

# Issues and Challenges for Iraq in Pharmaceutical Sector

## A WHO Perspective



**International Congress on Reform and Development  
of the Health Care System in Kurdistan Region-Iraq**

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World Health  
Organization



# WHO Medicines Strategy 2008 – 2013: WHO goal in medicines

**WHO's goal in medicines is to help save lives and improve the population health by ensuring access to quality, effective, safe and affordable medicines and by promoting their rational use, particularly for the poor and disadvantaged.**

# Medicines and other pharmaceutical products: Integral part of Essential Health Technologies

## *Health Technology: WHA Resolution 60.29, May 07*

- *“The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives”.*
- *The WHA Resolution calls upon member states – among other actions – to **formulate**, national **strategies** for assessment, planning, **procurement** and **management** of health technologies*

# Health Technologies in WHO Health System Framework

## THE WHO HEALTH SYSTEM FRAMEWORK

### SYSTEM BUILDING BLOCKS

**MEDICINES,  
VACCINES &  
OTHER HEALTH  
TECHNOLOGIES**

**ACCESS  
COVERAGE**

**National  
Regulatory  
Authority**

### OVERALL GOALS / OUTCOMES

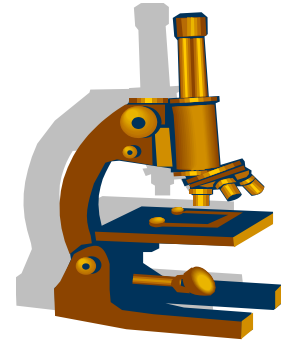
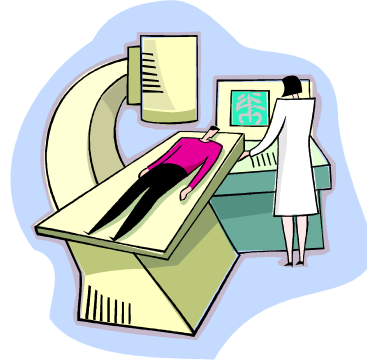
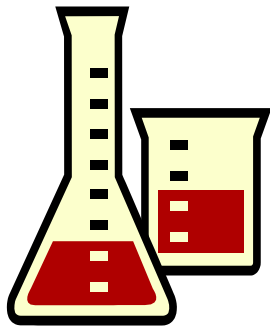
**IMPROVED HEALTH (LEVEL AND EQUITY)**

**RESPONSIVENESS**

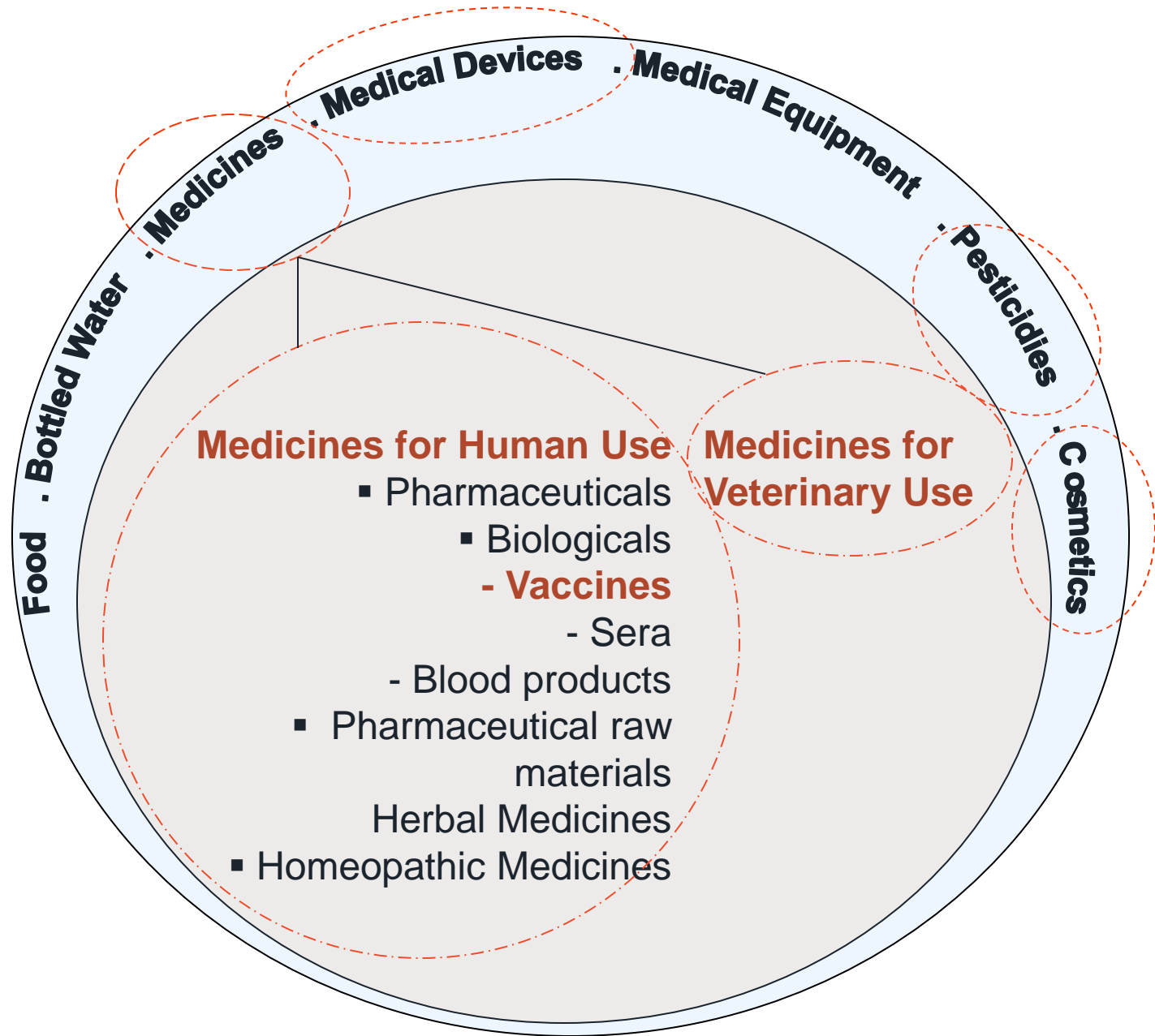
**SOCIAL AND FINANCIAL RISK PROTECTION**

**IMPROVED EFFICIENCY**

# Scope of Health Technologies



# Scope of National Regulatory Authorities



# Expenditure on medicines

from 9 NHA studies in the Region

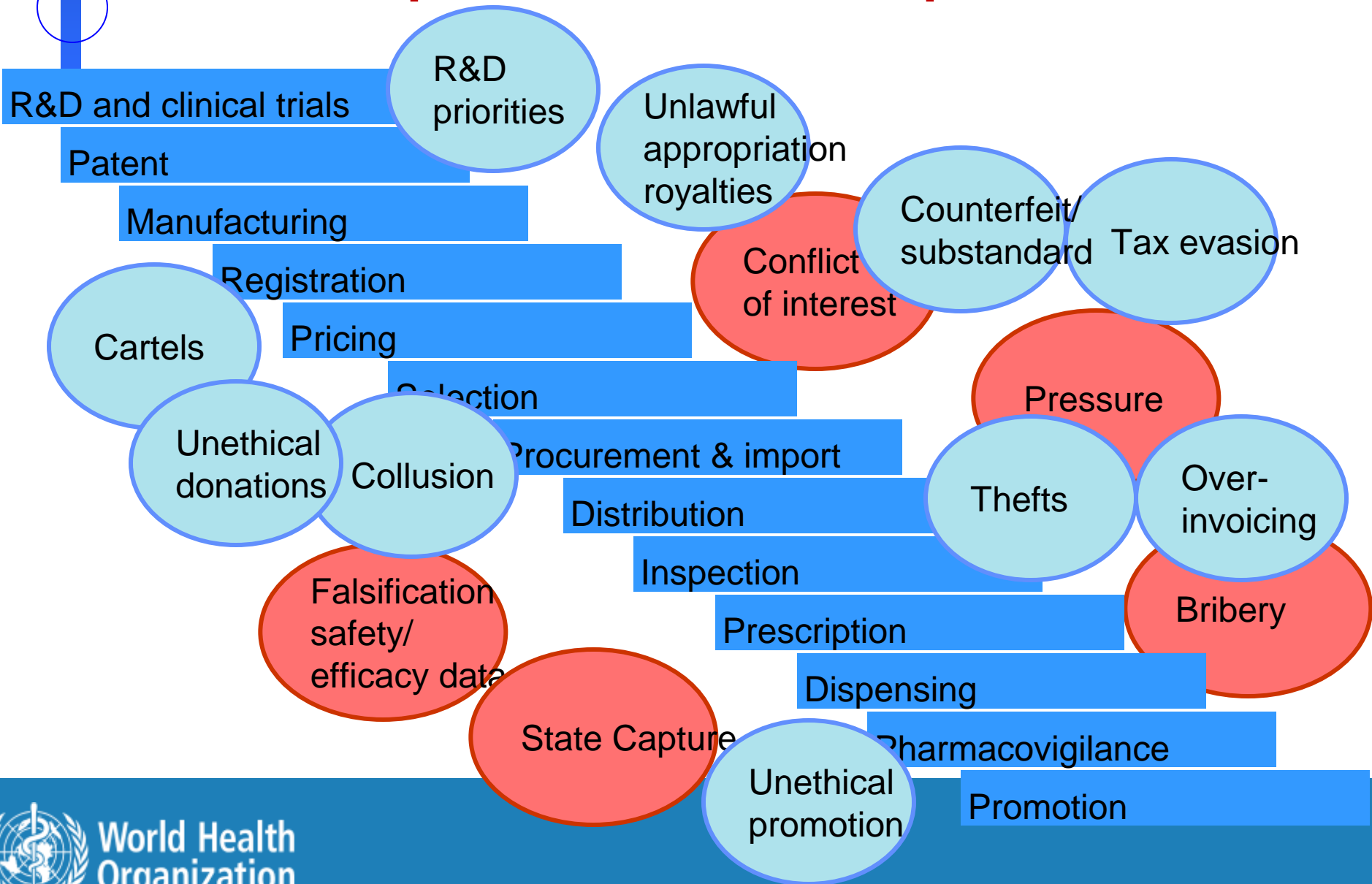
- **40% of total health expenditure is on medicines**
- **Up to 30% of the budget of ministries of health is spent on medicines**
- **Out-of-pocket expenditure is high**
  - **Egypt: 53% of all medicines are purchased directly by households**
  - **Morocco: 74%**

Medicines,  
Vaccines &  
other Health  
Technologies  
consume  
approximately  
50% of  
recurrent health  
budget.

**Well over  
50% of  
expenditure on  
Medicines,  
Vaccines & other  
Health  
Technologies is  
wasted due to  
one reason or  
the other.**



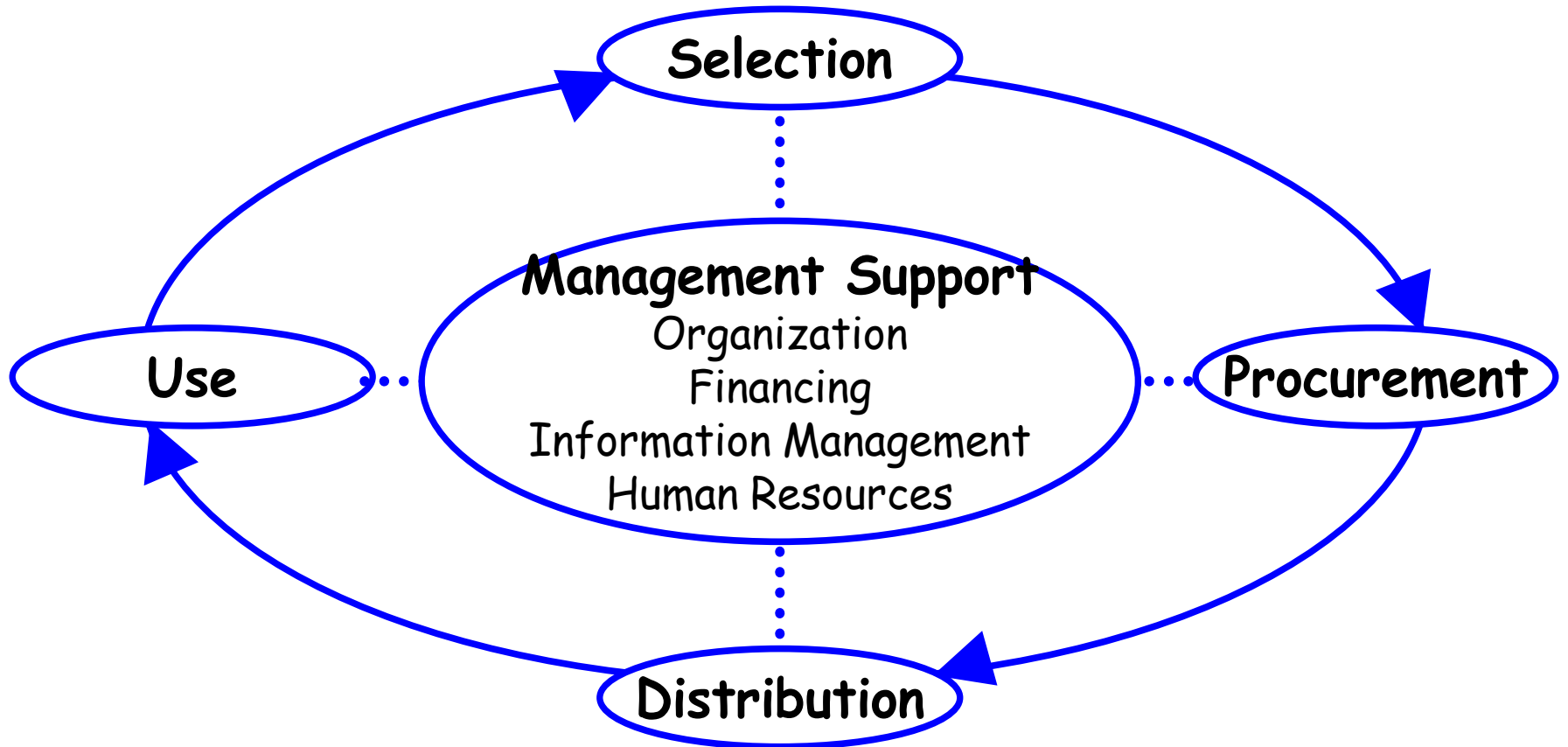
# The pharmaceutical sector is a great target to corruption and unethical practices



# Essential Medicines Programs: Priority Strategic Areas supported by WHO

- **Development of policies, strategies, guidelines and SOPs aimed at ensuring that the country has a sound National Medicines Policy**
  - ✓ National Medicines Policy, National Essential Medicines List
  - ✓ National Formulary and Standard Treatment Guidelines (STGs)
- **Quality assurance (NDQCL, support to GMP and GLP)**
- **National Drug Regulatory Authority**
- **Medicine Supply Management (Good Procurement Practices, Good Storage Practices, Information management system, etc)**
- **Rational Drug Use and Pharma-covigilance (PM Surveillance)**
- **Human Resources development and Capacity building**
- **Emergency Preparedness and Response: medicines in emergencies**

# Drug Management Cycle



Policy and Legal Frameworks

**1. Rational  
selection and use**

**3. Sustainable  
financing**

**ACCESS to  
Medicines**

**2. Affordable  
prices**

**4. Reliable  
health and supply  
systems**

# WHO Medicines Strategy

4 main objectives with 7 major components

## Objectives

## Components

- **Policy**

- 1. Implementation and monitoring of medicine policies**
- 2. Traditional and complementary medicines**

- **Access**

- 3. Fair financing and affordability**
- 4. Medicines supply systems (sustained)**

- **Quality & safety**

- 5. Norms and standards**
- 6. Regulations and quality assurance systems**

- **Rational use**

- 7. Rational use by health professionals and consumers**

# How to develop and implement a national drug policy

Second edition



World Health Organization  
Geneva

# Improving pharmaceutical sector: Some tools

- National Medicine Policy
- Strong NRA (Independent)
- National Essential Medicines List (WHO Model List of Essential Medicines): 156 Countries have EMLs and 16/22 in EMR
- Standards Treatment Guidelines (STGs)
- Professional Associations (Syndicates) and Technical Committees (i.e. PTCs)
- Recognizing the added value of the public/private collaboration and other stakeholders

# Quality & safety of Medicines

## Independent National Regulatory Authorities

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- Pre-market authorization

  - Regulation of Clinical Trials

- Market Authorization

  - Licensing of manufacturers/importers (GMP)

  - Registration of Medicines

  - Inspections

  - NQCL

- Post-market authorization

  - Pharmacovigilance

  - Adverse Drug Reaction Monitoring



# Irrational Use of Medicines

- WHO estimates that **more than half of all medicines** are prescribed, dispensed or sold inappropriately, and that **half of all patients** fail to take them correctly.
- **Solution** requires collaborative efforts and different types of **interventions** (Educational, Managerial, Economic & Regulatory).
- Experience shows that attention to **one aspect** of the problem **does not work**.

# Vaccines in EMR

- **More than 90% vaccines in the region are imported.**
- **Few countries have capability to produce vaccines**
- **None of the vaccines in the region is WHO prequalified.**

# National Regulatory Functions & vaccine supply source

Regulatory functions	Source of vaccines		
	UN agency	Procure	Produce
<i>Regulatory system</i>	✓	✓	✓
Marketing Authorization/Licensing	✓	✓	✓
Post marketing surveillance/AEFI	✓	✓	✓
Lot release	Functions undertaken in producing countries	✓	✓
Laboratory access		✓	✓
Regulatory inspections			✓
Authorization/Approval of CT	In countries that conduct clinical trials		

# Trends in global pharmaceutical situation

## New Challenges (1)

- Recognition that vertical programs need an integrated approach with horizontal health systems, supply systems
- More interest in medicine quality and quality assurance systems: Need for practical global standards and support to NRAs
- Several new global funding mechanisms for essential medicines: These need global health policy direction, global standards and technical support from WHO.
- More players and partnerships, complicating the landscape: This requires a multi-stakeholder (“MOH-Plus”) approach and coordination at country level.

# Trends in global pharmaceutical situation

## New Challenges (2)

- Intellectual Propriety Rights (IPR) shifting from global TRIPS discussions towards technical support to countries: new focus on innovation and public health and inter-governmental process
- Middle Income countries in medicine issues (e.g. pricing, reimbursement and quality and hence the need for relevant standards and high level technical support
- New priorities as guided by member states (PHC, Africa, women) This implies reshaping PHC and focus on public sector and essential medicines and reimbursement schemes
- Recent WHA resolutions (prices, IPR, rational use, medicines for children, etc.) This requires fund raising and producing Human Resources to expand these areas.

# Major recent achievements in Iraq

- Recognizing problems in Medical Supply Management System (studies on Kimadia with an attempt to find solutions)
- Reactivation of National Drug Quality Control Laboratory
- National Medicines Policy Drafted
- Capacity building/Support to different Ministerial Technical Committees:
  - ✓ Drugs Needs and Quantification
  - ✓ Iraqi EML(Workshop on selection and evidence based)
  - ✓ Therapeutic Drug Committees & Pharma-covigilance Center
- NRA supported (policies, strategies, Standards, Guidelines, Drug Registration, participation to ICDRAs)
- Monitoring the rational use of medicines at # levels of the Health System.

# Issues and Strategic decisions for future (1)

- Decision on appropriate organizational structure of the pharmaceutical sector (private vs public) and Kimadia
- Pharmaceutical Laws, Regulations and Drug Regulatory Authority (separate body promoting GGM and transparency approach)
- Separation Policy making & implementation (Kimadia can't play both roles)
- National Medicine Policy as integral part of the National Health Policy
- Decentralization, but normative & regulatory functions must remain at national level (avoid fragmentation)
- Funding mechanisms for the pharmaceutical sector, clarity on the administrative/financial status of Kimadia

# Issues and Strategic decisions for future (2)

- Streamlining needs assessment, importation, manufacturing of medicines and distribution (GPP, GMP, GLP, GSP, Logistics)
- Investing in HRD (skilled personnel)
- Investment in infrastructure and modern technology: Information, documentation, Internet, Data/Management Information System (MIS)
- Rationale use of drugs (STG, pharma-covigilence) and M&E of EMP
- Access to essential drugs and social protection (Health Insurance)



# Conclusions

- HT are important building blocks and resources of HS.
- To avoid huge wastage of resources and ensure adequate access, investments need to be made in developing appropriate policies, strategies and management systems (selection, procurement, storage, supply & maintenance).
- Safety and quality of HT require institutional development of resourceful NRA with appropriate independence in technical, administrative and financial decision making
- Appropriate use of HT needs urgent attention
- HT must be regulated for its affordability
- Unimpeded inter country transfer of technology (regulated)



QUESTIONS ?

**THANK YOU**