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CONFERENCE ABSTRACTS

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Regulatory sciences and quality

Timely designation of notified bodies within the European Union

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RFWE-02 - Rapid Fire Session Wednesday, P3-P4, September 27, 2023, 11:00 AM - 12:30 PM

Background
Notified Bodies play a crucial role for conformity of medical devices. The change in the European Union (EU) legislation aimed at providing a more robust and transparent harmonised regulatory framework, ensuring better safety and quality of devices. According to the new legislation, the designation process of Notified Bodies by the designating authorities is lengthy and of increased scrutiny. There are continuous apprehensions regarding the timely designation of Notified Bodies. The current few numbers of Notified Bodies are creating a bottleneck situation which could inevitably result in a backlog of medical device compliance assessments, limiting the availability of medical devices.

Purpose
To identify challenges of designation of Notified Bodies in medical device regulatory sciences through discussions with experts and capturing the perceptions and expectations of EU authorities in the field, with resulting proposals to overcome the identified setbacks.

Method
Challenges encountered by European Union (EU) competent authorities for medical devices when designating Notified Bodies were identified by reflective evaluation of the process and discussions with professionals and stakeholders. Study findings were validated in a focus group by an expert panel who were asked to assign a reasoned rate of severity of the challenges and propose ways to overcome these challenges. Subsequently, a tool was developed and disseminated to European experts involved with designation process. The developed tool covered three main domains with nineteen statements on: challenging timelines, setbacks encountered during designation and proposals on how to overcome these challenges.

Results
The identified challenges in the designation process were: quality of documents provided by the Conformity Assessment Body (CAB), efficiency in communication, timelines, time and cost associated with the CAB process, and expertise, with the latter three being classified as severe. The focus group (N=5) proposed that both timelines and lack of experts were challenges which could be overcome by means of training to develop expertise in the field. The response received from the experts (N=22), 20 respondents agreed the corrective action and preventive action (CAPA) plan development timeline is challenging, 20 respondents agreed a setback encountered during the designation process is the quality of documents submitted with designation application and 21 respondents agreed yearly refresher training for national expert assessors could overcome the challenges in the designation process.

Conclusion
Insights from this study into the European Union (EU) process and resulting European Union (EU) experts' evaluation on ways to overcome the setbacks mostly affecting timely designation of conformity assessment bodies, is contributing to the development of a framework that could be taken up by European Union (EU) member states for a smooth designation process, guaranteeing an uninterrupted continuity in the supply of medical technologies to patients and healthcare systems in the European Union (EU).

Validation and specificity study on the test of 4-aminophenol in the acetaminophen-containing drug products

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RFWE-02 - Rapid Fire Session Wednesday, P3-P4, September 27, 2023, 11:00 AM - 12:30 PM

4-Aminophenol (4-AP), the main degradation product of acetaminophen (AAP), has been controlled by monographs of USP, EP, BP and ChP. The quantity of 4-AP needs to be strictly controlled as it has nephrotoxic effects. As an example, USP specifies that the quantity of 4-AP is not more than 0.15% of labeled amount of AAP in drug products. USP general chapter <227> requires a ternary gradient mobile phase which needs a quaternary gradient HPLC pump, which is not popular. In this study, the validation and specificity of 4-AP in the presence of other combined active pharmaceutical ingredients (APIs) and three kinds of complex AAP tablets were investigated by using a binary gradient mobile phase so as to use a more popular binary gradient HPLC pump. Twenty one kinds of APIs were used for the specificity study and three commercial AAP-containing complex tablets were used for validation study of 4-AP test using a more convenient binary mobile phase according to the chromatographic adjustments described in the USP general chapter <227>. As a result, the specificity, linearity, accuracy, precision, detection limit and quantitation limit were acceptable with the guideline of validation of analytical procedures in KP. In addition, All APIs adopted have no interference in the specificity of 4-AP analysis. In conclusion, this binary mobile phase may be used as an alternative for the control of 4-AP in acetaminophen-containing drug products. This research was supported by a grant (22204MFDS102) from Ministry of Food and Drug Safety in 2022.

Developing and implementing an evidence-based drug selection model for a tertiary care hospital operating in a middle- and low-income country with regulatory challenges

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RFWE-02 - Rapid Fire Session Wednesday, P3-P4, September 27, 2023, 11:00 AM - 12:30 PM

Background: Formulary system provides a systematic method to review scientific evidence on clinical and cost effectiveness in drug selection decision, thus potentially improving health outcomes.
Drug Formulary Management and drug selection is a challenge in developing countries with regulatory challenges.
Pakistan's pharmaceutical industry is regulated by Drug Regulatory Authority of Pakistan (DRAP). The industry heavily relies on imports to meet the demand of basic raw material – Active Pharmaceutical Ingredients (APIs) etc. There are only a few API Manufacturers operating in Pakistan. The estimated reliance of manufacturers on imported APIs is more than 95%. Pakistan economic condition and Local Currency devaluation against US dollar has greatly impacted business margins and cost of goods. This has resulted in most of the manufacturers switching API sourcing and majority of sourcing now from manufacturers with lesser number of quality accreditations. Further the diminishing ease of doing business has also impacted expenditure on quality assurance and control.
There was a dire need of developing a drug selection guide to be used in the scenario mentioned above.

Purpose: The Aim of this study was to develop and implement Evidence based drug selection guide for tertiary care hospital operating in a middle- and low-income country to select the medications based on the major prince quality, efficacy and cost effectiveness for patients.

Methods: Checklist for drug selection Model was developed based on principles laid down by WHO, ASHP, USP, BP, international best practices and AKUH market experience containing key 12 points checklists. Implementation of the model Strengthened and safeguarded formulary system against the volatile Pharmaceutical Industry scenario since its implementation in 2021.
Request for RFQ was floated to 100+ pharmaceutical Manufacturers and Pharmacy technical review committee received 4000+ drug application brand dossiers against active 1685 formulary entries. Based on the selection models' dossiers were comparatively rated. Brands and branded generics were selected and shortlisted as suitable alternative formulary options.
45000+ quality parameters were checked, validated, and ranked accordingly as per 12-point checklist.
Further the exercise established an online bank for all drug dossiers to be use for prospective and retrospective formulary management evaluations. Active Pharmaceutical Ingredient (API) their sourcing and quality certifications.

Result: The Drug selection guide developed and acted as an affective screening tool for medications. Selection based primarily on Active pharmaceutical ingredients (API) sourcing and Quality accreditation. The other factors that were considered included manufacturer quality control/assurance structure, Market presence and experience. 4000+ Drug Applications / Dossiers were reviewed and ranked as per formulated 12-Point Checklist.
The drug selection guide has already resulted in 105 formulary brand switching based on quality evaluation both desktop audits and manufacturing plant visits.

Conclusion: For selection of safe, effective, and quality drug for AKUH in current pharmaceutical industry scenario, Drug selection guide plays a vital role for formulary management based on Quality, Safety, Efficacy and Cost effectiveness.
Since the implementation not a single drug related serious adverse event, therapy failure or sentinel event has been reported.

The African medicines agency and medicines regulation: Progress, challenges, and recommendations

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RFWE-02 - Rapid Fire Session Wednesday, P3-P4, September 27, 2023, 11:00 AM - 12:30 PM

Background: Africa, the second most populated continent, struggles to meet the health needs of its growing population and remains the only global region with the highest rates of mortality and the shortest average lifespan. The United Nations Economic Commission for Africa (UNECA) reported that Africa imports approximately 94% of its medicinal and pharmaceutical products. This implies that most patients have no access to locally manufactured drugs and may be unable to afford imported ones, many of which are either fake, substandard, or counterfeits. In response to this and other arising issues in the pharmaceutical sector, the African Medicines Agency (AMA) was formed; as a specialised agency of the African Union (AU) intended to facilitate the harmonisation of medicines and medical products regulation throughout Africa. Following a similar model to that of the European Medicines Agency (EMA), the AMA is intended to address the inefficiencies of the National Medicines Regulatory Agencies (NMRAs), which is essential in ensuring medical products' quality, safety, and efficacy in the continent. The AMA is expected to absorb and supervise roles currently performed by other regional bodies such as the African Vaccines Regulatory Forum (AVAREF) and the African Medicines Regulatory Harmonization (AMRH) initiatives.

Purpose: This study examines the key milestones in the establishment of the African Medicines Agency, the factors that have enabled AMA, the challenges faced by AU member states in ratifying the AMA treaty, the role of each member state in the operationalization of the AMA and its anticipated benefits.

Method: We conducted a review of data sources that explored the progress and challenges of the African Medicines Agency and Medicines Regulation in Africa. Further, we drew lessons from existing continental initiatives such as EMA and South-east Asia Regulatory Network (SEARN) and areas of applicability to AMA. The retrieved data were discussed narratively to address the aim of the study.

Results: The implementation of AMA is largely hindered by poor political commitment in some member states, corruption, differences in risk-benefits interpretation amongst the member states, differences in organizational structure, weak legal/regulatory frameworks, inadequate financial mechanisms, and inadequate political and policy leadership. Despite these challenges, the treaty has recorded remarkable successes which include the appointment of a Special Envoy, the selection of its headquarters, and the signing of the treaty by 33 member states.

Conclusion: The value of AMA in achieving optimal health outcomes and its other benefits cannot be overemphasized. Therefore, all member states should adopt the best procedures in signing and ratifying the treaty, and implementing associated commitments.

Risks in medical device vigilance

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Posters Tuesday, September 26, 2023, 12:30 PM - 2:30 PM

Background: Medical devices are products that vary from simple bandages to artificial bones, and intensive security measures are adopted from the approval up to the release of the device to the market for the safety of its users. The Medical Device Compliance Exchange Form (CEF) is a communication tool used for data exchange about medical devices between Competent Authorities (CA) and Designating Authorities (DA), in specific cases including Notified Bodies (NB), within the European Union (EU). In Malta, the Medicines Authority (MMA) is the Competent Authority for ensuring medical devices' safety, incident reports and investigation.

Purpose: The purpose of the study is to 1) evaluate the medical devices Compliance Exchange Form (CEF) received by the Authority from other EU member states, including countries under the European Free Trade Association (EFTA) and EU candidate countries, which contains dissemination of information and/or inquiry about medical devices' functions, approval and legal standing ; 2) assess the procedures used by the Authority in handling incident reports for medical devices; and 3) develop a risk management plan for mitigation of risks.

Method: The qualitative study is divided into four phases. Phase 1 is the evaluation and development of the database for the Compliance Exchange Form received by the authority. Phase 2 is the gap analysis of the current Standard Operating Procedures (SOP) of the authority through focus group discussion with three members of the Medical Devices and Pharmaceutical Collaboration Directorate. Phase 3 is the development of a risk management plan from the gap analysis and focus group discussion, and Phase 4 is the evaluation and dissemination of the risk management plan.

Results: For Phase 1, a database to store all of the received Compliance Exchange Form (CEF) was developed with the MMA OneDrive. From 2021 to 2022, 428 CEFs were saved and evaluated. A total of 9 CEFs involved Malta; 4 of which were addressed to Malta, 3 were sent by the Authority to all European Economic Area (EEA) states, specifically for the Netherlands and Germany, and 2 of the 9 CEFs were enquiries about medical devices that are available in Malta. In Phase 2, the focus group discussion identified 4 main

points: i) the present SOP is adequate for operations in Malta, ii) direct communication with stakeholders improves quality of investigation, iii) a gap in the triage system in regards to receiving incident reports is to be improved, and (iv) information dissemination plan to resolve under-reporting of medical device incidents are one of the safety-related projects of the Authority. In Phase 3, a risk management plan utilising a scoring system was developed from the discussion to contribute to the on-going SOP development and continuous vigilance.

Conclusion: The incorporation of the risk management plan with the current practices of the Authority solidifies the goal of safety and reduces the risks in vigilance as it proposes visual steps on handling reports. Further improvement with the risk identification and reporting system awareness can contribute in the continuous improvement of medical device vigilance.

A systematic review of pharmacist ability to independently perform CLIA-waived tests in the United States

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Background: Pharmacist scope of practice is determined in the United States (US) at the state level. This results in variability state-to-state as to services pharmacists can provide and what restrictions exist. While the COVID-19 pandemic spotlighted the need to engage the pharmacists to meet testing needs of communities, testing for other conditions, such as influenza, has been occurring in pharmacies for decades in some states while not allowed in others. Utilization of Clinical Laboratory Improvement Amendments (CLIA) waived tests in pharmacies is permitted federally, however varied state regulations result in inconsistency of access to care. This review aimed to summarize the authority of pharmacists to perform CLIA waived influenza tests in the US.

Methods: A PubMed search was conducted using keywords “pharmacist”, “CLIA waived”, “influenza" and "testing”. Other resources used were the National Alliance of State Pharmacy Associations as well as individual state statutes and regulations. The authority of pharmacists to independently perform CLIA-waived tests were categorized into four categories: Yes, No, Unclear, Silent to be consistent with the findings published in May 2021 by Doucette and Lavino. Data from this publication was updated with more recent resources and newly passed legislation related to CLIA-waives testing.

Results: Of the 50 states and District of Columbia, 22 (43.14%) allow pharmacists to independently perform CLIA-waives tests, 13 (25.49%) either allow through a protocol (non-independent) or do not allow pharmacist testing, 3 (5.88%) have conflicting regulations making it unclear, and 13 (25.49%) are silent regarding pharmacists independently performing CLIA-waived tests. Several states have made modifications related to CLIA-waived tests performed by pharmacists since the Doucette and Lavino publication in 2021 in response to the COVID-19 pandemic. Many of these states were already listed in the “no” category and, despite the changes, remained there due to restrictions. Two states that were categorized as “silent” previously passed legislation allowing testing per a protocol, moving them to the “no” category.

Discussion: Variability of pharmacist ability to independently perform CLIA-waived tests across the US creates difficulties for access to care, resulting in disparity among patients who can receive timely testing in a pharmacy. As the national shortage of primary care providers continues to worsen, it is imperative pharmacists are utilized to the highest extent of their training. Companies with pharmacies across multiple states have difficulty managing the varied rules and often make one company policy that complies with the most restrictive among the states. The federal allowance of pharmacists to perform CLIA-waived tests with no restrictions should serve as a guide for all states to follow. Additional barriers, such as age restrictions or limiting authority to specific tests, are often put into place due to a lack of understanding of pharmacist training and the process for a test to become CLIA-waived. A CLIA-waived test is deemed safe for patients to use on their own. How can a state deem a trained pharmacist performing the test should have more restrictions than if the patient used it without consulting a health care provider?

Guidelines for quality control of medical cannabis

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Background: Quality control (QC) tests required for analysis of compounds present in cannabis preparations for medicinal use are necessary to ensure safety and quality.

Purpose: To compare QC limits related to production of cannabis for medicinal use in different countries.

Method: Countries where medicinal cannabis is legalised and respective regulatory frameworks were identified. Focus was given to maximum cannabinoid concentrations permitted in the products, whether terpenes were tested for, and accepted limits of heavy metals, pesticides and mycotoxins.

Results: Twenty-six European countries have authorised the use of cannabis for medicinal use. These countries including Malta, follow the European Union Pharmacopoeia (Ph. Eur.) 'General Monograph for Herbal Drugs' for analysis of mycotoxins, pesticides and heavy metals. Countries that have set up their national monographs for medicinal cannabis include, the European Countries: Germany and Switzerland and non-European Countries Australia and the United States.
The German monograph has specific limits for THC and CBD, whereas Switzerland only specifies the maximum limit of 1% CBN. Malta has a list of approved products, each with specific percentages of THC and CBD and no limits are mentioned with respect to cannabinol (CBN). Germany, Malta and Switzerland follow the set Quality Control limits set by the European Pharmacopoeia, for allowed concentrations of Heavy Metals (Cadmium: 1 ppm, Lead: 5 ppm, and Mercury: 0.1ppm), Pesticides (E.g., Diazinon: 0.5ppm), Aflatoxins and Mycotoxins (Sum of Aflatoxin B1, B2, G1 & G2: 4mcg/kg).
The United States (US) has recently published its monograph for medicinal cannabis. This monograph does not set limits for cannabinoids such as THC or CBD. This might be because of the interstate variability present within the US regulatory frameworks. On the other hand, the US monograph sets limits for Heavy Metals, and these limits were observed to be the most stringent from the researched countries (Cadmium: 0.3ppm, Lead 0.5ppm, Mercury: 0.1ppm & Arsenic 0.2ppm). Pesticide analysis methods are mentioned in the pharmacopoeia, but limits vary from one state to the other. With regards to Aflatoxins, the limits set by the US (Sum of Aflatoxin B1, B2, G1 & G2: 20ppm) were more lenient than the limits set by the European Countries and Australia. Mycotoxin concentration limits also vary according to the state.
For requirements present in Australia, the limits are set according to the published Therapeutic Goods Administration Guidelines. The Australian market has available Medicinal Cannabis products with varying concentrations of THC and CBD. With regards to Heavy Metals, pesticides, Aflatoxins and Mycotoxins, Australia follows the limits set in the EU pharmacopoeia. Australian guidelines stipulate the limit of 3.0ppm for Arsenic and a limit of 20mcg/kg for Ochratoxin A.

Conclusion: Harmonisation between countries is present with regards to QC parameters of mycotoxins, pesticides and heavy metals, but not for allowed cannabinoid concentrations. Proposal of updated guidelines on QC tests related to the analysis of cannabinoids, terpenes, mycotoxins, pesticides and heavy metals will help contribute to safety, quality and efficacy of medicinal cannabis products.

A phase iIa clinical trial of KAND567, fractalkine receptor inhibitor, in patients with ST-elevation acute myocardial infarction undergoing percutaneous coronary intervention

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ST-elevation myocardial infarction (STEMI) is the most dramatic complication of coronary artery disease and is associated with a high morbidity and mortality rate worldwide. Immediate reperfusion is critical to restore blood flow to the heart, limit infarct size, and reduce the risk of post-STEMI complications, thereby improving long-term survival. However, reperfusion therapy itself is thought to eventually cause further damage to the myocardium, known as reperfusion injury, which enhances the already existing inflammatory response. This immune response can lead to adverse left ventricular remodelling and heart failure in the mid-and long term. Therefore, specific treatment targets are required to reduce excessive inflammation while maintaining immune defence. We have previously shown in 1,300 STEMI patients that immune cells, specifically T cells, are significantly decreased within minutes of reperfusion therapy, which may correlate closely with pathophysiological conditions. This significant reduction was observed in all cells expressing CX3CR1, the receptor for fractalkine. Fractalkine (FKN, CX3CL1) is a member of the chemokine family that facilitates the extravasation and recruitment of CX3CR1-expressing lymphocytes to sites of tissue inflammation. Thus, blocking fractalkine/CX3CR1 signaling is suggested as a promising anti-inflammatory strategy for the treatment of both acute and chronic cardiovascular disease. KAND567, a KANCERA AB drug candidate, is a small molecule, selective, non-competitive, allosteric antagonist of CX3CR1 and has been used as IMP (Investigational Medicinal Product) for this clinical phase IIa study in STEMI patients (ISRCTN 18402242).
The aim of this project is to investigate the dynamic changes in immune cell count and CX3CR1 expression after intravenous and oral administration of KAND567 to STEMI patients undergoing primary percutaneous coronary intervention (PPCI).
This study is a randomized, 2-arm, parallel-group, placebo-controlled, double-blind, multi-centre Phase IIa clinical trial, "FRACTAL Trial". Blood sampling was at nine-time points, including baseline (before IM administration), bolus (after IMP administration), 90 mins, 180 mins, 1 day, 3 days, 6 days, 30 days and 90 days., The leukocyte kinetics in 71 STEMI patients was analysed using flow cytometry.
The highest CX3CR1 receptor density at baseline was observed in CD4 and CD8+T cell subsets. Following different time points, CX3CR1 MFI in the CD8+ compartment remained low until day 6. In addition, CX3CR1-expressing effector T cell subsets, monocytes and NK cells decreased 90 mins after administration of IMP and recovered rapidly for up to 24 hours. Effector T-cells drop substantially after

reperfusion only in some patients. One possible explanation for this may be that KAND567 binds CX3CR1-expressing effector T-cell subsets, monocytes, and NK cells in the peripheral blood, preventing their migration to the heart and thus reducing the decrease in cell numbers in the peripheral blood. Another possible explanation could be cells released into the bloodstream from the lymph nodes or spleen. Another possible explanation could be that previously depleted cells return to circulation. Thus, the cell count can increase significantly within 1 day.

Challenges in establishing a sustainable official medicines control laboratory in a small member state

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Background: Official Medicines Control Laboratories (OMCLs) are public organisations that work independently from the pharmaceutical industry and assist regulatory agencies mainly to assure the quality of medicines and protect public health. OMCLs form part of a network which fall under the auspices of the Council of Europe and European Directorate for the Quality of Medicines and Healthcare (EDQM).

Purpose: To determine challenges in establishing an Official Medicines Control Laboratory in a sustainable approach in a small EU member state.

Method: The methodology was subdivided in two phases. Phase 1 determined the challenges in relation to the operations and structure of analytical laboratories through i) site visits to 7 quality control testing laboratories of EU GMP certified manufacturing sites in Malta, ii) onsite visits to 3 European based OMCLs and iii) audit of the European OMCL servicing Malta. Phase 2 consisted of a gap analysis using a focus group discussion with a panel of 8 experts representing the building industry, post-secondary and tertiary educational sector, the national competent regulatory authority for medical devices and medicinal products and quality control experts from the pharmaceutical industry. The focus group enabled the mapping out of challenges related to OMCLs taking into consideration design requirements, technical capacity, expertise and skills, accreditation, education and training needs. Phase 2 also consisted of a questionnaire developed and validated, focusing on the needs and challenges of public laboratories in Malta.

Results: Common themes in relation to challenges identified through Phase 1 (site visits) and Phase 2 (gap analysis through the focus group and survey) are i) planning and design requirements of the OMCL, ii) quality and information management systems, iii) essential equipment, iv) staff training, v) financing, vii) collaboration and best practices and viii) environmental sustainability. Challenges faced by local public laboratories in Malta comprised of i) lack of human resources with regards to the expertise and availability of laboratory staff, ii) financial resources to sustain laboratory activities, iii) accreditation processes, iv) equipment maintenance and calibration and v) recognition of importance of laboratory services.

Conclusion: The study attempts to highlight the challenges in relation to establishing an OMCL in small member states such as Malta. The identified challenges can be further translated into opportunities for networking and breaking down of silos making the establishment of an OMCL innovative and sustainable.

Quality of medicines for the prevention and management of hypertensive disorders of pregnancy: A systematic review

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Background: In 2020, globally, an estimated 287,000 women died due to complications of pregnancy and childbirth, equating to 223 maternal deaths per 100,000 live births. Hypertensive disorders of pregnancy are the second-leading cause of maternal mortality, accounting for approximately 27,830 deaths in 2019. Medicines such as magnesium sulphate, aspirin, calcium supplements, and antihypertensives- nifedipine, methyldopa, hydralazine, labetalol, amlodipine and enalapril, are recommended for the prevention, and treatment of hypertensive disorders of pregnancy. It is critical to access to quality medicines. There is evidence that the quality of medicines for pregnancy-related conditions is substandard in many low- and middle-income countries. Ineffective medicines thus present a major challenge to reaching the Sustainable Development Goal of reducing the global maternal mortality ratio to 70 deaths per 100,000 livebirths by 2030. Although several studies have been carried out assessing the quality of magnesium sulphate, aspirin, calcium supplements and antihypertensive medicines, the evidence from these studies has not been systematically synthesized.

Purpose: The aim of this systematic review was to synthesize available evidence regarding the quality of medicines that are recommended for the prevention and management of hypertensive disorders of pregnancy.

Method: A structured search strategy was applied to six electronic databases (PUBMED, MEDLINE, EMBASE, CINAHL, ProQuest and Cochrane Library) without year or language limitations. Any study assessing the quality parameters (Active Pharmaceutical Ingredients, pH, sterility, impurities) of medicines by using any valid laboratory methods was

eligible. Two reviewers independently screened the studies, extracted data and applied Medicine Quality Assessment Reporting Guidelines tool for quality assessment. Results were narratively reported and stratified by the drug types.

Results: Out of 5668 citations screened, 33 studies from 27 countries were included. The majority of studies (66.6%) were of good methodological quality (quality score ≥ 6 out of 12). Five studies evaluated the quality of magnesium sulphate, two of which from Nigeria and US found substandard drugs due to API content and contaminants respectively, and two studies from Nigeria and 10 lower-middle- and low-income countries found poor-quality drugs due to failing the pH criteria. Eight studies evaluated the quality of aspirin, of which seven found quality issues: degraded drugs were reported by 5 studies from Brazil, US, Yugoslavia and Pakistan. All five studies assessing the quality of calcium supplements found quality issues, particularly heavy metal contamination. Of 15 quality studies on antihypertensive drugs, only 2 studies reported the samples tested to be of good quality, whereas 12 studies reported the presence of substandard drugs and 1 study identified counterfeit medicines.

Conclusion: This systematic review identified pervasive issues of poor-quality medicines in all types of drugs used to prevent or treat hypertensive disorders of pregnancy, including magnesium sulphate, aspirin, calcium supplements and antihypertensive drugs (amlodipine, nifedipine, methyldopa, enalapril and hydralazine). This raise concerns as to their safe and effective use. Substandard medicines were identified from diverse countries, different origins of manufacture, and at numerous sites along the distribution chain.

Auditing in a medicinal regulatory framework

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Background: Auditing is an activity designed to add value and improve an organization's operations. It supports an organization to accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes. There are perhaps a few other areas than the pharmaceutical field where the relevance of audits could influence patients' safety. The Malta Medicines Authority has the internal auditing function outlined in a specific standard operating procedure. An independent internal audit system, based on all requirements of ISO 19011:2018, has been integrated in pharmaceutical operational functions.

Purpose: To investigate independent assurance that the principles of risk management, governance and internal control processes operate effectively at the heart of the pharmaceutical regulatory scientific field.

Method: The setting was at the Quality Assurance Unit within the Malta Medicines Authority. The audit strategy and annual audit programme were developed and implemented by Management and the respective process owners based on risk. Audit prioritisation followed a risk-based approach utilising a risk assessment tool. Audits were prioritised based on the criticality of the process, risk report, results of previous audits, and period from the former audit. Training on ISO 19011:2018 and ISO 9001:2015 pertaining to quality internal audit processes were organised internally. By virtue of this training the Authority secured a pool of inhouse trained auditors. As part of the training initiative, prior to occupying the role of an internal lead auditor, personnel accompanied experienced lead auditors in three separate internal audits. Internal auditors assigned to perform audits had to prepare a report, which highlighted the outcomes of such audits, including corrective actions and preventive actions (CAPAs). The quality system of pharmacovigilance was audited independently by the Quality Assurance Unit yet followed the common methodology. The pharmacovigilance system audits were risk based and performed at regular intervals to ensure that the quality system was effective and complied with the requirements set out in Articles 8, 14, 15 and 16 of the Implementing Regulation (EU) 520/2012.

Results: Twelve audits which were carried out in Year 2022 were examined in detail, out of which four CAPAs were investigated. Identified CAPAs were reflected in quality improvement forms which were then followed by the Quality Assurance Unit to ensure the implementation by a specific deadline to improve the efficiency and effectiveness of the system. The findings of the audits showed that pharmaceutical processes, such as certifying good manufacturing practices and good distribution practices, were in line with the approved template of certification. Positive outcomes in personnel performance correlated with the training initiatives provided, and when development needs were given priority. The four CAPA findings triggered the restructure of complex policies such as those pertaining to risk management, information security, strategic and operational processes which led to a more agile implementation and successful requirement fulfilment.

Conclusion: This study revealed insights that audits in a pharmaceutical regulatory environment are a significant management tool which allows the organisation to identify gaps, and patients' needs in the pharmaceutical sphere.

The stability of dabigatran etexilate (Pradaxa®) capsules in dose administration aids

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Objective: The objective of this study was to evaluate the physical and chemical stability of dabigatran etexilate (Pradaxa®) capsules when repackaged into dose administration aids. This research is valuable as this practice

is discouraged by the original manufacturer due to stability concerns and the current literature does not provide conclusive data.

Methods: Pradaxa® 110mg capsules containing dabigatran etexilate were subjected to two storage conditions (30°C/65% relative humidity and 25°C/60% relative humidity) in both the manufacturers original packaging, and after repackaging into heat sealed Webster® packs. Content assay, appearance, pH, and dissolution profile of capsules were determined at 0, 14, and 28 days of storage at conditions specified above. A validated HPLC method was used to determine the percentage content and dissolution profiles of the capsules.

Results: Pradaxa® capsules stored for 28 days in dose administration aids at 30°C/65% relative humidity were found to decrease in the extracted dabigatran content and in the dabigatran dissolved (through in vitro dissolution) compared with those capsules stored in original packaging ($p < .05$). In contrast, there were no significant changes to dissolution profile or drug content of capsules repackaged and stored at 25°C/60% relative humidity or ambient storage conditions.

Conclusion: Dabigatran etexilate is stable for up to 28 days when repackaged in dose administration aids and stored under climate zone II conditions (25°C/60% relative humidity) but not under climate zone IVA conditions (30°C/65% relative humidity).

Knowledge gaps for adverse drug reaction reporting by traditional medical practitioners in Kaduna, Nigeria

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Background: Traditional medicines (TM) are widespread in northern Nigeria, raising concerns about safety-related issues. Reporting adverse drug reactions (ADR) of TMs to the National Pharmacovigilance Center (NPC) or its affiliates is crucial to improve the safety of TMs. Therefore, understanding and promoting awareness of ADR reporting by traditional medical practitioners (TMPs) is essential.

Purpose: This study assessed the knowledge, perception, and potential barriers to ADR reporting among TMPs in Kaduna, Nigeria.

Method: A cross-sectional survey was conducted among 105 TMPs using a self-administered paper-based questionnaire containing questions on demographics, knowledge, perception, and barriers to ADR reporting. Data were analyzed using IBM SPSS version 23.0. Descriptive statistics were used to summarize the data, and the Pearson Chi-square test was used to determine associations between variables.

Results: Most TMPs were male (81.9%) with an average age of 40.8±12.9 years. Most practitioners had never encountered ADRs (61.0%) in practice and did not know how to report them (59.0%). Furthermore, 58.1% had not received any training in ADR reporting. However, most practitioners believed that reporting ADRs would improve healthcare systems (82.9%) and expressed interest in updating their knowledge on ADR reporting (80.0%), joining professional bodies (76.2%), and implementing reporting in their practice (81.0%). Significant associations were found between knowledge and age, type of practice, rank, and years of experience ($p<0.05$), perception and age ($p<0.05$), and barriers and practice setting ($p<0.05$).

Conclusion: Despite recognizing its importance, the study revealed a lack of knowledge of ADR reporting and pharmacovigilance among TMPs. Thus, there is a need for advocacy and training of TMPs on ADR identification and reporting to improve the safety and efficacy of traditional medicines.

Development of simple colorimetric method on the determination of dexamethasone in herbal medicine

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Background: To date, there are still reports that herbal medicine still contains undeclared synthetic drugs to increase the therapeutic effect. One of them is dexamethasone usually added in herbal medicine as pain relief. The development of dexamethasone determination is still growing to find a simple method compared with complex instruments.

Purpose: The simple analytical method was developed to analyze dexamethasone in herbal medicine based on colorimetric reaction using UV-Vis spectrophotometry measurement and indicator strips for on-site analysis.

Method: By using UV-Vis spectrophotometry, the dexamethasone-hydroxylamine complex was formed and then react with fluoranil to form yellow colour in the optimized condition. Using an indicator strip for on-site analysis, the strip was made by polymer polymethylmethacrylate (PMMA) mixed with sulfuric acid

(H2SO4) as a reagent to show orange-pink colour when reacting with dexamethasone.

Results: Determination of dexamethasone in herbal medicine using UV-Vis measurement show good results by fulfilling the requirement of validation with LOD and LOQ was 0.21 µg/mL and 0.64 µg/mL, respectively. By using the indicator strip, the minimum detection limit was 13.13 ppm, and the indicator strip was still stable for more than 1 month. The real sample analysis was carried out on both methods to show the method's performance. The result shows both methods have good analytical results confirmed with HPLC measurement as a standard method.

Conclusion: In conclusion, the development of a colorimetric method using UV-Vis spectrophotometry measurement and indicator strips is a simple and applicable method for the determination of dexamethasone in herbal medicine.

Comparative analysis of the regulatory guidelines for clinical trials in regulated and semi-regulated countries: Botswana, India and the US-FDA

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All drugs have safety concerns throughout their development. However, they are eventually approved for use by national health authorities on the basis that the benefits outweigh the risks through evidence provided by clinical trial research. The approval process and degree of regulation for clinical trial conduct differ across regions. A comparative analysis between two regulatory environments existing in these regions was done via literature review, case studies and through interviews to capture the experiential perspectives of key individuals with good working knowledge. These markets: the US-FDA, considered a regulated/ stringent market, and Botswana, considered a semi-regulated market, were examined to provide an understanding of what effects the degree of implementation of clinical trial regulations have on Investigational New Drug (IND) and New Drug Approval (NDA) approval timelines.
The number of clinical trials applied for and approved is exponentially higher with the US-FDA in comparison with semi-regulated countries like Botswana and India. The success rate of these clinical trials is also higher and their regulation is stringent as compared to semi-regulated markets.

Global evaluation on the impact of the BERC-Luso Project

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Background: The BERC-Luso Project (Biomedical Ethics and Regulatory Capacity Building for Portuguese Speaking African Countries, 2018-2022) involved 5 African countries (Angola, Cape-Verde, Guinea Bissau, Mozambique and São Tomé e Príncipe) and Portugal, through a network of National Ethics Committees and National Regulatory Authorities. Its main goal was to reinforce biomedical ethics and regulatory capacities in these countries, acting at the institutional and professional levels. Some of the project's activities included developing a legislative study comparing the current legal framework with international good practices, proposing recommendations for its implementation, and developing tailored educational programs.

Purpose: To measure and evaluate the global impact of the BERC-Luso Project in its multiple dimensions: legislative, institutional and capacity-building levels.

Method: A set of indicators was co-constructed with BERC-Luso partners, developing a national roadmap with actions to lever development at different levels. Roadmaps included strategic actions to reinforce ethics and regulatory capacities in each country. Indicators were evaluated at the end of the project (not completed, completed partially, completed) and compared with the action's descriptive analysis. Score points were attributed to each indicator, with the calculation of score mean values.

Results: 57 indicators were mapped within the 5 countries. 63.16% (n=36) were fully completed and 36.84% (n=21) were partially completed. There were no objectives that were not completed. Analysis per country shows varying degrees of success (from 60.00% to 96.43%). Overall, a high level of success (78.59%) was achieved through roadmap and indicators' analysis.

Conclusion: BERC-Luso had a high impact on every partner country, with the development of a sense of community and ownership due to the different bottom-up and top-down approaches. There is a need to invest more in the development of capacity-building of Portuguese Speaking African Countries and reinforce the implementation of best practices at legislative, institutional and training levels.

Evaluation of thalidomide education and risk management system (TERMS) in Japan: Patients' responses to a third-party survey on comprehension, compliance, and concerns from 2009 to 2019

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Background:
Although thalidomide was initially developed and used as a sedative, gastrointestinal drug, and treatment for morning sickness in pregnancy during the 1950s, thalidomide was later withdrawn from medical use due to its severe teratogenic effects. The worldwide number of people affected by thalidomide was reported to approximately 5,850, including teratogenic stillbirths and neonatal deaths. However, the drug showed therapeutic effects on type 2 leprosy in 1964, and other biomedical potentials such as immunomodulatory activity, TNF-α production inhibitory activity, and angiogenesis inhibitory activity were also recognized and evaluated. Consequently, thalidomide was re-approved for use in treating leprosy in 1998 and multiple myeloma in 2006 in the United States under a strict management system known as the System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.) program.
Subsequently, thalidomide was approved by regulatory authorities for the treatment of relapsed or refractory multiple myeloma (MM), leprosy, Crow-Fukase syndrome under a strict management system called the Thalidomide Education and Risk Management System (TERMS) to prevent fetal exposure. Compliance with the specified TERMS requirements is mandatory for thalidomide use. For instance, patients of childbearing potential must undergo regular pregnancy tests. Prior to prescribing or administering thalidomide, physicians and pharmacists are obligated to ensure that patients have understood and agreed to comply with TERMS. The TERMS Management Center and the TERMS Committee in Fujimoto Pharmaceutical Co., Ltd have controlled the operation and compliance status. Furthermore, TERMS Independent Evaluation Committee (TIEC) has been established to evaluate TERMS' operation via surveys of patients, physicians, and pharmacists from a third-party perspective and make regular reports to the government and the TERMS management center.

Objective:
Examine the extent of patients' comprehension, compliance, and concerns with the Thalidomide Education and Risk Management System (TERMS) in Japan.
Methods: Data were collected through interviews with patients prescribed Thalidomide in Japan by the TERMS Independent Evaluation Committee (TERMS-TIEC) from 2009 to 2019. Open- and closed-ended questions assessed patient perceptions of comprehension, compliance, and concerns about TERMS. Changes in the time series were detected.

Results:
4,670 and 7,837 responses were obtained in the initial and follow-up surveys. More than 97.7% had complete comprehension of congenital disabilities caused by thalidomide. All females with childbearing potential took pregnancy tests before receiving prescriptions and once four weeks during the use of thalidomide. All male patients showed successful contraception, and more than 98.6% understood not to donate sperm. Contrarily, not all patients and their partners use contraception separately; some patients did not know that breastfeeding should be forbidden for four weeks after the termination of thalidomide. Adverse events, includilimb numbness, constipation, and eczema, were frequent patient concerns. Concerns about drug prices were also detected when patients shifted the available route from individual physician imports to insurance coverage.

Conclusion:
Patients have good comprehension and compliance with TERMS. Further efforts are required to explain adverse events and less well-understood issues to patients.
Practice Implications: Continuous evaluation is needed, and better clinical practice may be achieved by answering patients' concerns about adverse events and providing more education.

Medicine quality post-market authorization in a suburban city in Sri Lanka: In-vitro pharmaceutical quality assessment of three medications dispensed by the public and private sectors

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Background: According to the World Health Organization, the prevalence of low-quality medications is higher in developing nations due to weak law enforcement and the unavailability of medicines. In addition, due to the price ceiling on medicines in Sri Lanka, some products had to decrease their prices, which might lead to poor quality. Hence, post-market quality evaluation of medicines is crucial.

Objectives: To analyze the in-vitro pharmaceutical quality of Metformin hydrochloride 500 mg tablets, Paracetamol 500 mg tablets, and Furosemide 40 mg tablets dispensed by public and private healthcare sectors in Karapitiya, Galle, Sri Lanka.

Methods: All the generic and branded products of the above three medicines available on the day of sample collection (22/06/2022) at randomly selected five community pharmacies, government hospital, and semi-government-owned pharmacy were included in the study. From each product, 100 tablets were collected bearing the same batch/lot number in the original packaging. The date of manufacturing, expiry, batch number, type of packaging, registration details with the National Medicine Regulatory Authority, and the temperature at the sample dispensing site were recorded during the sample gathering. Product identity was concealed using a code to rename the samples. Each product was analyzed following the respective pharmacopeial specifications (BP/USP/IP) claimed on the product label. Testing was performed at the laboratory of the Department of Pharmacy, University of Ruhuna. Results were analyzed using MS Excel and SPSS version 25.

Results: Six products each from Metformin hydrochloride 500 mg tablets & Paracetamol 500 mg tablets, and three products from Furosemide 40 mg tablets were analyzed. All samples passed the visual inspection test. Average tablet weight range; Metformin: 530.40 mg - 655.30 mg; Paracetamol: 533.44 mg – 633.13 mg; and Furosemide: 148.10 mg – 239.84 mg were within the specifications. The hardness of the three medicines' was higher than the specified minimum value of 40 N, except for two generic samples of Furosemide (Generic 1: 16.64 ± 1.32 N, Generic 2: 14.05 ± 2.58 N) which failed the hardness test. The percentage friability of three medicines was less than 1% and complied. All samples disintegrated within the accepted periods (uncoated tablets: within 15 min and film-coated tablets: within 30 min). The percentage dissolution of all tablet samples was higher than 80% after 45 minutes (Metformin: 82.3% – 104.3%, Paracetamol: 98.77% - 105.37%, Furosemide: 98.06% - 106.26%) and passed the dissolution test. The assay test of all the samples was within the specifications (Metformin: 93.0% - 100.3%, Paracetamol: 99.9% - 104.7%, Furosemide: 96.9% - 97.7%), except the hospital sample of Metformin which contained 93.0% of Metformin hydrochloride.

Conclusions: Except for one hospital sample of Metformin, all post-market samples of three medicines collected from community pharmacies, semi-government-owned pharmacy, and government hospital complied with the quality specification except the hardness test. However, the negative impact of lower hardness is minimum since the disintegration and dissolution test results were within the specific standards. Continuous post-marketing quality assessment of hospital supplies should be a high priority and it is recommended to ensure the pharmaceutical quality of future supplies.