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CONFERENCE ABSTRACTS

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Regulatory Sciences

Regulatory aspects of radiopharmacy

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Background: Radiopharmaceuticals have been around for several decades. Their increasing applications have revolutionised diagnostic and therapeutic fields but they require, due to their nature, specific regulatory and safety requirements.

Purpose: To review international, EU and national regulations regarding regulatory aspects of radiopharmaceuticals and to understand educational needs about awareness and protection of patients and healthcare professionals.

Methods: IAEA, EudraLex and the national legislation were used to identify and classify regulations mentioning radio-pharmaceuticals. General chapters in the European pharma-copoeia (EP) and US pharmacopeia (USP) were analysed and compared and three specific monographs found in both were chosen at random and compared.

Results: Twenty-five (25) regulations were found in total; five international, 14 from the European Union and six nationals. The majority of regulations focused on safety for healthcare professionals, patients or general safety. The USP has more detailed procedure descriptions whereas the EP is more general and allows for more flexibility. Within the specific monographs, differences can be attributed to information being provided in general chapters rather than in the specific monographs. Four regulations were found regarding education with a main focus on training, qualification and radiation protection.

Conclusion: Radiopharmaceuticals are a promising technology for innovative diagnostics and treatment for multiple sectors of the healthcare industry and is a promising technology where safety is a prominent feature. It is an evolving sector, where education of the healthcare professional and the patient is crucial.

Mercury - the element of challenge

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Background: With the arrival of new instrumental technologies to pharmaceutical laboratories, such as ICP-MS equipment and Microwave Digestion Systems, for the application of new requirements in the control of elemental impurities in pharmaceuticals, new technical challenges have also arrived.

Arsenic, Cadmium, Mercury and Lead are extremely toxic metallic elements and rank amongst the priority metals that are of public health significance.

Purpose: Among these elements, Mercury (Hg) is particularly challenging in analytical terms, especially in multi-element analysis. With this work we aim to develop a more robust and reliable methodology to quantify this relevant element.

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Methods: Hg is a highly volatile element in nature, easily adsorbed on polymeric materials, not stable in water or nitric solutions and frequently forms complexes that volatilise. The maximum temperature set-point, in the sample digestion method has been reduced and the addition of intermediate steps on the heating ramp making the process less abrupt. Gold (Au) and Hydrochloric acid (HCl) were added to pre-digestion samples, standards and rinse solution.

Results: We managed to avoid the loss of analyte in the digestion process, increasing the recovery percentages up to 60% compared to the previous results. Au acts as a competitor of the adsorption effect on polymers, reducing the number of rinses required. The stability of solutions was also improved with the addition of HCl ensuring the formation of a stable Hg complex [HgCl4]2-.

Conclusion: After the implementation of this technical modifications, the authors were able to perform a more robust and accurate Hg analysis, measure at lower concentration limits and obtain results with more statistical confidence.

Study of the occurrence of aflatoxin M1 in raw cows' milk samples in the Bekaa Valley, Lebanon

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Background: Milk is considered a major component of a healthy human's daily diet which is known to have a wide range of nutritional and health benefits. However, in addition of being a key source of macro- and micronutrients, milk might contain natural food contaminants such as aflatoxin M1 (AFM1) which is known for posing serious health concerns.

Purpose: This study aimed to assess the occurrence of AFM1 in raw cow's milk in the Bekaa Valley using competitive enzyme-linked immunosorbent assay (ELISA) technique and compare the findings with permissible limits of international standards.

Methods: A total of 40 samples of raw cow's milk were collected between March and May 2018 from 40 different farms located all across the Bekaa Valley (West Bekaa, Zahle, and Baalback Districts) and were analysed for their AFM1 content using ELISA technique.

Results: AFM1 was found at a detectable level in 35 (87.5%) of the Bekaa Valley's samples: in 11 (78.6%) of West Bekaa District's samples, in 14 (100%) of Zahle District's samples, and in ten (83.3%) of Baalback District's samples. AFM1 mean concentration was 17.667±1.735 ng/L in the Bekaa Valley's samples: 21.028±3.808 ng/L, 16.299±2.660 ng/L, and 15.884±2.399 ng/L in West Bekaa, Zahle, and Baalback Districts' samples respectively. None (0%) of the positive samples had a concentration above the Lebanese Ministry of Agriculture, European Union (EU) countries, and United States AFM1 regulatory limit.

Conclusion: Despite the low incidence of AFM1 in the Bekaa Valley's raw cow's milk compared to other regions worldwide, AFM1 should be evaluated on a regular basis throughout the year across Lebanon given the hazardous nature that AFM1 imposes on human safety.

Knowledge, perceptions, and practices of pharmacists towards generic drugs in China: A cross-sectional study

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Background: Generic substitution has been performed in China with the national centralised procurement pilot programme launched in 2019 in 11 pilot cities.

Purpose: This study aimed to evaluate the pharmacists' knowledge, perceptions and practices towards generic drugs in the 11 pilot cities.

Methods: An online questionnaire was undertaken. A convenience sampling technique was implemented. Mann-Whitney-U or Kruskal-Wallis tests were used to compare the differences. Spearman's rho rank correlation was applied to see the associations between variables. P-values of <0.05 were considered significant.

Results: Two thousand, two hundred and ninety-one (2,291) pharmacists participated in the study. Most of the respondents had a good knowledge of the consistency evaluation of quality and efficacy (92.4%), and the definition of generic drugs (90.7%). However, only 9.8% of the respondents gave a correct judgement on the acceptance criteria of bioequivalence. A significant high correlation between the perception of efficacy and safety of generic versus brand name drugs and their supportive attitude to generic substitution was demonstrated. 45.7% of the respondents stated a dramatic increase in the amount of generic drugs used. Efficacy, safety of generic drugs, national policies and hospital regulations were three main factors affecting application of generic drugs.

Conclusion: There were gaps identified in the knowledge and perceptions among respondents. Reliability and quality of generic drugs were still top concerns for pharmacists. The feedbacks suggested a demand for interventions to develop

public awareness on generic drugs. Pharmacotherapy monitoring and patient education of generic drugs provided by pharmacists could be considered to ensure safety or quality of medication.

Discriminant analysis of tablets using an ultra-compact Raman spectrometer

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Background: Falsified medicines have been becoming more common worldwide. An accurate and simple method to identify falsified medicines is required for field use.

Purpose: The authors performed non-destructive analysis of tablets using an ultra-compact Raman spectrometer. In addition, we established a technique for discriminating falsified medicines by performing multivariate analysis on the Raman spectra.

Methods: The subjects were three medicines for erectile dysfunction and one antifungal medicine: tadalafil (Cialis) 20-mg tablets, vardenafil (Levitra) 20-mg tablets, sildenafil (Viagra) 100-mg tablets and fluconazole (Diflucan) 100-mg tablets sometimes advertised as female Viagra. For each medicine, the standard product and products obtained by personal import via the Internet (genuine or falsified) were used. Discriminant analysis was performed on the Raman spectra with soft independent modelling of class analogy (SIMCA) and partial least squares discriminant analysis (PLS-DA).

Results: It was possible to identify all falsified products by SIMCA using the standard product model. With PLS-DA, the authors could not create a good model because of many outlier products. It could, however, show that standards and genuine products were different from falsified products. SIMCA might be more suitable than PLS-DA for discriminating falsified medicines.

Conclusion: Non-destructive analysis using an ultra-compact Raman spectrometer could be accurate and useful to distinguish falsified medicines with multivariate analysis.

Factors influencing reporting of medical device related incidents in the Maltese healthcare system

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Background: The use of medical devices (MD) is associated with adverse incidents. Reporting of MD-related incidents by healthcare professionals (HCPs) is essential for successful post-market surveillance systems.

Purpose: The research objectives were used to investigate the incident reports (IRs) received within the National Healthcare System (NHS) and to explore factors influencing the reporting of incidents by HCPs.

Methods: Incident Reports submitted at the NHS by HCPs in 2019 were collated in a database and analysed. A focus group consisting of HCPs and regulatory experts was set up to identify barriers to HCP IR and to provide recommendations for the development of an improved IR system.

Results: A total of 107 MD related incidents were submitted in 2019, with injury to patient reported in 18 cases. Barriers to MD IR identified during focus group session include attitudes of HCPs, blame culture, legal liability, deficiencies in the MD procurement process, lack of training and education, recognition of MD incidents, and deficiencies in the current reporting method. Areas identified for improvement in the reporting form were (i) incident details, (ii) details of reporter, (iii) administrative information and (iv) checklist of procurement documentation.

Conclusion: The results indicated that there is under-reporting of MD incidents in the NHS. Changes to the current system are warranted to improve the reporting rates. Strengthening a safety culture based on lessons learnt and educational needs of HCPs, in the context of MD IR is proposed to improve patient and user safety.

Comparison of medical devices effectiveness, safety and quality regulation in Europe and Africa

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Background: Medical device regulation worldwide is diverse. Regulation is evolving as a result of the necessity to enhance patient safety. In Europe, the medical device directives were reviewed leading to the development of the Medical Device Regulation (EU 2017/745). Scandals such as those involving the silicone breast implants and metal to metal hip implants drove the need to institute changes in regulation.

Purpose: To evaluate the regulations and guidelines for medical devices in Europe and five selected countries in Africa, namely, Uganda, Kenya, Tanzania, Rwanda and Ghana with the goal of identifying gaps and proposing areas of improvement.

Methods: Questionnaires were administered to 20 regulatory officers and a key informant guide used to interview key informants from the different regulatory agencies in the countries stated. Questionnaires were self-administered and the key informant interviews conducted via telephone, Skype or face-to-face. Data analysis of audio interviews, transcripts and notes based on qualitative thematic content was conducted and reviewed for consistency for qualitative data. Questionnaires were used to carry out quantitative data triangulation on the interviews.

Results: Regulation of medical devices in Africa is limited. The results of the study demonstrated different maturity levels with regards to existence of medical device regulations, guidelines and actual practice in the countries that participated.

Of the seven countries that participated, three namely Kenya, Rwanda and Uganda lacked regulations.

Conclusion: The absence of a regulatory framework for medical device regulation in Rwanda, Kenya and Uganda implies that the scope of regulation is ill defined

Falsified medicines directive: Challenges faced by small member states

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Background: Falsified medicines might not satisfy requirements for safety, efficacy and quality. The Falsified Medicines Directive (FMD) Directive 2011/64/EU was introduced to European member states in 2013 to address the problem of falsified medicines and came into force in 2019.

Purpose: The study aims to assess perspectives of the different National Medicines Verification Organizations (NMVO) and National Competent Authorities (NCA) as they supervise national implementation progress of the FMD and to identify problems with daily operations of FMD in local community pharmacies and wholesalers.

Methods: Three validated questionnaires were prepared to assess the implementation perspectives of NMVOs and NCAs of European member states, local community pharmacies and medicines wholesalers.

Results: Questionnaire one is intended for NMVOs and NCAs of the member states and is divided into three parts: part one assessed the NMVO and NCA connection with repository systems, parts two and three evaluated the access to the repository systems and alert auditing. Questionnaires two and three were also divided into three parts: part one assessed the pharmacists' and wholesalers' preparedness for FMD implementation, part 2 assessed the set-up of pharmacies and wholesalers for FMD scanning and part 3 is related to FMD processes.

Conclusion: Questionnaires assessing perspectives regarding current FMD implementation can benefit NMVOs and NCAs to identify potential problems met by member states and provide viable suggestions to improve the execution of the FMD.

Low-quality medicine discrimination of metformin tablets by Raman scattering analysis

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Background: Low-quality medicines are becoming a problem in developing countries. In Southeast Asian, it has been confirmed that low-quality diabetic medicines (metformin) are in circulation.

Purpose: The purpose of this study was to test the applicability of Raman scattering analysis in the detection of low-quality medicine.

Methods: Low-quality products (n=3) and high-quality products (n=30) of metformin were collected via the internet. The model tablets containing metformin hydrochloride content of 8% to 100% with lactose and containing three types of metformin hydrochloride contents with different additive were made. Raman scattering analysis was performed using handy Raman.

Results: The spectra obtained by Raman and the result of PCA of spectra revealed that there was no significant difference between low-quality products and high-quality products of metformin bought over the Internet. As a result of the Raman analysis using model tablets, a change in the spectra according to the metformin content was observed. The results of PCA of spectra revealed that they were divided into three groups, and the tablets containing metformin content were 8%~46%, 47%, 48%~100%. In the result of the additive test, the spectra were confirmed that the peaks from metformin, but the shape of the overall spectra varied according to the composition of the additives. The result of PCA of spectra, one group was the tablets with high content of metformin. And when the tablets with medium and low content of metformin were classified besides these areas.

Conclusion: By Raman scattering analysis, it was possible to distinguish low-quality medicine.

When technology precedes regulation: A scoping study of the challenges and opportunities of e-pharmacy in LMICs

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Background: Medicine sales over the internet is a new, yet growing phenomenon in low- and middle-income countries (LMICs). E-pharmacy in high-income countries has raised public health concerns, including sales of prescription-only medicines without a prescription, the sale of counterfeit and substandard medicines, and inadequate provision of information to patients. E-pharmacy also presents opportunities for enhancing health systems, improving both patient experience and public health outcomes.

Purpose: The regulatory environment in which firms operate is likely to have a major effect on its impact; yet little is known about this emerging sector. This work aims to address this gap.

Methods: Drawing on a set of in-depth interviews, we review the scale of the e-pharmacy business, the regulatory frameworks that are developing in response to it, and the regulatory challenges and opportunities e-pharmacy poses in three LMICs: Kenya, Nigeria and India.

Results: Regulation has not kept pace with this innovation and in some contexts e-pharmacy markets have evolved in a regulatory vacuum. Informants raised concerns over the danger of online medicine sales in the absence of regulation; the lack of regulatory capacity; and of both under- and over-regulation. They also identified the opportunities associated with consolidation in the sector and the prospect of traceability and the transparency that online records of medicine sales may bring.

Conclusion: E-pharmacy could potentially prove to be a catalyst for re-thinking regulatory approaches in this sector.