DRUG REGULATORY AUTHORITY OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS & COORDINATION

DRAP's NewsLetter

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"Under the visionary guidance of the Prime Minister of Pakistan, we reaffirm our unwavering commitment to strengthening Pakistan's pharmaceutical industry. Our focus is on establishing a robust regulatory framework within the Drug Regulatory Authority of Pakistan (DRAP) that prioritizes transparency, efficiency, and innovation. By fostering investment-friendly policies and nurturing an environment conducive to growth, we aim to support both local manufacturing and export potential in the pharma sector."

Dr. Mukhtar Ahmad Bharath
Coordinator to PM on Health

"With the Prime Minister's directives to uphold WHO standards in regulatory practices, the Ministry has led key advancements within DRAP. This includes launching new initiatives, particularly in digitizing operations through platforms like E-App, which streamline regulatory processes and enable efficient online application management. Additionally, the induction of skilled technical professionals has been prioritized to further enhance DRAP's capacity and responsiveness."

Mr. Nadeem Mahbub
Federal Secretary MNHSR&C

"Recognizing the importance of aligning with the evolving global landscape, DRAP is committed to implementing regulatory best practices that enhance transparency, accountability, and efficiency, ensuring the protection and well-being of our citizens."

Mr. Asim Rauf
CEO DRAP

Patron in Chief :
Mr. Nadeem Mahbub
Secretary MONHS&R

Editor in Chief :
Mr. Asim Rauf
CEO DRAP

Editor:
Dr. Akhtar Abbas Khan
Additional Director

COORDINATOR TO PM ON HEALTH, DR. MUKHTAR AHMAD BHARATH'S VISIT TO THE DRUG REGULATORY AUTHORITY OF PAKISTAN (DRAP)

Dr. Mukhtar Ahmad Bharath recently visited the Drug Regulatory Authority of Pakistan (DRAP) to discuss current regulatory affairs and address key challenges in the pharmaceutical sector. DRAP CEO Mr Asim Rauf provided a comprehensive briefing on the institution's ongoing operations and challenges faced by the organization. During the visit, Dr. Bharath, who is coordinating health sector reforms, highlighted the commitment to advancing Prime Minister's vision of a reformed healthcare agenda. He expressed dedication to establishing DRAP as a top-tier regulatory authority that adheres to the highest standards.

Key Highlights and Directives by Dr. Bharath:

- **Fast-tracking Regulatory Processes:** Dr. Bharath emphasized the need to expedite registration, licensing, and inspection processes to ensure efficiency in regulatory operations.
- **Promotion of Merit and Transparency:** He stressed the importance of promoting merit and transparency within DRAP to build trust and credibility.
- **Modernization of Regulatory Systems:** Recognizing the importance of evolving with modern standards, Dr. Bharath urged for updates in regulatory practices that align with contemporary global requirements.
- **Prompt Service Delivery:** He directed that all public inquiries and complaints be resolved in a timely manner to improve responsiveness and maintain public confidence in DRAP.
- **Uninterrupted Supply of Medicines:** The priority, he mentioned, should be ensuring an uninterrupted supply of essential medicines nationwide, addressing public health needs effectively.
- **Combating Counterfeit and Unregistered Drugs:** Dr. Bharath called for decisive actions against the distribution of counterfeit and unregistered drugs across the country.
- **Enhancing Exports and Local Manufacturing:** To boost Pakistan's pharmaceutical exports, he encouraged collaborative efforts with the pharma sector, aiming to create favorable policies that attract local and international investment in the industry.
- **Strengthening the Pharma Sector:** Acknowledging the country's growing population and the increasing demand for medicines, he emphasized strengthening local manufacturing capacity, which could also save valuable foreign exchange.

PROVINCIAL WORKSHOP ON THE IMPLEMENTATION OF INSTITUTIONAL DEVELOPMENTAL PLANS (IDPS) AIMED AT STRENGTHENING THE NATIONAL REGULATORY SYSTEM OF PAKISTAN BASED ON WHO RECOMMENDATIONS.

At Lahore on October 21-22, 2024, the Drug Regulatory Authority of Pakistan (DRAP), in collaboration with the World Health Organization (WHO) Pakistan, hosted a provincial workshop on the implementation of Institutional Developmental Plans (IDPs) aimed at strengthening the National Regulatory System of Pakistan based on WHO recommendations.

Mr. Nadeem Mahbub, Federal Secretary of the Ministry of National Health Services, Regulation & Coordination, and Ms. Ellen Mpangananji Thom, Officer In-charge, WHO Office in Pakistan participated in this workshop. Mr. Asim Rauf, CEO DRAP briefed the participants on the roadmap for strengthening the regulatory system of Pakistan.

This interprovincial coordination workshop was attended by key officials, including the Director General of Provincial Drug Control Administrations, the Chief Inspector of Drugs from all federating units, Directors of National Quality Control Laboratories (CDL and DTLs), officers from provincial regulatory institutions, and teams from DRAP working on the implementation of the Institutional Developmental Plans (IDPs) based on the WHO Global Benchmarking Tool for National Regulatory Authorities.

This 02-day workshop provided the opportunities to strengthen the regulatory framework in all federating units by developing collaborative working procedures in various areas including pharmacovigilance, Market Surveillance, Licensing, Inspection, Laboratory Testing and Quality Management System.

COMMERCIAL MANUFACTURING OF GENERICS

Minimum Does Not Give Guarantee And May Not Be Considered Good

Key Question: *Can all generics be considered equal while manufactured by different people with different levels of knowledge, skill, and experience?*

OBAID ALI, Ph.D
Lead, Strategic Office of
Science & Technology, DRAP

No, before explaining the reason, please do remember that one bioequivalence study and process qualification based on three batches manufactured under ideal conditions open the door to commerce, but it does not guarantee lifetime manufacturing of quality drugs.

It was a time long ago when extensive testing was relied upon to guarantee a quality drug, and all the quality affairs revolved around a classical tool (Testing). Later on, with the experience and expanding knowledge, it became evident that the manufacturing process has a greater impact on drug quality; hence, in-process controls were introduced and became part of the regulations. In moving upward on the ladder of knowledge, sampling limitation, such as representing the whole batch, is better appreciated.

Moreover, the limitations of "one size fit all" testing in pre-specified 10-20-30 unit samples from a batch consisting of millions of units posed a dilemma – can or when can these assure every unit's quality in a batch? Resultantly, emphasis was extended, reshaped, and focused more on the product development, process understanding, and control strategy to achieve consistency within a batch, time after time, and lot after lot.

Independent and integrated regulatory reviews under Good Review Practices (GRP) and regulatory inspections of manufacturing sites under Good Manufacturing Practices (GMP) standards to determine the strength of product and manufacturing capacity are indispensable. So, without understanding the entire manufacturing process and mechanism to keep controls efficient throughout the manufacturing, no one will be able to say that drug is consistent in the whole batch in terms of purity, right dose, and right delivery of medication inside the body and is without unreasonable contamination of germs, particles, and traces of other drugs. Such oversight also ensures eliminating any potential mix-up with other drugs, the same drug of different strength, or with sorted (defective) drugs during each step of the manufacturing and distribution process until it reaches the patient.

It is necessary to be abreast of the fundamental dimensions that repeatedly remind us about testing limitations via traditional compendial procedures. In most instances, testing is done on a small sample of a batch so that bulk of the batch can be used for patients rather than destroyed by testing. Therefore, we expect drugs are manufactured under conditions and practices required by the GMP regulations to assure that quality is built by design and manufacturing process at every step. Facilities in good condition, equipment that is properly maintained and calibrated, employees who are qualified and fully trained, and processes re reliable and reproducible are a few examples of how GMP requirements help assure the safety and efficacy of drug products. FDA clearly describes "the "C" in cGMP denotes "current." It requires companies to use technologies and systems that are up-to-date to comply with the regulations.

Systems and equipment that may have been "top-of-the-line" to prevent contamination, mix-ups, and errors 10 or 20 years ago maybe less than adequate by today's standards".

Complying with the cGMP principles assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications effectively and tolerably control manufacturing operations. This expectation includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. GMP via integrated System of Quality Management prevents errors that are difficult to catch by testing the finished products.

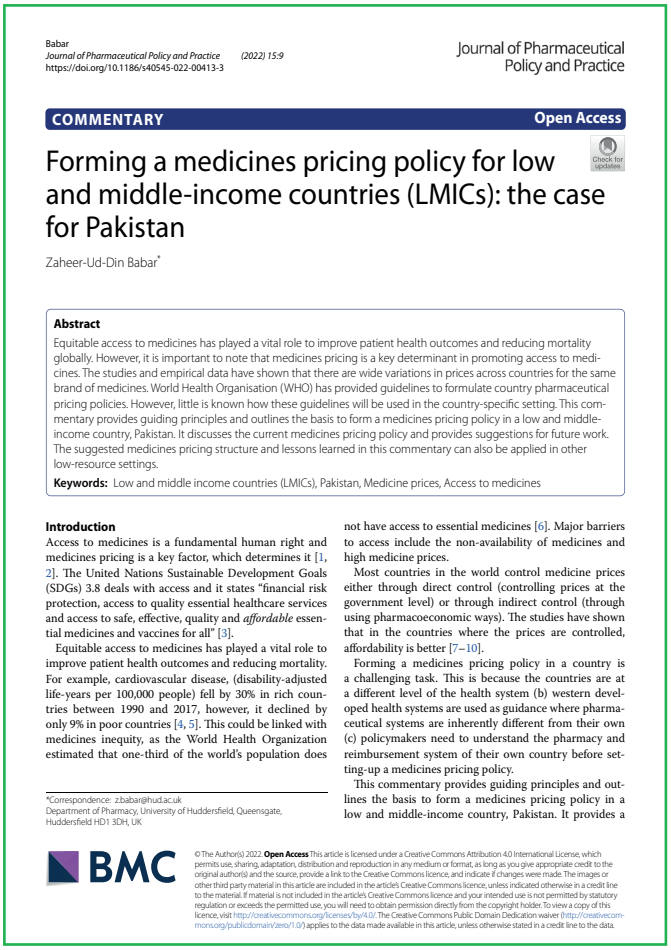
Advancement in technology, Continuous Manufacturing, Data Sciences, Artificial Intelligence, concepts of Culture of Quality & Quality System Maturity, etc., are reshaping GMP and prompting us to become aware of the tremendous storm of evolution in this field and the need for diving into molecular pharmaceutics. So let's align our professional development with the fast emerging technological landscape of the world. To ensure public safety and quality of the drug, we have no way left other than to enhance the capacity of learning, de-learning, and relearning that could make our walk compatible with modern science and get it trusted all around.

BUILDING EFFECTIVE MEDICINES PRICING POLICIES FOR LOW AND MIDDLE INCOME COUNTRIES: A DISCUSSION AND DISCOURSE

The Drug Regulatory Authority of Pakistan held an insightful discussion on "Building Effective Medicine Pricing Policies for Low and Middle-Income Countries". The session was led by Prof. Zaheer-Ud-Din Babar, Qatar University, Qatar and Editor-in-Chief of the Journal of Pharmaceutical Policy and Practice.

Senior management of the DRAP attended the session at DRAP HQ, Islamabad, while more than 100 colleagues from industry and academia participated in the session virtually. Prof. Babar's expertise and knowledge provided a wealth of understanding on this critical topic.

We had an engaging discussion on the challenges and potential solutions for medicine pricing policies, focusing on the unique circumstances of low and middle-income countries, with an illustration of 05 different pharmaceutical pricing strategies and key enablers to build effective policies.



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COMMENTARY Open Access

Forming a medicines pricing policy for low and middle-income countries (LMICs): the case for Pakistan

Zaheer-Ud-Din Babar*

Abstract

Equitable access to medicines has played a vital role to improve patient health outcomes and reducing mortality globally. However, it is important to note that medicines pricing is a key determinant in promoting access to medicines. The studies and empirical data have shown that there are wide variations in prices across countries for the same brand of medicines. World Health Organisation (WHO) has provided guidelines to formulate country pharmaceutical pricing policies. However, little is known how these guidelines will be used in the country-specific setting. This commentary provides guiding principles and outlines the basis to form a medicines pricing policy in a low and middle-income country, Pakistan. It discusses the current medicines pricing policy and provides suggestions for future work. The suggested medicines pricing structure and lessons learned in this commentary can also be applied in other low-resource settings.

Keywords: Low and middle income countries (LMICs), Pakistan, Medicine prices, Access to medicines

Introduction

Access to medicines is a fundamental human right and medicines pricing is a key factor, which determines it [1, 2]. The United Nations Sustainable Development Goals (SDGs) 3.8 deals with access and it states "financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and *affordable* essential medicines and vaccines for all" [3].

Equitable access to medicines has played a vital role to improve patient health outcomes and reducing mortality. For example, cardiovascular disease, (disability-adjusted life-years per 100,000 people) fell by 30% in rich countries between 1990 and 2017, however, it declined by only 9% in poor countries [4, 5]. This could be linked with medicines inequity, as the World Health Organization estimated that one-third of the world's population does not have access to essential medicines [6]. Major barriers to access include the non-availability of medicines and high medicine prices.

Most countries in the world control medicine prices either through direct control (controlling prices at the government level) or through indirect control (through using pharmacoeconomic ways). The studies have shown that in the countries where the prices are controlled, affordability is better [7–10].

Forming a medicines pricing policy in a country is a challenging task. This is because the countries are at a different level of the health system (b) western developed health systems are used as guidance where pharmaceutical systems are inherently different from their own (c) policymakers need to understand the pharmacy and reimbursement system of their own country before setting-up a medicines pricing policy.

This commentary provides guiding principles and outlines the basis to form a medicines pricing policy in a low and middle-income country, Pakistan. It provides a

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A conceptual framework to build effective medicine pricing policies for low and middle-income countries (LMICs)

Zaheer-Ud-Din Babar

University of Huddersfield, UK

ABSTRACT

Building effective medicine pricing policies is a challenging task in all high-, middle- and low-income countries. In high-income countries have stable health systems in place, trained workforce, as well as specialised agencies to evaluate innovative drugs for reimbursement. However, in low- and middle-income countries (LMICs) the challenges are manifold. A large majority of low- and middle-income countries lack technical expertise either to evaluate new medicines or to set efficient medicine prices. The countries also lack comparator reference pricing data to set prices. Also, there are significant out-of-pocket expenditures as people pay for medicines by themselves. An effective medicine pricing policy is vital in the context that it can be used as a tool to improve access and affordability among the masses. This discussion paper presents a conceptual framework to build effective medicine pricing policies for low and middle-income countries (LMICs). The enablers to build effective medicine pricing policies are also discussed. This includes (a) data and statistics on the pharmaceutical situation of the country (b) Having a national medicine policy in the country (c) The availability of the medicine pricing data and (d) Human resources and technical capacity. WHO has recommended several strategies including External Price Referencing (EPR), Internal Reference pricing, Value-based pricing, Cost-plus pricing, and Generic medicine policies to build a pricing policy. However, this information is generic and it's a complex task for countries to tailor to their needs, hence a critical analysis is provided on these policies. The concepts related to fair medicine pricing, providing information to consumers and price transparency are also discussed.

Professor Zaheer-Ud-Din Babar is the Professor of Clinical Pharmacy and Practice at the College of Pharmacy, Qatar University, and a Visiting Professor at the Department of Pharmacy, University of Huddersfield, United Kingdom. He is also the founding editor-in-chief of the Journal of Pharmaceutical Policy and Practice.

EXPERT CONSULTATION ON "ENHANCING THE NATIONAL CAPACITY TO CONDUCT RANDOMIZED CONTROLLED TRIALS AND LARGE SCALE STUDIES

In 2022 the 75th World Health Assembly endorsed resolution WHA 75.8 on strengthening clinical trials to provide high quality evidence on health interventions and to improve research quality and coordination. As part of the implementation DRAP in collaboration with WHO Regional office for Eastern Mediterranean held an expert consultation at Islamabad Pakistan in June 2024 for enhancing the national capacity to conduct randomized controlled trials (RCTs). The key objective was to promote scientifically and ethically sound clinical trials as well as provide guidance on best practices for the stake holders in the design and conduct of clinical trials towards strengthening the global clinical trial ecosystem. Moreover, to develop and implement strategies based on the original challenges and priorities by identifying key areas of action with the way forward.

This consultative meeting was attended by the WR/ Head of WHO Pakistan Mission H.E. Dr. Depang Lou, the Chief Executive officer of DRAP Mr. Asim Rauf, International and all the key stake holders comprising of more than 50 experts including Technical Representatives from WHO, Nationally Renowned Scientists, Clinicians, Researchers and Executives from the Clinical Research fraternity.

The CEO DRAP welcomed the participants and thanked the WHO secretariat, emphasizing upon the importance of clinical studies and its impact on public health. Director Pharmacy Sevices Dr. Obaidullah presented the performance of Division and its achievements that have earned global recognition. He also highlighted the objective and the desired outcomes of this consultative workshop.

Dr. Arash Rashidian, Director Science Information and Dissemination WHO EMRO presented the Regional Perspective and the importance of Multi Regional Clinical Trials (MRCT) with special emphasis on the need and potential of growth in research landscape to the region.

The WR H.E Dr. Depang Luo in his remarks appreciated the efforts of DRAP in promotion of the Clinical Research Ecosystem and emphasized that the importance of MRCT in the region specially Pakistan owing to the high prevalence of infectious and non-communicable diseases.

The consultation covered a range of key areas related to RCTs, Clinical Trials(CT) and large scale studies. There were nine sessions covering diverse areas of CT including WHO strategies for RCTs, RCTs in EMR countries, technical capacities for RCTs, Conducting Clinical Trials, Strengthening the RCTs ecosystem, the Clinical Research guidelines in Pakistan, publishing RCTs and management of conflicts of interest, experience and challenges of Clinical Trial Sites and CROs in Pakistan and the way forward.

Recommendations:

i. The expert consultation concluded with a set of recommendations to help strengthen the region's Clinical Trial ecosystem.

ii. Implement online submission of applications for efficient working and better coordination between NBC and CSC.

iii. Adopted separate procedures for processing and approval of the different phases of Clinical Trial (I - IV)

iv. Follow risk based approach in regulatory functions pertaining to Clinical Research Operations.

v. Take collective actions in areas of capacity building, infrastructure development, research and governance of RCTs and Clinical Trials.

vi. Ensure optimal utilization of Central Research Fund for the development of research ecosystem of the country.

vii. Amendments in the Bio Study Rules and subsequently the guiled lines to enhance clarity and ease of operation in the light of international best practices.

Picture Gallary

Mr Nadeem Mahbub, Secretary Ministry of NHSR&C delivering key note address to participants of workshop.

Mr Bob Tribe, Consultant to GMP Regulatory Authorities called upon Dr Malik Mukhtar Ahmad, Coordinator to PM on Health

CEO DRAP presented a souvenir to WR Pakistan during his visit to DRAP

Mr Asim Rauf CEO DRAP delivering welcome note at provincial workshop held at Lahore.

Ellen Thom Technical Officer WHO speaking at provincial consultative workshop held at Lahore.

Dr Obaidullah, Director Pharmaceutical Evaluation and Registration

ڈرگ ریگولیٹری اتھارٹی آف پاکستان
منسٹری آف نیشنل ہیلتھ سروسز ریگولیشنز اینڈ کوآرڈینیشن

ڈریپ نیوز لیٹر

نومبر: ۲۰۲۴
والیم: ۳
شمارہ: ۲

درخواستوں کی حیثیت کو آن لائن ٹریک کرنے کا نظام: شفافیت کی جانب ایک اور قدم

1976 میں ڈرگ ایکٹ کے لاگو ہونے کے بعد سے، فارماسیوٹیکل کمپنیوں کو یہ سہولت دی گئی تھی کہ وہ ڈرگ کنٹرول آرگنائزیشن کے دفاتر کا دورہ کر کے اپنی درخواستوں کی حالت کا جائزہ لیں۔ ریگولیٹرز اور درخواست دہندگان کے درمیان اس براہ راست رابطے نے جانبدارانہ تشخیص اور بدعنوانی کے امکان کے بارے میں خدشات کو جنم دیا۔

ریگولیٹری عملے تک براہ راست رسائی کسی خاص درخواست دہندہ کی پسندیدگی کا باعث بن سکتی ہے، جہاں کچھ کمپنیاں ریگولیٹرز کے ساتھ اپنے تعلقات کی بنیاد پر ترجیحی سلوک حاصل کر سکتی ہیں۔ یہ نہ صرف ریگولیٹری عمل کی سالمیت کو مجروح کرتا ہے بلکہ اتھارٹی پر عوامی اعتماد کو بھی ختم کرتا ہے۔

ان مسائل کو حل کرنے کی ضرورت کو تسلیم کرتے ہوئے، ڈریپ نے 2024 میں درخواست دہندگان کے لیے بلا روک ٹوک داخلے کی پالیسی پر پابندی لگا کر ایک آن لائن استفسار کے انتظام کا نظام (Online Query Management System) متعارف کروا کر ایک اہم قدم اٹھایا ہے۔

آن لائن استفسار کے انتظام کا نظام فارماسیوٹیکل کمپنیوں کو اپنے سوالات جمع کرنے اور ڈیجیٹل پلیٹ فارم کے ذریعے اپنی درخواستوں کی حیثیت کو ٹریک کرنے کی اجازت دیتا ہے۔ اس کے نفاذ کے ابتدائی مہینوں کے دوران، مئی سے جولائی 2024 تک، اس سسٹم کے ذریعے کل 1,959 سوالات موصول ہوئے۔ اس ڈیجیٹل پلیٹ فارم پر منتقلی ریگولیٹری عمل میں زیادہ شفافیت اور جوابدہی کی طرف ایک تبدیلی کی نمائندگی کرتی ہے۔

آن لائن استفسار کے انتظام کے نظام کے سب سے اہم فوائد میں سے ایک ڈریپ کے آپریشنز کی کارکردگی پر اس کا اثر ہے۔ سسٹم کے نفاذ کے ابتدائی مہینوں کے دوران پروسیس شدہ آن لائن درخواستوں کی تعداد میں اضافہ اس کی کارکردگی کا ثبوت ہے۔

استفسار کے انتظام کے عمل کی ڈیجیٹلائزیشن نے بھی شفافیت کو بڑھایا ہے۔ سوالات جمع کرانے اور ٹریک کرنے کے لیے ایک معیاری پلیٹ فارم فراہم کر کے، سسٹم اس بات کو یقینی بناتا ہے کہ تمام درخواست دہندگان کے ساتھ یکساں سلوک کیا جائے، جس میں ترجیحی سلوک کی کوئی گنجائش نہیں ہے۔

توقع ہے کہ یہ آن لائن نظام ڈریپ کے اندر بدعنوانی کو روکنے میں اہم کردار ادا کرے گا۔ درخواست دہندگان اور ریگولیٹری عملے کے درمیان براہ راست رابطے کو ختم کر کے، نظام فیصلہ سازی کے عمل میں رشوت اور غیر ضروری اثر و رسوخ کے مواقع کو کم کرتا ہے۔

اگرچہ اس آن لائن نظام نے اپنے ابتدائی مراحل میں امید افزا نتائج دکھائے ہیں، لیکن یہ اپنے چیلنجوں کے بغیر نہیں ہے۔ مینوئل سے ڈیجیٹل سسٹم میں منتقلی کے لیے ریگولیٹری عملے اور درخواست دہندگان دونوں کے لیے ٹیکنالوجی اور تربیت میں اہم سرمایہ کاری کی ضرورت ہے۔

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چیف ایگزیکٹو آفیسر ڈریپ

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