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Regulatory sciences and quality

Investigation of methanol impurities in commercial and formulated hand sanitisers using GC

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Background: The dramatic increase in demand of hand sanitisers happened during the Coronavirus disease 2019 (COVID-19) pandemic. Although usage of hand sanitiser is a viable alternative for hand hygiene, it can cause unanticipated toxicities if it contains methanol. A retinal blindness is one of methanol toxicity as marked by anion gap metabolic acidosis. Globally, there was outbreak of methanol toxicity such as in Iran, Arizona and New Mexico. In Oman, during pandemic, the hand sanitiser was implemented as one of the precautions in different sectors.

Objectives: Different brands of hand sanitisers are available which needed to be studied to avoid side effects of methanol contamination.

Methods: In the present study the investigators analysed the sanitisers available in Oman for their methanol content. Besides this, a survey was done to understand the use of sanitisers by population in Oman.

Results: The investigations showed effective results indicating that all the tested brands had methanol content within the permissible limits. The investigators also formulated a sanitiser in the laboratory using natural ingredients and studied the properties of the formulation. The physico-chemical parameters studied showed that the formulated sanitiser had uniform consistency and good spreadability. The microbiological studies also showed that the formulated sanitiser was effective against the microbes studied. The details will be presented.

Facilitating access to medicines in Latin America

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Background: The World Health Organization (WHO) provides guidance on the development of multisource pharmaceutical products for market authorisation using in vivo bioequivalence studies or, where applicable, an in vitro biowaiver strategy based on the Biopharmaceutical Classification System (BCS). Review of the regulatory framework guiding generic drug approval in Latin American countries revealed that less than 50% of regional health authorities offer a generic drug development pathway utilizing a BCS-based biowaiver strategy.

Objectives: Consistent with the ONE FIP Strategy to facilitate access to medicines, the focus of this regional pilot project is to advocate for broader implementation and harmonization of a BCS-based biowaiver regulatory strategy in Latin American countries.

Methods: The FIP Board of Pharmaceutical Sciences established a steering committee involving regional representatives from health authorities, pharmaceutical industry, and academia to coordinate educational outreach and workforce development activities. A series of digital engagement events were held in Spanish with representatives from Latin American health authorities as well as the broader scientific community in pharmaceutical industry and academic institutions of the region to disseminate knowledge about a BCS-based regulatory strategy, promote collaborations, and to explore alignment of biowaiver approval and regulatory pathway among Latin American countries.

Results: Feedback from diverse Latin American stakeholders demonstrated inconsistent implementation of bioequivalence testing within the region. However, there is support for a synergistic approach between countries to reduce duplication and increase efficiency in market authorization for generic drug products. This includes alignment with the WHO Prequalification of Medicines programme as well as development of a computational database for classification of active pharmaceutical ingredients for the demonstration of therapeutic interchangeability of immediate-release oral dosage forms according to the BCS.

Conclusions: FIP-facilitated digital learning opportunities raised awareness of a BCS-based biowaiver regulatory strategy among Latin American stakeholders and resulted in a plan to continuously strengthen collaborative efforts within the region to harmonize regulations relevant to generic drug development with the objective to introduce cost-effective drug products that benefit public health.

The quantity of anthocyanins in blueberry fruit based dietary products and juices

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Background: In the pharmacies of Republic of Serbia, three dietary products and food supplements with blueberry fruit preparations intended to improve eyesight were found and the content of anthocyanins in them was analysed.

Methods: According to Ph. Eur. 10, colorimetric method was used for determination of anthocyanins, which was given in the monograph of Myrthilli fructus recens. For comparison, the content of anthocyanins in two juices with blueberry fruit and other fruits with anthocyanins (aronia, grape) was analysed using an AOAC colorimetric method given by Lee and colleagues (2005).

Retin activ (ESI srl, Italy) a dietary product with a special medical purpose, contains vitamins A, C, E, 15mg of dry blueberry extract standardised at 25% anthocyanosides, lutein and zeaxanthin. The advice of the manufacturer for use is one capsule a day.

Results: the authors analysis have shown that Retin activ in one capsule contain 8.35 ± 0.17mg of anthocyanins, calculated as cyanidin 3-O-glucoside chloride.

Pro-Visio tablets (United Pharma, Bratislava, Slovakia), a food supplement with lutein, zeaxanthin, 20mg of blueberry extract, vitamin E and selenium, contained 5.14 ± 0.18 mg of anthocyanins, calculated as cyanidin 3-O-glucoside chloride in one tablet. The advice of the manufacturer for use is one capsule a day.

Visionace Original tablets (Vitabiotics, London, UK) contain 23 components including blueberry extract (60mg) and 0.02±0.0089 mg of anthocyanins per tablets.

The juices, Bravo - blueberry (RAUCH SERBIA DOO) and Nectar - apple, aronia, blueberry and grape (Nectar DOO, Serbia), contained 42.57 ± 2.66mg/L and 31.80 ± 0.01mg/L of anthocyanins, respectively.

Conclusions: According to the literature, blueberry anthocyanins has been reported to enhance night visual acuity and contrast sensitivity and are used in the supplements to improve vision health. Older studies (Vannini *et al.,* 1986) have shown significant improvement of the pupillary muscle contraction in reduced light conditions in healthy young subjects after administration of 240mg of blueberry extract containing 36% anthocyanins. The claimed effect refers to an improvement of visual adaptation to the dark. Newer studies were contradictory.

JECFA has established an Acceptable Daily Intake (ADI) of 2.5mg/kg bw/day for anthocyanins from grape skin. The dose of 50 mg of anthocyanins of black current concentrate have shown positive effect after 30 minutes of dark adaptation compared before and two hours after intake of test drink in 12 healthy subjects (Nomi *et al*., 2019).

In conclusion, these results suggest that the best option for better eye health is to use products with concentrated blueberry fruit extracts instead of juices, but the intake of at least 50 mg of anthocyanins per day should be ensured.

Active safety monitoring of the mRNA Pfizer-BioNTech (Comirnaty) vaccine using a recipient survey: A New Zealand first

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Background: New Zealand began vaccinating its population with the mRNA Pfizer-BioNTech (Comirnaty) vaccine in February 2021. Although Comirnaty demonstrated good efficacy and safety in phase III clinical trials, post-marketing surveillance is needed to understand its safety in the real-world, especially in New Zealand due to its unique demographic. The authors describe the establishment of the Post Vaccine Symptom Check, a participant based active surveillance approach to support the safety monitoring of Comirnaty in the population.

Objectives: To actively survey a randomly sampled New Zealand population, aged 12 years and older, to understand the rate, composition and individual impact of adverse events following immunisation (AEFI) after Comirnaty.

Methods: From the 27th August to 5th October 2021, an opt out survey was sent via automated short message service (SMS) to individuals, aged 12 years and older, who received a first or second dose of Comirnaty. From 14th December 2021, the survey was also sent to individuals, aged 18 years and older, who received a booster dose of Comirnaty. Participants were asked if they had experienced a side effect after a dose of Comirnaty. A supplementary survey, including the types of symptoms experienced, was sent to respondents who experienced an AEFI. Priority equity groups, namely Māori and Pacific Peoples, were oversampled up to 30% and 20% respectively to ensure the data was representative of New Zealand's unique demographic.

Results: Up to and including 1st April 2022, the opt out survey was sent to 481,236 individuals (aged 12 years and above), following the first, second and booster dose of Comirnaty. Respondents were 54% female and 46% male, with 17% and 8% of these Māori and Pacific Peoples respectively. There were no differences in the proportion of people who reported an AEFI across ethnic groups. Of the participants that completed the survey, injection site reaction was the most reported AEFI (16.24%), followed by fatigue or tiredness (15%). Less common symptoms were fever and high temperature (3.6%), stomach symptoms (3.2%), and rashes not at the injection site (0.4%). Of those surveyed, 0.4% reported visiting a doctor in the days following the first dose, this increased to 0.6% and 0.7% following the second and booster dose respectively. Overall, there was a higher incidence of AEFI reported following the second and booster dose compared to the first.

Conclusions: The authors findings provide further reassurance on the safety of the vaccine, as the AEFI reported were relatively mild and consistent with those reported in the Comirnaty phase III clinical trials and New Zealand's passive system. This study illustrates the effectiveness of active, participant-based surveillance systems, such as New Zealand's Post Vaccine Symptom Check, at providing near real-time data on AEFI in a population setting.

Enhanced post-marketing surveillance of the COVID-19 vaccines in Aotearoa New Zealand

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Background: The post-marketing surveillance of medicines and vaccines in New Zealand has been traditionally delivered using a spontaneous reporting system by Medsafe, the medicines regulator, and the Centre for Adverse Reactions Monitoring (CARM), part of the New Zealand Pharmacovigilance Centre (NZPhvC). The emergence of SARS-CoV-2 in 2019 led to the establishment of New Zealand's largest ever immunisation programme with the aim to vaccinate as many of the eligible population against COVID-19. Considering the public attention surrounding the novel COVID-19 vaccines and the scale of the COVID-19 Vaccine and Immunisation programme (CVIP), there was a need to both establish new and enhance existing post-marketing surveillance tools to promptly detect and investigate any potential safety signals, and thereby maintain public confidence.

Objectives: To enhance the existing pharmacovigilance system and incorporate new methodologies and technologies for identifying and evaluating possible adverse events associated with COVID-19 vaccinations in New Zealand.

Methods: A unified approach was taken by Medsafe, the NZPhvC and the CVIP to evaluate the existing pharmacovigilance systems and identify limitations. A safety monitoring strategy was established highlighting the need for an additional technology-based database to handle the expected increase in reports of adverse events following immunisation (AEFI) after COVID-19 vaccines. The requirement for frequent and timely reporting of AEFI to the public, sponsors and government Ministers was noted. The need for a panel of experts in various medical and scientific fields was identified to provide external expert advice on the vaccines. The inherent limitations of the passive system, including underreporting, incomplete reports, and reporting biases, highlighted the need for more robust active surveillance systems and research to facilitate the early detection of AEFI in the population.

Results: New databases were developed on the same electronic platform to capture national COVID-19 immunisation events and spontaneous AEFI cases reported by healthcare professionals and the public. Importantly, this facilitated data linkage between these and existing databases, including New Zealand's electronic health record system. Qlik Sense, an analytics and visualisation application, was leveraged to understand trends in the AEFI data and for various reporting purposes including input into the COVID-19 Vaccine(s) Safety Report. The COVID-19 Vaccine Independent Safety Monitoring Board (CV-ISMB) was established in February 2021 and provided expert advice on serious and fatal case reports, potential safety signals, and ensured that equity and the risk-benefit ratio of the vaccine remained at the forefront of the CVIP. Research was commissioned to understand background incidence rates of adverse events of special interest, and statistical methods were employed to facilitate active surveillance using linked electronic healthcare records enabling the timely detection of potential safety signals associated with the COVID-19 vaccines.

Conclusions: The magnitude of the COVID-19 vaccine roll-out in New Zealand provided an opportunity to enhance current systems and develop new, systematic approaches to vaccine safety surveillance that will make both a national and global contribution.

Managing bridging data for regulatory purposes

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Background: Due to the complexity of biosimilar drugs, regulations concerning biosimilars were considered highly difficult to be addressed. Thus, the evaluation procedure requires a more profound structure. By managing bridging data more efficiently, we may lower down technical barriers to cross-regional trade may be and drug quality, safety and efficacy may be improved.

Objectives: Aiming at reducing technical barriers and improving drug quality, safety and efficacy. This article aims to provide regulatory insights on an international scale and general principles when handling bridging data.

Methods: The method applied in this article is literature review. Followed by a brief conclusion.

Conclusions: The clashes between safety and approval speed regulatory logic had been a major issue in the statutory agencies. There is a wide gulf between efficacy and quality in the case of biologics, for it contains active substances and it requires falsifying its likelihood of provoking both identifiable and unidentifiable risks. Bridging data provides

interoperability and tangible communication options across jurisdictions. Knowledge articulated in this article provides atoning measures for both the sponsor and the regulators across different regions.

Availability and quality assessment of different brands of artemisinin-based combination therapy (ACT) tablets circulating in Kaduna State, Nigeria

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Keywords: Artemisinin-based combination therapy, Community pharmacy, Hospital pharmacy, Kaduna state, Malaria, Nigeria, Open drug market, Patent medicine store, Treatment failure

Background: Malaria treatment failure is one of the challenges facing malaria control, especially in developing countries where the malaria prevalence is high. Quality assessment of the current WHO-recommended Artemisinin-based Combination Therapy (ACT) for uncomplicated malaria is essential to properly address issues of ACT counterfeiting and circulation of fake ACT drugs. Such investigations could also help to formulate policies for the planning and implementation of malaria control programmes.

Objectives: This study aims to assess the availability and quality of ACT tablet brands circulating in Kaduna state, Northwestern Nigeria.

Methods: Within a defined period and using a purposive sampling approach, different brands of ACT tablets were sourced from formal settings (Community pharmacies, Hospital pharmacies, Patent medicine stores) and non-formal settings (Open drug markets) across Kaduna state, Nigeria. Pharmacopeial methods and WHO standards were used to carry out in-vitro quality control tests, namely, visual

inspection, friability, crushing strength, disintegration, and weight uniformity.

Results: A total of 82 different brands of ACT tablets were sourced from the four settings. Some of the brands were manufactured within Nigeria, and some were imported from other countries. The different brands were mainly artemether/lumefantrine (AL), dihydroartemisinin/ piperaquine (DP), artesunate/amodiaquine (AA), and artesunate/mefloquine (AM). Of the 82 brands, 34% were from Community pharmacies, 35% from Open drug markets, 17% from Hospital pharmacies, and 13% from Patent medicine stores. The tablets are of different types, i.e., uncoated, film-coated, dispersible, and some not specified. Further, visual defects were detected from some of the brands as far as WHO standards such as cracks, and/or breaks, presence of powder or foreign materials. The friability ranges between 0.01 – 4.70%, while the crushing strengths of the tablet are within 3.05 ± 0.60 – 30.22 ± 5.14 KgF. Thus, Overall failures on the various tests conducted were 17% from community pharmacies, 25% from hospital pharmacies, 20% from patent medicine stores, and 11% from open drug markets. The highest proportion of failure was from the physical assessment.

Conclusions: Numerous brands of ACT tablets were found to be available from the four different drug sources in Kaduna state, Nigeria including unauthorised outlets. Some of the ACT tablet brands tested complied with the official quality requirements while others failed. Thus, the results show the need for constant monitoring of the quality of ACT tablets circulating in Nigeria in order to abort the potential of malaria treatment failure. There is also the need for the medicine regulatory agency in Nigeria to ensure a proper supply chain of medicines including ACTs by enforcing laws to ensure the public only gets prescription drugs such as ACTs from registered pharmacies.

An overview of biosimilars approval in Brazil

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Background: Brazil has a universal health system that aims to provide care for more than 200 million citizens. Biological medicines consume a significant part of the health budget and the entrance of biosimilars into the market is expected to reduce expenditure and increase access to these therapies. The Brazilian Health Regulatory Agency (Anvisa) has adopted the term biological products developed by the comparability pathway to refer to biosimilars and distinguish them from non-innovator products. The regulatory framework in Brazil was published in 2010 and followed the World Health Organization guidelines on the evaluation of similar biotherapeutic products.

Objectives: This study aims to provide an overview of biosimilars approved by Anvisa in Brazil.

Methods: A cross-sectional study of biosimilars approved by Anvisa until December 2021. Initially, a list of products with marketing authorisation was requested from Anvisa based on the access to information law. Data were extracted from public assessment reports of registration applications. Data collection covered information regarding the manufacturer, approved indications, clinical studies of comparability with the reference product, extrapolation of indications at application and after-approval changes. Data was compiled in a Microsoft Excel spreadsheet and assessed by methods of descriptive statistics.

Results: From 2015 to 2021, 43 similar biotherapeutic products were approved by Anvisa, including 14 antineoplastic agents and 12 immunosuppressants. The public assessment reports were publicly available for 18 (41%) of the products. In 2019, 16 biosimilars were registered in Brazil. Amgem and Wyeth were the leading pharmaceutical companies with five market-authorised biosimilars. Rituximab and trastuzumab were the most frequently approved products, summing six brand names each. In most of the approvals, extrapolation of indications were authorised by Anvisa and, after approval, no new indications were included. For rituximab, the clinical trials of comparability were conducted for follicular lymphoma and rheumatoid arthritis and there were extrapolations to non-Hodgkin's lymphoma, granulomatosis with polyangiitis and microscopic polyangiitis. In addition, for trastuzumab, breast cancer was the main condition evaluated in the clinical trials.

Conclusions: The number of biosimilars approved has risen in the last three years in Brazil. Oncology and rheumatology represents the most competitive therapeutic areas with the highest number of authorised products. Extrapolation of indications in the application was common and there were no post-approval changes related to extensions to other diseases or to additional subsets of the population.

Quality of liquid measuring devices enclosed with paediatric oral liquid dosage forms in Sri Lanka

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Background: Though there is a shift in the preferred oral dosage forms for children, liquid dosage forms remain common in low and middle income countries. Accuracy of the liquid dosage form dosing depends on measuring devices. Lack of quality of oral liquid measuring devices will lead to medication errors. There are no mandatory standards on quality of liquid measuring devices in Sri Lanka. Hence there was an urgent need to describe the quality of manufacturer supplied measuring devices enclosed with paediatric oral liquid dosage forms currently registered in Sri Lanka.

Methods: Standards for measuring devices were developed after a detailed literature search. Panel of experts rated the necessity criteria on a nine point Likert scale. Standards with overall panel median score of greater or equal to seven with agreement were selected. All the available measuring devices were evaluated against the developed standards. Three volumes of liquid antibacterials (5 mL, 3.75 mL and 2.5 mL) were measured using the enclosed measuring device. Accuracy of the volumes was measured.

Results: 12 standards on liquid measuring devices were finalized. Out of 202 products only 62% were packed with a dosing device. More than half of the measuring devices aligned with all the standards developed. When measuring liquid antibacterials less error was seen with measuring cups when compared to other dosing devices. Less error was seen when measuring 5mL when compared to other two volumes.

Conclusions: A novel set of standards on liquid measuring devices were developed. These standards will reduce variability in the measuring devices of oral liquid dosage forms, thereby improving the correct dosing by parents and caregivers. Though the standards developed were not mandatory standards, the quality of available oral liquid measuring devices were satisfactory.

Weak regulations threaten the safety of consumers of harmful weight-loss supplements (WLS) globally: Results from a pilot global policy scan of weight-loss supplement regulation

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Background: Over 80% of the world's population uses dietary supplements and herbal medicines. Prior research has observed that policies relating to the regulation of dietary supplements vary markedly across countries, even among countries that are similar culturally, legally, and economically. Weak regulation has led to the growth of the dietary supplement industry, which is valued at over $300 billion globally and is predicted to continue to grow. A growing body of literature has documented that weight-loss supplements (WLS) often contain illegal and toxic adulterants, which have been associated with acute liver failure and even death. WLS, particularly those containing adulterants can also have clinically important interactions with other medications. In the United States, WLS account for 25% of emergency room (ER) visits related to dietary supplements use every year. Yet the public's perception is that WLS are safe and adequately regulated.

Objectives: To pilot a global policy scan study assessing how governments worldwide regulate weight-loss supplements.

Methods: Five countries from each of the six World Health Organization regions that varied within the four World Bank income classifications were non-randomly sampled, making a total of 30 countries. One expert on WLS policies from each of the 30 countries completed an online survey on WLS regulation in their country covering the following domains: legal frameworks; pre-market requirements; claims, labelling, and advertisements; product availability; adverse events; and monitoring and enforcement. WLS were defined as any dietary supplements promoted for weight loss. Experts were identified through searches on regulatory agency websites, Google Scholar, and LinkedIn, as well as through professional networks, and included regulators, pharmacists, researchers, or other professionals with expertise in food and drug regulation. 'Don't know' responses were excluded from the analyses. Qualitative responses were analysed and re-categorised into pre-existing answer categories, including 'Yes,' 'No,' and 'Don't Know'.

Results: Only 12 and nine countries independently evaluate the safety and efficacy of a new WLS, respectively. 17 countries have specific labelling requirements (e.g., warnings, disclaimers, instructions for consumption, etc.) for WLS. 14

countries have regulatory limitations on advertising WLS, with only six having limitations on advertising WLS to children. Nigeria is the only country with a minimum legal age to purchase WLS. Only seven countries require certain WLS to be sold only with a prescription. Only Latvia and Botswana have limitations on where WLS can be sold. In 11 countries, reports on adverse events related to WLS are available to the public. In 17 countries, the presence of non-registered or non-licensed WLS on the market are monitored. Penalties for WLS non-compliance with pre-market regulations exist in 12 countries, with labelling regulations in 16 countries, with advertisement regulations in 12 countries, and with adverse event reporting regulations in ten countries.

Conclusions: Results document wide variability in federal WLS regulations globally. Gaps exist in consumer protection regulatory frameworks, particularly those relating to child health. There is a need for the World Health Organization global nutrition policy review to include the assessment of WLS and dietary supplements policies.

A comparison of European and Japanese pharmaceutical regulations: Drug information and over the counter products perspective

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Background: Japanese and European Union (EU) regulatory bodies historically have in principle accepted regulations issued by each other and mutually agreed on the requirements and regulatory processes to provide drugs in a timely manner while ensuring safety, quality, and efficacy. However, there are still a number of pharmaceutical regulations in Japan and the EU which are different.

Objectives: The aims of the study were to compare pharmaceutical regulations in Japan with those in the EU and identify differences and similarities between the two regulations.

Methods: Pharmaceutical regulations related to drug information and classification of over-the-counter medication (OTC) were obtained from the websites of the Japanese and European regulatory bodies and journals. The pharmaceutical regulations of Malta, a European country, were used as an example for comparative purposes. The content and layout of the documents used for drug information were compared by reviewing regulatory guidelines for the preparation of each document or a sample of an actual document.

Results: Two types of documents are mainly used as drug information references in Japan and the EU. Japanese Drug Information Sheet (DIS) and European Patient Information Leaflet (PIL) are intended for patient use. The Japanese Package Insert (PI) and European Summary of Product Characteristics (SmPC) are used by medical professionals. The DIS and PIL provide accurate drug information for patients, however, their publishers and contents are different. The DIS is issued by each pharmacy in Japan, tailormade for each patient, while the PIL is officially issued from industries. The PI and SmPC are similarly issued from industries and the information contained is confirmed by the regulatory authorities. The information within the PI focuses on providing cautions and warnings for safe use. Japan has classified OTC drugs into risk categories since 2009. OTC drugs are categorised as (i) Guidance-mandatory (GM) drugs, (ii) Type I, (iii) Type II, and (iv) Type III drugs by evaluating the extent of harmful impact on human health and the results of post-marketing surveillance. All OTC drugs can be distributed online, except for GM drugs. Type II and III drugs can be purchased without pharmacist intervention. In Malta, there is no classification within OTC drugs, and all pharmaceutical products must be dispensed only in pharmacies.

Conclusions: Regulatory harmonisation between Japan and the EU does not extend to drug information documents and non-prescription medicines. There are differences in regulation in Japan and Malta. Harmonisation between Japanese and European pharmaceutical regulations can possibly be achieved through discussion and allowance for cultural differences.

Quality systems of pharmacy services of a research centre

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Background: The Pharmacy Services of Jesús Usón Minimally Invasive Surgery Centre has the functions of acquisition, custody and dispensing of medicines and medical devices for the realisation of the activities that are carried out here.

In addition, we have a fully equipped formulation laboratory to develop magistral preparations and reconstitute any test product used in preclinical studies.

Objectives: Having quality systems guarantees us that the procedures that are carried out in the pharmacy services are carried out correctly and always in the same way.

Methods: This service is certified with ISO-9001 quality systems and Good Laboratory Practices (GLP), with quality procedures for both accreditations. There are general and

specific quality procedures for each equipment and the activities carried out.

Results: The general quality procedure describes the acquisition, reception and dispensing of medicines and medical devices. They are made through a computer programme and in paper format with official requests. For the dispensing of specially controlled medications (psychotropic and narcotic) we have internal dispensing orders.

Among the specific procedures for the formulation laboratory, the workflow that must be carried out to ensure the correct storage of any test items. Entry and exit registers, temperature control and locked storage. The order specific procedures focus on the usefulness and handling of the specific equipment.

Conclusions: The importance of quality management and the need to have standard procedures for the different talks carried out, help to protocolize and improve the operation of the pharmacy services and its involvement in different research projects.

Good laboratory practice in a research clinical analysis laboratory

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Background: Good Laboratory Practices (GLP) is a quality system that involves the organisation of a research laboratory. In order to control the entire clinical analysis process, it is essential that the laboratory is equipped with, applies and maintains a quality system. Its compliance is a minimum requirement that clinical laboratories must meet to increase adherence to standardised practices and procedures and improve the delivery of reproducible and reliable results, while ensuring safety.

Objectives: In order to correctly use and interpret a laboratory analysis and the results obtained, it was necessary to validate the analytical techniques performed in our laboratory before using them routinely in order to guarantee the analytical results performed in preclinical research studies.

Methods: For the implementation of Good Laboratory Practices the validation of all analytical methods routinely used in the clinical analysis laboratory of the Jesús Usón Minimally Invasive Surgery Center (CCMIJU) was carried out.

The validation parameters measured were the intermediate precision and repeatability of the method. The study was performed on each analytical parameter in the different species used in preclinical studies, including hematological and biochemical parameters.

Results: : With the results obtained from the analytical validation, the statistical study was carried out and a verification report was written. The results obtained show that the degree of dispersion and the degree of concordance of the results obtained between a series of measurements obtained from multiple sampling of a homogeneous sample of each species studied under the prescribed conditions are good and reproducible.

Conclusions: The analytical method used to determine the blood parameters of the different species studied and analysed in the Clinical Analysis Laboratory of the CCMIJU is repetitive and reliable, considering that the preclinical studies carried out are safe, verifying the quality of the results obtained in our laboratory under GLP regulations.

Pharmaceutical regulation, policy and access to medicines in the European Union

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Background: European health systems have traditionally aimed at the provision of high-quality care and equity of access. This has become increasingly challenging over the past decades, with unabated pressure to deliver more and better services with insufficient resources. More specifically, in the pharmaceutical arena, there is growing concern and interest in the area of access to medicines in the European Union. Whilst member states are bound by a legislative infrastructure which addresses the quality, safety and efficacy of medicinal products on the market, patients in these territories experience disparate levels of access to these therapies. Paradigms for improvements in this field most often focus on the individual barrier and do not relate to the wider perspective.

Objectives: To investigate stakeholders' perceptions of barriers to medicines' access and to examine the influence of pharmaceutical policy and regulation in this area.

Methods: A systematic mixed-method approach was adopted, primarily comprising qualitative techniques. The study incorporated unstructured interviews with doctors and nurses, questionnaires to pharmacists and to prescribers and semi-structured interviews with experts seeking their perspectives on health care provision, payer advocacy, health economics, pharmaceutical policy and pharmaceutical

regulation. A focus group was conducted with the aim of consolidating and validating the findings and proposals of the study. Directed content analysis was used to evaluate and interpret the results. The initial coding guide was developed through the literature review. As the analysis evolved the coding scheme was reviewed and modified to embrace the differentiated categories of data.

Results: Deterrents to medicines' access are entrenched, and sometimes replicated, at various strata of the health systems of the member states. The advantages that a documented national medicines policy may bring in this context are not fully understood or implemented. The multiplicity of factors impacting access are also over-arching at a pan-European level. It would be difficult for a pan-European policy targeting access to medicines to accommodate the wide spectrum of divergences between the member states. Additionally the consensus in the member states is that Europeanisation of the pharmaceutical arena should not be further developed at this time. However the European Union's potential for providing technical support, networking and co-operation, establishing scientific norms, capacity building and the co-ordination and dissemination of information, should be exploited. The current initiative by the European Union to revise the legislation should strategise access to medicines as a focal point.

Conclusions: Measures to mitigate the challenge of medicines' access are best taken conjointly at European Union level and in the member states. The latter should adopt a transparent, cohesive and documented national policy which explicitly upholds access to medicines, provides clear direction and serves as a platform towards fostering this goal. To be fit for purpose, such a policy must be participative and inclusive of all actors and must be developed in accordance to each country's needs and resources. The Commission has a role in supporting and complementing the member states by developing generic facilitating frameworks.

Exploring Mongolian healthcare professionals' experience adverse drug reaction reporting: Part of a questionnaire survey

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Background: Spontaneous reporting of adverse drug reactions (ADRs) is a main regulatory approach of monitoring the medicines safety in the market. Current regulation requires each suspected case of ADR should be reported by healthcare professionals to the Medicine, medical devices regulatory agency. This study has evaluated existing practices by various levels of healthcare professionals for their implementation of current regulation on medicines safety.

Objectives: Aim of this study is to evaluate existing practice being implement ADR reporting procedure by health professionals at different health organisations.

Methods: The study is a qualitative and questionnaire survey containing 56 questions to evaluate sociodemographic characteristics, knowledge, attitude, practice behaviours of health professionals for ADR reporting and information. A sampling attendee was collected among physicians, pharmacists and nurses working in state and private hospitals, clinics, and pharmaceutical companies. Due to pandemic, data was collected by both approach paper and online-based way from May to September 2021. To process data, Stata 13 and MS Excel programmes were used.

Results: Of the total 1450 questionnaires distributed in urban and rural health organisations, 1199 health care professionals responded to the questionnaire (82.62% response rate). Among all healthcare professionals, nurses (40.53%) had a better attitude to respond in questionnaires. Total of 79.15% of respondents assumed that ADR reporting is advantageous, and that's the most high-rated response out of the total questions. Total of 53.71% of respondents assumed that Reporting of ADRs is not encouraged by someone, and that's the second high-rated response out of the total questions.

Conclusions: As initial result of the study, although most of health care professionals tend to support ADR reporting due to understand the importance of the reporting, they need more motivation to effective implementation of the existing procedure.

Ensuring equitable access to medicines, vaccines and supplies through a health systems approach: Recommendations from the Commonwealth Civil Society Policy Forum 2021

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Background: Inequities in access to medicines, vaccines and medical supplies are a global issue, with one-third of the world's population lacking access to essential medicines. The World Health Organisation (WHO) and the United Nations (UN) sustainable development goal (SDG) 3.8 aim to improve access to safe, effective, genuine, quality and affordable essential medicines and vaccines for all as a vital component of achieving Universal Health Coverage (UHC). Access to medicines and vaccines can be influenced by a variety of social and environmental factors.

Objectives: This study focused on exploring and understanding the determinants of access to medicines and vaccines across Commonwealth countries from a whole health system's perspective and applying that knowledge to develop a logic model targeting grass -root level strategies, with the aim of improving access to medicines and vaccines across commonwealth countries.

Methods: Using a mixed methods approach, data was collected between February and May 2021 by the civil society policy forum (CPSF) organising committee. A quantitative survey was developed, pilot-tested and distributed by the organisational committee to their respective networks over three months. Qualitative data was collected from stakeholder presentations (five purposively chosen experts) and panel discussions (six experts and forum attendees) during the CSPF held on 18th May 2021. Survey data was analysed using descriptive statistics, whereas qualitative data was thematically analysed using framework analysis Data from all methods was triangulated to develop a model for improved access to medicines and vaccines which was then used to draft policy recommendations presented to the Commonwealth health ministers at their annual meeting. Consent was sought from each participant in the study, and the study was deemed exempt from ethical approval, because it was designed to inform the CPSF forum proceedings and was part of the organisational aims.

Results: Several barriers to access were identified including public hesitancy and lack of health literacy; unaffordability and inaccessibility of medicines; ineffective and non-supportive trade agreements; and lack of the following: essential medicines, national/regional capacity to manufacture medicines, pricing transparency, population need-based health policies, infrastructure and workforce capacity and, intellectual property rights affecting knowledge transfer. Five key policy recommendations were developed, including taking a health systems approach, ensuring price transparency, supporting local manufacturers and medicines suppliers, prioritising vaccine equity, and sharing knowledge and capacity building to ensure sustainable access to medicines and vaccines.

Conclusions: Access needs to be considered from a whole health systems perspective, including interlinked factors relating to the individual, the broader societal context, the health workforce and the systems that implement and enable these determinants. The logic model presents grassroot level strategies to overcome barriers currently causing access issues to medicines and vaccines across Commonwealth countries.