IRAQ

PHARMACETUICAL COUNTRY PROFILE

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Iraq Pharmaceutical Country Profile

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Dr. Ali Azeez Al-Jumaili, BS Pharm, MS, MPH, PhD, Baghdad, Iraq

Ali.baraak@copharm.uobaghdad.edu.iq

Foreword

The 2020 Pharmaceutical Country Profile for Iraq has been produced by the Ministry of Health, in collaboration with the World Health Organization.

This document describes eight domains related to pharmaceuticals in Iraq including pharmaceutical expenditure and demographic data, medicines policies, financing, procurement and supply management system, medicines trade and intellectual property, regulation of medical products, local manufacturing, and rational use of medicines.

The data of this report mainly rely on the World Health Organization (WHO) Survey (Access to Medicines and Vaccines in the Eastern Mediterranean Region) which was conducted of health officials across the Ministry of Health (MOH) during July and August 2020 . The source of each section is indicated intext and at the bibliography section.

The consultant (Dr. Ali Azeez Al-Jumaili) who conducted this report and the related survey is a faculty member at the University of Baghdad College of Pharmacy. He has a PhD in Pharmaceutical Socioeconomics and a master's degree in public health from the University of Iowa, USA (2017) with adequate background about the MOH pharmaceutical departments and policies. He is also a consultant at the Section of Pharmacoeconomics Studies within the Department of Drug Need Estimation, Directorate of Technical Affairs, MOH.

It is my hope that partners, researchers, policymakers and all those who are interested in Iraq pharmaceutical sector will find this profile a useful tool to aid their activities.

Deputy Minister of Health

Dr. Hazem A Al-Jumaily

Date: 20/9/ 2020

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Director of Technical Affairs Directorate: Dr. Hani Mousa Badr, MD

Pharmacist: Ali AlBaldawi, Deputy Director General for Procurement Affairs, KIMADIA

Pharmacist Haider Hussain Motlak, Deputy Director General for Technical Affairs Directorate.

Dr. Asaad Mahdi Asaad/Deputy Director General/Public Health Directorate.

Dr. Sami Shati Obaid, Director of Specialty Centers Department.

Dr. Abd Raheem Taha Hamody, Director of Therapeutics Department.

Pharmacist: Abbas Badr AlFurtusi, Director of Medical Appliance's Procurement Department, KIMADIA

Pharmacist: Salam Jasim, Director of National Center for Drugs Control & Research (NCDCR)

Dr. Shakir Mahmood Muhammed, MD, Head of Research and Knowledge Management, Center for Training and Human Resources Development

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Pharmacist: Samir Hasson, National Center for Drugs Control & Research (NCDCR)

Pharmacist: Mazin Mahdi Hussein, Coordinator of National Committee of Drug Selection.

Pharmacist: Hala Hadi Abdulla. Director of National Industry Section, Pharmacy Department.

Pharmacist: Nabeel Hasan Hussain, National Industry Section, Pharmacy Department.

Specialist: pharmacist: Haidar Al-Jawadi, Clinical Pharmacy Section, Pharmacy Department.

Pharmacist: Maha Sahker, Inspection Directorate.

Pharmacist: Rana Mahdi, Antimicrobial Unit, Public Health Directorate.

Pharmacist: Amnah Gahzi Mahdi, Director of Information Center, KIMADIA

Pharmacist: Ahmed Mohammed Abdul Hameed, Director of Planning Department, KIMADIA.

Specialist Pharmacist: Renata Awni, Director of Herbal Medicines Department.

Pharmacist: Alaa M. Al Hareeri, Coordinator of the National Committee for Selection of Herbal Medicines and Food Supplements.

Specialist pharmacist: Jamila Z. Lafta, Director of Pharmacy in Public Sector Health Institutes Section, Pharmacy Department.

Specialist pharmacist: Noor Najim, Clinical Pharmacy Section, Pharmacy Department.

IT employee: Razzaq Enad AbdulAbbass, Deputy Director of Information Technology Department

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Main sections of the Pharmaceutical Country Profile 2020

Abbreviations

Acronym	Full name
DTA	Directorate of Technical Affairs
IqPhvc	Iraqi Pharmacovigilance Center
LNMPs	League for National Medicine Producers
LPMMAs	League for Promotion of Medicines and Medical Appliances
MOH	Ministry of Health
NCDS	National Committee for Drugs Selection
NCDCR	National Center for Drug Control and Research
NEML	National Essential Medicines List
NMP	National Medicine Policy
PGY2	Postgraduate year two (Clinical Pharmacy residency program)
SIP	Syndicate of Iraqi Pharmacists
WHO	World Health organization

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Introduction

This report is an updated version of Iraqi Pharmaceutical Profile which was conducted by the Chief Pharmacist Jamila Z. Lafta in collaboration with the WHO in 2011. This year (2020) survey was modified and shortened compared to 2011 survey. One of the WHO missions is to help countries assessing and promoting their pharmaceutical regulations and policies. This new report comes after nine years of the previous one to help evaluating the progress in the Iraqi pharmaceutical profile and highlighting areas in need of further work. This report is conducted simultaneously with 22 similar reports in the region to have a comprehensive picture about pharmaceutical profile in the participating countries.

The aim of this document is to compile all relevant, recent information on the pharmaceutical sector and make it available to the public in a user-friendly format. This report summarizes pharmaceutical-related regulations and policies in the Iraqi MOH in Baghdad given the three Kurdistan provinces have their own MOH in Erbil. However, all official orders and documents are distributed from the MOH in Baghdad to Kurdistan MOH.

The contents of this reports compile eight essential sections including (1) Health, Pharmaceutical Expenditure and Demographic data, (2) Medicines policies, Governance, Evidence-based selection and Health Technology Assessment, (3) Financing, Pricing, Availability and Affordability of medicines, (4) Procurement and supply management system, (5) Medicines trade and intellectual property, (6) Regulation of Medical Products, (7) Local Manufacturing, Session (8) Rational Use of Medicines.

The information on these eight sections can provide comprehensive information about the pharmaceutical sector which is crucial to the Iraqi healthcare system. The questionnaires of the WHO Survey (Access to Medicines and Vaccines in the Eastern Mediterranean Region) were filled by more than 25 Iraqi health officials and employees who provided related documents when needed (from July 26 through August 24, 2020).

The questionnaire covered five directorates within the MOH (Technical Affairs, KIMADIA, Public Health, Inspection, and Planning) in addition to Drug Policy Committee, the National Center for Training and Human Development, Financial Planning Department, and Information Technology (IT) Department. The Directorate of Technical Affairs (DTA) had the lion's share of the questions since it is the main regulatory agency within the MOH related to pharmaceuticals. The included DTA departments were Pharmacy Department, Registrations Department, National Committee of Drug Selection (NCDS), National Center for Drug Control and Research (NCDCR), Consulting Committees, Therapeutics Department, and Need Estimation Department. In turn, Pharmacy Department includes Iraqi Pharmacovigilance Center (IqPhcv), Governmental Healthcare Facilities Section, Clinical Pharmacy Section and National Pharmaceutical Industry Section. Some questions needed answers outside the MOH such as private pharmaceutical sector and national pharmaceutical manufacturers.

All the included departments were very collaborative in answering the survey questions which reflects their intentions to assess the current pharmaceutical profile and their willingness to promote the country pharmaceutical policy and regulations in the future.

The main challenge of conducting this report and filling the related survey was COVID-19 pandemic since the MOH employees' working hours were reduced to 50% as a preventive measure to reduce the availability of personnel within the building.

Finally, we would like to express our deep appreciation to all healthcare providers who have served Iraqi patients during COVID-19 pandemic.

What can Pharmaceutical Sector Country Profiles offer:

Completing this questionnaire takes extra time for national experts and responsible officers but it is worthwhile as Iraqi MOH and its partners will benefit from it in a number of ways:

I) The questionnaire offers a unique opportunity to consolidate, in one place, information that is available in different locations and institutions e.g. the National Medicines Regulatory Authority, Central Medical Stores, National Health Accounts, etc.

II) The methodology proposed for filling in the questionnaire will ensure that good quality data are collected and that the source and date of information are known and reported.

III) Data on structure, process and outcomes are collected, and the questionnaire has been pre-filled with data available in the public domain; indicators are divided into core and supplementary in order to make it easier to identify what is more important.

IV) The data collected will highlight the strengths and weaknesses of the pharmaceutical sector and will be made available in a national database as official country information, for use by decision-makers, health and pharmaceutical experts, researchers and international partners and the public..

V) The data collected could be transformed into a narrative report with bibliographic references, that will summarize the medicines situation in the country.

VI) Based on experiences from previous surveys, a detailed glossary of key definitions and a manual for use of the questionnaire have been developed and can be found at the end of the questionnaire.

Section 1 Health, Pharmaceutical Expenditure and Demographic data

1.1 Population

In 2019, Iraq had a total population of 39.128 million [1].

1.2 Gross Domestic Product (GDP) per capita

In 2019, the total budget of Iraqi government was $ 110.83 Billion (with current exchange rate) (=133 trillion Iraqi Dinars)[2] and the gross domestic product (GDP) per capita was $2,833 (2019).

1.3 Population covered by a public health service

All Iraqi people are covered by public health services [3]. In other words, everyone is eligible for public health services which are heavily subsidized by the government. The government owns all healthcare facilities in the public sector and all healthcare providers working there are governmental employees receiving monthly salaries.

According to the annual MOH Statistical Report[1], there were 30,106,943 patient visits to primary public healthcare facilities across the 18 provinces in 2019. On the other hands, secondary and tertiary healthcare facilities served 62,958,897 outpatients and 3,166,563 inpatients in the same year.

1.4 Population covered by private health insurance

Private health insurance companies only started recently in Iraq and no accurate data are available about the number of their beneficiaries. Ministry of Oil provides health insurance coverage to its employees. When the employees receive services at the private sector (physician clinics or community pharmacies), they can request reimbursement from their employer (Ministry of Oil). Some private hospitals may provide in-patient and out-patient services that are covered by employer-based health insurance. Although the public health services are either free or heavily subsidized, patients usually pay 100% out of pocket for private sector services given

that fees are not subsidized [4]. In average, patients pay 58% of total healthcare service fees out of pocket [5].

1.5 Government annual expenditure on health

In 2014, total health expenditure represented 5.5% of gross domestic product (GDP)[6]. The Current Health Expenditure (CHE) per capita was $210 in 2017 [5]. In 2019, government annual expenditure on health was only 6 trillion IDs ($5.0 billion) which represented 4.5% of total government budget [2].

1.6 Pharmaceutical expenditure

In 2019, the governmental (public) pharmaceutical expenditure was $1.25 billion for all population which represented 25% of the health expenditure in the public sector [2]. Public sector share was 1.25 billion on pharmaceutics, while private sector share was $ 1.87 billion in 2019 [2](source: LPMMAs). Thus, the total pharmaceutical expenditure in 2019 was $3.12 billion ($79.7 per capita). The share of public expenditure on pharmaceuticals was 40.1% of total expenditure on pharmaceutics. According to the State Company for Marketing Drug and Medical Appliances (KIMADIA) statistics in 2019, generic medicines represented 70% of total procured essential medicines and vaccines for the public sector (governmental healthcare facilities). In contrast, the private sector (scientific bureaus) has no statistics about the market share of generic medicines.

Section 2: Medicines policies, Governance, Evidence-based selection and Health Technology Assessment

2.1 The National Medicines Policy (NMP) official document

In 2015, the Drug Policy Committee in collaboration with Pharmaceutical Affairs Section/ Technical Deputy Minister Office, developed the Document of National Pharmaceutical Policy which represents the national medicines policy (NMP). The Technical Deputy Minister is the head of Drug Policy Committee which reviews drug policy and developed five-years plan (2016-2021) which should be active during any crisis.

Drug Policy Committee oversees drug selection (NCDS), registration, procurement, and distribution (KIMADIA). The included departments (Registration, NCDS, KIMADIA and Need Estimation) in the Drug Policy Committee have their own annual implementation plans. In other words, there is an implementation plan for each department.

The current Document of National Pharmaceutical Policy does not include sections related to regulatory procedures and supply chain management in cases of emergency, pandemics, and crisis situations. However, Iraq has a couple committees which are involved during the current COVID-19 crisis: Drug Policy Committee and Emergency Committee of COVID-19. These committees have been trying to secure COVID-19 medications, personal protection equipment (PPE), ventilators, oxygen and other essential equipment. The Drug Policy Committee was founded in 2015 while Emergency Committees of COVID-19 was founded after March 2020 to develop treatment protocols and facilitate obtaining, registration, procuring and testing COVID-19 medications.

2.2. National Essential Medicines List (NEML)

National Committee for Drugs Selection (NCDS) is responsible for selecting medicines and vaccines for the essential and comprehensive drug list [7]. The NCDS usually includes 12-16 specialist physicians and pharmacists representing different specialties and departments. However, no conflict of interest declarations is required for the membership of this committee

There is a documented process and criteria for selecting medicines for inclusion on the National Essential Medicines List (NEML). The NEML (levels 1, 2 & 3) includes 827 medicines by active ingredients and 1105 by complete products (different dosage forms) as of June 23, 2020. Medicines on the NEML (level 1) should be secured by KIMADIA to public healthcare facilities. In contrast, medicines on levels 2 and 3 of the NEML are approved for public facilities but are not required to be secured by KIMADIA. However, level 2 and 3 medications can be procured by peripheral healthcare facilities (decentralized public procurement) given that priority is for level 2 over level 3 medications. On the other hand, the comprehensive drug list includes 3700 (essential and non-essential) medicines as of June 23, 2020. Some medicines are approved for the comprehensive list, but not for the essential list. Those medicines can be made available for the private sector only.

On the other hand, the NCDS sometimes request pharmacoeconomic studies (e.g. cost-effectiveness analysis) from the Section of Studies and Data Analyses at the Need Estimation Department particularly for high cost medications such as oncology and biological medicines. During the last ten months, the section conducted 12 pharmacoeconomic studies to help the NCDS to select the most cost-effective medications among those applied to be listed in the NEML. The Section of Studies and Data Analyses was founded in 2009 and its pharmacoeconomic studies have potential of saving millions of USD to the MOH (KIMADIA and public sector).

The traditional medicines are included in Herbal Drug List (HDL), but not in the essential medicines' list. According to the National Committee for Selection of Herbal Medicines and Food Supplements, the HDL includes 869 approved herbal medicines, and athletic/food supplements (May 2020).

2.3 National framework for good governance for medicines (GGM)

On 21 February 2012, the MOH of Iraq and the MOH for the Kurdistan Regional Government (KRG), in collaboration with the World Health Organization (WHO) have launched the field

implementation of phase I of the program of Good Governance for Medicines (GGM). However, the program was stopped [8]. It will be a great value if the GGM is implemented.

According to the WHO, the GGM program objectives are to increase transparency and accountability in medicine regulatory and supply management systems, enhance awareness on the negative influence of corruption in the pharmaceutical sector, promote individual and organization integrity in the pharmaceutical sector and finally to implementation good governance in the national pharmaceutical sector [9].

2.4 The conflict of interest management policy in the pharmaceutical sector.

The conflict of interest management policy in the pharmaceutical sector follows the Iraqi Law of Practicing Pharmacy Profession no. 40 in 1970. There is a formal code of conduct for public officials which is the Code of Conduct for Public Service in 1960 and its updates[10].

2.5 National Standard Treatment Guidelines (STGs)/ protocols endorsed by the Ministry of Health (MOH)

There are National Standard Treatment Guidelines (STGs)/ protocols endorsed by the MOH for most common illnesses such as hypertension, cardiac diseases (myocardial infarction), stroke, coma, gynecology, cesarean section, epilepsy, blood disorders, , myopathy, pediatric orthopedic, peripheral neuropathy, spinal cord, kidney transplant, tuberculosis, oncology, radiology, newborn diseases, burns, CPAP protocol, epistaxis, osteoporosis, total knee replacement and osteoarthritis. These clinical guidelines were developed by Therapeutics Department in collaboration with Consultation Committees while the Inspection Directorate has to impose these guidelines on healthcare facilities. However, there are no accurate data about the implementation of these guidelines/protocols by the public hospitals.

There is a national clinical guideline for treatment of COVID-19 includes hydroxychloroquine tablet, azithromycin tablet, lopinavir/ritonavir (Kaletra®) tablet, remdesivir vial, favipiravir, corticosteroids (dexamethasone), tocilizumab, interferon-β-1a and plasma therapy. The most updated protocol (June 28, 2020) classifies COVID-19 infection into three levels: Mild,

moderate and severe. Above medications may be used in one or more levels. For example, hydroxychloroquine is used for mild cases while corticosteroids, tocilizumab, and remdesivir are indicated for severe cases. On the other hand, favipiravir is indicated for both moderate and severe cases. It is worth mentioning that a domestic pharmaceutical manufacturer started producing generic favipiravir and made it available for both private and public sectors.

Section 3 Financing, Pricing, Availability and Affordability of medicines

3.1 Patient groups receive medicines free of charge

In the public sector (governmental healthcare facilities) the following patient groups receive medicines free of charge: Patients who cannot afford the medications, children aged less than 5 years, pregnant women, senior people (geriatrics), children in orphanages, nursing home residents, victims of bombs and displaced people (Department of Financial planning Letter, Feb 25, 2019).

3.2 Medicines are provided free of charge to patients

In the public sector, the following medicines are provided free of charge to specific group of patients: Medicines for selected non-communicable diseases (NCDs), medicines for malaria, medicines for tuberculosis, HIV/AIDS medicines, Expanded Program on Immunization (EPI) vaccines. Other eligible categories include medicines for thalassemia, hemophilia, renal failure, cancers, burns, hepatitis B, pregnant women, WHO preventive programs are provided for free of charge by governmental healthcare facilities. In fact, the availability of these medications relies on KIMADIA procurement for this particular year (i.e. their availability is non-sustainable).

3.3. Legal or regulatory provisions that determine the prices of medicines

Registration Department at the Directorate Technical Affairs (DTA) determines the prices of medicines in the private sector given that medications at the public facilities are either provided for free or fixed subsidized prices ($0.8-2.5) It is worth mentioning not all medicines in private sector have price sticker (only officially procured).

The Inspection Directorate (for non-governmental facilities) at the MOH and Iraqi Pharmacists Syndicate (IPS) maintain an active national medicines price monitoring system. However, this price monitoring includes only registered medications in the private sector which represent 30-40% of all private sector medications[2]. In contrast, 60-70% of available medicines in the private sector (drug stores and community pharmacies) are not registered and do not have price sticker [2]. There are several reasons behind availability of unlicensed medicines in the private sector which need a multifactorial solution.

The disciplinary actions of non-compliance facilities in the private sector could be compulsory closure for certain period (weeks to months). The lack of trace and track system which helps to track medications from manufacturers to retailers (community pharmacies) is the main reason for the lack of control over these substandard medications. According to scientific bureaus and pharmaceutical company representatives, the main incentive for smugglers who bring unregistered medications through non-official ways is the financial profit. The prices of these parallel (genuine, but not registered) medications in neighboring countries are lower than the counterpart registered medicines in the Iraqi market due to different reasons (e.g. having packaging license or lower processing fees) which are the main incentives to bring them unofficially to the Iraqi private market. Inadequate restrictions of border security may help them bring these parallel medications from neighboring countries, particularly Turkey, Iran, Jordan, and even Egypt. Another reason can be unavailability of some highly needed medications of chronic diseases from certain well-known multinational companies.

3.4 Methodology used for drug pricing

Registration Department at the MOH relies on prices in British National Formulary (BNF) and neighboring countries. The MOH has its own pricing methodology and does not follow WHO/HAI methodology of pricing (DTA letter no. 294 on Feb 2, 2017).

3.5 Duties are imposed on imported pharmaceutical products and active ingredients

According to the regulations of Ministry of Finance-General Commission for Taxes in 2016, the imposed taxes on imported finished pharmaceutical products are 2.5-10%. If it is only one shipment, the rate of tax is 10%. On the other hand, the imposed custom duties by General Commission of Customs were reduced from 10% to 0.5% on imported medicines and medical appliances according to order no. 255 on July 24, 2019, issued by Council of Ministers.

According to the League of National Medicines Manufacturers (LNMMs), 5% duties are imposed on imported active pharmaceutical ingredients (APIs) and could reach to 15% for certain ingredients. Thus, there are neither provisions for tax exemptions or waivers for pharmaceuticals products nor for active ingredients.

The high duties imposed on active pharmaceutical ingredient may negatively impact national pharmaceutical manufacturers and reduce their ability to compete in prices with low-cost imported medications from some Asian countries such as India.

Section 4 Procurement and supply management system

4.1 Public procurement and the agency responsible for public procurement

KIMADIA is a public company founded in 1964 and is governed by the General Companies Law No.22 of 1997. KIMADIA is the agency responsible for public sector procurement. Historically, it was responsible for procurement of medicines and medical appliances to both public and private sectors before 2003. KIMADIA is semiautonomous financially (gains 6.5% of imported product costs to pay expenses and employee salaries). KIMADIA has a written public sector procurement policy (2017). KIMADIA procures medicines and medical appliances for public facilities in all 18 provinces and all health directorates in the provinces also have permission to procure medicines in some cases. Thus, public sector procurement of medicines in Iraq is centralized (by KIMADIA) and decentralized (by healthcare directorates). In 2019, KIMADIA was able to procure 60% of essential medicines (level 1) in the NEML [11].

Public procurement includes the following mechanisms: National competitive tenders, international competitive tenders, and direct purchasing. According to the Prime Minister Office Letter (2015), national manufacturers have priority to apply for tenders (the regulations indicate when a medication is produced domestically, it should be procured by KIMADIA and not be imported). National manufactures had 47.8% of total KIMADIA contracts of medicines in 2019; however, this represented only 15.1% of the total procurement values which means they only produce low-cost medicines. KIMADIA has domestic guidelines and standard operating procedures (SOPs) for the procurement of medical products in the public sector. Finally, there is national guidelines on the donation of medical products to the MOH according to Pharmacy Department, DTA (2017).

4.2 National Good Distribution Practices (GDP) & Good Storage Practices (GSP)

The Inspection Directorate (on non-governmental facilities) has the legal provisions requiring wholesalers and distributors to comply with good distribution practices (GDP) and good storage practices (GSP). The Inspection Directorate imposes both GDP and GSP on public distribution and storage facilities which belong to KIMADIA. On the other hand, the MOH inspection is conducted on private facilities (scientific bureaus) to ensure compliance with GSP while medicine distribution to community pharmacies is usually done by scientific bureaus or wholesalers without supervision. It is worth noting that medicine distribution from wholesalers (drug stores) to community pharmacies is usually done by usual sedan/minivan cars.

On the other hand, the National Center for Drugs Control & Research (NCDCR) has to assess the quality of procured products and also report the storage conditions during their sampling visits to medicine storage sites before giving release permission.

4.3 Prequalification of suppliers for public sector procurement

Registration Department Regulations has its own pre-qualifications to register medicine suppliers. The most important requirements include Good Manufacturing Practice (GMP) certificate, certificate of pharmaceutical product (CPP) and preferably certificate(s) from one or more of the following medicine regulatory agencies: The US-FDA, European Medicines Agency

(EMA), Therapeutic Goods Administration (TGA), Australia, MHLW (Japan), the Medicines and Healthcare Products Regulatory Agency (MHRA), U.K., Swiss surveillance authority for medicines (Swissmedic), Health Product and Food Branch (HPFB), Canada or Gulf Cooperation Council (GCC).

International manufacturers that do not have one of the above well-known certifications, must be inspected by an MOH team before registering as a supplier. Every five years, suppliers should apply to renew the registration certificate; otherwise the certificate will be suspended.

4.4 Medication shortages during the COVID-19 crisis

According to the Pharmacy Department assessment on July 28, 2020, based on the centers of COVID-19 requests there was shortage in four medications used to treat COVID-19: Lopinavir-ritonavir (Kaletra®) tablet, remdesivir inj, tocilizumab vial and interferon beta inj. However, KIMADIA has been working to procure the first three medications as soon as possible since they are included in the COVID-19 treatment protocol. Subsequently, KIMADIA successfully procured Kaletra®, remedesivir and tocilizumab by the end of August 2020.

To achieve rapid registration of COVID-19 medications, the Registration Department adopted Temporarily Registration for Emergency Used Medicines. This quick response from the Registration Department is to secure needed medications for COVID-19. As of August 31, 2020, the collaboration between DTA and KIAMDIA has secured most medications listed in the current Iraqi protocol of COVID-19 management.

4.5 National guideline on the donation of medical products

According to the Pharmacy Department regulations on May 3, 3017, donated medicines should be approved by the NCDS, registered and should pass the quality assurance test of the NCDCR. These medicines should also have expiration date longer than six months, provided in adequate amount and needed by public healthcare settings. Additionally, any donation should enter to KIMADIA warehouse before being released to its destination. The Ministerial order of the MOH no.128 on Jan 13, 2020 determines four conditions for donating medicines to Iraqi MOH. The type and source of donating medicines should be determined. Financial status of the donating

entity should also be declared. Furthermore, the target institution which needs to receive this donation should be also specified. Finally, the donor should also declare on what basis they determined the need/type of medicines and the institution receiving the donation.

Section 5 Medicines trade and intellectual property.

5.1 Membership in The World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO)

Iraq is not a full member in the World Trade Organizaiton (WTO) yet, but it is an observer member. “Iraq's Working Party was established on 13 December 2004. The Working Party met for a second time in April 2008” [12]. In contrast, Iraq is a member of the World Intellectual Property Organization (WIPO) since 1976 [13].

5.2 Granting, managing, and enforcing intellectual property rights

Ministry of Planning/ Central Organization for Standardization and Quality Control/ Department of Industrial Property Management was founded in 1979 and it grants industrial patents according to the Law of Patent & Industrial Samples no.65 in 1970 and its update in 2004 [14]. The above law grants patency for local manufacturing products, but there is no linkage between patent status and marketing authorization in Iraq.

5.3 Agreement of Related Aspects of Intellectual Property Rights (TRIPS)

Since Iraq is not a full member in the WTO, KIMADIA does not follow TRIPS agreement and it has its own trade regulations and flexibilities.

Section 6: Regulation of Medical Products

6.1 Regulation of Medical Products

6.1.1 National Regulatory Authority (NRA)

Directorate of Technical Affairs (DTA) is part of the MOH and considered the main national regulatory authority (NRA) for medicines and medical appliances in Iraq. The DTA includes several medicine-regulatory departments: Registration Department, Pharmacy Department, National Committee for Drug Selection (NCDS), National Center for Drug Control and Research (NCDCR), Therapeutics Department, Consulting Committees Department, Need Estimation Department, and National Committee for Selection of Herbal Medicines and Food Supplements and National Center for Herbal Medicines [15](Table 1).

6.1.2 The Functions of the National Regulatory Authority

The DTA conducts the following duties: Issuing marketing authorization, regulatory inspection, licensing establishments, laboratory testing (quality control and assurance), lot release, and pharmacovigilance (see Tables 1 & 2). The DTA neither conducts market surveillance and control nor oversees clinical trials. Thus, it needs help from other directorates and departments in the MOH. For example, Inspection Directorate is responsible for conducting market surveillance, while ethical/scientific committee(s) (at the National Center for Training and Human Development) oversee clinical trials. Additionally, Public Health Directorate helps in some regulations related to medicines for communicable diseases and vaccines. That means the regulations and monitoring/ surveillance of medicines are distributed within the MOH directorates. The collaboration/communication among these different departments (within the DTA directorate) and different directorate (within the MOH) relies mainly on paper-document processing.

Table 1: The departments of Technical Affairs Directorate that are related to pharmaceutical profile and summary of their functions [15]

Department	Functions
Registration Department	Registering medications, vaccines, medical appliances and international companies and deciding medication prices for private sector and the estimated cost for public sector
Pharmacy Department	Granting importing license for international pharmaceutical companies and working license for national companies, supervising pharmacy and clinical pharmacy sections in public facilities and conducting regulatory inspection for domestic pharmaceutical manufactures.
National Committee for Drug Selection (NCDS)	Selecting/approving medicines and vaccines for essential and comprehensive medicine lists
National Center for Drug Control and Research (NCDCR)	Testing national and international medications and vaccines (before drug registration and release)
Therapeutics Department	Helping to develop medical and treatment guidelines/ protocols and infection control
Consulting Committees	Working with other departments to develop treatment guidelines, assess annual needs of public facilities and advice on effectiveness and adverse drug events.
Herbal Medicines Department	Approving and registering crude herbs and granting license and training to traditional medicine/herbal agents
National Committee for Selection of Herbal Medicines and Food Supplements	Selecting/approving herbal/natural medicines, and athletic and food supplements in the National Herbal List.
Need Estimation Department	Measuring the needs of public facilities of medicines, vaccines and medical appliances in addition to conduct pharmacoeconomic studies (mainly cost-effectiveness analyses) of new medications for the NCDS

Table 2: The main sections of Pharmacy Department, DTA and their functions

Section	Function
Iraqi Pharmacovigilance Center (IqPhcv)	Ensuring the safety of medicines, vaccines, herbals and biologics in public and private facilities (monitoring adverse drug events and falsified/ substandard medications)
National Medicine Industry Section	Regulatory inspecting and granting license for national medicine manufacturers
Private Importation Section	Granting importation license to international pharmaceutical companies
Clinical Pharmacy Section	Supervising Clinical Pharmacy Program, Specialized hospital residency programs (PGY2), Electronic Clinical Pharmacy Programs and Units in public hospitals and developing/ participating in clinical pharmacy activities and awareness programs (e.g Continuing Education, Drug Information Center, and Antibiotic Awareness Week, patient safety activities, and therapeutic drug monitoring)
Pharmacy in Governmental Health Institutes Section	Regulating functions and needs of pharmacy sections in peripheral healthcare directorates
Narcotics, psychotropics and chemical precursor Section	Granting license to import and produce narcotic medicines by local manufacturers and monitoring regulations of these substances in both private and public sectors in addition to collaboration with the International Narcotics Control Board
Medical Supplies Section	Regulating and controlling the path and the needs of medical supplies in peripheral healthcare directorates
Pharmacy and Therapeutic Committee Unit	Assessing all recommendations of Drug and Therapeutics Committees (DTCs) at public hospitals

6.1.3 Health products that are regulated by the National Regulatory Authority

The NRA (DTA) regulates the following health products: Medicines, biotherapeutics, vaccines, blood and blood components, plasma derived medicinal products, herbal or traditional medicines, food supplements, medical devices and diagnostics, narcotics.

6.1.4 Assessment of the National Regulatory Authority

An assessment of the NRA has not been conducted in the last five years. The last comprehensive assessment of Iraq Pharmaceutical Country Profile was conducted in 2011 in collaboration with the WHO [16]. However, each department of the DTA has its own annual assessment. Additionally, all department of the DAT have regulations that control their functions and responsibilities.

6.1.5 The use of a computerized information management by the NRA

The DTA is partially using a computerized information management system to store and retrieve information on drug approving, registration, and testing. This means they still heavily rely on paper-documentation. For example, Registration Department uses excel sheet for information archiving and retrieving, but not for management or processing. Additionally, they still use paper-based documents for any official decision or when they contact other departments within the same directorate (DTA).

Thus, scientific drug bureaus need to send documents and follow-up processing in-person via their representatives. According to the director of the Registration Department, “computerization has recently started, but has not been completed yet”. He hopes to have a complete electronic management system, so scientific drug bureaus can apply and follow-up their applications online without sending their representatives to the MOH headquarter which can cause distraction to the employees and slow down the registration process.

In the U.S., the Electronic Common Technical Document (eCTD) is used to submit applications, amendments, supplements, and reports to FDA’s Center for Drug Evaluation and Research

(CDER)[17]. The implementation of electronic management system such as eCTD can save time and efforts. In Iraqi MOH, such an ambitious step needs resources and trained information technology (IT) personnel. The current IT staff perhaps are not ready yet for this upgrading since they do not have enough training and expertise to implement and maintain electronic management system. Thus, a private advanced IT company can help the MOH to install, process and maintain eCTD system.

6.2 Legal provisions and regulation in case of crises/emergencies/outbreaks

The Iraqi MOH has legal provisions and regulation in case of crises/emergencies/outbreaks for the regulation, registration, control, release, and emergency use of health products.

In 2015, the Document of National Pharmaceutical Policy was developed to promote fast drug registration, procuring by KIMADIA and assessing by NCDCR of medications during crisis such as COVID-19 medications.

6.3 Management of confidential information

On September 22, 2016, Iraqi Parliament issued Document Protection Law to protect valuable and confidential documents and information. Thus, a mechanism for the management of confidential information exists in Iraqi institutions [18].

6.4 Marketing Authorization (registration) for medical products on the market

The Law of Practicing Pharmacy Profession no. 40 for 1970 requires marketing authorization (registration) for all medical products on the market [19]. The Registration Department, DTA is responsible for registration of medical products for both private and public sectors whether they are produced nationally or internationally. Unfortunately, large percent of substandard medications enter the private sector through non-official ways and without registration [2].

6.5 Information on registered medical products and authorized companies

According to the Registration Department regulations, information on registered medical products, authorized companies and licensed facilities should be recorded, reviewed, and updated

every five years by the Registration Department. Any scientific bureau or pharmaceutical company fail to send updated information after five years of the registration, their registration will be cancelled (revoked) automatically.

6.6 The recognition and reliance of the regulatory decisions

The DTA has mechanisms for recognition and reliance of the regulatory decisions particularly in the Registration Department [20], the NCDCR and the National Committee for Drug Selection (NCDS).

The regulatory decisions of the Registration Department regarding medicines and pharmaceutical company registration recognize the reliable certifications (FDA, EMA, UK, Japan, Canada, Australia, WHO).

According to the Registration Department regulations, the determination of prices of brand medicines relies on the prices in the British National Formulary (BNF) and neighboring counties (KSA, Jordan). Calculating the price of generic medicines relies on the region of the manufacturers. For example, the price of generics equal to 60% of lowest brand price when the manufacturer is in countries of North America, Europe, Australia, South Korea, and Japan. When the manufacturer is in the Middle East, Arabic countries, neighboring countries and South America, the price of generic equals to 40% of the lowest brand price. Finally, the price of generic medicine equals to 20% of lowest brand price when manufacturer is located in Far East Asia (e.g. China, India).

Any pharmaceutical companies have one or more well-known certificate(s) such as from EMA/ FDA, will be exempted from the inspection visit before company registration. The NCDCR typically tests every batch of imported medications, but for companies with high-standards certificates, it may test some batches and release others without testing. Additionally, the NCDS usually recognizes new medications having EMA/ FDA/NICE approval in their decisions to be included in the essential or comprehensive lists of medicines.

6.7 Publicly available criteria for assessing applications for Marketing Authorization of pharmaceutical products

Most needed forms are available online on the Registration Department website [21], while all other lists of required documents are available in the Registration Department as a compact disc (CD). However, there are no explicit and publicly available criteria for assessing applications for marketing authorization of pharmaceutical products. In other words, required documents may be available publicly, but the criteria for application assessment are not publicly available. Thus, in-person follow-up is needed by a company representative to check the status of any registration application. Again, this mechanism may interfere with routine workflow of the employees and slow-down the registration process in addition to follow-up expenses and efforts needed from scientific bureau/company side.

6.8 Number of medical products registered in Iraq

According to the Registration Department record, there were 4665 registered medicines and vaccines as of August 12, 2020. This list is updated regularly (weekly) since many new medications are added to the list and some previously registered medications can be removed in case of not renewing their registration after the five years cycle.

The Registration Department was able to increase the number of registered medicines from 2,500 in December 2018 to 4665 in August 2020 by adopting Fast Track Registration (FTR). The FTR allows pharmaceutical companies that have certificate of pharmaceutical product (CPP) from a credible health organization (FDA/EMA/WHO) to have temporarily registration and receive importing license within one month and they have a year to complete their long-term registration process.

6.9 Legal provisions require the establishment of an expert committee involved in the marketing authorization process

The law of Practicing Pharmacy Profession (no. 40 for 1970) requires expert committees to study the applications of any new medications or pharmaceutical companies before registration in the MOH [19]. The Registration Department has successfully increased the number of registered

pharmaceutical companies from 1,481 in December 2018 to 1,801 companies in August 2020 by adopting quick registration policy and assigning specialized expert registration committees for each type of companies (pharmaceutical, medical appliances or lab material producers).

6.10 Applicants appealing against NRA decisions

According to the DTA regulations, applicants (scientific bureaus and national companies) can appeal against Registration Department and the NCDS decisions [21].

6.11 Time limit for the assessment of a Marketing Authorization application

According to the Registration Department Letter no. 38 on 21/2/2019, fast-track drug registration can be done within one month and requires few documents: Certificate of pharmaceutical product (CPP), characteristics, compositions, analytic methods, stability study and price certificate. Fast- track registration helps companies to receive importing certificate quickly. However, the applicant/company should complete the full drug registration within one year by providing all other required documents.

6.12 Inspection of premises where pharmaceutical activities are performed

The law of Practicing Pharmacy Profession (no. 40 for 1970) permits inspectors to inspect premises where pharmaceutical activities are performed. Thus, Pharmacy Department experts should inspect local pharmaceutical companies before granting work license. On the other hand, experts from Pharmacy and Registration Departments should visit international pharmaceutical companies to make sure they follow GMP before registration and exporting medications to Iraq.

6.13 Institutions to be licensed and inspected by NRA

Pharmacy Department, DTA, MOH has the authority to grant license to importers and national manufacturers. In contrast, private wholesalers and pharmacies are licensed by Syndicate of Iraqi Pharmacists (SIP) (non-governmental organization)[4], but are inspected by both MOH and the SIP [22]. Non-government Facilities Department, Inspection Directorate, MOH also has the authority to inspect private medication-related institutions (see Table 3).

Table 3: Licensure and inspection authorizes of medication manufacturers, distributors, and sellers in Iraq

Institutions	License authorities	Inspection authorities
Importers (international pharmaceutical companies)	Pharmacy Department (MOH)	Pharmacy & Registration Departments (MOH)
National pharmaceutical manufacturers	Pharmacy Department (MOH)	Pharmacy Department and Inspection Directorate (MOH)
Private scientific bureaus	Syndicate of Iraqi Pharmacists	Inspection Directorate (MOH) & Syndicate of Iraqi Pharmacists
Private wholesalers (drug stores)	Syndicate of Iraqi Pharmacists	Inspection Directorate (MOH) & Syndicate of Iraqi Pharmacists
Private pharmacies	Syndicate of Iraqi Pharmacists	Inspection Directorate (MOH) & Syndicate of Iraqi Pharmacists

6.14 Requiring both domestic and international manufacturers to comply with Good Manufacturing Practices (GMP)

According to the Registration Department Regulations, any international pharmaceutical manufacturers should have GMP, while national manufacturers need to have a license (according to the WHO requirement) from the National Industry Section at Pharmacy Department, DTA.

6.15 Recalling, suspension, withdrawal medical products and destruction substandard and falsified medical products by the NRA

Iraqi Pharmacovigilance Center (IqPhcv) in collaboration with the Inspection Directorate, MOH have the authority to recall, suspend, and withdraw medical products when there is an evidence of problems with quality, safety, or efficacy. On the other hand, the Inspection Directorate has the authority to confiscate and destruct substandard and falsified medical products.

Unfortunately, both public and private sectors do not have electronic tracking system to facilitate identifying the locations of falsified/parallel medications. Thus, MOH totally relies on inspection visits by inspectors and reports from people or healthcare providers.

Recently, the Inspection Directorate has been using the temporary closure (e.g. for 3 weeks to 3 months) as disciplinary actions for drug stores (wholesalers) that have substandard/falsified medications. According to the Registration Department, the reason behind entering unlicensed and S/F medications to the private sector is beyond MOH control. However, some efforts have been made towards the registration of good quality medicines, and post-marketing surveillance activities. These include maintenance of product authorization through marketing authorization renewals or variations, routine inspections of manufacturers and entities across the supply chain. They however need improvement. IqPhvc reports continue to show high prevalence of substandard and falsified medicines in the market. Illicit trade across common borders further complicates the challenge.

6.16 National laboratory of reference in the country for quality control testing (national control laboratory)

National Center of Drug Control and Research (NCDR), founded in 1984, is part of Directorate of Technical Affairs which represents the NRA in the country. The NCDR tests the quality of medications before registration and releasing to the private or public sectors.

6.17 Legal provisions requiring laboratories to comply with standards for Good Laboratory Practices (GLP)

The NCDCR follows the regulations of the Pharmacy Department/ DTA. In other words, the NCDCR complies with a national version of minimal requirements for Good Laboratory Practices (GLP).

6.18 National guidelines or Standard Operating Procedures (SOPs) for GLP

According to the NCDCR, the center tests drug biological, chemical and physical characteristics depending on pharmacopeia (British, US, European) for compendial products and on

manufacturer validated inhouse methods for non-compendial products. However, there are no national guidelines or Standard Operating Procedures (SOPs) for GLP implemented by the NCDCR.

6.19 Situations in which Medicines and vaccines should be tested

The NCDCR tests medications in five situations: As part of the assessment for product registration and before being procured by the public sector (spot check), before new batch release, for quality monitoring in the public sector (routine sampling), when there are complaints or problems identified. In contrast, there is no testing for quality monitoring in the private sector (routine sampling). After testing, the NCDCR sends the result to the Registration Department or KIMADIA (depends on the entity requested).

Almost all batches of imported and national medications should be tested by the NCDCR except those having FDA, EMA, UK certificate(s) which can be released without testing or testing one batch out of several batches. The total number of samples were tested by the NCDCR have increased over the last three years: 15,843 samples in 2017, 17,087 samples in 2018 and 19,388 samples in 2019 (Figures 1).

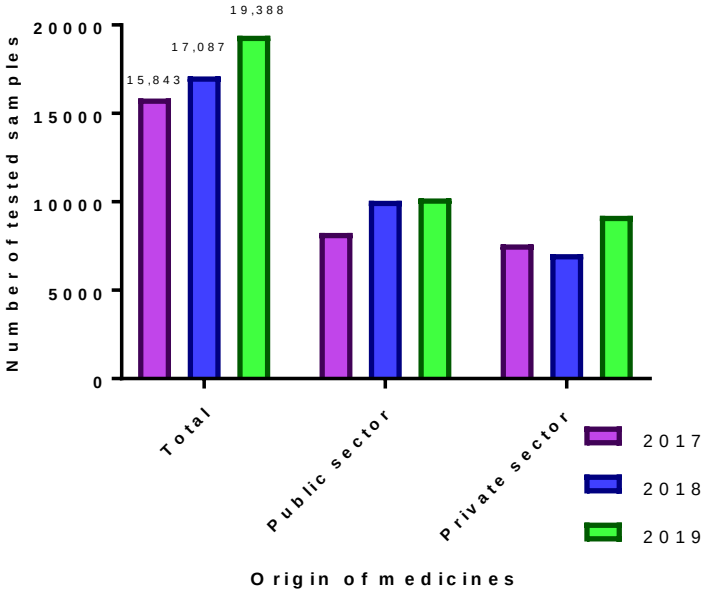

Figure 1: The total numbers of the tested samples by the NCDCR for the public and private sectors over three years

6.20 Legal provisions to control the promotion and/or advertising of prescription medicines to healthcare providers.

Two domains (17 & 18) in the law of Practicing Pharmacy Profession (no. 40 for 1970) control the promotion and/or advertising of prescription medicines [19]. Additionally, the Drug Information Center/ DTA, issued Ethical Rules for Medicines and Medical Appliance Promotion, No. 472 on March 28, 2016.

6.21 Legal provisions prohibiting advertising of prescription medicines to the public

The law of Practicing Pharmacy Profession (no. 40 for 1970) prohibits advertising of prescription medicines to the public. The Inspection Directorate enforces this prohibiting provision. Prescription drug promotion should target healthcare providers rather than general population.

6.22 Legal provisions requiring NRA authorization for conducting clinical trials

There are legal provisions requiring National Center for Training and Human Development authorization for conducting clinical trials at the MOH facilities.

There are two central committees at MOH. The first is the Scientific Research Committee and the second is the Research Ethical Committee. The ethical committee reviews the ethical consideration while the scientific committee makes sure that the steps of the research methodology are correct [23]. The ministerial (MOH) order of assigning duties to the Central Scientific and Ethical Committees for Research was issued on July 2, 2017

Additionally, at each Iraqi health directorate there is a research committee (like Institutional Review Board, IRB). These committees have the right to approve any research protocol and to follow up on its conduction at any stage.

6.23 Good Clinical Practice (GCP) standards/guidelines

The Code of Ethics in Research (2018) manual provides medical researchers with good clinical practice (GCP) standards/guidelines for clinical trials.

6.24 Legal provisions requiring the sponsor and investigator to comply with Good Clinical Practice (GCP)

The Ethical committees at the MOH requires investigators to follow the GCP required by the MOH and Iraqi Medical Association. The two central Scientific and Ethical Committees require researchers to follow the Code of Ethics in Research which was issued in 2018 by the National Center for Training and Human Development, MOH [24]. The GCP is more required when clinical trials are conducted at public healthcare facilities.

6.25 Legal provisions permit inspection of facilities where clinical trials are performed.

The central and health directorate ethical/scientific committees have the right to inspect and oversee all the clinical trials and request all clinical trial documents and consent forms from

researchers. However, the inspection of clinical trial facilities does not happen very often due to limited staff of these committees. The committees usually inspect and follow-up high risk trials, those using new medications and when there is a complain.

6.26 National pharmacovigilance Centre in Iraq

The Iraqi Pharmacovigilance Center (IqPhcv) is responsible for ensuring medication safety across private and public healthcare facilities. The IqPhcv was founded in 2010 and it is part of the Pharmacy Department/ DTA/ MOH. Pharmacovigilance activities are part of the NRA (DTA) mandate.

The IqPhcv has regional center at each province which has “hospital safety responsible person” at each public hospital. Those persons work as a point of contact and report any adverse drug reactions (ADRs) to the IqPhcv at the MOH. Consequently, the IqPhcv will distribute warnings to all public healthcare facilities about the reported ADRs particularly serious ADRs and those reported from more than one health facility. The IqPhvc uses database of Uppsala Monitoring Center (UMC) VigiFlow for public healthcare ADR reports. Additionally, the IqPhcv uses electronic system to receive reports from pharmaceutical companies (uses E2B system) regarding ADRs from both private and public healthcare facilities (source: IqPhvc Director).

6.27 Legal provisions that require monitoring of Adverse Drug Reactions (ADR) and adverse event following immunization (AEFI)

Public Health Directorate controls immunization which is conducted mainly at primary public healthcare facilities. Thus, Public Health Directorate reports adverse event following immunization (AEFI) to the IqPhvc which compiles, and processes ADR reports then distributes warnings to other public healthcare facilities. The IqPhvc has a critical role in monitoring adverse events of medicines and vaccines in both private and public sectors.

6.28 Pharmacovigilance Advisory Committee(s) for pharmaceuticals and vaccines to review serious adverse events

There is a department within the DTA called Consulting Committees Department. This department has a monthly meeting including a group of clinicians for certain disease. The IqPhvc has collaboration with Consulting Committees Department. In other words, the IqPhvc collaborates with 40-50 consulting (expert) committees to evaluate the seriousness of adverse events of medicines and vaccines. When the IqPhvc has a report of ADR and needs consultation, it requests meeting with certain group of clinical advisors (related to the specialty of the ADR) to discuss the casualty and seriousness of this ADR before taking further actions (source: IqPhvc Director).

6.29 Membership in the WHO Program for International Drug Monitoring

The IqPhvc is a member in Uppsala Monitoring Centre (UMC), WHO Program for International Drug Monitoring, since 2010.

6.30 Collecting adverse effects related to use of medicines to prevent/ treat COVID-19

The IqPhvc collects adverse effects related to use of medicines to treat COVID-19 from its regional centers that collects them from COVID-19 centers. Since COVID-19 is treated in public healthcare facilities /centers, any ADRs can be reported to the IqPhvc. The IqPhvc received several ADRs related to the treatment of COVID-19. For examples, Q-wave prolongation/arrhythmia cases were reported for patients used combination of hydroxychloroquine (HCQ) and azithromycin. Additionally, enoxaparin-induced bleeding, dexamethasone -induced increase in blood glucose level and Kaltera®-induced gastrointestinal adverse events were also reported.

6.31 Written criteria to cover emergencies/crises linked to the Risk Management Plan (RMP)

The Prime Minister' chairs the National Disaster Committee which oversees the implementation of a wide range of national disaster management [25]. According to the National Health Policy (2014–2023), Iraq has been working to enhance the public health preparedness and response to different types of emergencies[25]. However, the MOH does not have written criteria to cover emergencies/crises linked to the Risk Management Plan (RMP). The Public Health Directorate started preparation for the RMP.

6.32 Rapid alert system for managing the threats by substandard and falsified products and for recalling these products from the market

Iraqi MOH is a member in the WHO Global Surveillance and Monitoring System for substandard and falsified (S/F) products. This is global rapid alert system for managing the threats by S/F products [26]. The MOH has a focal point with the WHO Global Surveillance and Monitoring System. Iraqi MOH sent its first alarm about S/F medicine(s) through this rapid alert system on September 15, 2020.

On the other hand, the focal point receives WHO signals about S/F medications and distributes them among public healthcare facilities. Internally, the IqPhvc receives reports about S/F products from private sector (community pharmacies) mainly from the scientific bureaus or pharmaceutical companies of the original (legitimate) medicines. The IqPhvc is active to receive and distribute alerts about S/F products via Directorate of Inspections and Syndicate of Iraqi Pharmacists (SIP). The Directorate of Inspection will take the proper action against S/F medications. The SIP receives warning from the IqPhvc about S/F in the private sector and then the SIP distributes the warnings to private wholesalers (drug stores) and community pharmacies through their official website and Facebook page [22].

Session 7 Local Manufacturing

7.1 Total number of licensed pharmaceutical manufacturers in Iraq in terms of ownership

Iraq has 23 local pharmaceutical manufacturers (2 governmental and 21 private). All of them produce finished products only, and none of them produces biopharmaceuticals (see Table 4) (source: Pharmacy Department, National Medicine Industry Section). As shown in Table 4, national pharmaceutical manufacturers currently produce finished products only, neither produce biopharmaceuticals nor WHO prequalified products. A recent Iraqi study (2020) about national pharmaceutical manufacturers shows they face many financial and regulation barriers which slow their growth and limit their market share [27].

Table 4: The total number and categories of licensed national pharmaceutical manufacturers

Category	Number
Total number of licensed pharmaceutical manufacturers in Iraq in terms of ownership	
Governmental manufacturers:	2
Private (national) manufacturers:	21
Private (multinational) manufacturers:	0
Total number of local manufacturers for each manufacturing stage	
Packaging of already formulated imported products:	0
Finished products:	23
Active pharmaceutical ingredient	0
Research and development of new active substance	0
Other classifications	
National manufactures biopharmaceuticals	0
Manufactures with WHO prequalified product locally produced	0

7.2 Governmental vision and strategic plan for the domestic production of medical products

On August 23, 2020, the National Pharmaceutical Industry Section, Pharmacy Department, DTA issued their officially documented vision and mission for the domestic production of medical products. The goals focus on enhancing the production quality and making Iraq self-sufficient in terms of pharmaceutical products. The department has still been working to achieve these challenging goals. Currently, national pharmaceutical manufacturers have low shares in the domestic pharmaceutical market, and they do not export their products. This is may be because there are several decision and policy makers in different ministries (MOH, Ministry of Finance and Boarder Security, Ministry of Industry, Ministry of Trading) who can play essential roles in restricting or promoting national pharmaceutical industry. A high-level committee established by the Cabinet to support the National Pharmaceutical Industry. The MOH was represented by the Technical Deputy Minister.

7.3 Percentage of total market share by value produced by of domestic manufacturers

In 2019, domestic drug products had $ 331.267 million share value which represented 11% of total pharmaceutical market value (source: LNMMAs).

7.4 Market Share of local manufactured pharmaceuticals in Public Sector (KIMADIA) only by value and volume

Total value of all KIMADIA contracts in 2019 was $1,131,056,670 (with exchange rate of 1182 IDs=$1.0) in 2019. The value of national medicines in KIMADIA contracts was $173,438,484 (in 2019). Thus, local pharmaceutical products contributed 15.3% of total value of KIMADIA contracts (i.e. contribute for 15.3% of public pharmaceutical supply) (Source: KIMADIA statistics, 2019). Although, national medicines contributed 15.3% of total value, they represented 47.8% of total volume of KIMADIA medicine contracts. This means most of national products were low-cost medicines.

7.5 Percentage of market share by volume produced by domestic manufacturers

According to the League of National Medicines Manufacturers (LNMM), the market share by volume produced by domestic manufacturers was 20-25% in 2019. This percent is approximation since no accurate data are available about the volume share in the private sector (source: LNMM).

In contrast, the market share by volume in the public sector procurement (by KIMADIA) was 47.8%. That means the market share of domestic medicines was lower in the private sector (in both volume and value) compared to the public sector. This is because national products have priority in KIMADIA contracts, while they cannot compete with low-price imported products in the private sector [27].

7.6 WHO prequalified product locally produced

According to the National Pharmaceutical Industry Section/ Pharmacy Department, there is no WHO prequalified product locally produced so far. However, some local medicine manufactures have been working to achieve this goal.

7.7 Legal provisions that give priority in public procurement to goods produced by local manufacturers

According to the Prime Minister Office Letter on December 1, 2015, the MOH should give priority in public procurement to goods produced by local manufacturers. Thus, KIMADIA should not import any locally produced products. Additionally, the National Medicine Industry Section (MOH) in collaboration with Prime Minister Counsel decided in 2016 to prevent granting import license for 23 generic items that can be produced nationally to increase the market share of national medicines. These medicines include paracetamol oral dosage forms, oral antihistamines (ketotifen, chlorpheniramines and diphenhydramine), few oral antibiotics (amoxycillin, metronidazole and co-trimoxazole), oral corticosteroids (dexamethasone and prednisolone) and few cough and skin preparations. Nevertheless, national pharmaceutical products only contributed to 15.1% of KIMADIA contracts value and about 11% of total pharmaceutical market in 2019. This probably because national manufacturers do not produce

many types of medicines, vaccines or biosimilars. The low market share percentages express the difficult situation that national manufacturers experiencing.

7.8 Shortages in active ingredients occurred due to the COVID-19 crisis

According to the LNMM, there was a shortage in most active ingredients during COVID-19 crisis due to stopping of exportation and most countries keeping all medicines and medical appliance for their own people. For example, one local manufacture confirmed that it experiences shortage in active ingredients of vitamin C, ibuprofen, and metronidazole due to COVID-19 pandemic.

Session 8 Rational Use of Medicines

8.1 National program/committee to monitor medicine use and promote rational use of medicines

According to the Clinical Pharmacy Section, Pharmacy Department, there is a Unit of Rational Use of Medicines which was founded in 2008. This unit promotes rational use of medicines particularly in public healthcare facilities.

The Clinical Pharmacy Section in the DTA in collaboration with Clinical Pharmacy Units at public healthcare facilities lead the rational use of medications particularly through clinical pharmacists who graduated from Clinical pharmacy Program which has been going for 23 years. Additionally, the Clinical Pharmacy Section uses the electronic IT systems to follow up the rational use of medicines including electronic clinical pharmacy intervention sheet (ECPIS).

To extend the rational use of medications to subspecialty disciplines including oncology, anticoagulants and emergency medicines, specialized clinical pharmacy program (post graduate year 2, PGY2) was developed by the Clinical Pharmacy Section. The clinical pharmacy residents of this program work side by side with specialist clinicians in the fields to ensure selecting safe and effective medications in addition to monitoring adverse drug events ADEs.

8.2 Legal provision which prohibits dispensing prescription medicines without prescription

The Practicing of Pharmacy Profession Law (1970) prohibits dispensing prescription medicines without prescription. This law is more enforced in public healthcare facilities since hospital pharmacists cannot dispense any medicines without physician prescription. In contrast, in community pharmacies, this law is not enforced adequately due to the absence of auditing and electronic system [28].

8.3 Generic substitution is allowed at the point of dispensing

According to the Syndicate of Iraqi Pharmacists regulations, generic substitution is allowed at community pharmacies[22]. On the other hand, hospital pharmacists only dispense the available medications whether they are brands or generics depending on KIMADIA procurement.

8.4 Public or independently funded national medicines information center which provides information on medicines

According to the Pharmacy Department, drug information center exists in each public hospital and they are controlled by Clinical Pharmacy Section, MOH (Table 2). These centers provide information and counseling to healthcare providers as well as patients.

8.5 Public education campaigns have been conducted on rational use of medicines topics

Clinical Pharmacy Section/ Pharmacy Department conducted Antibiotics Awareness Week in 2018 across most public healthcare facilities in the country. This awareness program targeted public to minimize the antibiotics misuse and antibiotics consumption without doctor prescription.

8.6 National Data on national antimicrobial consumption

The MOH does not have electronic national data on national antimicrobial consumption yet. Antimicrobial Unit at Public Health Directorate received the hard copy of raw data of antibiotic consumption at the public sector from KIMADIA. However, they are waiting for the training by local WHO staff to enter the data to the computer which is on hold due to COVID-19 pandemic.

The MOH started to adopt the Antimicrobial Consumption Surveillance (AMCS) to achieve the fourth goal of the national strategic plan for controlling antimicrobial resistance in March 2020. The MOH has been working according the AMCS strategy time-table to ensure surveillance data for the central level be released by the end of 2020, and the surveillance data of antimicrobial consumption to be completed and includes all levels by the end of 2022 (Source: Antimicrobial Unit at Public Health Department, August 2020).

In Feb 2020, Clinical Pharmacy Section in collaboration with the Therapeutics Department and the Department of Consultant Committees issued the Iraqi National Antimicrobial Guideline (INAG). There is also an antimicrobial stewardship committee in every hospital that includes hospital director, a physician, a chief nurse, and a clinical pharmacist. A hospital antibiogram is prepared in collaboration between the stewardship committee and the drug information center at each public hospital.

8.7 Regulations require hospitals to establish Drug and Therapeutics Committees (DTCs)

The MOH regulations required the Pharmacy Department to establish Drug and Therapeutics Committees (DTCs) (one at each public hospital) in 1997. The Pharmacy and Therapeutic Committee Unit at Pharmacy Department controls all hospital DTCs in addition to receiving and assessing their meeting recommendations (Table 2) (source: Director of Clinical Pharmacy Section, Pharmacy Department).

8.8. Continuing education for medical doctors and pharmacists that includes rational use of medicines

Continuing education (CE) is available for healthcare providers, but it is not mandatory. It is more mandatory on governmental healthcare providers rather than on private sector providers. Clinical Pharmacy Section (MOH), the SIP and national colleges of pharmacy provide CE sessions and lectures, but they are optional. There is no connection between having CE and renewing pharmacy license. The private pharmacy license is renewed annually by the SIP without any CE requirements.

8.9 Medical doctors and pharmacists are encouraged to use generic medicines.

There are no regulations encouraging physicians and pharmacists to use generic medicines. However, KIMADIA relies on the lowest-price basis to select among available acceptable offers. KIMADIA is encouraged to procure generic medicines. Additionally, the Registration Department allows to register 10 generic medicines in addition to the brand one.

In public facilities, providers typically prescribe/dispense only medications that are available in their hospital pharmacies. In contrast, in the private sector, physicians and pharmacists have flexibility to choose brand medicines. Some physicians prefer brand over generic medicines because they believe brand medicines are more effective than their counterpart generics [29].

8.10 Self-medication in relation to prevention/ treatment of COVID-19

In public healthcare facilities, there is no recommendation for self-medication in relation to prevention/ treatment of COVID-19. Any COVID-19 medications can only be used for inpatients within COVID-19 centers. However, since June 2020 when the cases of COVID-19 have been increasing dramatically from couple hundreds to 3000-4500 daily, public hospitals become overwhelmed and patients with mild and moderate conditions are encouraged to stay home for treatment. Those patients visit physician clinics who prescribe COVID-19 medications and sometimes recommend self-medication as prevention for their household. Thus, private physicians may recommend the use of supplements (vit. C, vit. D3, zinc) as prophylaxis from COVID-19.

Summary of areas that need improvement

1. Currently, all document transitions between departments are done through paper documents.
2. Any application and follow-up should be done in-person (by a pharmaceutical company representative)
3. The websites of some MOH departments are not updated regularly.
4. In 2019, KIMADIA procured 60% of total essential medicines (level 1).
5. The national framework for good governance for medicines (GGM) has started in 2012 in collaboration with WHO but stopped.
6. There is no national database to assess the effectiveness of COVID-19 medications.
7. About 60-70% of medications in the private sector are not officially entered the country which need a multifactorial solution.
8. The share of domestic pharmaceutical products is low in the national drug market (≈11%) and there is no WHO prequalified product locally produced.
9. There are no private multinational manufacturers in Iraq.
10. There are no local manufacturers can produce biopharmaceuticals.

Strategies to Improve Access to Medicines and Vaccines in Iraq: Vision, Strategic Objectives and Priority Actions:

1. Having written standard operating procedures (SOPs) in all pharmaceutical activities can minimize the interference in duties between different departments/sections.
2. To improve the management process, the MOH can adopt electronic system such as Electronic Common Technical Document (eCTD) to manage drug processing steps from approval till release.
3. In the future, Iraq may need to compile all pharmaceutical regulatory departments in one independent agency (like FDA).
4. To strengthen the management system inside the MOH departments and with other external entities, the settlement of a strong internet signal network will be needed.
5. Regular assessment and evaluations of the strategic and implementation plans can be done by a central agency and enforced by regulation-enforcement agency.
6. Provision of more publicly available and updated information on the websites of the different MOH departments. This will save time and efforts of pharmaceutical companies and their representatives and allow focused working environment for the employees.
7. Reactivation and implementation of National framework for good governance for medicines (GGM) can be conducted by the MOH in collaboration with WHO.
8. KIMADIA can work with Technical Affairs Directorate to provide 100% of essential drug list. KIMADIA can achieve that through two important mechanisms: Effective budgeting and accurate pharmacoeconomic system for procurement process, in addition to clear and fast process mechanism in emergency crises.
9. Budget management is very necessary; thus, all new costly medications to be studied by the NCDS have to be assessed by the Pharmacoeconomic Committee at Need Estimation Department to show whether they are cost-effectiveness compared to the already approved medications before listed in the essential medicine list.
10. The new pharmacists/staff in the Registration Department may need regular (annual) training about how to evaluate new medication dossiers to achieve quicker registration.

11. Implementing a trace and track system can help minimizing unregistered medications in the private sector.
12. Strengthen the capacity of the NCDC, through work on achieving ISO certificate in the near future
13. Developing national electronic database to assess the effectiveness and safety of COVID-19 medications is a necessity.
14. National pharmaceutical companies need more financial support, facilitations in importing active ingredients and an extension of the duration of their importing license.
15. More frequent assessment of Iraqi Pharmaceutical Profile is necessary to identify areas that need improvements and monitor progress in implementations, regulations, and policies. This can be done in collaboration with the WHO.
16. The assessment of this report can help update the National Pharmaceutical Policy.
17. Clinical Pharmacy Section is planning to extend the hospital residency programs in Clinical Pharmacy including post-graduate year 2 (PGY2) to more specialties.

WHO Recommendations

A. Formulate, update, implement and monitor comprehensive national policy for medicines and vaccines (NPMV), while ensuring all stakeholders' commitment to its implementation:

1. Establish and adopt a national good governance of medicines program through formulation and implementation of appropriate policies and procedures that ensure the effective, efficient, and ethical management of pharmaceutical systems, in a manner that is transparent.
2. Institute mechanisms to continuous measurement of access to medicines and vaccines, by identifying core set of indicators to become part of routine data collection and analysis including COVID-19 data collection.
3. Facilitate information exchange across national and international stakeholders and between countries on issues related to access to medicines and vaccines.

B. Secure adequate and sustainable funding, and effective financing mechanisms with necessary flexibilities, to ensure regular supply of essential medicines and vaccines, with emphasis on priority diseases and vulnerable populations.

1. Secure sufficient public financing for essential medicines and vaccines, through improved financial management, especially for the public sector, based on properly quantified health care needs.
2. Establish a mechanism of collaboration between Ministries of Health and Ministries of Financing to promote more public financing for essential medicines and vaccines with better public financial management rules.
3. Undertake regular financial and economic analysis of medicines expenditures using cost-effectiveness and other economic evaluation analytical tools, especially in the public sector.

C. Ensure the availability of medicines and vaccines at affordable and fair prices in in both the public and private sectors.

1. Establish and promote mechanism that improve collaboration and information exchange between neighboring countries on the prices of medicines and vaccines.
2. Conduct periodic surveys of medicine prices and availability; establish a routine monitoring system for medicine prices and availability; and investigate the underlying determinants of any issues encountered.
3. Encourage collaboration among stakeholders involved in pricing and reimbursement schemes.

4. Formulate and update pricing policies, promote the use of quality assured generics and biosimilars and reference pricing.

D. Strengthen national regulatory authorities to ensure quality, safety and efficacy of medicines and vaccines.

1. Provide needed means, infrastructure and funds for the establishment of independent and autonomous comprehensive regulatory body.
2. Conduct National Regulatory Authority (NRA) self-assessment, NRA benchmarking exercise, and formulate institutional development plan to be implemented for strengthening enforcement of legislation and regulatory capacities.
3. Explore approaches to utilize concept of reliance and collaborative decision-making to increase timely access to safe and effective medical products.
4. Support capacity building of regulatory activities, including pharmacovigilance, regulation of biotherapeutics, GMP, combating substandard and falsified medical products**.**
5. Establish tracing systems, e.g., barcode identifying the manufacturers and the batches produced**.**

E. Enhance appropriate use of medicines by health professionals and consumers.

1. Develop and implement a comprehensive strategy on rational use of medicines, including interventions to contain antimicrobial resistance.
2. Develop educational programs and other effective mechanisms to promote rational use of medicines by all health professionals.
3. Develop and implement standard treatment guidelines and formularies linked to the national essential medicines list.
4. Conduct public campaigns and consumer education programs to raise awareness of rational use of medicines.

F. Promote local production of quality medicines and vaccines that meet public health needs.

Develop a national strategy for promoting local production with policy coherence, including promoting an enabling business environment for local production, providing incentives that support/promote local production of essential medicines, and scaling up the production in cases of pandemic and emergency

References

1. Health/Environment, M.o., *Annual Statistics Report 2019*, P. Directorate, Editor. 2020: Baghdad.
2. Alaa AlAlwan, M., *Health Situation in Iraq: Challenes and Priorities for Action*, M. Iraqi Ministry of Health, Editor. 2019, Ministry of Health: Baghdad.
3. Parliament, I., *Public Health Law no. 89 in 1981*. 1981: http://iraqld.hjc.iq:8080/LoadLawBook.aspx?SC=291120057072056.
4. Al-Jumaili, A.A., S.A. Hussain, and B. Sorofman, *Pharmacy in Iraq: history, current status, and future directions.* Am J Health Syst Pharm, 2013. **70**(4): p. 368-72.
5. Orgainzation, W.H., *Global Health Expenditure Database: Health Expenditure Profile Iraq*. 2017: https://apps.who.int/nha/database/country_profile/Index/en(please select Iraq profile).
6. Organization, W.H., *Iraq Statistics*. 2014: https://www.who.int/countries/irq/en/.
7. Selection, N.B.F.D., *Technical Affairs Directorate*. 2012: http://www.tec-moh.com/mfollow.php.
8. Organization, W.H., *Implementation of the Good Governance for Medicines programme in Iraq*. 2012, The WHO Regional Office for the Eastern Mediterranean http://www.emro.who.int/iraq-press-releases/2012/implementation-ggm-programme.html.
9. Organization, W.H., *Good Governance for Medicines* in *Compilation of country case studies and best practices*. 2010: https://www.who.int/healthsystems/topics/financing/healthreport/25GGM.pdf?ua=1.
10. parliament, I., *Code of Conduct for Public Service* 1960: https://mop.gov.iq/static/uploads/8/pdf/1505800349921e1772308612b261249161920a81bc--%D9%82%D8%A7%D9%86%D9%88%D9%86%20%D8%A7%D9%84%D8%AE%D8%AF%D9%85%D8%A9%20%D8%A7%D9%84%D9%85%D8%AF%D9%86%D9%8A%D8%A9.pdf.
11. KIMADIA, *The State Company For Marketing Drug AND Medical Appliances*. 2020, IRAQI MINISTRY OF HEALTH: http://kimadia.iq/en/.
12. ORGANIZATION, W.T., *Accession: Iraq*. 2020, WTO: https://www.wto.org/english/thewto_e/acc_e/a1_iraq_e.htm.
13. Organization, W.I.P., *Country Profile: Iraq*. 2020, WIPO: https://www.wipo.int/directory/en/details.jsp?country_code=IQ
14. Control, C.O.f.S.a.Q., *Department of Industrial Property Management* 2020, Ministry of Planning: http://www.cosqc.gov.iq/html/Patent/master.html.
15. Directorate, T.A., *Technical Affairs Departments* 2020, Ministry of Health: http://www.tec-moh.com/herbals.php.
16. Lafta, J.Z., *Iraq Pharmaceutical Country Profile*. 2011, Iraqi Ministry of Health in Collaboration with World Health Organization https://www.who.int/medicines/areas/coordination/Iraq_PSCPNarrativeQuestionnaire_01022012.pdf?ua=1. p. 3-30.
17. Administration, T.U.S.F.a.D., *Electronic Common Technical Document (eCTD)*. 2020, FDA: https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd.
18. Parliament, I., *Document Protection Law*. 2016: http://iraqld.hjc.iq/(S(pnr3ts45cgwfjiue0eh3u345))/LoadLawBook.aspx?SC=280320068198249.
19. Parliament, I., *Law of Pharmacy Profession* 1970: http://iraqld.hjc.iq/LoadLawBook.aspx?SC=021220051244781.

20. Al-Kinani, K.K., et al., *Iraqi regulatory authority current system and experience with biosimilars.* Regulatory Toxicology and Pharmacology, 2020. **117**: p. 104768.
21. Directorate, T.A., *Registration Department*. 2020, Iraqi MOH: moh-reg.net.
22. Pharmacist, S.o.I., *Iraqi Pharmacists Syndicate Official Website*. 2020, IPS: http://www.iraqipharm.com/.
23. Ministry of Health, I.T.C., *The National Center for Training and Human Development*, in *NCTHD*. 2020, MOH: https://moh.gov.iq/index.php?name=Pages&op=page&pid=79.
24. The National Center for Training and Human Development, R.U., *The Code of Ethics in Research*, in *Guide for Condcting Medical Studies*. 2018, Ministry of Health: https://moh.gov.iq/upload/upfile/ar/886.pdf.
25. ORGANIZATION, W.H., *JOINT EXTERNAL EVALUATION OF IHR CORE CAPACITIES of the REPUBLIC OF IRAQ*, in *Mission report:*. 2019, WHO: https://apps.who.int/iris/bitstream/handle/10665/325488/WHO-WHE-CPI-2019.61-eng.pdf?sequence=1.
26. Organization, W.H., *WHO Global Surveillance and Monitoring System*. 2013, WHO: https://www.who.int/medicines/regulation/ssffc/surveillance/en/.
27. Ahmed, K.K., et al., *Determinants of national drug products acceptance across patients, pharmacists, and manufacturers: A mixed method study.* Journal of Generic Medicines, 2020. **https://journals.sagepub.com/doi/abs/10.1177/1741134320926625**: p. 1741134320926625.
28. Bashar G. Alfetlawi, A.A.A.-J., Munaf H Zalzala,, *Evaluating Factors Related to the Abuse of Oral Corticosteroids among Community Pharmacy Customers: Using Theory of Reasoned Action.* Innovations in Pharmacy, 2020. **11**(1): p. 10.
29. Layla Abdullah Mahdi, D.J.K., Ali Azeez Al-Jumaili, *Knowledge, perception and attitude regarding generic medicines among Iraqi physicians.* Innovations in Pharmacy, 2020. **11**(1): p. 10.

WORLD HEALTH ORGANIZATION
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Bureau régional de la Méditerranée orientale

منظمة الصحة العالمية
المكتب الإقليمي لشرق المتوسط

Access to Medicines and Vaccines in the Eastern Mediterranean Region

Short version

Iraq

July 26-August 24, 2020

Section 0 General Info **0.01 Contact Info**		
0.01.01	Country	Iraq
0.01.02	Name of coordinator	Dr. Ali Azeez Al-Jumaili, BS Pharm, MS, MPH, PhD
0.01.03	Phone number	+964 7711350203
0.01.04	Email address	Ali.baraak@copharm.uobaghdad.edu.iq
0.01.05	Institution	University of Baghdad College of Pharmacy, Iraq

Section 1 Health, Pharmaceutical Expenditure and Demographic data				
Main sources: MOH report 2019 (Health Status in Iraq, Challenges and priorities for Action) Annual Statistics Report 2019, Planning Directorate, Ministry of Health, Issued in 2020 League for Promotion of Medicines and Medical Appliance (LPMMA).			**Year**	**Source**
1.1	Population, total (,000)	39,128	2019	Annual Statistics Report
1.2	Gross Domestic Product (GDP)per capita (US$)	2,833	2019	MOH report 2019
1.3	Population covered by a public health service or public health insurance or social health insurance (% of total population)	100	1981	Public Health Law No. 89
1.4	Population covered by private health insurance (% of total population)	N/A		
1.5	Total health expenditure as percentage of Gross Domestic Product (GDP) (%)	5.5	2014	WHO (Iraq statistics)
1.6	Government annual expenditure on health as percentage of total government budget (%)	4.5	2019	MOH report 2019
1.7	Total pharmaceutical expenditure per capita (US$)	79.7	2019	MOH report & LPMMA

1.8	Pharmaceutical expenditure as a percentage of Health Expenditure (% of total health expenditure) Note: This percent (25%) is out of the public sector health expenditure since there are no available data about total health expenditure.	25	2019	MOH report 2019
1.9	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	41.1	2019	MOH report & LPMMA
1.10	Market share of generic pharmaceuticals by value (%)	70	2019	KIMADIA
Section 2 Medicines policies, Governance, Evidence-based selection and Health Technology Assessment				
Main Sources: Deputy Minister Office letter, 17-9-2015, MOH, Pharmacist Mazin Mahdi Hussein, National Committee for Drugs Selection (NCDS). Mzn.email@yahoo.com Iraqi Law of Practicing Pharmacy Profession, no.40 for 1970 Dr. Abdul Raheem Taha Hamody, Therapeutics Department Director: abdraheem_ra@yahoo.com Razzaq Enad AbdulAbbass, IT Department razakenad@gmail.com			**Year**	**Source**
2.1	The National Medicines Policy (NMP) official document exists	Yes ☒ No ☐	2015	Deputy Minister Office letter
	2.1.1 If yes, please write the year of the most recent document in the "year" field	2016-2021		
	2.1.2 Name of agency responsible for developing and updating the NMP	Name of agency: Drug Policy Committee		
	2.1.3 The NMP includes sections related to regulatory procedures and supply chain management in cases of emergency, pandemics and crisis situations	Yes ☐ No ☒	2015	The Document of National

				Pharmaceutical Policy
2.2	There is a NMP implementation plan 2.2.1 If yes, please write the year of the most recent document in the "year" field	Yes ☐ No ☒	2020	The Document of National Pharmaceutical Policy
2.3	A National Essential Medicines List (NEML) exists	Yes ☒ No ☐	2020	NCDS
	2.3.1. If yes, please write the year of the most recent document in the "year" field 2.3.2 Please provide the name of the agency responsible for selection of NEML		2020	NCDS
		Name of agency: National Committee for Drugs Selection (NCDS)		NCDS
	2.3.3 There is a formal committee or other equivalent structure for the selection of products on the NEML.	Yes ☒ No ☐	2012	NCDS
	2.3.4 If yes, conflict of interest declarations are required from members of NEML committee.	Yes ☐ No ☒	2020	NCDS
	2.3.5 There is a documented process and criteria for selecting medicines for inclusion on the NEML?	Yes ☒ No ☐	2020	NCDS
	2.3.6 Number of medicines on the NEML (by active ingredient)	Number of medicines: 827 by active ingredients. 1105 by complete products	23-6-2020	NCDS

	2.3.7 There are traditional medicines on the NEML	Yes ☐ No ☒	2020	NCDS
2.4	There is a national framework for good governance for medicines	Yes ☐ No ☒	2020	Clinical Pharmacy Section
2.5	There is a conflict of interest management policy in the pharmaceutical sector	Yes ☒ No ☐	1970	Pharmacy Law
2.6	There is a formal Code of Conduct for public officials	Yes ☒ No ☐	1960	Code of Conduct for public service
2.7	There are National Standard Treatment Guidelines (STGs)/ protocols endorsed by the Ministry of Health: - For most common illnesses - only Individual guidelines exist	Yes ☒ No ☐ Yes ☐ No ☒	2018	Therapeutic Department
2.8	There is a national clinical guideline for treatment of COVID-19 2.8.1 If yes, the following medicines are included in the national clinical guideline for treatment of COVID-19:	Yes ☒ No ☐ Chloroquine ☐ Hydroxychloroquine ☒ Azithromycin ☒ Lopinavir/ritonavir☒ Remdesivir ☒ Umifenovir ☐ Favipiravir ☒	2020	Therapeutic Department, MOH letters (June 1 & 28, 2020)

		Tocilizumab ☒ Interferon-β-1a ☒ Plasma therapy ☒		
2.9	There is a national institution responsible for Health Technology Assessment (HTA) 2.9.1 If yes, what is the name of the institution?	Yes ☐ No ☒	2020	Informational Technology Department
		Name of the institution: N/A		
	2.9.2 There is a legislative or regulatory requirement to consider the results of HTAs in the process of health policy decisions for the use of a health product (particularly when it is new product)	Yes ☐ No ☒		Informational Technology Department
Section 3 Financing, Pricing, Availability and Affordability of medicines				
	Main sources: Dr. Omar AbdulAmeer, Department of Financial planning. dromarabdulameer@yahoo.com Dr. Asaad Mahdi Asaad/Deputy Directorate General/Public Health Directorate. Asaad1312@yahoo.co.uk Pharmacist: Nawfal Kareem Abdulhadi, Director of Registration Department. Nawfal9abd@yahoo.com Pharmacist Maha Shaker, Inspection Directorate. mostafex@gmail.com Pharmacist: Amnah Gahzi Mahdi. KIMADIA Information Center. Gen.relat@kimadia.iq Finance Ministry-General Commission for Taxes Letter, 9 Oct. 2016 Iraqi League for Medicine Producers (ILMPs)		Year	Source

3.1	In the public sector the following patient groups receive medicines free of charge:	Patients who cannot afford them ☒ Children aged less than 5 years ☒ Pregnant women ☒ Elderly persons ☒	2019	Department of Financial planning Letter, Feb 25, 2019
3.2	In the public sector the following medicines are provided free of charge to patients: <u>Other eligible categories</u> include medicines for thalassemia, hemophilia, renal failure, cancers, burns, hepatitis B, pregnant women, WHO preventive programs are provided for free of charge by governmental healthcare facilities .	All medicines on the NEML ☐ Medicines for selected NCDs ☒ Medicines for Malaria ☒ Medicines for Tuberculosis ☒ HIV/AIDS medicines ☒ Expanded Programme on Immunization (EPI) vaccines ☒ Others ☒ please specify:	2019	Department of Financial planning Letter Feb 25, 2019 & Public Health Directorate

3.3	There are legal or regulatory provisions that determine the prices of medicines in the private sector (Price is controlled)	Yes ☒ No ☐	2017	Medicine Pricing instructions, Feb 7, 2017
	3.3.1 If yes, please name the agency responsible for pricing of medicines	Name of the agency: Registration Department		
3.4	The government maintains an active national medicines price monitoring system	Yes ☒ No ☐	2020	Inspection Directorate
3.5	Medicines availability and prices surveys have been conducted (using WHO/HAI methodology or other study designs)	Yes ☐ No ☒	2020	Registration Department
	3.5.1 If yes, what is the year of the most recent survey:			
3.6	Duties are imposed on imported finished pharmaceutical products 3.6.1 If yes, what is the rate of duty applied to finished pharmaceutical products (in %)	Yes ☒ No ☐ Rate of duty: 2.7% & 10%	2016	Finance Ministry-General Commission for Taxes
3.7	Duties are imposed on imported Active Pharmaceutical Ingredients (APIs) 3.7.1 If yes, what is the rate of duty applied to APIs (in %)	Yes ☒ No ☐ Rate of duty: 5%	2019	Iraqi League for Medicine Producers (ILMPs)
3.8	There are provisions for tax exceptions or waivers for pharmaceuticals products 3.8.1 If yes, on which categories of pharmaceuticals are these exemptions applied	Yes ☐ No ☒	2019	Finance Ministry-General Commission for Taxes
		Categories:		

Section 4 Procurement and supply management system				
	Source: Pharmacist: Amnah Gahzi Mahdi. KIMADIA Information Center. Gen.relat@kimadia.iq		**Year**	**Source**
4.1	Name of the agency responsible for public procurement	Name of the agency: The State Company for Marketing Drug AND Medical Appliances (KIMADIA).	1964	http://kimadia.iq/en/
4.2	Public sector procurement of medicines in your country is:	Decentralized ☐ Centralized and decentralized ☒	2020	KIMADIA
	4.2.1 If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:	Part of MOH ☒ Semi-Autonomous ☒ Autonomous ☐		KIMADIA
4.3	Public procurement includes the following mechanisms:	National competitive tenders ☒ International competitive tenders ☒ Direct purchasing ☒	2020	KIMADIA

4.4	There are guidelines and standard operating procedures (SOPs) for the procurement of medical products in the public sector	Yes ☒ No ☐	2012	KIMADIA
4.5	There is a national guideline on the donation of medical products	Yes ☒ No ☐	2017	Pharmacy Department, 3-8-2017
4.6	There are legal provisions requiring wholesalers and distributors to comply with Good Distribution Practices (GDP) & Good Storage Practices (GSP)	Yes ☒ No ☐	2020	Inspection Directorate
4.7	National GDP and GSP are published by the government	Both GDP and GSP ☒ Only GSP ☐ Only GDP ☐ Neither ☐		Pharmacy Department
4.8	There is prequalification of suppliers for public sector procurement	Yes ☒ No ☐	2019	Registration Department Regulations
4.9	There is a written public sector procurement policy	Yes ☒ No ☐		KIMADIA
	4.9.1 If yes, please write the year of the last updated policy		2017	
4.10	A process exists to ensure the quality of products procured	Yes ☒ No ☐	1984	NCDCR
4.11	Medication shortages occur during the COVID-19 crisis 4.11.1 If yes, please list the medication shortages which have occurred so far	Yes ☒ No ☐ Medication shortages: 4	July 28, 2020	Pharmacy Department

		medications: Lopinavir-Ritonavir (Kaletra) tablet, Remdesivir inj, Tocilizumab vial, Interferon Beta vial		
Section 5 Medicines trade and intellectual property				
Main sources: Ministry of Planning/Central Organization for Standardization and Quality control, Department of Industrial Property Management. Law of Patent & Industrial Samples no.65 in 1970 and its update in 2004.			**Year**	**Source**
5.1	Your country is a member of the World Trade Organization (WTO) 5.1.1 If yes, please indicate the year it became a member	Yes ☐ No ☒	2020	https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm
5.2	Your country is a member of the World Intellectual Property Organization (WIPO) 5.2.1 If yes, please indicate the year it became a member	Yes ☒ No ☐		https://www.wipo.int/directory/en/details.jsp?country_code=IQ
			1976	WIPO website

5.3	Please provide name of the institution responsible for managing and enforcing intellectual property rights and the date of its establishment	Name of the institution: Ministry of Planning/Central Organization for Standardization and Quality control, Department of Industrial Property Management.		
		Date of its establishment: 1979		
5.4	National legislation has been modified to implement the TRIPS Agreement	Yes ☐ No ☒	2020	KIMADIA
5.5	Legal provisions exist for granting patents	Yes ☒ No ☐	1970	Law of patent & industrial samples no.65
5.6	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☐ No ☒	2020	KIMADIA
5.7	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☒	2020	Registration Department

Section 6 Regulation of Medical Products

Sources: Dr. Manal Mohammed Younus. Iraqi Pharmacovigilance Center (IqPhvc), Pharmacy Department. manalyounus@yahoo.com
Pharmacist: Ammar Sedkhan Salman, Director of Pharmacy Department. ammar1977za@gmail.com
Pharmacist Hala Hadi Abdulla. National Pharmaceutical Industry Unit, Pharmacy Department. Hha3pharm@yahoo.com
Pharmacist Mustafa Saadi, Unit of Pharmaceutical Affairs. Mshf.2008@yahoo.com
Dr. Shakir Mahmood Muhammed, MD, Head of Research and Knowledge Management / MOH. shakshamcar@yahoo.com
Iraqi Parliament, Document Protection Law. 22-9-2016

Pharmacist: Samir Hasson, National Center for Drugs Control & Researches (NCDCR) . Ramadhandr.samer_2007@yahoo.com

Ethical Rules for Medicines and Medical Appliance Promotion, No. 472 on 28-3-2016

			Year	Source
6.1	There is a National Regulatory Authority (NRA)	Yes ☒ No ☐	2020	MOH
	6.1.1 If yes, please name the institution:	Name of the institution: Directorate of Technical Affairs (DTA)		
	6.1.2 Please provide the URL to the website of the NRA, if this exists	URL:http://www.tec-moh.com/		
	6.1.3 The NRA of medical products is:	Part of the Ministry of Health ☒ Semi-autonomous agency ☐ Autonomous agency ☐	2020	Directorate of Technical Affairs (DTA)
	6.1.4 The NRA has legal provisions that establish its functions and responsibilities	Yes ☒ No ☐	2020	DTA
	6.1.5 Functions of the NRA include the following: Note: The oversight of clinical trials is the responsibility of ethical/scientific committee(s) at the National Center for Training and Human Development and local healthcare directorates. Inspection Directorate is responsible for market surveillance and control	Marketing Authorization ☒ Regulatory Inspection ☒ Market Surveillance and Control ☐	2020	Dr. Manal Mohammed, Pharmacy Department, DTA.

		Licensing Establishments ☒ Laboratory testing ☒ Lot release ☒ Clinical trials oversight ☐ Pharmacovigilance ☒		
	6.1.6 Health products that are regulated by the NRA include:	Medicines ☒ Biotherapeutics ☒ Vaccines ☒ Blood and Blood components ☒ Plasma derived medicinal products ☒ Herbal or traditional medicines ☒ Medical devices & diagnostics ☒	2020	Registration Department & Dr. Manal Mohammed, Pharmacy Department, DTA
	6.1.7 An assessment of the NRA has been conducted in the last five years	Yes ☐ No ☒	2011	Iraq Pharmaceutical

				Country Profile
	6.1.8 The NRA is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☐ No ☒	2020	Registration Department
6.2	There are legal provisions and regulation in case of crises/emergencies/outbreaks for the regulation, registration, control, release and emergency use of health products	Yes ☒ No ☐	2016	Drug Policy Committee
6.3	A mechanism for the management confidential information exists	Yes ☒ No ☐	2016	Document Protection Law.
6.4	Legal provisions require a Marketing Authorization (registration) for all medical products on the market	Yes ☒ No ☐	1970	Law of Pharmacy Profession
6.5	Information on registered medical products, authorized companies and licensed facilities are available and periodically reviewed and updated	Yes ☒ No ☐	2020	Registration Department
6.6	There are mechanisms for recognition and reliance of the regulatory decisions (e.g. registration, inspection, control, etc..)	Yes ☒ No ☐	2020	Registration Department
	6.6.1 If yes, please provide the name of countries or NRA which your country relies upon for recognition and reliance of the regulatory decisions	Name of countries or NRA: Neighboring countries (KSA, Jordan), EMA, FDA, UK, Japan, Canada, Australia, WHO		
6.7	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☐ No ☒	2020	Registration Department

6.8	Number of medical products registered in your country (medicines and vaccines)	4665	August 12, 2020	Registration Department
6.9	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☒ No ☐	1970	Pharmacy Profession Law
6.10	Legal provisions allow applicants to appeal against NRA decisions	Yes ☒ No ☐	2020	Registration Department
6.11	Time limit for the assessment of a Marketing Authorization application (months)	1 month for Fast-Track and 1 year for complete Registration	2019	Registration Department Letter No. 38 on 21/2/2019
6.12	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	1999	Pharmacy Profession Law & Pharmacy Department Regulations
6.13	The following institutions to be licensed and inspected by NRA Note: Private wholesalers and pharmacies are licensed by Iraqi Pharmacists Syndicate (IPS) but are inspected by both MOH and IPS	Importers ☒ Local manufacturers ☒ Private wholesalers and distributors ☐	2020	Pharmacy Department

		Private pharmacies ☐		
6.14	Legal provisions exist requiring both domestic and international manufacturers to comply with Good Manufacturing Practices (GMP)	Yes ☒ No ☐	2020	Pharmacy Department
6.15	There are legal provisions that allow the NRA to recall, suspend, withdraw medical products and destruct substandard and falsified medical products when there is evidence of problems with quality, safety or efficacy	Yes ☒ No ☐	2020	IqPhcv in collaboration with Inspection Directorate
6.16	There is a national laboratory of reference in the country for quality control testing (national control laboratory)	Yes ☒ No ☐	1984	National Center for Drugs Control & Research (NCDCR)
	6.16.1 If yes, it is part of the NRA	Yes ☒ No ☐		
6.17	There are legal provisions requiring laboratories to comply with standards for Good Laboratory Practices (GLP)	Yes ☐ No ☒	2020	NCDCR
6.18	There are national guidelines or Standard Operating Procedures (SOPs) for GLP	Yes ☐ No ☒	2020	NCDCR
6.19	Medicines and vaccines are tested in the following situations:	For quality monitoring in the public sector (routine sampling) ☒ For quality monitoring in the private sector (routine sampling) ☐ When there are complaints or problems identified ☒ As part of the assessment for product registration ☒		NCDCR

		Before being procured by the public sector (spot check) ☒		
6.20	There are legal provisions to control the promotion and/or advertising of prescription medicines	Yes ☒ No ☐	2016	Ethical Rules for Medicines and Medical Appliance Promotion
6.21	There are legal provisions prohibiting advertising of prescription medicines to the public	Yes ☒ No ☐	1970	Pharmacy Profession Law
6.22	There are legal provisions requiring NRA authorization for conducting clinical trials	Yes ☒ No ☐	2017	MOH order
6.23	Good Clinical Practice (GCP) standards/guidelines exist.	Yes ☒ No ☐	2018	The Code of Ethics in Research
	6.24.1 If yes, there are legal provisions requiring the sponsor and investigator to comply with GCP	Yes ☒ No ☐	2018	https://moh.gov.iq/upload/upfile/ar/886.pdf
6.24	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☒ No ☐	2017	The National Center for Training and Human Development
6.25	There is a national pharmacovigilance Centre/ Department/ Unit in your country	Yes ☒ No ☐	2010	IqPhvc

6.26	Pharmacovigilance activities are part of the NRA mandate	Yes ☒ No ☐	2010	IqPhvc
6.27	There are legal provisions that require monitoring of Adverse Drug Reactions (ADR) and adverse event following immunization (AEFI)	Yes ☒ No ☐	2010	IqPhvc
6.28	There is a/are pharmacovigilance Advisory Committee(s) (Expert Committees) for pharmaceuticals and vaccines to review serious adverse events	Yes ☒ No ☐	2010	IqPhvc
6.29	Your country is a member in the WHO Programme for International Drug Monitoring (UMC member)	Yes ☒ No ☐	2010	IqPhvc
6.30	Did your country collect adverse effects related to use of medicines to prevent/ treat COVID-19?	Yes ☒ No ☐	2020	IqPhvc
	6.30.1 If yes, please list the medicines and adverse events related to their use	Medicines and adverse events: Hydroxychlorquine (HCQ) and Azithromycin (Q-wave prolongation-arrhythmia), enoxaparin-induced bleeding, Dexamethasone (increases blood glucose level) and Kaletra (gastro-intestinal side effects).		
6.31	There are written criteria to cover emergencies/crises linked to the Risk Management Plan (RMP)	Yes ☐ No ☒	2020	IqPhvc
6.32	There is a rapid alert system for managing the threats by substandard and falsified products and for recalling these products from the market	Yes ☒ No ☐	2018	IqPhvc
Session 7 Local Manufacturing				
	Sources: Pharmacist Hala Hadi Abdulla. National Pharmaceutical Industry Section, Pharmacy Department. Hha3pharm@yahoo.com Pharmacist: Ahmed Mohammed Abdul Hameed, Planning Department, KIMADIA. ahmedmun67@yahoo.com Pharmacist Ahmed Ibrahim, League of National Medicines Manufacturers (LNMM), aadsb2003@yahoo.com		**Year**	**Source**

7.1	Total number of licensed pharmaceutical manufacturers in your country in terms of ownership is:			
	1. Governmental manufacturers:	2		National Pharmaceutical Industry Section
	2. Private (national) manufacturers:	21		
	3. Private (multinational) manufacturers:	0		
7.2	Total number of local manufacturers for each manufacturing stage:			
	1. Packaging of already formulated imported products:	0		National Pharmaceutical Industry Section, Pharmacy Department
	2. Finished products:	23		
	3. Active pharmaceutical ingredient:	0		
	4. Research and development of new active substance	0		
7.3	The government has a vision and strategic plan for the domestic production of medical products	Yes ☒ No ☐	23-8-2020	National Pharmaceutical Industry Section letter
7.4	Country manufactures biopharmaceuticals	Yes ☐ No ☒	2020	National Pharmaceutical Industry Section
	7.4.1 If yes, what is the number of local manufacturers producing biopharmaceuticals	Number of local manufacturers: zero		
7.5	Market Share of local manufactured pharmaceuticals by value (%)	15.3% of total KIMADIA contracts (public sector)	2019	KIMADIA Planning Department

7.6	Percentage of market share by value produced by domestic manufacturers (%)	11% of total (public and private sectors)	2019	KIMADIA & LNMM
7.7	Percentage of market share by volume produced by domestic manufacturers (%)	20-25%	2019	LNMM
7.8	There is WHO prequalified product locally produced 7.8.1 If yes, please write its name/s	Yes ☐ No ☒	2020	National Pharmaceutical Industry Section
		Name of product:		
7.9	There are legal provisions that give priority in public procurement to goods produced by local manufacturers	Yes ☒ No ☐	2015	Prime Minister Office Letter (no. 16964)
7.10	Shortages in active ingredients occurred due to the COVID-19 crisis	Yes ☒ No ☐	2020	LNMM
	7.10.1 If yes, please list the shortages so far	Shortages in active ingredients: Many including Vitamin C, Ibuprofen, and metronidazole		League for Medicine Manufacturers (LNMM)

Session 8 Rational Use of Medicines				
	Source: Specialist Pharmacist: Haidar Al-Jawadi, Clinical Pharmacy Section, Pharmacy Department. Haidaraljawadi2@yahoo.com Pharmacist: Rana Mahdi, Antimicrobial Unit, Public Health Directorate ranamahdi2@yahoo.com Syndicate of Iraqi Pharmacists. http://www.iraqipharm.com/		**Year**	**Source**
8.1	There is a national programme/committee to monitor medicine use and promote rational use of medicines	Yes ☒ No ☐	2008	Unit of Rational Use of Medicines
8.2	There is a legal provision which prohibits dispensing prescription medicines without prescription	Yes ☒ No ☐	1970	Pharmacy profession Law
8.3	Generic substitution is allowed at the point of dispensing	Yes ☒ No ☐	2020	Clinical Pharmacy Section & Syndicate of Iraqi Pharmacists
8.4	There is a public or independently funded national medicines information centre which provides information on medicines to: Health care professionals: Consumers/patients:	Yes ☒ No ☐ Yes ☒ No ☐	2020	Clinical Pharmacy Section (Drug Information Centers)
8.5	Public education campaigns have been conducted in the previous two years on rational use of medicines topics	Yes ☒ No ☐	2018	Antibiotics Awareness Week
8.6	Data on national antimicrobial consumption is available	Yes ☐ No ☒	2020	Antimicrobial Unit, Public

				Health Directorate
8.7	Regulations require hospitals to establish Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐	1997	Clinical Pharmacy Section
8.8	There is mandatory continuing education for medical doctors and pharmacists that includes rational use of medicines	Yes ☐ No ☒	Optional 2020	Clinical Pharmacy Section
8.9	Medical doctors and pharmacists are encouraged to use generic medicines.	Yes ☐ No ☒	2020	Clinical Pharmacy Section
8.10	Self-medication in relation to prevention/ treatment of COVID-19 occurred 8.10.1 If yes, please list the name of medicines used for self-medication in relation to prevention/treatment of COVID-19	Yes ☐ No ☒	2020	Clinical Pharmacy Section
		Medicines:		