ملخصات مشاركات المؤتمرات

#	عنوان البحث (Title)	ملخص البحث (abstact)	اسم الباحث المشارك (Presnting Author)	الحدث العلمي (Scientific Event)	السنة Year
1	Potential Risk of Dry Mouth: Local Case Report Triggers Review of Levofloxacin Safety	Background: Dry mouth also refers medically to Xerostomia is the patient's subjective feeling of dry mouth while hyposalivation is the objective measure. Xerostomia occurs when secretion is reduced to a bout half the normal quantity, but may also be a result of changes in the composition of the saliva. In such cases, the saliva may become viscous, stringy and / or frothy. [1][2] Levofloxacin is abroad-spectrum, third-generation fluoroquinolone antibiotic used to treat bacterial infections. In 1996, levofloxacin received the first approval by U.S.FDA. [3]Recently, the signal detection team in Saudi Arabia received a local case-report of dry mouth reported with the use of levofloxacin, which triggers this investigation. Aim: To evaluate the risk of dry mouth associated with the use of levofloxacin and to suggest regulatory recommendations if required. Methods: Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between dry mouth and levofloxacin use. Results: While only one case report found in Saudi vigilance database, we found 857 global cases resulted in WHO database at march 2023 (figure1-2). Authors applied WHO-UMC causality assessment criteria on cases with completeness score1.0 (n=30). [4]Among them, 29 cases of Dry mouth were either probably or possibly linked to levofloxacin. Moreover, the authors also looked or more supportive evidence from literature. A search for eligible publication using terms “levofloxacin” and “Dry mouth” was done at that point of time. As a result, evidence from literature found supportive for this signal, the risk of dry mouth was reported in a published randomized double-blind controlled trial.[5] Conclusion: Based on this comprehensive review, the cumulative evidence identified from assessed cases and literature are sufficient to suggest causal association between levofloxacin and dry mouth. Health care professionals and health regulators must be aware of the potential risk in drug recipients and we suggest monitoring signs and symptoms in treated patients.	محمد فودة (Mohammed Fouda)	22nd ISoP Annual Meeting	2023
2	Traceability of Infliximab Reference Medicinal Product and Its Biosimilar Products Adverse Drug Events Reports in Saudi Arabia	"OBJECTIVES: Infliximab reference product and two biosimilar products were approved by the Saudi Food & DrugAuthority (SFDA) for the treatment of a wide variety of inflammatory conditions such as rheumatoidarthritis, Crohn's disease, and ankylosing spondylitis. Recording both the product trade name and thebatch number are essential in the spontaneous reporting of adverse drug events (ADEs) of biologicalmedicines due to the variability of the bio-manufacturing process that may cause safety risks such asimmunogenicity. This study aims to assess the availability of batch number and trade name in the ADEreports of Infliximab (reference product) and biosimilar products in the National PharmacovigilanceCenter (NPC) database at SFDA. METHODS: We performed a descriptive analysis of spontaneous ADE reports of Infliximab (reference and biosimilarproducts) in Saudi Arabia reported to the NPC from December 1, 2017, to January 03, 2023. The analysisexamined the reporting frequency of batch number, and trade name. RESULTS: Overall, a total of 731 cases were retrieved from the NPC database. We found reported trade names in626 (85.6%) cases [150 (23.9%) for the reference product and 476 (76%) reports for biosimilar products].However, the batch number identifier was only included in 39 (5.3%) out of 731 cases [7 (17.95%) inreference product and 32 (85.05%) in biosimilar products). 479 (89%) of case reports were received fromhealthcare professionals (pharmacists), whereas 146 (19.9%) cases have been reported from marketingauthorization holder. CONCLUSIONS: Our study showed a lack of reporting batch number with Infliximab reference and biosimilar products inthe NPC database. It is essential to raise awareness of the importance to report trade name and batchnumber of reference and biosimilar products among healthcare providers and the public to improve thedata quality of biologic and biosimilar products’ ADE reports."	(Fares Alrubaish) فارس الربيش	ISPOR 2023	2023

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#	عنوان البحث (Title)	ملخص البحث (abstact)	اسم الباحث المشارك (Presnting Author)	الحدث العلمي (Scientific Event)	السنة Year
3	Active Surveillance for Safety monitoring of COVID-19 vaccines in Saudi Arabia	"Objective: It is generally accepted that the world will not return to the pre-pandemic normally situation until safe and effective vaccines become available. However, the rare and unknown adverse events following immunization (AEFIs) are not usually detected in the clinical trials. Thus, monitoring the safety of coronavirus disease of 2019 (COVID-19) vaccines in real-world population is essential. Therefore, the Saudi Food and Drug Authority (SFDA) performed a post-marketing safety surveillance of AEFIs following administration of COVID-19 vaccines. Methods: A prospective cohort study conducted and followed subjects who received COVID-19 vaccines from the first day of vaccination for seven days after the first and second doses, then biweekly for three months. All information from the vaccinee (demographic information, vaccine type and AEFIs) were collected by phone through a standardized online questionnaire. Baseline characteristics and AEFIs were analyzed descriptively by SPSS software. AEFIs were classified according to medical Dictionary for Regulatory Activities (MedDRA). Results: 544 subjects of 8867 agreed to be part of the study. Among them, 218 subjects completed the study. Out of 218, 87 (39.91%) individual received Pfizer-BioNTech vaccine, 45(20.64%) received Oxford/AstraZeneca vaccine, 5(2.3%) individual received Moderna vaccine, and 81 (37.2%) received two different COVID-19 vaccines. The reported events were categorized to system organ class (SOC) according to MedDRA. The most reported SOCs were skin and subcutaneous tissue disorders (n=66 with Pfizer-BioNTech vaccine, n=34 with Oxford/AstraZeneca vaccine, n=5 with Moderna vaccine), infections and infestations (n=23 with Pfizer-BioNTech vaccine, n=33 with Oxford/AstraZeneca vaccine, n=4 with Moderna vaccine), musculoskeletal and connective tissue disorders (n=53with Pfizer-BioNTech vaccine, n=46 with Oxford/AstraZeneca vaccine, n=7 with Moderna vaccine). Only 10 (4.6%) cases were serious and required medical intervention. Conclusion: The preliminary results shows the short-term safety profiles of included COVID-19 vaccines are acceptable in Saudi Arabia. "	(Fawaz Alharbi) فواز الحربي	22nd ISoP Annual Meeting	2023
4	Proactive Drug Safety Monitoring of Adverse Drug Events in Saudi Arabia: 2022 Experience	"OBJECTIVES: Saudi Food and Drug Authority (SFDA) established the Proactive Drug Safety Monitoring Program tomonitor the safety of registered medicinal products in Saudi Arabia more proactively and efficiently. TheProactive Drug Safety Monitoring Program evaluated the relatedness of adverse drug event (ADE) casereports exported from VigiBase, the World Health Organization global database of individual case safetyreports, with a group of medications approved by SFDA. METHODS: At the beginning, a list of medications was selected for all registered products by SFDA in 2021. Then, theADE case reports of the selected medicines were retrieved from VigiBase. After that, a crosschecking ofthe U.S. Food and Drug Administration, European Medicines Agency and local label information waspreformed to exclude the labeled ADEs using the list of retrieved ADEs lists for each medicine. Finally, acomprehensive drug safety review for the unlabeled ADEs was performed using different evidencesources including unpublished clinical trials, literature, local and global spontaneous reports and PeriodicBenefit-Risk Evaluation Reports. RESULTS: A total of 44 medicines were selected with 4762 reported ADE case reports retrieved from VigiBase. Thelabelness assessment resulted in requesting of label update for 30 medicines (68.18%). A total of 22comprehensive drug safety reviews were performed for 40 potential safety signals. The safety reviewrecommendations were requesting additional safety data from pharmaceutical companies (n=5 signals),keeping routine monitoring of the risk (n=21 signals) and closing the signal (n=14 signals). CONCLUSIONS: The Proactive Drug Safety Monitoring Program in SFDA successfully improved the identification of newsafety information for medicinal products."	(Solaiman Alhawas) سليمان الحواس	ISPOR 2023	2023

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5	Food Safety Practices during Hajj: On-Site Inspections of Food-Serving Establishments	The presence of crowds during Hajj increases the risk of foodborne infection. Yet, research on the practices of food handlers during Hajj is limited. This study aimed to assess compliance with food safety practices and its associated factors during Hajj 2022. An observational cross-sectional study was conducted in Mecca and Madinah before and during Hajj 2022 and involved 195 food-serving establishments (FSEs) contracted for Hajj catering. Collected data included visit time, establishment location, licensure, whether food handlers had food safety training (professional training), and whether FSEs were under supervision from a consulting office (professional supervision). The included FSEs were 168/195 (86.2%). Two-thirds of FSEs surveyed (113, 67.3%) were under professional supervision, and 91 (54.2%) hired trained food safety workers. Compliance rates varied between outcomes (72.67 ± 17.21% to 88.3 ± 18.8%). Compared to Mecca, Madinah FSEs were more adherent to cleanliness (80.5 ± 27.9% vs. 91.5 ± 19.9%, respectively, p = 0.006). FSEs with trained workers were more likely to comply with proper food safety practices compared to those with untrained workers: cleanliness (OR: 7.2, 95% CI [2.6–20.23], p < 0.001); workers' commitment to health requirements (OR: 2.8, 95% CI [1.1–6.9], p = 0.025); handling of refrigerated and frozen food (OR: 5.27, 95% CI [1.83–15.20], p = 0.004); and food storage practices (OR: 12.5, 95% CI [2.0–12.5], p < 0.001). The role of professional training in increasing food safety practices compliance was highlighted. FSEs in Madinah were more compliant with food safety practices than those in Mecca. Therefore, Mecca FSEs may need stringent safety measures.	ريوف النفيسة Ruyuf Alnafisah	المؤتمر الخامس الدولي لطب الحشود The Fifth International Conference on Mass Gathering Medicine (ICMGM)	2023
6	Impact of Additional Risk Minimization Measures in Reducing the Risk of Teratogenicity in Sodium Valproate: A Cross-sectional Study Among Healthcare Providers in Saudi Arabia	"Background: Sodium valproate is an antiepileptic medication. Teratogenicity is one of the most serious risks in children of women exposed to valproate during pregnancy. The Saudi Food and Drug Authority (SFDA) have approved additional risk minimization measure, which is a ""pregnancy prevention program (PPP)"" to minimize this risk and raise the awareness among healthcare professionals. This program includes tools such as patient card, patient guide, health care provider guide, and an acknowledgement form. Aim: To evaluate the effectiveness of the Additional Risk Minimization Measures (aRMMs) in improving the knowledge and the practices of targeted HCPs about the indications and safe use of sodium valproate. Method: A cross-sectional, multi-center, survey-based study targeted healthcare professionals (HCPs)who had previously listed to receive aRMMs of sodium valproate in Saudi Arabia. The web-based Survey was distributed by email between March and December of 2021. Descriptive statistics were performed to represent demographic characteristics and knowledge level and practices using Excel 2016 program. Results: Only 42 of 813 HCPs responded to the e-survey, and 26% (11) of them acknowledged receiving the educational materials of sodium valproate. Furthermore, 98% (41) of HCPs were aware of the potential risk of ""teratogenicity,"" and 86% (36) of HCPs provided adequate patient counseling before using sodium valproate regarding potential risk of teratogenicity. Additionally, 60% (25) of HCPs requested a pregnancy test for a female of childbearing potential prior to prescribing sodium valproate and 64% (27) of HCPs confirmed that their female patients in childbearing age used effective contraception methods. Conclusion: The impact of aRMMs of valproate was not optimal. However, the results should be interpreted carefully due to the low sample size. Further epidemiological studies are needed to assess the effectiveness of aRMM implementation of sodium valproate in Saudi Arabia.	(Aljawharah Albabtain)الجوهرة أبابطين	ISoP 2023 Annual Meeting	2023

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7	Management and Reporting of Adverse Reaction by Marketing Authorization Holders: Challenges and Opportunities Observations of Pharmacovigilance Inspection	"Title: Management and Reporting of Adverse Reaction by Marketing Authorization Holders: Challenges and Opportunities Observations of Pharmacovigilance Inspection Author(s): A. Arafah, A. AlOtaibi Affiliation(s): Pharmacovigilance system inspection department, Saudi Food & Drug Authority, Riyadh, Saudi Arabia. Text: Background: Adverse Events reporting had special attention from the executive president of the Saudi Food & Drug Authority (SFDA) since early 2018. Accordingly, reporting adverse events became one of the remarkable indicators for well-established and supported systems in Saudi Arabia. Since 2018 to date, the inspection program of SFDA have identified that management and reporting of adverse events activities as the most violated Guideline on Good Pharmacovigilance Practices (GVP) module at inspected marketing authorization holders (MAHs). Aim: To identify the gaps by assessing the performance pattern of the inspected MAHs in managing and reporting adverse reaction activities, and suggest the opportunity for change. Methodology: A retrospective observational study documenting various inspectional findings of eighty inspection visits from December 2018 to December 2022. All inspected MAHs were included to measure the performance & compliance of MAHs toward the management and reporting of adverse events activities through the number of findings of that section. Statistical analysis used in the study included descriptive analysis, including frequency/percentages for categorical variables analyzed using Microsoft Excel software. Results: The total number of inspection findings detected in management and reporting of adverse reactions was 226 out of 1066 (21%); among them 29% (n=65) of the total result was seen in data collection methods, 23% (n=52) in assessments of seriousness, causality, and expectedness, 20% (n=46) in literature screening, and 15% (n=35) in submissions and follow up processes. The major findings were the dominant finding among all the results, representing 65% of the total findings. The findings were divided by 49% (n=111) for global MAHs, 35% (n=79) for regional MAHs, and 16% (n=36) for local MAHs. The global and regional MAHs were similar in the topics ranking to the total findings; however, the regional added the quality control process as a one of the significant findings (10%, n=8). On the other side, the local MAHs were different which recorded literature screening as reported (25%, n=9), followed by data collection methods and submissions and follow-up processes at the percentage (19%, n=7), medical review (17%, n=6), and assessments of seriousness, causality, and expectedness (11%, n=4) Conclusions: The study has identified variations in the pharmacovigilance performance, developing distinguished patterns between these classifications. The inspection team considers the significant variation to address these topics in the annual educational sessions that the national pharmacovigilance center department plans to deliver the targeted recommendation for each MAH category. References/ Further sources of information (maximum 6 References): 1. Saudi Food and Drug Authority, 2015. Guideline on Good Pharmacovigilance Practices (GVP). Riyadh: Saudi Food and Drug Authority: National Pharmacovigilance Center. 2. National pharmacovigilance center, 2021. Pharmacovigilance Inspections Report December 2018– December 2020. Riyadh. 3. National pharmacovigilance center, 2022. Pharmacovigilance Inspections Report 1st Jan 2021 to 31st Dec 2021. Riyadh. 4. National pharmacovigilance center, 2023. Pharmacovigilance Inspections Report 1st Jan 2022 to 31st Dec 2022. Riyadh.	(Amal Arafah) امـــل عرفـــه	22nd ISoP Annual Meeting	2023

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السنة Year	الحدث العلمي (Scientific Event)	اسم الباحث المشارك (Presnting Author)	ملخص البحث (abstact)	عنوان البحث (Title)	#
2023	ISoP 2023 Annual Meeting	(Fadi Alanazi) فادي العنزي	Background: The purpose of Additional Risk Minimization Measures (aRMMs) is to prevent or lessen the likelihood or severity of adverse reactions that may result from exposure to a medicine. As of 2022, the Saudi Food and Drug Authority has approved 265 aRMMs in English and Arabic languages. The continuous evaluation of RMMs is a crucial part of products' risk management systems, and assessing healthcare professionals' perception of their understandability is recommended for the overall improvement of risk communication means. Objective: The aim of this study was to obtain healthcare professionals' opinions on aRMMs of three sampled products in terms of design, content, and layout, and to identify opportunities for improvement. The study also aimed to assess the understandability and actionability of the aRMMs. Methodology: A cross-sectional, multi-center survey-based study was conducted among healthcare professionals who had previously received aRMMs of three sampled products (nilotinib, valproate, and baricitinib) which were selected according to pre-defined criteria. The self-administered online survey consisted of 25 questions designed to explore gaps in the current approved aRMMs' design, content, and layout. The survey was published online in English and distributed via mailing lists and to Pharmacovigilance Regional-Center offices in multiple medical centers across Saudi Arabia. Results: A total of 40 healthcare professionals responded to the survey. Of these, 76% were physicians and 24% were pharmacists. All participants agreed that the educational material's purpose was completely evident, and the material clearly identified the action that the healthcare professional or patient should take. A majority of the healthcare professionals (87%) agreed that the material uses common, everyday language, that the medical terms were defined properly, and that the information was presented in a logical sequence. Conclusion: Involving Healthcare professionals in the continuous assessment of aRMMs can provide valuable insight. According to the survey results regarding educational materials, healthcare professionals have an overall positive perception towards the content of the educational materials that are part of the aRMMs. It is evident that development opportunities exist for simplifying the language used and incorporating more everyday language. This approach will enhance the accessibility and comprehension of educational materials, making them more effective. Further studies are required to incorporate more HCPs in Saudi Arabia to assess their utilization of aRMM tools.	Exploring Healthcare Providers' Perspectives on Risk Minimization Measures' Content	8

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9	Citalopram and Fluconazole Drug Interaction and Potential Risk of Serotonin Toxicity	Background Fluconazole, a triazole antifungal agent, is a potent inhibitor of cytochrome P450 (CYP) isoenzyme 2C9 and a moderate inhibitor of CYP3A4. It is also an inhibitor of the isozyme CYP2C19. Fluconazole has been associated with QT interval prolongation, hence the co-administration of drugs known to prolong the QT and metabolized via CYP3A4 are contraindicated. Citalopram is indicated for the treatment of depression, and it is mainly metabolized by CYP3A4 and CYP 2C19 which are substrates influenced by fluconazole administration. Citalopram as well known to cause QT prolongation Objectives This review aims to assess the potential risk of QT prolongation due to the drug-drug interaction between fluconazole and citalopram, as part of drug interactions' assessment project initiated by the Saudi Food and Drug Authority (SFDA). Methods The safety review utilized several sources. First, conduct causality assessment of the global cases of interacting drugs retrieved from the World Health Organization (WHO) database (VigiBase) and local adverse drug reactions database at the SFDA from inception to May 2023. Second, a systematic literature search was conducted in Cochrane, Embase and PubMed. In addition, the Google Scholar and Drug Interactions Checker Databases such as (Micromedex®, Lexicopm®, medicine's complete®) were also searched. The search included published studies from inception to May 2023, for eligible English publications with the appropriate keywords. Third, an overall assessment of the drug interaction using the Drug Interaction Probability Scale (DIPS) to assess drug interaction relation to adverse event was performed. Results The literature search yielded one case series, which discussed two cases of life threatening serotonin toxicity due to a drug interaction between citalopram and fluconazole. Using the DIPS scale, the assessment of the interaction is probable in both cases. In addition, 51 cases were identified in WHO global database that reported fluconazole interaction with citalopram. Out of that, 17 cases reported Serotonin Syndrome while five cases reported QT prolongation as drug-drug interaction outcome. The time to onset and dechallenge / rechallenge information were not provided to assess the causality. Out of the 5 QT prolongation cases, three cases were confounded by other medications known to cause QT prolongation (azithromycin, erythromycin). No local cases were found. Conclusion The available evidence shows a probable pharmacokinetics/ pharmacodynamics interaction between fluconazole and citalopram. The cumulative effect of decreased citalopram metabolism and pharmacodynamics interaction with fluconazole could lead to serotonergic effect and /or QT prolongation. Further assessment by epidemiological studies is needed.	(Maha Alghamdi) مها الغامدي	ISoP 2023 Annual Meeting	2023

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السنة Year	الحدث العلمي (Scientific Event)	اسم الباحث المشارك (Presnting Author)	ملخص البحث (abstact)	عنوان البحث (Title)	#
2023	ISPOR 2023	(Manal Alruhami) منال الرحيمي	"OBJECTIVES: This project aims to identify signals of congenital anomaly (CA) related to potentially teratogenicmedications use and evaluate these signals based on the available evidence. METHODS: Individual case safety reports (ICSRs) of CA were retrieved from the World Health Organization (WHO)global database of individual case safety reports (VigiBase) using specific keywords, in February 2022.Then, the following exclusion criteria were applied; ICSRs with chromosomal anomaly, skeletal dysplasia,or genetic syndrome were excluded since aetiology is assumed not to be teratogenic; ICSRs with onlyexposed to (folic acid, minerals and/or vitamins); ICSRs with only exposed to topical medications, or non-locally registered drugs. Following, included drug-CA events ICSRs were crosschecked in the local product'sinformation comparing to U.S. Food and Drug Administration and European Medicines label information,then, identified signals underwent in-depth assessment by conducting a comprehensive safety evaluationusing several different evidence sources including literature, global cases retrieved from VigiBase and localcases retrieved from the national pharmacovigilance database of the national pharmacovigilance center atSaudi Food and Drug authority (SFDA) and Periodic Benefit-Risk Evaluation Reports. RESULTS: A total of 181 drug-CA pairs were subjected to initial assessment. Of these, 151 drug-CA events werelabeled in the Saudi product's leaflet; 18 drug-CA events were labeled in other stringent regulatoryauthorities; and 12 drug-CA events were referred to in-depth assessment. The assessment results wereone-drug-CA event was probably related, 11 were possibly related, and one was excluded due to off-labeluse in pregnancy. CONCLUSIONS: Post marketing data from VigiBase has successfully improved signal detection of CA related to potentiallyteratogenic medications use. Further epidemiological studies are needed to quantify the CA risks to helphealth care professionals to make risk versus benefit decision for using medicines in pregnancy."	Identification and Evaluation of Congenital Anomaly Safety Signals: SFDA Experience	10

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11	Assessment the effectiveness of implementing Registry as Risk Minimization Measures of Ivabradine in Saudi Arabia	"Background: Ivabradine is a heart rate lowering agent approved in Saudi Arabia in 2007 for treatment of angina pectoris and chronic heart failure. In 2015, SFDA withdrew the marketing authorization of Ivabradine due to serious cardiac adverse events. After that, in 2017, ivabradine was re-registered under SFDA-approved restrictions, in which Ivabradine was restricted to the indication of chronic heart failure with implemented additional risk minimization measures (aRMMs) (registry, prescriber and patient guides. A registry was requested in order to follow up patients who taking Ivabradine as part of the risk minimization activities and to support that ivabradine is only used in patient who are eligible for receiving the treatment and in which the benefits of ivabradine therapy outweighs its risks. Objective: To assess the compliance of ivibradine prescribers to instructions in approved aRMMs in Saudi Arabia. Methods: A retrospective cohort study was conducted using data from drug registry. Patients was included if they initiated ivabradine treatment between November 2018 until end of July 2022. Patient information were obtained from registry forms that received from marked authorization holder (MAH) or health institutions in Saudi Arabia. We assessed prescriber adherence to the following instructions: left ventricular ejection fraction ≤ 35% at time of therapy initiation, Heart rete (HR) greater than or equal to 70 bpm at time of initiation, the initiation dose does not exceed 5 mg twice a day, the maintenance dose does not exceed 7.5 mg twice a day, and no concomitant use of verapamil or diltiazem at treatment initiation or during 6-month follow-up. Results: 652 patients enrolled in our registry. Mean age was 55.1 years old. 68% of patients aged <75 years old and 6% of patients aged ≥75 years old. None of patients exceeded 7.5-mg bid as maintenance dose Ivabradine was not used concurrently with verapamil or diltiazem in any patients except two patients (0.3%), (one on diltiazem and the other one on verapamil). Conclusion: The study shows that aRMMs for ivabradine are implemented successfully in Saudi Arabia.	(Nada Alageel)ندى العقيل	ISoP 2023 Annual Meeting	2023

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12	Safety Monitoring of Orphan Drugs Project: SFDA Experience	OBJECTIVES: Orphan drugs are developed to treat rare diseases. Some regulatory bodies established orphan drugdesignation with incentives to help pharmaceutical companies to develop orphan drugs. However, there isa lack of pre-marketing safety data for orphan drugs because limited number of patients involved, due tothe rarity of the diseases. Considering that post-marketing long-term safety of orphan drugs still uncertainand the low utilization profile which make it challenging to monitor the safety of orphan drugs.The SaudiFood and Drug Authority (SFDA) initiated a project to monitor the safety of orphan drugs registered. METHODS: First, a list of SFDA registered orphan drugs from 2016 to 2022 were selected. Second, published reportedadverse events retrieved from AdisInsight database. Third, labelness assessment was performed on theretrieved adverse drug event (ADEs) lists by crosschecking the label of U.S. Food and Drug Administration,European Medicines Agency label and local label information to exclude labeled ADEs. Fourth, acomprehensive drug safety review for the unlabeled ADEs was conducted using different evidence sourcesincluding unpublished clinical trials, literature, local and global spontaneous reports and Periodic Benefit-Risk Evaluation Reports. RESULTS: From 2016 to 2022, 35 orphan medications registered by SFDA, with a total of 1403 reported events onAdisInsight. The crosschecking resulted in requesting of local label update for 13 orphan drugs. Projectyielded a total of 18 comprehensive drug safety reviews were performed for 22 potential safety signals.The safety review recommendations were requesting additional safety data from pharmaceuticalcompanies (n=6 signals), routine monitoring of the risk (n=11 signals) and closing the signal (n=5 signals). CONCLUSIONS: Safety Monitoring of Orphan Drugs Project in SFDA successfully improved the identification andassessment of new potential signals with medications use. It is important raise the ADEs reportingawareness associated with medicines especially orphan drugs.	(Nouf Al-Fadel) نوف الفاضل	ISPOR 2023	2023

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13	Post-marketing Safety Assessment of Tisagenlecleucel: Analysis of Individual Case Safety Reports in VigiBase	Background: Tisagenlecleucel is the first Chimeric Antigen Receptor (CAR)-T cell therapy approved by Saudi Food & Drug Authority (SFDA) for B-cell lymphomas and leukemia treatment. Objective: To describe the individual case safety reports (ICSRs) associated with tisagenlecleucel use reported to the World Health Organization (WHO) Global Database of ICSRs (VigiBase) and identifying potential safety signals. Methods: A descriptive analysis of ICSRs associated with tisagenlecleucel use. A search has been conducted in VigiBase in December 2022 to retrieve all reported cases with use of tisagenlecleucel from inception to 31 December, 2022 via signal detection tool “Vigilyze”. Then, labelness assessment was performed on retrieved ICSRs lists by crosschecking the label of United States Food and Drug Administration, European Medicines Agency and SFDA to exclude labeled ADEs. Results: A total of 2,660 ADEs associated with use of tisagenlecleucel were reported in VigiBase. The United States was the most reported country (63.7%). The ADEs occurred more frequently in males (60.4%) and the mean age was 38 years. Majority of ICSRs were serious (91.2%) and 22.3% of ICSRs reported fatal outcome. Approximately 93% of ICSRs were reported between 2019 to 2022. After removal of vague and duplicate events, 938 ADEs were identified. We excluded 915 ADEs had missing information, labeled in product information, or confounded by indication. The remaining 23 signals were referred for ICSRs causality assessment utilizing the WHO- Uppsala Monitoring Centre (UMC) causality assessment system. The majority of the signals were refuted due to un-assessable cases with limited information provided. We identified a single probable case of intracranial hypertension and bradycardia, 6 possible cases of shock and unlikely association with bradycardia (n=3), shock (n=2), myocarditis, pericardia effusion cerebellar syndrome, mydriasis and lymphadenopathy (n=1, each). Conclusion: Based on the analysis performed, the retrieved data from ADE reports reveals no new or unexpected safety information. However, it highlights considerable variability in the quality and completeness of ADE reports. Incomplete data is a known limitation of drug safety surveillance based on ADE reporting after marketing authorization and our evaluation indicates this is also true for CAR-T-cell products.	(Nouf Al-Fadel) نوف الفاضل	ISoP 2023 Annual Meeting	2023

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14	New safety measures to minimize exposure risk of oral Hazardous medications: SFDA experience	"Introduction Medications are classified as hazardous when they exhibit one or more of the six toxicity criteria in humans, animal models, or in vitro systems including: carcinogenicity, developmental toxicity (including teratogenicity), reproductive toxicity, genotoxicity, organ toxicity at low doses, and chemical structure or toxicity profile that mimic existing drugs determined to be hazardous. These medications include chemotherapy, antiviral drugs, hormonal replacement medications, and immunosuppressive agents.1 Objectives To assess the safety measures related to safe handling and disposal of hazardous oral medications in the current local product information of hazardous oral medications Methodology First, we identified a list of oral hazardous medications that are registered in Saudi Arabia and listed as hazardous drugs in Healthcare Settings in the National Institute for Occupational Safety and Health (NIOSH). Then, we assessed the current safety measures (instructions and precautions) that available in product leaflets of all targeted registered hazardous medications. After that, the safety measures were classified as complete or incomplete based on whether (or not) the provided information was sufficient regarding safe handling and disposal of hazardous oral medication. We requested labeling update from pharmaceutical companies for oral hazardous medications that classified their content of safety measures as incomplete. Result A total of 84 out of 139 NIOSH oral hazardous medications were registered in Saudi Arabia. Carcinogenic medications account for 26.2% (n=22) of oral hazardous medications. After our assessment of safety measures, we have requested an update for 77 (90.6%) out of 84 oral hazardous products from pharmaceutical companies to add new safety measures in related sections to safe handling and disposal of hazardous medications to minimize the risk of exposure to healthcare personnel, patients and the environment. These new safety measures was adopted from the United States Pharmacopeia (USP) General Chapter <800> for safe handling of hazardous drugs in healthcare settings and American Society of Health-System Pharmacists (ASHP) guidelines on handling hazardous drugs. Conclusion Important safety measures for safe handling and disposal of hazardous medications was lacking in the local product information of oral hazardous medications. Further efforts are required to improve awareness among healthcare professionals and patients regarding safe handling and disposal of hazardous medications. "	(Nouf Al-Fadel) نوف الفاضل	ISoP 2023 Annual Meeting	2023

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15	Detection and Assessment of Herbal-Drug Interaction Project: SFDA Experience	"OBJECTIVES: There is a general perception of safety and efficacy of herbal medicine compared to conventionalmedicine. However, limited studies addressed herbal-drug interaction (HDI) in the literature. The SaudiFood and Drug Authority (SFDA) established the HDI Project to detect safety signals related to HDI andassess these signals based on available scientific evidence. METHODS: First, a list of SFDA registered herbal products (N=30) were selected and prioritized based on commonlyused herbs in Saudi Arabia. Second, reported HDIs were retrieved from the World Health Organization(WHO) global database of individual case safety reports (VigiBase), AdisInsight® and Natural Medicinesdatabase. We excluded the interactions of non-registered drugs in Saudi Arabia and labeled interactions indrug and herbal product information, using SFDA, the U.S. Food and Drug Administration and Europeanmedicines agency product information. Finally, comprehensive safety evaluation of potential interactionsignals were conducted using several evidence sources including literature, results of causalityassessment of global cases retrieved from VigiBase and local cases retrieved from the nationalpharmacovigilance database and other relevant documents. The Drug Interaction Probability Scale (DIPS)was used to assess the probability of a causal relationship between the potential HDI and the events. RESULTS: The project yielded 566 potential HDI signals, and 41 interactions had published evidence and referred forextensive evaluation. The assessment results based on DIPS and available evidence were; 24 possiblyrelated (85.5%), 5 probably related (12.1%) and 12 doubtful (29.2%) interactions. The recommendation wasto include the probable HDI in the local product information of herbal products and medications includeTurmeric-Tacrolimus, Etoposide-Echinacea, Ginkgo Biloba-Ibuprofen, Green Tea-warfarin and Licorice-thiazides interactions. CONCLUSIONS: The HDI project in SFDA successfully improved screening and identification of potential drug-herbalinteractions. The action plan of this project can be used in post-marketing activities worldwide to identifypotential drug interactions."	(Waad Alghamdi) وعد الغامدي	ISoP Advances in Pharmacovigilance for Herbal Medicines Conference	2023
16	Prevalence, Serovars, and Antimicrobial Susceptibility of Salmonella Isolated from Eggs in Local Markets in Riyadh, Saudi Arabia	Salmonella is a globally prevalent foodborne pathogen that causes salmonellosis. Contaminated eggs are a significant source of various Salmonella serovars that can cause outbreaks and the spread of antimicrobial resistance. Information regarding Salmonella in eggs is limited in Saudi Arabia. Hence, this study aims to evaluate the occurrence of salmonella in both the shell and contents of eggs obtained from local markets in Riyadh, Saudi Arabia. Additionally, the study investigates the susceptibility of these Salmonella strains to various antibiotics. Over the course of 1 year (April 2021-April 2022), 260 egg samples were collected from different local markets. Salmonella was detected and isolated according to ISO 6579-1:2017. Positive Salmonella samples were identified and tested their susceptibility to 32 antibiotics from 12 classes. The prevalence of Salmonella in eggs in Saudi Arabia was (20/260, 8%). Among the samples, the prevalence of Salmonella in eggshells was (12/260. 5%), while that in the liquid was (8/260, 3%). The predominant serovar was S. Enteritidis, accounting for (21%, 4/20) of positive samples, followed by S. Heidelberg, S. Bareilly, and S. Typhimurium at (15%, 3/20). S. Minnesota, and S. Blijdorp, were identified in (10%, 2/20) of the positive samples, and S. Infantis was isolated in (4%, 1/23) of the positive samples. The antibiotics sensitivity results show that 7 isolates exhibited resistance to 3 or more of the 32 antibiotics. One of the most resistant isolates was S. Infantis, which is resistant to 13 antibiotics. All isolates were intermediate to colistin except for S. Blijdorp. This study provides new information on the prevalence and antimicrobial resistance of Salmonella in eggs available in the local markets in Riyadh, Saudi Arabia. Investigation of Salmonella in eggs can help fill knowledge gaps and facilitate enhanced surveillance of the emergence and prevalence of diverse Salmonella serovars. Ultimately, this has led to the advancement of salmonellosis control caused by eggs and improved management of antimicrobial resistance.	أماني السفياني(Amani alsufyani)	The Federation of Infection Societies conference (FIS)	2023

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17	The Impact of Generic Drug Marketing on Drug Prices in Saudi Arabia	Purpose: The increased drug spending has been driven mainly by brand-name drugs. Introducing generic drugs, bioequivalent replicates of brand-name drugs, into the market has been associated with a reduction in the prices of brand-name drugs. Specifically, this study aims to assess the extent of the reduction in the baseline prices of brand-name drugs associated with the introduction of generic drugs. Additionally, the study will compare the average prices of generic drugs to those of brand-name drugs to determine the extent of the price difference between the two. Methods: In this retrospective study, the Saudi Food and Drug Authority (SFDA) pricing database was used to collect pricing information for brand-name and generic drugs in Saudi Arabia. The study included all drugs based on the Anatomical Therapeutic Chemical (ATC) classification system for cardiovascular disease, diabetes, antibiotics, antidepressants, antipsychotics, and antacids, with the exception of brand-name drugs that did not have a generic equivalent and vice versa. An analytical approach was used to analyze the collected data, in which product prices and registration data were tracked retrospectively based on decisions made by the MOH and the SFDA Registration Committee, with up to four cycles of pricing events analyzed. Results: The average percentage difference between generic and brand-name drugs across all therapeutic classes, according to the study, was 32%. The average percentage difference, however, varied across therapeutic classes, with antidiabetics, antidepressants, and antacids having lower differences of 21%, 18%, and 26%, respectively, whereas antibiotics, antipsychotics, and cardiovascular drugs had higher differences of 40%, 40%, and 28%, respectively. The study also discovered that drug production in the Gulf, the Middle East, and Europe has a lower price compared to that produced in Saudi Arabia. Furthermore, the current drug price was more sensitive to immediate price changes than previous price changes. Conclusions: The study's findings have significant implications for pricing policies aimed at promoting value-based healthcare and facilitating competition in the prescription drug market. Policymakers can use this information to inform legislation and enforcement efforts that align with market share by demonstrating the potential cost savings associated with the approval of lower-cost generic medicines. Furthermore, the study's findings emphasize the importance of promoting the availability of equally effective generic drugs in order to lower prices and improve consumer affordability. Overall, these findings can help inform efforts to ensure that pricing policies are aligned with market dynamics and promote value-based healthcare.	رسيل الربع Raseel A. Alroba	الاتحاد الأوروبي لعلوم الصيدلة european federation of pharmaceutical sciences (EUFEPS)	2023
18	Effect of glycerin concentration on levels of toxicants emissions from water-pipe tobacco smoking (WTS)	Background: Glycerin, flavorings and sweeteners collectively constitute up to 70% of water-pipe tobacco smoking (WTS) mixtures. The combustion of such ingredients produces smoke particulates that are known toxins and carcinogens including nicotine, nitrosamines and carbonyl compounds. The type and quantity of toxic emissions generated in the vapor exhaled are highly dependable on the formulation of the smoked mixture. Glycerin combustion produces known toxic and carcinogenic emissions including acetaldehyde, benzaldehyde, acrolein, and acetone. Recent evidence indicate that increasing glycerol concentrations lead to significant increase in toxicant emissions. However, the literature is lacking evidence regarding glycerin addition effects in WTS mixtures. According to WHO, there are no currently approved international upper limits regulations on WTS mixture ingredients. This study aims to assess toxicant emission levels in response to increasing glycerin concentration in WTS mixtures. Methods: This is a laboratory experimental study. The experiment measures levels of toxic compounds in emission (smoke) resulting from WTS using tobacco mixture samples with varying glycerin concentrations and fixed other main ingredients. Tobacco samples were prepared by two leading brands in the market and an equivalent generic lab-made (prepared with same tobacco mixture main ingredients). Results: Of all toxicant emissions observed, acrolein emission was associated with glycerin addition in WTS mixture indicated by lab-made samples throughout all glycerin concentrations (10%, 20%, 40% and 60%), and brand samples with glycerin concentrations 10% to 20%. In contrast to lab-made samples, brand samples showed no increase in acrolein emissions corresponding to the increase in glycerin concentrations from 20% to 60%. Conclusion: According to two water-pipe tobacco brand products, increased glycerin concentration from 20% to 60% does not yield increasing levels of acrolein emission, while lab-made tobacco sample shows significant correlation between glycerin addition and increased acrolein emission. Regulatory recommendations for water-pipe smoking products require further investigations regarding potential confounders in acrolein emissions and health effects of glycerin concentrations with corresponding toxicant emissions.	سلوى المؤمن Salwa Almomen	المؤتمر الأوروبي التاسع حول التبغ والصحة 9th European Conference on Tobacco or Health (ECToH)	2023

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19	Critical Vs Major finding; According to the classification of MAH in Saudi Arabia	Introduction: Pharmacovigilance system inspections are designed to review the procedures, systems, personnel, and facilities in place and determine their compliance with regulatory pharmacovigilance obligations. The objective is monitor activities and protect public health by ensuring the continued safety of medicines that authorized in Saudi Arabia. Aim/Objective: To count and review the inspection findings that documented through inspections visits for local, regional and global MAHs, then to find what are the main characteristics and differences of those findings. Methods: Using the Pharmacovigilance inspection database to review the inspection findings that conducted between December 2018 to December 2022 for all inspection visits of local, regional and global MAHs that registered in Saudi Arabia. Results: This study analyzed 80 pharmacovigilance inspections of Marketing Authorization Holders (MAHs) in Saudi Arabia, revealing 135 critical and 704 major findings. The most findings were identified in global MAHs (55 critical, 305 major), followed by regional (61 critical, 277 major), and local MAHs (19 critical, 122 major). For global and regional MAHs, the top critical findings were in data collection methods and system oversight, while major findings were most common in assessments of seriousness, causality, and expectedness, and dataset used for signal detection. Local MAHs showed the most critical findings in data collection methods and system oversight, whereas major findings were concentrated in areas such as backup and disaster recovery processes, periodicity of data review, and the audit and corrective and preventive actions process. Conclusion: In conclusion, this study illustrates that pharmacovigilance inspections revealed a higher number of critical findings in global MAHs and major findings in various areas across different types of MAHs in Saudi Arabia. The prevalent issues across all MAHs included data collection methods and system oversight, indicating areas that require significant improvement to ensure drug safety and compliance with pharmacovigilance regulations	عبداللطيف العتيبي (Abdullatif alotaibi)	22nd ISoP Annual Meeting	2023
20	An Assessment of Validated Algorithms for Identifying Multiple Sclerosis Cases, Subtypes, and Relapses in Real-World Databases: A Systematic Review	Though real-world data (RWD) are increasingly used to study multiple sclerosis (MS), MS diagnostic codes vary across RWD datasets. In addition, no specific diagnosis codes exist for either MS subtypes or MS relapses. Using validated algorithms to identify and characterize specific diseases or conditions is thus a priority for reducing systematic RWD bias.This study aimed to (1) identify all original validation studies used algorithms to identify MS (e.g., cases, subtypes, and relapses) in RWD, (2) assess evidence for algorithm validity, and (3) identify knowledge gaps for future research.A systematic review was completed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Four key bibliographic databases were searched, and gray literature was included. The reporting of studies conducted using observational methods and routinely collected health data was used to assess the quality of the included studies. Data synthesis was qualitative (i.e., narrative).Of 5,056 identified articles, 48 underwent detailed review, and 21 met inclusion criteria. Most included studies (43%) aimed to identify MS cases; others focused on MS subtypes (28%), relapses (15%), diagnosis and severity (9%), or disability status (5%). Only eight (38%) reported all four algorithm validity metrics: sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Specificity was most frequently used (76 %), followed by sensitivity (71%), PPV (67 %), and NPV (52 %). Manual validation was the gold standard (76.1%) for sixteen studies, all of which found at least one algorithm with high sensitivity (77–99%), while specificity ranged from 88 to 99.9%, PPV from 38 to 95%, and NPV from 70 to 100%. All the studies aimed at identifying MS cases reported sensitivity (44%–100%) and specificity (87–100%), but only five reported PPV and NPV (38–99% and 17–100%, respectively). All three studies that identified MS relapses used administrative health databases with manual validation as the gold standard, finding sensitivity to range from 70 to 100%, specificity from 87 to 100%, PPV from 64 to 100%, and NPV from 53 to 100%. The best preformed algorithm for MS relapse identification included diagnoses, medications, hospitalization duration, or outpatient visits (sensitivity 70%, specificity 100%, PPV 100%, and NPV 96%).This study supports the current recommendation by combining the advantages of using different disproportionality statistics methods in SRS analysis. In the case of a low number of reports, the IC and the EBGM provide more accurate results.	عمر البلوي Omar Albalawi	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2023

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21	Preliminary Risk Assessment of 3-monochloropropane diol and Glycidyl Fatty Acid Esters from Infant Formula & Baby Food Products in the Saudi market	3-Monochloropropanediol fatty acid esters (3-MCPDE) and glycidyl esters (GE) are well-identified processing-induced chemical toxicants detected in infant formula and baby foods worldwide. We analysed the levels of 3-MCPDE and GE in infant formula and baby food products available in Saudi Arabia, followed by a dietary risk assessment for exposure to these contaminants in infants and young children from birth to 3 years. Eighty-five commercial infant formulas (n = 35) and baby foods (n = 50) available for consumption by infants and babies purchased from the Saudi market during 2022 were analysed for these contaminants using gas chromatography-tandem mass spectrometry. 3-MCPDE and GE were detected in 100 and 80% of the samples, with a mean concentration of 57 µg/kg (range: 2–285 µg/kg) and 30 µg/kg (range: not detected–217 µg/kg), respectively. The highest concentration was found in milk-based formula for infants 0–6 months (285 µg/kg) and the lowest was found in fruit purees (2 µg/kg). Preliminary exposure and risk assessment showed increased exposure to 3-MCPDE for infants exclusively fed infant formula with exposure declining with age due to the introduction of solid foods. GE exposure levels reached 0.8 µg/kg body weight per day, which declined over time with margin of exposure values below 25,000. These results indicate that the levels of 3-MCPDE and GE in infant formula may pose potential risks to infants exclusively fed formula; therefore, adopting EU regulations should reduce the presence of these processing contaminants in essential infant foods.	لمى الميمان (Lama Almaiman)	The 4th International Conference on Food Bioactives & Health (FBHC2023)	2023
22	Food and beverage placement in child-focused YouTube channels in Saudi Arabia: a content analysis study	Background High exposure to food content encourages unhealthy dietary practices among children. Nowadays, children are exposed to many food products through social media, which influences their eating behaviors. Due to the growing social media use, the number of food advertisements via YouTube has increased. Therefore, regulatory agencies worldwide are investigating social media content to implement appropriate restrictions on unhealthy food marketing. However, in Saudi Arabia, no existing studies investigated food placement and marketing on children's social media channels. Methods This quantitative content analysis study aims to analyze the food content in the child-centric channels of Arabic speakers' vloggers on YouTube in Saudi Arabia. The researchers developed a codebook to measure the food presentation and promotional techniques associated with food and/or beverage placements and determine the type of food product placement. The variables in this study were measured by quantifying the appearance of each variable in each video. Results Four of the top subscribed channels in Saudi Arabia were selected; 96 videos were analyzed by watching 17 hours. Food placements appeared in 65 videos (67.7%), and the duration of the food placement was cumulatively 304 minutes. Among videos that featured food and beverages, 87.7% of the vloggers consumed the food that appeared. The most commonly employed persuasive marketing techniques were emotional and taste appeals, with a percentage of 90%. Unhealthy foods comprised 66.8% of the total number of products that appeared in the analyzed videos. Conclusion The prevalence of food content in the analyzed videos is high, which increases the chances of its influence on children in Saudi Arabia. The study also found that the placed foods were associated with fun and taste appeals. Besides, most of the foods that appeared in the videos were low-nutrient food products, which may be threatening to the global efforts to combat obesity.	لولو المطيري Lulu Al mutairi	المؤتمر الأوروبي للصحة العامة EUROPEAN PUBLIC HEALTH CONFERENCE (EPH Conference)	2023

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السنة Year	الحدث العلمي (Scientific Event)	اسم الباحث المشارك (Presnting Author)	ملخص البحث (abstact)	عنوان البحث (Title)	#
2023	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	ملاك المطيري Malak Almutairi	Background: This study aims to explore the characteristics of drug recall announcements issued over six years by the SFDA in Saudi Arabia. Additionally, to examine the patterns of voluntary drug recall requests by pharmaceutical companies (both innovator and generic) in response to product defects. Methods: A retrospective data analysis was conducted on drug recall announcements issued by the SFDA between 2017 and December 2022. The study included recalls of registered and unregistered drugs posted on the SFDA Drugs Circulars and Withdrawal webpage. Descriptive analysis was performed on relevant variables: recall year, therapeutic class, recall type, pharmaceutical company type, recall reasons and voluntary or involuntary product defect reports. Results: During the study period, a total of 371 products were recalled, with the majority being involuntary recalls (82.4%). About two-thirds of the recalls (66.0%) were related to registered products. The most common reasons for recalls were non compliance with the manufacturer's specifcations (33.2%), contamination (23.7%), and violations (20.5%). A total of 109 pharmaceutical companies were associated with the recalled products, with (85.3%) being generic pharmaceutical compa nies. The majority of innovator pharmaceutical companies (68.8%) requested voluntary drug recalls of defective products. Innovator pharmaceutical companies requested voluntary recalls more often than generic pharmaceutical companies. Conclusion: The study fndings highlight the most frequent causes of drug recalls and the patterns of voluntary recall requests by pharmaceutical companies. Non-compliance with manufacturer's specifcations was the most common reason for recalls. Signifcantly, more innovative pharmaceutical companies request voluntary recalls for product defects compared to generic pharmaceutical companies.	Content Analysis of Drug Recall Announcements in Saudi Arabia: Between 2016 and 2022	23
2023	The 4th International Conference on Food Bioactives & Health (FBHC2023)	نجلاء الحربي (Najla Alharbi)	Early childhood exposure to heavy metals like arsenic (As), cadmium (Cd), and lead (Pb) through baby foods unfolds many concerns about their toxic effects on growth and health. In this study, occurrence and dietary intake of As, Cd, and Pb in stage 1 infant formula (0–6 months), stage 2 infant formula (7–12 months), cereal-based meals, and biscuits were estimated. First, the levels of As, Cd, and Pb were determined with ICP-MS, followed by the calculation of estimated daily intake (EDI), target hazard quotient (THQ), and hazard index (HI) for As and Cd, and margin of exposure (MoE) for Pb. Mean levels of As, Cd, and Pb were the highest in cereal-based meals and biscuits as 15.5–11.1, 5.18–8.76, and 35.2–53.8 µg/kg, respectively. Newborns to 6 months old infants were estimated to be the highest exposed population to Cd and Pb (0.08 and 0.36 µg/kg bw/day), while infants aged 7–12 months old were exposed the highest to As. Based on the THQ, HI, and MoE findings, the current exposure levels from the selected baby foods to As, Cd, and Pb pose low potential chronic risks to both infant age groups. This research provides a roadmap for future investigations in chemical contaminants often detected in baby foods consumed regularly by Saudi infants.	Occurrence and dietary exposure assessment of heavy metals in baby foods in the Kingdom of Saudi Arabia	24