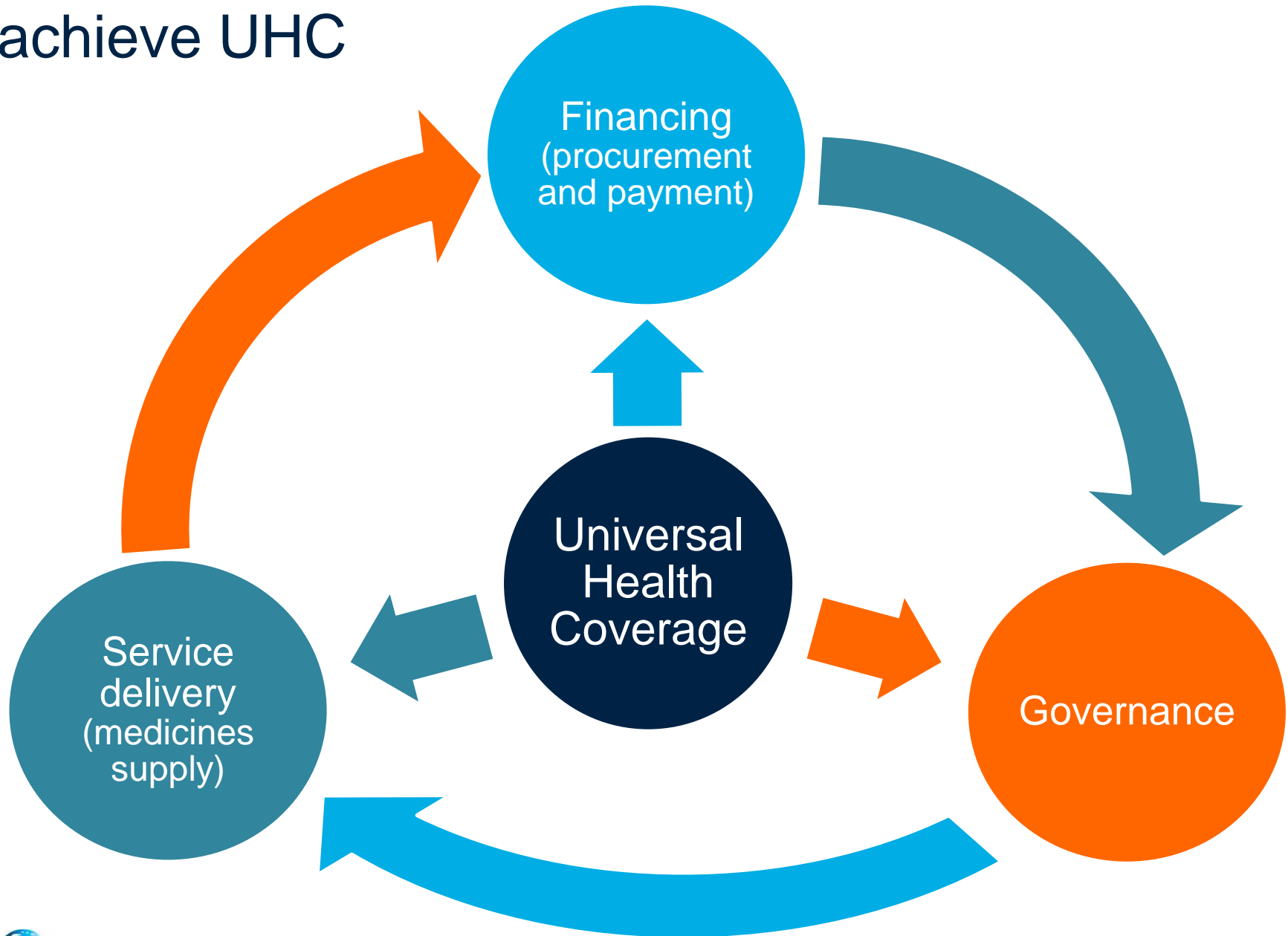
NMRA as a key stakeholder of pharmaceutical governance

- Essential to ensure safe, effective and acceptable quality medicines reach the patient
- Across the value chain:
 - Registration, quality assurance and controls, distribution, dispensing and use
- Limited resources hence priority setting and mutual share of activities
 - GCC central procedure: single dossier filing
 - Mutual recognition project between Morocco and Tunisia
- Need to foster emergence of regional champions

Pharmaceutical governance and domestic industry

- Incentives may be misaligned between pharmaceutical governance and support to local industrial or economic sectors
- Promotion of local generic manufacturing *vs* taking advantage of generics as a commodity market
 - e.g. generics pricing policy in Jordan,
 - drug registration and selection in Algeria...
- Support to local wholesalers/traders *vs* generics uptake
 - e.g. pricing and margins in Lebanon

Pharmaceutical governance as a key pillar to achieve UHC



Pharmaceutical governance from a UHC perspective

Health Financing

- Establish process and institutions setting priorities for pharmaceutical expenditures to cope with limited resources
- Health insurance and pharmaceutical benefit management (organization, financing, payment)
- Procurement processes for optimized purchasing
- Pro-generics policy

Service Delivery

- Private sector engagement and regulation for improved supply chain performance
- Quality assurance and controls for drugs and devices
- Strengthen regulatory authorities
- Foster enforcement capabilities to fight against corruption and counterfeit medicines