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CONFERENCE ABSTRACTS

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Industrial pharmacy

On-going method performance verification: A tool to ensure method's fitness for purpose through its lifecycle

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

Background
As part of analytical lifecycle management approach, on-going method performance verification is an important step that provide assurance that the method is in a state of control. For that purpose, an on-going program to collect, evaluate, analyze and understand information and data related to analytical method performance should be established. As an outcome, method performance attributes will be monitored to maintain method state of control and/or to provide an early warning of drift or changes in the method capability.

Purpose
Cannabis dried flower, used as an herbal drug, presents an inherent ability to absorb elemental impurities from the soil and other sources of contamination. Thus, the control of these impurities is critical to assure product quality and safety. Therefore, it is extremely important to ensure method fitness for purpose, through its entire lifecycle. The present work aims to demonstrate the advantages of applying a monitorization program for the implemented method used to determine heavy metals content by ICP-MS in medicinal cannabis flower.

Method
The monitorization program included method performance data collection (critical method attributes identified in the system suitability), generated in the routine use of the analytical method. Statistical Process Control tool for trend analysis, namely Control Charts (Shewhart's charts), was used to analyze and understand the results obtained.
Results
A normal distribution was verified for all the critical method attributes evaluated. Meeting a target for the recovery between 70-150% for the sample solution spiked with Hg reference standard, is one of the method attributes. An analysis of approximately 100 different system suitability (SS) indicated that the results are randomly distributed. However, it is observed a trend in obtaining in several SS values lower than the acceptance criterion. Additionally, the mean for recovery is approximately 75%, which is closed to the lower limit of the acceptance criterion. This is evident in the established control chart since the lower control limit (57%) is below the acceptance criterion and the upper control limit (93%) is significant lower when compared to the upper acceptance criteria (150%). This low recovery values for Hg is justified by its challenging behavior, such as: Its highly volatile, it is easily absorbed on polymeric materials and its instability in aqueous solutions at sub-ppb levels. This led to the conclusion that the failures are not method performance related. Based on this information and on trend identified in the control charts, it was established new acceptance criterion for this attribute.

Conclusions
The advantages of using a monitorization program to evaluate method's performance was highlighted in this work. In the example presented, it was collected, established, and analyzed control charts for an analytical method for elemental impurities determination by ICP-MS, in cannabis medicinal flower. For one of the critical method attributes, a problem was identified, and a corrective action was defined in order to reduce the risk of future failures. Therefore, this methodology gave a proactive behavior on determining whether action must be taken to correct, anticipate and prevent problems to ensure method fitness for purpose through its lifecycle.

Developing competency standards for clinical research associates

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Background
Growth of the therapeutics industry in Australia is constrained by a lack of suitably qualified personnel, especially clinical research associates (CRA). Furthermore, it is difficult for professionals to determine their need for future development without a framework within which to assess their competencies. Today, CRAs face a highly dynamic and complex environment for delivering clinical trials with the shift to a decentralised, hybrid clinical trial ecosystem. This new environment requires an agile clinical research workforce with appropriate competencies to effectively monitor and manage risks. This project was undertaken in the context where recognition of the need to address a highly dynamic ecosystem and preparedness of the CRA workforce for current and emerging roles and ways of working is imperative.

Purpose
We are developing a competency framework for professionals in CRA roles in industry.

Method
Initial development of the competency framework was informed by a literature review, a review of online job descriptions and a review of educational programs designed for clinical research professionals. A workshop with senior industry-based clinical research professionals was used to further refine the framework and a survey of industry professionals was conducted to determine acceptability and usability of the framework.

Results
We have developed a draft competency framework comprising eight domains: scientific concepts and research design, ethics and participant safety, therapeutic product development and regulation, clinical trial operations, study and project management, data management and informatics, leadership and professionalism and communication and teamwork. These eight domains are further subdivided and classified according to experience levels. The domains are linked by core attributes that are required by all CRAs. The project is at the point where it can be taken up by industry management, professional associations, academic institutions and individuals to inform the future development of the CRA role.

Conclusion
The competency framework will be useful for developing a competent, suitably qualified CRA workforce in Australia. It can be used for setting professional standards and establishing suitable education programs to support the supply of clinical research professionals in Australia.

Investing in health: Access to innovation through application of ESG principles and criteria? An investigation proposal

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Background
Universal health coverage includes access to safe, effective, quality and affordable medicines.Since the last pandemic government bodies, regulators, investors and patients have increased expectations for responsible pharmaceutical business practices. Beside disruptions in supply chains market failures still exist in terms of disease areas, special patient groups and clinical trial diversity.

Purpose
As world community we experienced a shift in pharmaceutical companies' business model. Additionally we observe a move from a shareholder economy to a stakeholder economy. The question is whether and how the application of ESG (environmental, societal and governance)- principles and criteria within the drug development process could have an impact on access to innovative medicines.

Method
A multi-stakeholder approach has been chosen. Stakeholders' perspectives are categorized and applied to already existing ESG-frameworks regarding their expectations, their criteria, transparency in and measurability of the drug development process, development plan and clinical trials details and later pricing, therapy affordability and costs as well.

Results
At the Brisbane conference 1st results will be presented. This includes perspectives of a variety of stakeholders involved and aspects of sharing the value product development plans might create for society, sharing data, and working with stakeholders in a pro-active approach. Strategies, tactics and measurements identified to hold companies' business and drug development process accountable to ESG principles will be shown.

Conclusion
A mutual understanding of the evidence generation, transparency and the learnings alongside the entire product's development could create a sustainability criterion. ESG performance can be a good indicator of sustainable global health investments, of company's success and of patient's access to innovation.

Physicochemical and microbiological stability of tacrolimus oral compounded suspensions

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Background: Tacrolimus is an immunosuppressant prescribed to transplant patients for the prevention of organ rejection. In the United States (US), tacrolimus for oral use is commercially available as capsules and granules. The granules (for oral suspension) represent an important therapeutic alternative for children who cannot swallow capsules. However, tacrolimus has a narrow therapeutic index and it is important to adjust the dosage strength to meet the individual patient needs. There is a lack of an age-appropriate formulation for tacrolimus which allows dosing flexibility.

Purpose: To develop a tacrolimus oral compounded suspension with an extended beyond-use-date (BUD) for use particularly in pediatric patients.

Method: Oral compounded suspensions for tacrolimus 0.5 and 1 mg/mL were prepared by adding the contents of tacrolimus 5 mg commercial capsules (Astellas and Sandoz) to an oral suspending vehicle (SuspendIt). A batch of 500 mL was prepared for each strength and for each commercial source of tacrolimus, which resulted in four different batches. Each of the oral compounded suspensions were evenly distributed into six prescription oval amber plastic bottles and stored at room temperature for 6 months. At pre-determined time points [0, 14, 30, 60, 90 and 180 days], a study sample of each strength and each commercial source was withdrawn from the storage condition, shaken vigorously and tested for physicochemical and microbiological stability. The physical characterization consisted of observing all samples for appearance/color and testing for pH. The chemical characterization consisted of assay testing employing a stability-indicating High Performance Liquid Chromatography (HPLC) method (Waters Acquity) developed and validated by Eagle Analytical Laboratories (Texas, US). The microbiological stability followed the United States Pharmacopoeia (USP) Chapter <51> Anti-Microbial Effectiveness (AME) testing method.

Results: The tacrolimus oral suspensions exhibited a homogeneous white color and the pH did not change significantly throughout the study. The chromatographic assay method demonstrated to be linear, precise, accurate, robust and suitable, as well as stability-indicating. The percent potency was calculated taking into account the baseline measurements on day 0. The potency of the oral suspensions remained within ±10% of the specifications throughout the study, for the two commercial sources of tacrolimus, namely: Astellas (95.2%-101.0% and 98.4%-105.0% for tacrolimus 0.5 and 1 mg/mL); Sandoz (96.4%-103.0% and 95.1%-101.0% for tacrolimus 0.5 and 1 mg/mL). The preservative system in SuspendIt successfully protected the compounded suspensions from microbial contamination since there was no growth of challenge microorganisms throughout the study for all samples.

Conclusion: Oral compounded suspensions are rapidly prepared, allow dosing flexibility and are easy to administer. However, hospital pharmacists need validated stability studies to prepare oral liquids with quality and safety. A palatable, sugar-free formula was developed for tacrolimus 0.5-1 mg/mL in SuspendIt to facilitate the extemporaneous preparation in the hospital setting. The corresponding BUD was determined using a valid, stability-indicating analytical method and it was concluded that the two versions of tacrolimus 5 mg commercial capsules (Astellas and Sandoz) are physically, chemically and microbiologically stable in SuspendIt at room temperature for up to 180 days.

Novel anti-solvent precipitation and wet milling methods for manufacturing inhaled drug particles

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Background: This research demonstrates the preparation and characterization of inhalable ibuprofen (IBP) with excipients by controlled crystallization and wet milling techniques.

Purpose: The objectives of this study were to manufacture controlled-sized IBF particles with improved solubility and aerosolization to develop a dry powder inhaler formulation for pulmonary delivery.

Method: Anti-solvent precipitation method includes the dissolution of hydrophobic IBP in ethanol from where the IBF is crystallized by the controlled addition of antisolvent water to produce required-sized particles at a specific temperature. The wet milled method was conducted by using high shear homogenization at 17,000 rpm for 15 mins in the presence of 0.05% Tween 80 at room temperature.

Results: The solubility of IBF was 172.4 µg/mL) (anti-solvent method) in the presence of 1.52% leucine, 5.22% mannitol, 0.25% HPMC, 1.55% Pl F127 and 10.75% w/w ethanol. The prepared IBP microparticles (<5 µm)showed higher dissolution compared to that of the original IBP particles. The wet-milled method reduced the particle size from 71.3-1.7 µm in 0.05% Tween 80 solution. The presence of 2.5% magnesium stearate in the selected formulations produced the highest solubility (252.8 µg/mL) of IBF compared to that of unmilled IBF (147.4 µg/mL) without alcohol. The prepared IBF particles containing 2.5-6.25% leucine showed significantly higher dissolution (100%) compared to that of the original drug (55.9%). The solubility and dissolution of the prepared microparticles were substantially enhanced with the addition of 5-6.25% leucine. The fine particle fraction (FPF) of the DPI formulations significantly increased from 3.7 ± 0.9% to 38.5 ± 3.8% in the presence of leucine and magnesium stearate in the milling process.

Conclusion: The controlled crystallization and wet milled methods were useful techniques for preparing inhalable complex IBP microparticles and were suitable for developing inhaled formulations.

Cyclin dependent kinases 4 and 6 inhibitors- Real-world data analysis

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Background: Inhibitors of cyclin-dependent kinases 4 and 6 (iCDK4/6) are a newly approved drug class for the treatment of metastatic or locally advanced breast cancer. Currently, the drugs available on the market are abemaciclib, palbociclib and ribociclib, being indicated in combination with endocrine therapy such as aromatase inhibitors (AI) or fulvestrant. Questions related to the efficacy and safety profile motivate a growing search for evidence in the real world (Real World Evidence - RWE) of the clinical use of these drugs.

Purpose: To compare real-world results obtained with iCDK4/6 with the results of PALOMA 2 and PALOMA 3 clinical trials and to better understand the importance of the real-world studies for complementarity in the decision of Authorization for Introduction in the Market (AIM) and in the clinical activity itself.

Methods: A search was carried out in PuBMed, using the terms: “Abemaciclib” OR “Palbociclib” OR “Ribociclib” OR "CDK 4/6 inhibitors" OR "Cyclin-dependent kinase inhibitors" AND "Real-World" and relevant information was collected on the efficacy profile and safety of these drugs. This search was conducted in august 2022.

Results: The search resulted in 55 articles, of which only 4 were related to real-world studies, all involving palbociclib, containing information on efficacy and safety data that were intended to be analysed. The double-blind randomized controlled trials PALOMA 2 and 3 showed significant efficacy and safety results when combining palbociclib with letrozole or fulvestrant. By the evaluated RWE, when palbociclib is combined with an AI or fulvestrant, efficacy results similar to those obtained in clinical trials were observed. These studies still point to a lower incidence of adverse effects compared to the PALOMA trials, however in both scenarios the adverse effect neutropenia predominates.

Conclusion: The real-world studies are an essential tool in the clinical foundation for the approval of new pharmacotherapeutic regimens, providing real information that can improve their safety and efficacy. There is still a lack of RWE on iCDK4/6, especially with regard to abemaciclib and ribociclib. The RWE studies already carried out allow us to conclude that palbociclib has an efficacy profile similar to that observed in clinical trials, with safety data being even more favorable.

Formulation of plant-based liposomal skin care preparation

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Background
Natural cosmetic products are considered safer alternatives for treating skin disorders and beautification. However, the dermal application of preparations containing phytoconstituents may be limited by their instability, poor solubility, permeability and bioavailability. Encapsulation technology like liposomal delivery system is of great interest these days in topical formulations as a carrier for transdermal delivery of active phytoconstituents.

Purpose
Objective of this study was to formulate skin care preparation using a novel liposomal delivery system, encapsulating active phytoconstituent.

Method
Extracts from Glycyrrhiza glabra, Moringa oleifera and Morus nigra were collected and their phytochemical screening was carried out. Emulgel base was prepared using carbopol, liquid paraffin, acacia, glycerin, stearic acid, sodium hydroxide, tween 90, and sodium benzoate. Emulgel base was optimized with 13 formulations using central composite design keeping liquid paraffin and carbopol as variables.
Liposomes were prepared using thin film hydration method and were characterized using Zetasizer. After optimization, liposomes of Moringa oleifera were prepared.
Optimized emulgel base, liposome suspension and the plant extracts were combined to prepare plant-based anti-aging moisturizing cream.

Results
Antioxidant activity and total phenolic content was found to be maximum in the extract of Morus nigra. IC50 was found to be 104.96 ppm for Morus nigra, 261.46 ppm for Glycyrrhiza glabra and 320.42 ppm for Moringa olieifera. Percentage yield was found to be satisfactory from all the plants selected.
For the desirable texture of emulgel base, concentration ranges of carbopol and liquid paraffin identified were 0.2 - 1.7% and 0 - 10% respectively. For optimal occlusive property, required concentration of these were found to be above 1.6% and 16% respectively; for optimal pH, carbopol concentration range required is 1 - 1.7% and liquid paraffin less than 2%. For the optimal density of formulation, carbopol and liquid paraffin should be below 0.8% and 6% respectively.

Moisturizing anti-aging cream was prepared using the optimized emulgel base with extracts of Glycyrhhiza glabra and Morus nigra in the external phase and extract of Moringa oliefera encapsulated in the liposomes.
Diffusion profiles of Moringa olifera from plain emulgel and liposomal emulgel formulations at time intervals of 30 minutes, 1, 2, 3, 4, 5, 6 hours were found to be 7.02%, 10.12%, 13.40%, 14.29%, 14.59%, 15.86%, 18.46% and 9.45%, 11.58%, 16.90%, 17.36%, 19.22%, 21.35%, 23.82% respectively. This advocate better skin penetration of liposomal delivery system.

Conclusion
Liposomal emulgel improves chemical stability, skin permeability and dermocosmetic efficiency of phytochemicals due to the similarity in architecture to the human skin. Phytoconstituents can be delivered deeper down the epidermis faster and hence maximizes the effectiveness of the formulation.
Nepalese cosmetic industries are still relying on the conventional formulation techniques and transfer of this platform technology can be advantageous.

Estimation of vancomycin area under erug concentration-time curve (AUC): Bayesian software or equations-embedded excel?

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Background:
Vancomycin remains as the mainstay of therapy for invasive or serious infections caused by methicillin-resistant Staphylococcus aureus. The 2020 Infectious Diseases Society of America (IDSA) guideline for vancomycin therapeutic drug monitoring (TDM) shifted towards recommending AUC monitoring with an AUC/MIC ratio of 400 to 600 (assuming minimum inhibitory concentration, MIC of 1 mg/L) as the target to achieve clinical efficacy while minimizing nephrotoxicity. This is a stark difference from the comparatively straightforward vancomycin trough concentration-based monitoring ingrained in current practice. The guideline recommended two approaches for vancomycin AUC calculation, using Bayesian software with one or two vancomycin concentration and first-order pharmacokinetic equations with two vancomycin concentrations obtained within the same dosing interval.

Purpose:
To determine the most practicable approach for AUC calculation as part of the evaluation for uptake of AUC-based vancomycin TDM in our hospital.

Methods:
Five Bayesian software accessible to our institution – TDMx, BestDose, MwPharm++, PrecisePK and ClinCalc, and a self-developed first-order pharmacokinetic equations-embedded Excel were evaluated. Detailed TDM data of 18 adult hospitalized patients given vancomycin for treatment of MRSA bacteremia were used. Each Bayesian software and the pharmacokinetic equations-embedded Excel were compared in terms of AUC value derived, dosing recommendations to achieve AUC of 500 and program characteristics, including cost, user-friendliness, and functionality. Bias (difference between each Bayesian software and Excel for calculated AUCs and dosing recommendations) and percentage bias were calculated.

Results:
Only AUC estimates derived from TDMx and BestDose were significantly different from that of equation-embedded Excel. Variations in AUC were also observed for the different Bayesian programs. Notwithstanding this, the dosing recommendations from both approaches to achieve AUC of 500 were highly similar, with median bias and percentage bias values being 0 ($p>0.05$). Only PrecisePK provided dosing recommendations that were statistically different to Excel, with a median (interquartile range) lower dose difference of 250 mg (-250 to 0). Each Bayesian software posed significant limitations for use in our local context mainly due to restricted internet access. The equations-embedded Excel fared better than Bayesian software in terms of cost, user-friendliness, practicality, and data transparency.

Conclusion:
The equations-embedded Excel is a more practicable method for AUC-based vancomycin TDM in our hospital. However, it requires a mindset and workflow shift as two vancomycin concentrations within the same dosing interval will be required for AUC computation. Further studies focusing on challenges in implementation and ground receptivity should be conducted before implementation.

Interaction and potential mechanisms between atorvastatin and voriconazole, two agents used in fungal infections with dyslipidaemia pharmacotherapy

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Purpose: Atorvastatin (ATO) is combined with voriconazole (VOR) to treat fungal infections in patients with dyslipidaemia in the clinical. However, the pharmacokinetic interaction and potential mechanisms between then is unknown. Therefore, this study aimed to investigate the pharmacokinetic interaction and potential mechanisms between ATO and VOR.

Patients and methods: We collected plasma samples from three patients after using ATO and VOR. Rats were administered VOR for 6 days or Blank and on Day 6, a single dose of 2 mg/kg ATO and then collected the plasma samples in different time point. The incubation model of human liver

microsomes or HepG2 cells were constructed in vitro. A high-performance liquid chromatography-tandem mass spectrometry (HPLC-MS/MS) was developed to determined the concentration of ATO, 2-hydroxy, 4-hydroxy-ATO and VOR.

Results: In patients, VOR significantly reduced the metabolism of ATO and slowed down the formation of 2-hydroxy and 4-hydroxy-ATO. After being pretreated with oral administration of VOR for 6 days or Blank and on Day 6, a single dose of 2 mg/kg ATO was administered orally, the t1/2 of ATO is significantly prolonged from 3.61 to 6.43 h, the AUC0-24h values of ATO were increased from 53.86 to 176.84 h μg/L. However, the pharmacokinetics parameters of VOR (20 mg/kg) with or without pretreatment of ATO (2 mg/kg) were in only a slight change in the pharmacokinetic parameters. In vitro studies indicated that VOR inhibited the metabolism of ATO and testosterone, and the IC50 values were 45.94 and 49.81 μM. However, no significant change in transporter behaviors of ATO was observed when VOR or transporter inhibitors were co-administered.

Conclusion: Our study demonstrated that VOR have significant interaction with ATO, which is probably because of the inhibition of the CYP3A4-mediated metabolism of ATO by VOR. Based on the clinically cases and potential interactions, the basic data obtained in our study are expected to help adjust the dose of ATO and promote the design of rational dosage regimens for pharmacotherapy in fungal infections with dyslipidaemia.

Presence of heavy metals in natural waters in the area of the Central Bosnia Canton in Bosnia and Herzegovina

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The analysis of the presence of heavy metals in natural waters in the area of the Central Bosnia Canton in Bosnia and Hercegovina was carried out with the aim of assessing the quality of water and comparing the values obtained with national regulations and guidelines of the World Health Organization (WHO). Samples were collected at five selected locations, in the municipalities of Busovaca, Vitez, Kiseljak, Turbe, Travnik.

After sampling, the solution for calibration curve was prepared. Imaging on an atomic absorption
spectrophotometer. They were also re-concentrated. The heavy metals that have been the subject
of this experimental determination are cadmium, lead, cobalt and zinc. Their content was
determined by atomic absorption spectophotometry (AAS).

The results showed that the natural waters from the tested sites, in the vast majority of cases, do not contain heavy metal testing above the MRLs (maximum residue limit) required by the
ordinances and guidelines. Excedance of the maximum permitted concentration was only
recorded in the presence of lead in the municipalities of Kiseljak, Turbe and Travnik.

The conclusion of the determination is that the tested heavy metals in this area are present in
permissible quantities and that, except for minor variations in the amount of lead, the other three
metals are not present above the prescribed concentrations.

Simple, IT (information technology) based solutions for increasing productivity in a small scale pharmaceutical manufacturing industry

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RFTU-03 - Rapid Fire Session Tuesday, M1-M2, September 26, 2023, 2:30 PM - 4:00 PM

Background
Pharmaceutical industry comprises of majority small scale manufacturing units. These industries strive to achieve compliances with global standards which are common for all industries large or small. Th standards remain same but challenges differ for small and large scale industries. Small scale manufacturing industries face challenges which mainly includes limited Human Resources and limited investment capacities. These challenges can even obstruct their daily work schedules. Implementing automation through customised softwares is beyond their investment capacity. Simple IT based solutions freely available can assists in calendar preparations and reminders.

Purpose
The purpose of this study is to make use of IT solutions without financial strain to achieve higher productivity. The study aims at increasing productivity of quality control department of a small scale pharmaceutical industry.

Method
The roles and responsibilities of quality control department were reviewed. The quality management system of the department was also reviewed. Large areas of deviation were identified. Calender plans for their departmental training, stability testing and calibration was prepared. This was then recorded into software system using IT solutions. The timely reminders received were used to make the daily work plans. The backlog of work of quality control department was compared after a month.

Results
It was noted that quality control department could complete only daily testing on time. They found it difficult to manage stability samples testing, periodic calibration and on job training within specified time. Many deviations were filed due to lack of time management. Calendar system were used to prepare the schedule of training, stability sample

testing and calibrations. Daily reminder system were also set. This resulted in better work management. Daily working planning was easier which lead to completion of required work apart form daily testing on time. The number of deviations filed after the implementation of this reminder system were reduced by 60 % in a month.

Conclusion
The challenges of small scale industries can be overcomed by use of simple non expensive IT solutions. Many such IT solutions can be explored for other departments. It can also be explored as a solution for other productivity requirements.

The presence of pharmacists in the strategic leadership of manufacturing pharmaceutical companies with operations in South Africa

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RFTU-03 - Rapid Fire Session Tuesday, M1-M2, September 26, 2023, 2:30 PM - 4:00 PM

Introduction: The World Health Organisation (WHO) appreciates the role of pharmacists in the life cycle of medicines, as they assume the role of custodianship for pharmaceuticals. The role of pharmacists in the manufacturing sector of the pharmaceutical industry has been identified at technical levels as pharmacists are often leading production operations, batch release functions and quality assurance. There has been limited exploration of the presence of pharmacists in the leading of the strategy of manufacturing pharmaceutical companies (MPCs).

Method: The objective of the study was to determine the presence of pharmacists, as the profession that is the custodian of medicines, in the strategic leadership of pharmaceutical companies that have operations in South Africa, although headquartered globally. A 4-phased, observational study, inclusive of semi-structured interviews, assessment of the professions in strategic leadership and development of a leadership competency assessment tool for pharmacists working in the manufacturing sector was employed. An analysis of the MPCs, including the professional background of the board members and executive leaders of the MPCs that are publicly listed was done.

Results: The companies had operations in an average of 86,6 countries (SD ± 46,2). The professions represented in positions of strategic leadership of the MPCs included commerce at 22,7% (232; n=1023), sciences at 15.6% (160; n=1023), engineering at 15,1% (154; n=1023). A pharmacy qualification was found in 3,2% (33; n=1023). This was the professional background with the lowest representation. Linear regression was applied and found the relationship between the number of MPCs in a country and number of pharmacists in the strategic leadership of the MPCs in that country to be statistically significant ($P \leq 0.05$).

Conclusion: Pharmaceutical companies provide medicines to meet the healthcare needs of the world's population, thereby providing a healthcare service. The Board members and executive leaders are responsible for directing the strategic objectives of responsible sites or manufacturing sites, as defined by the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The results are indicative of a limited presence of pharmacists in positions of leadership. Pharmacists were likely to assume positions of strategic leadership if they were male, in possession of additional qualifications and located in selected countries such as India and South Africa. Often, pharmacists are the authorised persons responsible for manufacturing sites. It has been found that such pharmacists possessed limited power and were excluded from decision–making processes that had dire consequences for the company and users of the company's products. The strategic objectives of these pharmacies are determined by other professionals with the subsequent absence of pharmacists who are the actual custodians of medicines.

Perceptions of board members on the presence of pharmacists as strategic leaders of manufacturing pharmaceutical companies operating in South Africa: A qualitative study

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RFTU-03 - Rapid Fire Session Tuesday, M1-M2, September 26, 2023, 2:30 PM - 4:00 PM

Introduction: Life-saving medicines are produced by manufacturing pharmaceutical companies (MPCs) with operations around the world. The COVID-19 pandemic resulted in unequal access to vaccines, which led to advocacy around health rights and MPCs needing to prioritise saving lives over profits. The aim of this study was to determine the perceptions of board members of the largest listed MPCs in South Africa, regarding the presence of pharmacists in the strategic leadership of MPCs, as custodians of medicines.

Methods: A snowball sampling method was used to identify board members of the listed MPCs on the Johannesburg Stock Exchange (JSE). The board members were approached and requested to participate, in their personal capacity. Data were collected through semi-structured interviews. Transcription, coding and narrative thematic analysis was applied, under six (6) themes with emerging themes identified. A theoretical framework was developed to describe pharmacists at the strategic leadership of an MPC.

Results: The data collected were from five (5) respondents (80% male and 20% female), with a mean age of 57 years (SD±=2,24), from medical, business and pharmacy professional backgrounds. The respondents indicated that there was a limited presence of pharmacists in the strategic leadership of MPCs, especially the larger ones. The reasons for the limited presence were inclusive of the limited diversity of corporate and leadership skills that are necessary to lead at a strategic level by pharmacists. Some of the barriers of entry into strategic leadership by pharmacists included the lack of recognition of pharmacy specialisations by the regulator of the pharmacy profession, a mismatch of skills of a graduate and what the industry needs and inadequate governance of the pharmacy profession in South Africa. The respondents agreed that having a pharmacist with ambition, business skills and experience would be beneficial for the MPC and users of products manufactured thereof.

Conclusion: The role and need for pharmacists in the strategic leadership of MPCs was established. It is clear, however, that while pharmacists have a value in the leadership of MPCs, their entry should be supported by diversifying their skills in business, leadership and corporate management in order to extend their value beyond the technical level.