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CONFERENCE ABSTRACTS

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Regulatory sciences and quality

Non-Essential Fluoride Exposure in Consumer Products: Cumulative Risk, Regulatory Blindspots, and the Need for Global Reassessment

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Background: Fluoride is widely used in pharmaceutical products for dental caries prevention ,yet its safety for human consumption remains under debate, particularly in the context of cumulative exposure from multiple daily sources especially essential consumer products -milk, salt,beverages etc.Despite its biological activity and potential toxicity at elevated doses, regulatory approvals remain largely product-specific and based on single-source assumptions. The World Health Organization (WHO) and European Food Safety Authority (EFSA) acknowledge that fluoride is not nutritionally essential and in 2025, EFSA reassessed safe intake levels; however, population-level exposure persists without comprehensive consideration of aggregate risk, while existing safety thresholds remain largely derived from single-source exposure models.

The aim of the study is to evaluate whether current regulatory frameworks adequately address cumulative, multi-source, and long-term fluoride exposure, and to examine the potential role of a pharmacovigilance-style system in strengthening detecting associated toxicity.

Method: A structured narrative review (2000–2025) synthesized mechanistic, toxicological, and epidemiological evidence on chronic fluoride exposure. Regulatory frameworks and aggregate exposure models from international authorities were compared and outcome was evaluated in relation to vulnerable groups.This methodology was used due to the need to integrate heterogeneous scientific and regulatory evidence while addressing a policy-focused research question .Concepts from pharmacovigilance and exposome research were explored for long-term safety monitoring.

Results: Although regulatory science is evolving toward aggregate exposure assessment, models remain largely pathway-specific most focusing particularly drinking water—while comprehensive cumulative exposure assessment across consumer products remains limited. Realistic scenarios indicate that combined intake from multisources e.g tea, fluoridated salt, milk ,water and dental products may approach or exceed safety thresholds despite individual product compliance to health-based guidance values and labelling protocol if fluoride was added to the product . Mechanistic evidence demonstrates oxidative stress, mitochondrial dysfunction, and tissue-level effects at chronic exposure. Surveillance remains fragmented, lacking integrated biomonitoring and long-term outcome tracking.

Conclusion: Non-essential fluoride is regulated through fragmented, product-centric systems that may underestimate cumulative exposure and lack long-term vigilance. Given widespread exposure, available substitutes, and proximity of adverse effects to current limits, global reassessment becomes imminent . Integrating fluoride into an exposome-informed, pharmacovigilance-style framework could improve early detection of chronic toxicity and support more protective, person-centered regulation

Towards One Internationally Harmonized Hazardous Drug List: Bridging Science, Practice and Global Regulatory Frameworks

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Background: Occupational exposure to hazardous drugs continues to pose significant risk to healthcare workers, yet HD classification frameworks differ substantially across global regulatory bodies. The resulting fragmented landscape is neither nimble nor real time, and often lacks inclusion of chemical hazards, biologic agents, and investigational medicinal products. Since the onus is placed on individual entities to develop their own HD list, discrepancies emerge in work practices, personal protective equipment Which expectations, and interpretation of manufacturer information and safety data sheets, which are not harmonized internationally. These challenges are further compounded in settings handling investigational products where manufacturers rarely disclose toxicity data. As new therapies rapidly emerge across our global healthcare environment, the need for a harmonized and scientifically grounded global hazardous medication list has become evident.

Objectives: This presentation aims to (1) compare major HD classification systems currently in use, including those with national regulatory lists and those relying on regional frameworks; (2) highlight methodological differences in how HDs are defined, categorized, and updated; (3) examine gaps related to chemical hazards, biologic agents, and investigational medicinal products; and (4) identify opportunities to advance toward a unified, globally relevant hazardous medication list.

Method: A comparative review was conducted including:
• The U.S. National Institute for Occupational Safety and Health (NIOSH) List of HDs, influential but challenged by lengthy update cycles.
• The European Commission's 2025 Indicative List of Hazardous Medicinal Products, grounded in carcinogenicity, mutagenicity, and reproductive toxicity (CMR) criteria.
• Saudi Arabia's List of Hazardous Medications (Approved June 2025), which adapts NIOSH based principles within a national regulatory framework.
• Frameworks in Australia, New Zealand, and Japan, which rely on state level guidance, professional society recommendations, or institution specific formularies rather than national lists.
• Canadian provincial systems, which apply NIOSH aligned criteria through compounding and occupational safety standards.
Comparisons evaluated inclusion criteria, toxicological determinants, handling requirements, categorization structures, frequency of updates, and treatment of investigational agents, chemical hazards, biologic hazards, and trace waste ("cradle to grave") expectations.

Results: Substantial variability was identified in the scope, criteria, and evidence thresholds used to classify hazardous medications globally. These differences directly affect labeling, PPE requirements, environmental monitoring expectations, and frontline workflow design. Countries lacking national lists rely heavily on institutional interpretation of toxicology data, contributing to inconsistent handling precautions. Investigational products and biologic hazards are unevenly addressed across frameworks, further complicating safety practices. The cumulative effect is a global mosaic of guidance that creates avoidable complexity and prevents consistent protection for healthcare workers, patients, and caregivers.

Conclusion: Findings from this analysis underscore the ongoing need for an internationally harmonized hazardous medication list that is scientifically grounded, inclusive of chemical and biologic hazards, and equipped with standardized criteria for investigational products. A unified and adaptable framework would streamline guidance, reduce ambiguity, strengthen global workforce safety, and support a common language for HD handling across borders. As global education around hazardous drug safety continues to expand, an internationally harmonized list represents a critical step toward safer and more coherent practice worldwide.

Medical cannabis: A jeopardy-style session to advance global pharmacy competency, clinical use, safety regulation and documentation

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Background: As medical cannabis adoption accelerates globally, pharmacists are increasingly required to navigate complex clinical and regulatory landscapes despite wide variation in training and preparedness. This session responds to persistent educational disparities by employing a team based jeopardy game with buzzers to facilitate audience participation in real-time case based discussions as the program helps equip pharmacists with the skills needed to make informed clinical decisions.

Method: The focus and flow will be driven by the attendees through allowing the audience to pick from categories based on their own practice setting priorities to drive discussions towards clinical, regulatory, practical implementation and documentation pathways.

Results: Participants will explore evidence based cannabis therapeutics, including appropriate indications, contraindications, and evolving research. A focused pharmacology category covers cannabinoids, dosing consensus, and current studies. Safety and quality content

builds skills for mitigating drug–drug interactions and understanding the variability of products derived from nature, botanical extraction, or chemical synthesis; supporting pharmacists as the trusted source on product quality and safety. Learners focus on the global regulatory mosaic shaping real-world practice, including differences in scheduling, access pathways, and professional responsibilities. Finally, the session highlights the often-overlooked importance of documenting cannabis use in the medical record, addressing common barriers, strategies for improving accuracy and consistency, and potential legal risks for patients, clinicians, and institutions.

Conclusion: Participants will walk away with positive memories of the lively game style session, remembering both new friendships and the energy brought forth by peer learning through real-time clinical reasoning in cannabis patient care.

Development of a novel terminological framework for quality assurance signal management in pharmaceutical regulatory systems

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Background: The evolving complexity of pharmaceutical regulatory systems has diversified the compilation of data, yet to date the systematic management of quality assurance (QA) signals remains conceptually and methodologically underdeveloped. In contrast to pharmacovigilance, where signal management is underpinned by well-established terminologies, taxonomies, and analytical methodologies, QA signal management remains unexplored within existing regulatory, quality management, and scientific lexicons. The absence of terminological constructs contributes to interpretative variability, limits methodological harmonisation, and impedes the advancement of quality assurance signal assessment within pharmaceutical regulatory sciences. Addressing this gap, the study introduces a novel glossary framework intended to provide definitional clarity, conceptual consistency, and terminological traceability in the management of QA signals. The framework aims to characterise identified QA signals and support a structured conceptual lexicon to sustain the systematic identification, interpretation and application within a pharmaceutical regulatory context.

Method: An inductive-interpretative analytical approach informed the development of a terminological glossary framework. The terminological constructs were derived from the iterative application of the Quality Assurance Signal Analytical Framework to dataset sources, namely quality improvement forms submitted at the Quality, Continuous Improvement and Internal Audits Unit at the Malta Medicines Authority. The approach involved iterative rounds of QA signal data analysis, signal-to-principle mapping, and thematic clustering. The framework was validated through a structured expert focus group (N=7) consultation. The criteria of the glossary framework were evaluated using the Content Validity Method to assess clarity, relevance, and structure and layout. Suggestions and recommendations made during the validation process informed the development of the framework to achieve conceptual clarity and linguistic precision.

Results: The glossary framework incorporates a foundational knowledge-building element required to support the application of quality assurance signal intellect. The glossary is presented in a structured tabular format comprising three core criteria: (i) terminological -omics constructs, (ii) conceptual definitions, and (iii) scientific rationales. Analysis indicated that QA signals arose not solely from discrete quality assurance practices but from multidimensional dynamics spanning across governance-associated influences, integrative system interactions, organisational capability and resources-related dynamics, and stakeholder-driven outcomes. To capture these multidimensional QA signal origins, four novel terminological constructs were developed. 'Governomics' characterises governance-related signals reflected through the evaluation of the quality management system documentation framework and procedural consistency. 'Integromics' reflects interdependencies across quality management systems, operational interfaces, and process integration performances. 'Capacitomics' represents organisational capacity-related QA signals, including resource allocation, workforce competencies, infrastructure adequacy, and system maturity. 'Stakeholderomics' encompasses behavioural, cultural, communication, and inter-stakeholder interaction. Collectively, the four terminological constructs provide a structured taxonomy enabling consistent classification and interpretation of QA signals.

Conclusion: The glossary framework is envisioned as a dynamic conceptual tool intended to focus on a shared scientific understanding amongst quality management and pharmaceutical regulatory professionals. The introduction of a validated QA terminological construct grouping supports the invention of QA intelligence and provides a foundation for future methodological development, professional competency development, and evidence-based decision-making. The evolvement and integration of the framework represent a pioneering advancement towards the development of a structured lexicon for QA signal management within medicinal products regulatory sciences.

Impact of regulatory framework in the volume of clinical trials in Albania and Balkan countries

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Background: Clinical trials are crucial for evidence-based medicine and access to new treatments. A supportive regulatory framework is perceived as one of the main factors promoting their development. In Albania, clinical trials are mentioned in the law "For drugs" since 1994, however a special instruction "On Clinical trials" has entered into force only in the year 2018.

The purpose was to evaluate whether the improvement of clinical trials' regulatory framework in Albania has had an impact on their volume conducted in the country and to compare the results with the situation in North Macedonia and Bosnia and Herzegovina, being those Balkan countries and candidates for the European Union (EU) membership as well, with a population close to that of Albania's.

Method: The publication of the World Health Organization (WHO) "Number of clinical trial registrations by location, disease, phase of development, age and sex of trial participants (1999-2025)" was analysed related to Albania, evidencing the volume of clinical trials registered in the WHO International Clinical Trials Registry Platform (ICTRP) before the year 2018 and after. The same approach was followed for North Macedonia and Bosnia and Herzegovina related to the years of their national laws and regulations. The legal frameworks of the three countries were compared aiming to find the root causes behind the different number of clinical trials performed in each of them.

Results: Albania counts 142 trials (0.01% of the world total), with 55 trials between 1999-2017 and 87 trials between 2018-2025, showing an increase of 4.1 times of the trials/year. North Macedonia counts 384 trials (0.04% of the world total), with an increase of 3.27 times of the trials/year since the official enter into force of the Good Clinical Practice (GCP) in local language in 2009. Bosnia and Herzegovina counts 597 trials (0.06% of the world total), with an increase of 4.87 times of the trials/year since 2010 when the Ordinance on Clinical Trials on Medicinal Products and Medical Devices and the Medicinal Products and Medical Devices Act were already in force.

Conclusion: The improvement of policy framework regarding clinical trials, being a law, a regulation or GCP, has clearly had a positive outcome on the volume of trials in each of the countries discussed. Among them, North Macedonia has the highest number of trials per capita, followed by Bosnia and Herzegovina and Albania. Further legislative alignment is needed for Albania considering the approaches of these countries and those of the EU.

Assessing the feasibility of manufacturing sites for remote good manufacturing practice inspection

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Background: The COVID-19 pandemic caused unprecedented disruption to traditional on-site regulatory inspection models due to travel restrictions. In response, regulatory authorities rapidly implemented remote inspection methodologies using digital technologies as one of the mitigation measures. While these approaches proved valuable, their application was often ad hoc, with limited structure or harmonised criteria guiding when remote inspections were appropriate. The absence of a standardised framework risked inconsistency in regulatory decision-making and potential variability in inspection outcomes. This study aimed to develop a structured, risk-based assessment tool to support competent authorities in determining the feasibility and appropriateness of conducting remote Good Manufacturing Inspections (GMP) while maintaining confidence in regulatory oversight.

Method: The risk assessment tool was developed through a comprehensive literature review and stakeholder engagement. Existing regulatory guidance, published studies, and inspection practices were analysed to identify key risk factors influencing remote inspection feasibility. In parallel, feedback was collected through a structured questionnaire distributed to regulatory and industry experts. The tool was designed to evaluate whether a remote inspection could provide a level of assurance comparable to an on-site inspection. Key considerations included the robustness of IT infrastructure, data accessibility and integrity, site complexity, and prior knowledge of the manufacturing facility from previous inspections or regulatory interactions.

Results: A semi-quantitative risk assessment tool was developed and subsequently validated by two independent expert groups. The tool comprises eight domains, each containing four indicators, resulting in a total of 32 criteria for assessment. The domains include: product and patient risk; GMP compliance history; inspection and regulatory background; manufacturing and process complexity; quality management system maturity; change management and external signals; data integrity and computerized systems; and technical feasibility for remote inspection. Each indicator is assigned a score of 1, 3, or 5, with higher scores representing greater risk severity. Domain-specific weightings are applied to reflect their relative importance,

and weighted scores are calculated for each domain. These are then aggregated to produce an overall risk score. The final score is categorised into three ranges: low risk, where remote inspection is considered appropriate; medium risk, where remote inspection may be conditionally appropriate; and high risk, where an on-site inspection is recommended. The tool demonstrated consistency and usability across expert groups, supporting its potential application in regulatory settings.

Conclusion: The COVID-19 pandemic demonstrated that digital technologies can effectively support continuity of regulatory oversight; however, remote inspections cannot fully replicate the depth of insight, contextual understanding, and trust established through on-site inspections. The proposed risk assessment tool introduces a structured and harmonised approach to decision-making, enabling competent authorities to assess the suitability of remote inspections in a consistent and transparent manner. While remote methodologies offer advantages, particularly in situations where physical access is restricted, challenges related to technology, cybersecurity, human factors, and limitations in observing non-verbal cues remain. Future work should focus on refining remote inspection frameworks, enhancing digital infrastructure, and integrating hybrid inspection models, ensuring that innovation complements rather than compromises the rigour and reliability of established regulatory practices.

The reform of the European Union pharmaceutical legislation

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Background: The European Union is reforming its pharmaceutical legislation to improve medicine availability, reduce delays in access, strengthen shortages governance, and realign innovation incentives. This is important because the EU marketing authorisation system has not ensured equitable access across Member States. Persistent inequalities remain after authorisation, when manufacturer launch decisions interact with national pricing, reimbursement, procurement, and administrative capacity. These challenges are particularly evident in smaller markets, such as Malta, where commercial incentives are weaker and administrative capacity is more limited. This study assessed whether the proposed reform contains implementable mechanisms capable of reducing inequalities in availability, speed of access, affordability, and supply resilience, and compared the reform with approaches in the United States and Türkiye.

Method: A qualitative comparative design combined documentary analysis with expert stakeholder evidence. European Union draft legislation and the December 2025 political compromise were analysed alongside primary regulatory and policy documents from the United States and Türkiye and relevant peer-reviewed literature. Findings were translated into an eight-theme discussion guide, piloted in one focus group, and applied in a second expert focus group. Two stakeholder sessions were analysed as one dataset of ten participants, including regulatory, legal, procurement, and supply-facing perspectives. Sessions were recorded, transcribed, and analysed using framework analysis, and findings were integrated using a strengths, weaknesses, opportunities, and threats approach.

Results: Triangulated findings identified a consistent pattern. The reform was found to be strongest in structured governance tools, particularly shortage prevention plans, critical medicines monitoring, and support for earlier generic and biosimilar entry. Under the political compromise, central scientific assessment would fall from 210 to 180 days, while protection would become eight years of data protection plus one year of market protection, with capped extensions. Its main implementation weakness was access-linked conditionality, as launch, sufficient supply, and continuous availability were difficult to define and verify across Member States. Comparative analysis further showed that, in the United States, litigation architecture and enforceable shortage-reporting deadlines shape competition and supply, while, in Türkiye, pricing rules, exchange-rate mechanisms, and pack-level traceability influence launch incentives and post-authorisation continuity. In the expert group, five of ten stakeholders reported familiarity (mean scores 3.30/5; range 2.75-4.00). The conditions with regards to the launch and supply of medicines in the reform (Article 82) attracted the strongest scepticism: four of ten stakeholders considered it unworkable, one expressed a conditional view, and one rated its workability one out of five. Shortage governance and critical medicines tools received the strongest support, with two of ten stakeholders agreeing and two expressing conditional views.

Conclusion: The proposed reform introduces credible governance innovations, but reducing access inequalities will depend more on operational definitions, evidence standards, and administrative capacity than on legislative ambition. Shorter authorisation timelines alone are unlikely to narrow inequalities arising after authorisation. For smaller markets, success will depend on whether final rules are measurable, enforceable, and workable across national access pathways.

Assessing the feasibility of manufacturing sites for remote good manufacturing

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Background: The COVID-19 pandemic caused unprecedented disruption to traditional on-site regulatory inspection models due to travel restrictions. In response, regulatory authorities rapidly implemented remote inspection methodologies using digital technologies as one of the mitigation measures. While these approaches proved valuable, their application was often ad hoc, with limited structure or harmonised criteria guiding when remote inspections were appropriate. The absence of a standardised framework risked inconsistency in regulatory decision-making and potential variability in inspection outcomes. This study aimed to develop a structured, risk-based assessment tool to support competent authorities in determining the feasibility and appropriateness of conducting remote GMP inspections while maintaining confidence in regulatory oversight.

Method: The risk assessment tool was developed through a comprehensive literature review and stakeholder engagement. Existing regulatory guidance, published studies, and inspection practices were analysed to identify key risk factors influencing remote inspection feasibility. In parallel, feedback was collected through a structured questionnaire distributed to regulatory and industry experts. The tool was designed to evaluate whether a remote inspection could provide a level of assurance comparable to an on-site inspection. Key considerations included the robustness of IT infrastructure, data accessibility and integrity, site complexity, and prior knowledge of the manufacturing facility from previous inspections or regulatory interactions.

Results: A semi-quantitative risk assessment tool was developed and subsequently validated by two independent expert groups. The tool comprises eight domains, each containing four indicators, resulting in a total of 32 criteria for assessment. The domains include: product and patient risk; GMP compliance history; inspection and regulatory background; manufacturing and process complexity; quality management system maturity; change management and external signals; data integrity and computerized systems; and technical feasibility for remote inspection. Each indicator is assigned a score of 1, 3, or 5, with higher scores representing greater risk severity. Domain-specific weightings are applied to reflect their relative importance, and weighted scores are calculated for each domain. These are then aggregated to produce an overall risk score. The final score is categorised into three ranges: low risk, where remote inspection is considered appropriate; medium risk, where remote inspection may be conditionally appropriate; and high risk, where an on-site inspection is recommended. The tool demonstrated consistency and usability across expert groups, supporting its potential application in regulatory settings.

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The proposed risk assessment tool introduces a structured and harmonised approach to decision-making, enabling competent authorities to assess the suitability of remote inspections in a consistent and transparent manner. While remote methodologies offer advantages, particularly in situations where physical access is restricted, challenges related to technology, cybersecurity, human factors, and limitations in observing non-verbal cues remain. Future work should focus on refining remote inspection frameworks, enhancing digital infrastructure, and integrating hybrid inspection models, ensuring that innovation complements rather than compromises the rigour and reliability of established regulatory practices.

Organochlorine pesticides in cowpea: Attended health and environmental consequences

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Background: Cowpeas (Vigna unguiculata (Walp) L.) are affordable and alternative source of proteins but are ravaged by Callosobruchus maculatus, leading to huge crop losses. Merchants have unscrupulously used some organochlorine pesticides (OCPs) as preservatives, but these pesticides may gain access to the water bodies.

Purpose: This study aims to detect and quantify some of these OCP in cowpeas collected from some states in southern Nigeria, comparing the levels obtained with maximum residual limits (MRL) set by European Union (EU) and determining the health index (HI) from daily intake.

Method: I. Cowpea samples were randomly collected from wholesale and retail markets in the South-West and South-South Nigeria. They were pulverised, extracted with

dichloromethane in a Soxhlet apparatus, cleaned up using silica gel and subjected to gas chromatography-mass spectrometer analysis (GC-MS) using a Restek Stx-CL column.

II. Samples of cowpea (10g) (A) and without testa (B) were separately immersed in 100 mL of distilled water for 1 h with intermittent agitation. The waters obtained from A and B were separately extracted with dichloromethane (3x) according to a previously established method. The subsequent clean-up and analysis with GC-MS using Restek Stx-CL column enabled the identification and quantification of various OCPs in the residual water.

Results: The highest concentrations in South-West for o,p'-DDT (11.42±2.42 µg/kg), lindane (64.26±1.38 µg/kg), aldrin (406.80±0.12 µg/kg), endosulfan (315±0.16 µg/kg) and heptachlor epoxide (29.41±4.68 µg/kg) were detected in the cowpeas. Whereas the highest concentrations in South-South for o,p'-DDT (182.24±2.13 µg/kg), lindane (23.80±1.40 µg/kg), aldrin (445.076±0.36 µg/kg), endosulfan (142.94±2.04 µg/kg) and heptachlor epoxide (18.93±0.32 µg/kg) were detected in the cowpeas.

The concentration of OCP of water obtained from immersed cowpea (A) from South-West gave lindane (51.73±0.90 µg/kg), aldrin (341±2.23 µg/kg), endosulfan (104.33±0.07 µg/kg) and heptachlor epoxide (14.11±0.02 µg/kg), showing a reduction of 16.01-66.88 % of OCP. However, no OCPs were detected in the water obtained from immersed cowpea (B). The assessed HI in adults and children were given as o,p'-DDT (0.01;0.07), lindane (0.88;6.13), aldrin (0.08;0.55), endosulfan (0.06;0.40) and heptachlor epoxide (2.03;14.22). The limit of detection (LOD) and limit of quantification (LOQ) for the method used for pesticide determination were in the range of 0.03-0.18 µg/L and 0.10-0.60 µg/L, respectively. The relative standard deviation (RSD) of the migratory time was between 3.2-7.5 %, showing that the method is reproducible. Recoveries of the spiked pulverised cowpeas were in the range of 84-104 % respectively.

Conclusion: The study revealed that pesticides were used unscrupulously in the preservation of cowpeas, and the concentration of some of these OCPs exceeded the MRL set by the EU. The HI also revealed that some of these cowpeas may not be fit for human consumption. The processing of cowpea into various food delicacies could result in the discharge of pesticides into water bodies, with its attendant health and environmental consequences. Strong regulatory advocacy and regular quality assurance are strongly recommended.

High-throughput, eco-friendly LC-MS/MS analysis of tyrosine kinase inhibitors in plasma using an ultrasonic-assisted magnetic sorbent-wrapped stick for dip extraction

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Background: Tyrosine kinase inhibitors (TKIs) are pivotal targeted therapeutics for various cancers, but their marked inter-patient pharmacokinetic variability necessitates reliable therapeutic drug monitoring (TDM). Liquid chromatography-tandem mass spectrometry (LC-MS/MS) is the gold standard for TKI quantification, yet conventional sample pretreatment methods are labor-intensive, resource-consuming, or prone to matrix effects. This study aimed to develop a high-throughput, green, and user-friendly extraction approach to address these limitations.

Method: A novel ultrasonic-assisted magnetic sorbent-wrapped stick dip extraction (UA-MSWS-DE) method was established. The extraction device was prepared by immobilizing octadecylphosphonic acid-functionalized magnetic nanoparticles (OPA/MNPs) onto magnets embedded in flame-sealed glass capillaries. Plasma samples were diluted with phosphate buffer (1:9, v/v) and subjected to ultrasonic-assisted extraction under optimized conditions: sample pH 5.0, OPA/MNP dosage 10 mg (20 nm particle size), extraction time 20 min, and desorption with 150 µL ethanol for 8 min. Analytes were quantified via LC-MS/MS using a Waters ACQUITY UPLC BEH C18 column and Xevo TQS mass spectrometer under multiple reaction monitoring mode.

Results: The method exhibited excellent linearity ($R^2 > 0.99$) for seven TKIs (alectinib, dasatinib, erlotinib, ibrutinib, lapatinib, lenvatinib, sorafenib) over their respective concentration ranges. Limits of quantification (LOQ) ranged from 0.1 to 5.0 ng/mL, with intra-/inter-day precision (RSDs < 14.95%) and accuracy (87.13–112.33% in blinded spiked plasma) that met bioanalytical validation criteria. Compared to conventional magnetic dispersive solid-phase extraction (MDSPE), the UA-MSWS-DE method offered simpler handling, enabled parallel processing in a single ultrasonic bath, and prevented sorbent loss and cross-contamination. Five greenness metrics (GAPI, AGREE, AGREEprep, SPMS, BAGI) confirmed its high sustainability, with AGREE/AGREEprep scores of 0.73 and SPMS score of 7.47. The modular design facilitates its adaptation to other analytes through modification of the sorbent coating.

Conclusion: The UA-MSWS-DE-LC-MS/MS method offers a sensitive, high-throughput, and environmentally friendly alternative for TKI quantification in plasma. Its operational

simplicity, minimal solvent/sorbent consumption, and compatibility with automation make it well-suited for routine TDM. Future improvements could focus on replacing hazardous solvents in sorbent synthesis and enhancing sorbent reusability. This work advances green bioanalytical chemistry and provides a versatile platform for therapeutic drug monitoring in clinical settings.

Regulatory loopholes and fixed-dose combination pricing in Nepal: A political economy approach

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Background: price regulation is applied selectively, leaving substantial segments of pharmaceutical markets outside effective oversight. Although maximum retail price (MRP) ceilings aim to improve affordability, narrow regulatory scope and infrequent price revision can generate strategic market responses. Evidence on how such regulatory design features shape pricing outcomes—particularly for fixed-dose combinations (FDCs)—remains limited.

Method: We conducted a mixed-methods political economy analysis of medicine price regulation in Nepal, integrating policy document review, a cross-sectional survey of retail medicine prices (February– June 2025), and 19 key informant interviews with multisectoral stakeholders. Using diabetes and hypertension medicines as tracer categories, we compared MRPs of FDCs and modified formulations with aggregated MRPs of equivalent single-ingredient medicines under price regulation and triangulated quantitative results with qualitative evidence.

Results: Nepal's MRP system regulates a limited set of single-ingredient medicines, while most FDCs and modified formulations remain unregulated. MRP analysis showed consistent price premiums for unregulated formulations: FDC prices exceeded aggregated MRPs of regulated single-ingredient components by over 60%, and by more than 200% in several high-volume oral antidiabetic and antihypertensive products. Observed price differentials were largely attributable to unregulated modified-release formulations. These patterns were consistent across manufacturers and reinforced by stakeholder accounts highlighting selective regulation, weak revision mechanisms, and limited enforcement.

Conclusion: Selective, static price regulation in Nepal has enabled formulation-based regulatory arbitrage, undermining chronic disease affordability. Effective health system reform in LMICs requires pricing policies with comprehensive scope, routine revision, and alignment between price controls and therapeutic substitutability. Pharmaceutical pricing, Regulatory design, Fixed-dose combinations, pharmaceutical policy

Power, politics, and price: Governance failures in Nepal's pharmaceutical system and the UHC challenge

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Background: Equitable pharmaceutical pricing is fundamental to Pharmacoequity and Universal Health Coverage (UHC), yet in Nepal it is dictated less by policy than by power. Market dominance, federal fragmentation, and geopolitical dependence now shape price formation in the absence of a coherent national pricing policy. This policy vacuum has institutionalized regulatory loopholes and enabled political-commercial interference, eroding state control over medicine access. This study analyzes how actor power, administrative asymmetries, and geopolitical market dependence drive price variation and constrain Nepal's UHC goals.

Method: A mixed-methods design was applied, comprising: (1) a systematic review of peer-reviewed and grey literature (2000-2025; n = 56); (2) secondary analysis of medicine price data from public hospitals, private pharmacies, and national procurement records across all seven provinces of Nepal (n = 348 observations); and (3) semi-structured stakeholder interviews with regulators, providers, pharmaceutical industry actors, insurers, and patient advocates (n = 24). Affordability was assessed using WHO/HAI methodology as the number of days' wages required by the lowest-paid unskilled worker. A comparative policy benchmarking framework was applied with five lower-middle-income countries.

Results: Substantial price variation was observed across essential medicines, with minimum-maximum price ratios exceeding five-fold within the same therapeutic categories. Non-revision of discretionary price ceilings and weak enforcement of retail mark-up limits were strongly associated with wide intra-market dispersion. Stakeholders reported persistent political and commercial interference through regulatory delays and selective enforcement, while pharmacies operated predominantly as profit-maximizing commercial entities. Comparator countries with centralized price oversight and formal reference pricing frameworks demonstrated consistently narrower price bands.

Conclusion: Nepal's pharmaceutical pricing crisis reflects a governance and political economy failure rather than a technical policy gap. Advancing UHC requires establishment of an independent pricing authority, statutory reference pricing and mark-up regulation, mandatory periodic price revision, and integration of pricing governance with national health insurance and procurement systems.

Strengthening global medicine quality and securing supply chains through Practical approaches to economically motivated adulteration

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Background: Economically motivated adulteration (EMA)—the intentional substitution, dilution, or misrepresentation of medical products for financial gain—poses a persistent threat to medicine quality, patient safety, and the integrity of pharmaceutical supply chains. EMA may affect excipients (inactive formulation components), active pharmaceutical ingredients (APIs), finished dosage forms, and packaging-related materials. These risks are heightened by globalised supply networks, uneven regulatory oversight, and economic pressures that incentivise fraudulent practices. Pharmacists and quality professionals increasingly contribute to the identification and mitigation of EMA across community, hospital, industry, regulatory, and academic settings. This work presents a practice-oriented approach that incorporates risk intelligence, structured assessment, and cross-sector collaboration to strengthen health-system resilience against EMA.

Method: A multi-pillar framework was constructed from cross-sector quality-systems practices and professional experience:

-Threat sensing and signal triage: integrating open-source intelligence, supplier performance insights, and cross-domain alerts—such as food-integrity signals—into routine horizon scanning.
-Structured risk assessment: applying a systematic process to identify plausible fraud vectors, prioritise vulnerabilities by potential patient impact and detectability, and assign proportionate controls.

-Analytical and verification strategy: combining targeted confirmatory methods with risk-based screening to verify the identity and quality of materials most susceptible to adulteration.

-Supplier and network assurance: strengthening supplier-qualification criteria, clarifying documentation and transparency expectations, and conducting targeted audits in high-risk segments.

-Response and learning loop: implementing consistent escalation pathways, root-cause analysis, corrective actions, and knowledge-capture processes to refine mitigation strategies over time.

The framework is illustrated conceptually through scenarios involving high-risk excipients, constrained-supply APIs, and medicines subject to rapid demand changes.

Results: Theoretical application of this framework suggests multiple potential benefits. First, earlier detection of EMA risks may be possible when horizon scanning and intelligence-gathering activities are embedded into routine quality and procurement functions. Secondly, a structured, transparent approach could encourage more proportionate and risk-aligned verification, ensuring analytical resources are directed towards higher-risk materials or supply-chain nodes. Thirdly, integrating the framework into supplier-assurance activities may enhance supply-chain resilience, supported by clearer expectations for transparency, traceability, and documentation. Additionally, standardised tools—such as checklists, risk matrices, and decision trees—may support greater internal consistency and cross-functional coordination, particularly where resources are limited. Finally, structured response pathways and mechanisms for capturing lessons learned may facilitate faster organisational learning, enabling continual refinement of EMA-mitigation strategies even when empirical event data remain limited.

Conclusion: A practical, system-level approach to EMA—anchored in proactive threat identification, structured risk assessment, proportionate verification, and strengthened supplier assurance—offers a feasible path to improving medicine quality and securing global supply chains. Although conceptual, the framework highlights actionable roles for pharmacists and quality professionals across the product lifecycle. Future priorities include defining shared metrics for assessing effectiveness and supporting capacity-building in low-resource settings. Collaboration among regulators, standards-setting bodies, manufacturers, and healthcare organisations will be essential to validate and embed approaches that can adapt to evolving EMA risks.

Building global competency: Training the pharmaceutical workforce for stronger quality and regulatory systems

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Background: A skilled pharmaceutical workforce is central to ensuring that medicines are safe, effective, and of assured quality. As global supply chains expand and therapeutic modalities grow more complex, quality assurance and regulatory oversight require continuously evolving competencies. Pharmacists and regulatory professionals

working across community and hospital practice, industry, academia, and national regulatory authorities must be equipped to interpret standards, apply quality principles, and respond to emerging risks. Yet persistent gaps remain in foundational knowledge, practical skills, and regulatory understanding. This work examines how structured learning and competency based training can strengthen global pharmaceutical quality and regulatory systems by enabling practitioners to navigate increasing technical and regulatory complexity.

Method: A competency based training framework was developed through analysis of workforce needs, quality systems principles, and effective instructional models. The framework comprises four core components:
1.Foundational learning: developing shared understanding of pharmaceutical quality systems, risk management, current good manufacturing practice, and major regulatory frameworks.
2.Skills based training: using simulation, case based scenarios, and inspection focused exercises to build practical proficiency in standards interpretation, deviation analysis, and evidence based decision making.
3.Digital and hybrid learning approaches: integrating virtual modules, interactive digital tools, and remote mentoring to expand access, improve scalability, and support continuous professional development.
4.Cross sector capacity building: fostering collaboration among professional bodies, regulators, academic institutions, and manufacturers to harmonise expectations and reinforce quality culture.
The framework was conceptually applied to diverse environments including quality control laboratories, regulatory agencies, industrial quality units, and pharmacy practice settings.

Results: Theoretical application of the framework suggests several potential benefits for global health systems. Structured, competency based learning may enhance consistency and reliability in regulatory and quality related decisions across practice settings. Simulation driven and case based training may support earlier detection of quality risks, enabling practitioners to anticipate and respond to deviations, supply chain vulnerabilities, or compliance concerns more effectively. Digital and hybrid learning models may improve equitable access to high quality training, particularly in resource constrained contexts where traditional in person instruction is limited. Furthermore, cross sector collaboration may strengthen alignment between regulators, manufacturers, and healthcare providers, improving communication across the product lifecycle and supporting coherent regulatory oversight. Overall, these theoretical outcomes suggest the potential for stronger quality culture, greater regulatory maturity, and improved system level resilience.

Conclusion: Competency based workforce development is fundamental to strengthening pharmaceutical quality and regulatory systems worldwide. The training framework described offers a practical, adaptable approach for enhancing professional skills across diverse practice settings. By investing in structured learning, modern educational tools, and collaborative partnerships, health systems can better prepare their workforce to safeguard medicine integrity and address emerging quality and regulatory challenges. Ongoing commitment to global learning initiatives will be essential for developing resilient, future ready pharmaceutical systems that protect public health.

Drug repurposing: patient-centric ai-driven medicines regulatory-by-design translation

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Background: Drug repurposing has emerged as a strategic approach to address unmet clinical needs, particularly in therapeutic areas with limited treatment options. By identifying new indications for existing, approved medications, this strategy accelerates development timelines by 30–40%, reduces costs by 50–60%, and increases clinical success rates 2–3 times compared with de novo drug development. Next-generation artificial intelligence (AI) tools—especially generative models—are transforming biomedical research and patient-centric drug repurposing by enabling rapid hypothesis generation, target identification, biomarker discovery, and prioritization of candidates for preclinical and early clinical studies.

This work aims to characterize the role of AI-driven, patient-centric drug repurposing tools within the evolving landscape of biomedical research and digital health. Specifically, it seeks to evaluate how such tools can be responsibly deployed to leverage multi-omics data, scientific literature, and clinical repositories to uncover novel disease mechanisms, predict therapeutic responses, and generate insights with direct relevance to patient outcomes—while aligning with regulatory, ethical, and quality requirements.

Method: A structured review and analysis framework was applied, integrating evidence from multi-omics data sources, published literature, and clinical repositories. The regulatory alignment of AI-driven drug repurposing tools was assessed against the EU AI Act, focusing on risk-based governance, transparency, traceability, and human oversight requirements as applicable to outputs intended to inform clinical research or trial design. Ethical, Legal, and Social Implications (ELSI) were systematically evaluated, with particular attention to algorithm validation, bias mitigation, dataset representativeness, GDPR compliance, and patient data anonymization. Applicability of Good Laboratory Practices (GLP) to preclinical and early clinical study outputs was also examined.

Results: AI-driven patient-centric drug repurposing tools demonstrated significant capacity to uncover novel disease

mechanisms and predict therapeutic responses by integrating heterogeneous biomedical data across multi-omics, literature, and clinical repositories. Their regulatory classification depends primarily on intended purpose and are outside of MDR/IVDR. However, where outputs are designed to inform early clinical studies or trial design, a pathway toward higher regulatory oversight becomes applicable. Under the EU AI Act, such tools may qualify as high-risk AI systems, requiring robust risk-based governance frameworks and meaningful human oversight mechanisms. ELSI assessment confirmed that comprehensive algorithm validation, continuous performance monitoring, thorough technical documentation, GDPR-compliant data handling, bias mitigation, and equitable dataset representation are foundational to ensuring scientific rigour, reproducibility, and responsible patient data stewardship. Collectively, patient-centric drug repurposing tools occupy a distinctive and evolving regulatory space, bridging biomedical discovery, patient-centred innovation, and compliance-driven translational research, requiring proportionate and proactive engagement with regulators as their clinical relevance increases.

Conclusion: Patient-centric drug repurposing tools powered by AI represent a transformative convergence of discovery science and digital health, with the potential to meaningfully accelerate and de-risk the identification of new therapeutic applications. Their outputs can directly influence clinical trials, patient safety, and therapy decisions, necessitating a higher standard of regulatory and ethical oversight than purely preclinical tools. Responsible deployment requires alignment with emerging AI governance frameworks, proactive regulator engagement, and rigorous ELSI safeguards. When implemented within these parameters, AI-driven drug repurposing tools bridge discovery, patient-centred innovation, and compliance-driven translation into clinically meaningful impact.

Next gen precision oncology: Nature-derived nanobiotechnology & new approach methodologies (NAMs) as a regulatory-by-design translational framework

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Background: Breast cancer remains the most prevalent malignancy in women globally, with approximately one in seven to eight women affected during their lifetime, and incidence rising by approximately 2.5% annually in the EU. Despite therapeutic advances, significant unmet needs persist for treatments that combine precision targeting, reduced systemic toxicity, and sustainability. Nature-derived bioactive compounds, integrated with advanced nano(bio)technology delivery systems, represent an emerging and underexplored class of next-generation oncology therapeutics. Their translation from promising preclinical evidence into first-in-human clinical trials requires navigating a complex regulatory science landscape, where New Approach Methodologies (NAMs) offer a transformative and ethically responsible pathway, provided a proactive Regulatory-by-Design strategy is embedded from the earliest development stages.

Method: A regulatory science framework analysis was conducted across the translational development pathway of nature-derived nanobiotechnology oncology platforms, using AI-powered meta-analysis and multi-omics integration as enabling tools. NAM platforms, including patient-derived organoids, organ-on-chip systems, and AI-driven computational models, provide human-relevant solutions that improve predictive validity, mechanistic insight, and ethics, while replicating tumour biology specific to individual patients and supporting biomarker discovery. The regulatory qualification pathway for NAMs was assessed against EMA's framework: EMA interacts with NAM developers through ITF briefing meetings for informal discussions on NAM development and readiness for regulatory acceptance, EMA Scientific Advice for context-of-use-specific questions on incorporating NAM data into clinical trial or marketing authorisation applications, and the CHMP Qualification procedure for NAMs with sufficient robust data to demonstrate regulatory utility. European Medicines Agency Applicable frameworks, including EU CTR (536/2014), GLP, and the 3Rs principles, were mapped against the preclinical-to-first-in-human transition.

Results: NAMs, including in vitro assays, in silico modelling, omics-based profiling, and organ-on-chip platforms, are poised to transform nonclinical regulatory evaluation in oncology drug development by enabling faster decision-making, increasing human biological relevance, and reducing costs. For nature-derived nanobiotechnology platforms, NAMs offer a particularly compelling regulatory pathway: organoid-based tumour models can recapitulate the tumour microenvironment and validate targeted delivery mechanisms, while AI-driven meta-analysis accelerates evidence synthesis across preclinical datasets to build a weight-of-evidence package suitable for first-in-human trial applications. The EMA Qualification of New Methodologies procedure leads to an opinion on the acceptability of a proposed NAM for a specific context of use, enabling confident regulatory deployment once qualified. Early ITF engagement with the EMA was the most immediate entry point, allowing informal discussions on NAM readiness, the classification of the nanobiotechnology formulation, and aligning the preclinical work with regulator expectations at the early development stage.

Conclusion: Nature-derived nanobiotechnology platforms represent a disruptive and sustainable frontier in precision oncology, uniting the specificity of targeted delivery with the biological potency of natural bioactive compounds. Their translation into first-in-human clinical trials requires a NAM-enabled, Regulatory-by-Design approach, one that uses

organoid models, AI-driven evidence synthesis, and early EMA engagement to replace animal testing where scientifically justified and reactive regulatory strategies that delay and destabilise clinical development. When NAMs are integrated as a core pillar of the translational framework from the outset, nature-derived oncology innovation can reach patients safely, efficiently, and equitably.

Precision oncology: AI-driven organoids platform as a regulatory-by-design translation framework

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Background: Precision oncology is undergoing a paradigm shift driven by the convergence of patient-derived tumour models, multi-omics integration, artificial intelligence (AI), and digital twin simulation. These technologies hold transformative potential to personalise cancer treatment by modelling individual tumour behaviour, predicting drug responses, and generating patient-specific therapeutic recommendations. However, this convergence simultaneously engages three major and partially overlapping EU legislative frameworks, creating a regulatory science landscape of unprecedented complexity.

Method: A structured regulatory science framework analysis was conducted across the principal technology components of next-generation precision oncology platforms. Patient-derived organoids used to examine drug responses for individual clinical decisions were assessed against IVDR, distinguishing their diagnostic function from purely research use. AI-driven digital twin and clinical decision-support components were assessed against EU AI Act (2024/1689) high-risk system criteria, which confirms that an AI system qualifies as high-risk under the AI Act where it serves as a safety component of an MDR (2017/745)/IVDR (2017/746)-regulated product subject to Notified Body conformity assessment. The full spectrum of early-stage EU regulatory engagement tools, including EMA Innovation Task Force (ITF) briefing meetings and EMA–HTA parallel consultation, was mapped against the precision oncology AI development lifecycle.

Results: AI-driven precision oncology tools integrating organoid-based diagnostics, digital twins, and clinical decision support occupy a multi-framework regulatory space where MDR, IVDR, and EU AI Act obligations apply concurrently. Patient-derived organoids intended to inform individual treatment decisions qualify as IVDs under IVDR, triggering Notified Body involvement and EMA consultations. AI components serving as safety-critical decision-support qualify as high-risk AI systems under the EU AI Act Annex III. The EU now requires developers to demonstrate safety and clinical performance under MDR or IVDR, whilst proving that AI algorithms are fair, transparent, and explainable under the EU AI Act, with full high-risk AI obligations for medical devices. Early-stage regulatory tools were found to be both available and strategically applicable: EMA ITF briefing meetings, accessible at any development stage, and explicitly covering AI, digital twins, and novel diagnostic methodologies, represent the most immediate and valuable regulatory entry point. EMA Scientific Advice provides the subsequent formal mechanism for clinical evidence strategy and CDx performance requirements, while EMA–HTA parallel consultation aligns regulatory and reimbursement evidence generation at the translational stage. ELSI assessment confirmed that GDPR-compliant data governance, bias mitigation, algorithmic explainability, and equitable patient access must be embedded from inception to ensure scientific rigour and responsible patient benefit.

Conclusion: Next-generation AI-driven precision oncology platforms represent one of the most regulatory science-complex innovations in contemporary digital health. Their simultaneous engagement of IVDR, MDR, and the EU AI Act demands a structured, sequential, and proactive regulatory strategy initiated at the earliest stages of development. When precision oncology innovators engage the available EU regulatory toolkit, from ITF briefing meetings through EMA Scientific Advice to EMA–HTA parallel consultation, regulatory science becomes not a constraint on innovation but its most reliable enabler, translating cutting-edge oncology tools into safe, evidence-based, and equitably accessible clinical impact.

Next-Gen precision oncology: AI-driven nanorobots within a regulatory-by-design translational framework

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Background: Breast cancer remains the most prevalent malignancy among women globally, with approximately 1 in 7 to 8 women expected to develop the disease in their lifetime. In 2022, the European Union recorded approximately 375,000 new cases, representing one quarter to one third of all cancers diagnosed in women across many EU member states. Despite meaningful therapeutic advances, breast cancer continues to be a leading cause of cancer-related morbidity and mortality, underscoring an urgent and unmet need for novel, precision-targeted treatment strategies. Conventional systemic therapies are frequently limited by off-target toxicity, resistance mechanisms, and suboptimal tumour penetration, challenges that next-generation nanotechnology and AI-integrated platforms are positioned to address.

This work aims to explore the translational potential of AI-designed nanorobots loaded with biologic drugs, produced through bioreactor systems, as a precision oncology paradigm for breast cancer. Specifically, it seeks to define how AI and digital twin technologies can accelerate nanorobot design and optimise biologic payload selection, while critically evaluating the applicable regulatory classification landscape, spanning Advanced Therapy Medicinal Products (ATMP), EU Medical Device Regulation (MDR), and the EU AI Act, and identifying the Ethical, Legal, and Social Implications (ELSI) essential for responsible clinical translation.

Method: A structured translational analysis was conducted, integrating current evidence on nanorobot engineering, bioreactor-based biologic manufacturing, and AI-driven drug design. AI and digital twin modelling approaches were examined for their capacity to simulate tumour microenvironment interactions, integrate multi-omics and patient-specific clinical data, and optimise therapeutic regimens from proof-of-concept through to preclinical and early clinical studies. The regulatory classification of nanorobots loaded with biologics was assessed against the EU ATMP Regulation (EC 1394/2007), EU MDR (2017/745), and the EU AI Act (2024/1689), with attention to combination product requirements and GxP and ELSI considerations were systematically evaluated.

Results: AI-driven modelling demonstrated significant potential to accelerate nanorobot design by simulating tumour microenvironment interactions, predicting patient-specific biologic responses, and optimising controlled-release mechanisms to reduce systemic toxicity and overcome resistance. Bioreactor integration was identified as a critical enabling component for sustainable, GxP-compliant, high-quality biologic production at scale. Regulatory analysis confirmed that nanorobots loaded with biologics occupy a complex classification interface: depending on the primary mode of action, such combination products may qualify as ATMPs, medical devices under MDR, or AI-enabled systems under the EU AI Act, or require assessment under multiple overlapping frameworks simultaneously. Early and proactive regulator engagement was identified as essential to resolve classification, define conformity assessment pathways, and align technical development with GxP and ELSI standards.

Conclusion: AI-driven nanorobots integrated with bioreactor-based biologic manufacturing represent a transformative and convergent precision oncology paradigm with the potential to meaningfully shift the breast cancer treatment landscape, particularly for patients where existing therapies fall short. Their unique position at the intersection of nanotechnology, biologics, advanced manufacturing, and AI demands a Regulatory-by-Design approach: one in which classification clarity, multi-framework compliance, and ELSI safeguards are embedded from the earliest stages of development rather than addressed retrospectively. When translated within rigorous regulatory and ethical frameworks, this paradigm holds genuine promise for improving patient outcomes.

Methanol extract of Hydrocotyle javanica Thunb. exhibits potent antihypertensive effects in spontaneously hypertensive rats.

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Hypertension remains a major global health challenge and is recognised as a leading contributor to cardiovascular morbidity and mortality. Hydrocotyle javanica Thunb. (H. javanica), a medicinal herb traditionally used in Southeast Asia, has recently attracted scientific interest for its potential antihypertensive properties. This study aimed to evaluate the antihypertensive effects of H. javanica in spontaneously hypertensive rats (SHRs) using non-invasive blood pressure monitoring techniques.

Fresh whole plants were washed, oven dried and ground, followed by sequential maceration using petroleum ether, chloroform, ethyl acetate, methanol, and water to obtain five crude extracts: HJPE, HJCE, HJEA, HJME, and HJWE. Each extract was administered orally to SHRs at 500 mg/kg for 28 days, with verapamil (15 mg/kg) serving as the positive control. Systolic blood pressure (SBP) was measured using the non invasive tail cuff computerised method on days 0, 7, 14, and 28.

Among the extracts, the methanol extract (HJME) produced the greatest reduction in SBP, demonstrating an antihypertensive effect comparable to verapamil. This suggests that HJME contains a high concentration of active constituents responsible for the antihypertensive effect. Phytochemical profiling using reverse phase high performance liquid chromatography (RP HPLC) identified catechin, rutin, and quercetin as major bioactive compounds. These flavonoids are known for their potent antioxidant properties, their ability to improve endothelial function, and their potential to modulate calcium channels, all of which likely contribute to the observed antihypertensive activity.

In conclusion, H. javanica exhibited significant antihypertensive effects in SHRs, with the activity primarily attributed to its polar flavonoid constituents. These findings support the herb's traditional use and highlight its potential as a natural source of antihypertensive agents.

Development and optimization of disposable pipette extraction coupled with UPLC-MS/MS for therapeutic drug monitoring of 28 tyrosine kinase inhibitors and active metabolites in human plasma

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Background: Tyrosine kinase inhibitors (TKIs) are widely used in first line targeted cancer therapy. However, as TKIs are administrated orally with fixed doses and metabolized by CYP 450, studies have reported that pharmacokinetic parameters vary between patients. Therefore, in 2017, Netherlands Cancer Institute (NKI) launched practical TDM recommendations of TKIs in oncology. Although TDM of TKIs has not been routinely conducted in standard patient care yet, many studies have underscored the potential benefits of individualized dosing to optimize efficacy and minimize toxicity. To meet the demand, this research sought to develop and optimize a disposable pipette extraction (DPX) approach integrated with UPLC-MS/MS for the concurrent analysis of 28 TKIs and their active metabolites in human plasma. This multi-analyte method enables precise assessment of plasma TKI levels, thereby promoting personalized dosing regimen and facilitating the forward integration of TDM into clinical oncology protocols.

Method: In this study, 37 analytes including 28 parent drugs and their active metabolites were quantified, and 14 stable-isotope-labeled internal standards were also used. The MS/MS parameters were optimized to achieve better signal intensity. Meanwhile, the UPLC C18 column was used, and the LC inlet condition was modified for 37 analytes well separation. After the instrument method improvement, the DPX extraction method for human plasma samples was preliminarily established, followed by optimization evaluation.

Results: After the transitions were identified and confirmed for each analyte, the MS parameters—including capillary voltage, desolvation temperature, desolvation gas flow, and cone gas flow—were optimized, yielding maximum analyte intensity and sensitivity. Additionally, mobile phases composition and additives, LC gradient profile, and column temperature were systematically evaluated to achieve optimal chromatographic performance. Consequently, 0.1% formic acid in water and 0.1% formic acid with 5 mM ammonium acetate in methanol/acetonitrile (60:40, v/v) were selected as mobile phase A and B, respectively, enabling desired separation efficiency of all 37 analytes within a 15-min gradient. Calibration curves ranging from 0.5 to 5,000 ng/mL demonstrated excellent linearity for all analytes (r^2 > 0.99). Subsequently, a 4-step DPX extraction procedure, including conditioning, sample-loading, washing and eluting, was initially developed, followed by optimization of elution solvent composition and aspirating/dispensing cycles in the loading and eluting steps. The optimal protocol was determined by comparing analyte peak areas across different conditions.

Conclusion: The DPX-UPLC-MS/MS method was successfully developed and optimized for simultaneous quantification of 28 TKIs and their active metabolites in human plasma, with remaining validation parameters pending confirmation. The assay demonstrated high signal intensity and sensitivity, adequate peak separation, and excellent linearity across therapeutically relevant ranges. This approach enables reliable TDM to support individualized dosing, optimize therapeutic efficacy, minimize toxicity, and advance precision oncology in clinical practice.

Medicines safety monitoring a strategic approach in the fight against substandard and falsified medicinal products in Liberia

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Background: Substandard and falsified medicinal products (SFMPs) continue to plague low-income countries especially Africa, of which Liberia is of no exception. The World Health Organization (WHO) projects that at least 1 in 10 medicines in low- and middle-income countries are substandard or falsified something that can lead to serious health risks, treatment failures and even death. Hence, the fight to curb this scourge requires every available resource, structure and system. In Liberia, the Liberia Medicines and Health Products Regulatory Authority (LMHRA) is the competent body responsible to regulate all medicinal products in Liberia, this includes the fight against substandard and falsified medicinal products (SFMP). The Medicines Safety Monitoring (MSM) system joins the traditional Post Market Surveillance to combat the scourge of SFMP. The WHO published a report on a falsified Phenobarbital 100mg reported from Liberia at one

of the hospitals that lacked efficacy in treating Patients with epilepsy, (Medical Product Alert N° 1/2016). Several hard copies of ADRs reporting forms have been distributed to health facilities with health workers not only train to report on ADRs or AEFIs but also trained to report suspected SFMP that made have slipped through the regulatory cracks. In this vein, the LMHRA has conducted several workshops aimed at building the capacity of ADRs reporters and distributed tablets to facilitate reporting of ADRs and AEFIs including SFMPs. Herein, we describe how MSM is significantly contributing to combating SFMP in Liberia.

Method: By carefully cataloging ADRs reported from various health facilities, analyzed reports, interviewing some reporters and victims and documenting these reports. These ADRs reports also include suspected SFMP reported to have contributed towards therapeutic failures or suspected to have caused ADRs or quality defects identified by the reporters.

Results: Differentiation of data shows that out of 934 ADRs reported during the period of 2016 to 2025, 0.75% were identified to be attributed to Suspected SFMPs. This figure reveals how Pharmacovigilance activities can also contribute significantly to the fight against SFMPs. The figure could have been higher, but due to under reporting caused by poor reporting culture, limited logistics for reporting and among others have contributed to limited results in reporting ADRs.

Conclusion: Medicine safety monitoring approach complements the traditional post market surveillance approach in combating SFMPs. Through Signal Detection, we have detected signals and patterns that indicated the presence of SFMPs at various health facilities. Although many of these challenges still remain, the LMHRA's medicine safety monitoring approach has nevertheless succeeded in making significant strides in combating SFMP in Liberia.

Strengthening narcotics supply chain security through GS1 traceability technology: evidence from Nigeria's NAFDAC traceability pilot

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Background: Pharmaceutical traceability systems are increasingly recognized as critical tools for improving medicine security, preventing diversion, and strengthening regulatory oversight of controlled substances. In Nigeria, the National Agency for Food and Drug Administration and Control (NAFDAC) implemented a 12-month traceability pilot for narcotics and controlled substances between January 2024 and January 2025 to evaluate the feasibility of applying GS1 global standards across the private-sector supply chain, and to assess the level of supply-chain visibility.

Method: A total of 376 supply-chain entities was onboarded, including importers, local manufacturers, overseas manufacturers, distributors, wholesalers, and pharmacy outlets. Approximately 140 Marketing Authorization Holders (MAHs) played a central role in the pilot because regulatory oversight through the NAFDAC annual Narcotics Import Permit process required compliance with traceability requirements. Traceability events were captured in the NAFDAC Traceability Information System (NTIS) using GS1 identifiers, namely Global Trade Identification Number (GTIN), Global Location Number (GLN), Serial Shipping Container Code (SSCC), and Serialized Global Trade Item Number (SGTIN). Supply-chain visibility was assessed by comparing actual events recorded in the NTIS with the number of events expected based on typical product handovers within the narcotics distribution chain.

Results: A total of 26.16 million serialized secondary packs were commissioned into the NTIS, demonstrating strong upstream compliance with serialization requirements. This high level of commissioning compliance was driven largely by regulatory oversight of MAHs through the narcotics import permit framework. However, downstream visibility remained limited. NTIS recorded approximately 6.54 million shipping events and 97,485 receiving events across the supply chain. Based on expected event generation across three to four supply-chain handovers, the overall visibility score for the pilot was estimated at 14–18%, indicating strong upstream traceability but substantial gaps in downstream event capture.

Conclusion: The results show that GS1-based pharmaceutical traceability is technically feasible within Nigeria's narcotics supply chain. Regulatory oversight proved effective in driving upstream compliance, while downstream participation requires sustained capacity building and operational integration across trading partners.

Strengthening pharmacovigilance in Mongolia: A roadmap for national regulatory and donor collaboration

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Background: Pharmacovigilance (PV) is a critical regulatory function that underpins patient safety, public trust, and the effective use of medicines. By ensuring the timely detection, assessment, and prevention of adverse drug reactions and other medicine-related risks, PV strengthens regulatory

oversight and safeguards public health investments. As global health donors increasingly prioritize sustainability and resilient and sustainable systems for health (RSSH), pharmacovigilance has gained recognition as an essential component of regulatory system strengthening. Effective PV systems not only protect patients but also enhance the long-term impact and accountability of donor-funded health programs.

This paper aims to present a regulatory-led roadmap for strengthening pharmacovigilance in Mongolia through coordinated national leadership and structured donor collaboration. It seeks to inform policy dialogue and identify scalable investment priorities aligned with regulatory sustainability principles.

Method: The analysis draws on national regulatory documentation, existing PV system assessments, and international guidance frameworks. Comparative review of pharmacovigilance strengthening approaches in Global Fund–supported countries was conducted to identify best practices relevant to Mongolia's context. System gaps were analyzed across governance, workforce capacity, reporting mechanisms, data management, signal detection, and risk communication.

Results: Although Mongolia has established foundational PV structures within its national regulatory authority—including a legal framework and a national reporting mechanism—the system remains constrained by limited technical capacity, underreporting, and insufficient integration with public health programs. The review identified priority interventions, including strengthening regulatory workforce competencies, integrating PV into disease-specific programs, enhancing signal detection capacity, and developing a phased donor engagement model aligned with RSSH objectives.

Conclusion: Positioning PV as both a patient safety function and a strategic regulatory investment is essential for sustainable health system development. A coordinated, regulatory-led approach—supported by targeted donor collaboration—can enhance system performance, ensure accountability of health investments, and build long-term resilience.

Regulatory assessment of novel food ingredients in dietary supplements: A market analysis from the Republic of Srpska

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Background: Novel food ingredients are increasingly used in dietary supplements as sources of bioactive substances intended to support health and improve nutritional status. Scientific and technological developments have enabled the use of substances that were not traditionally part of the human diet but may exhibit various functional properties. In the European Union (EU), novel foods must undergo a safety assessment and receive official authorisation before being placed on the market, in accordance with the Union List of Novel Foods and the defined conditions of use, including maximum recommended daily intake levels. Systematic monitoring of the composition of dietary supplements is essential to ensure regulatory compliance and consumer protection. This study evaluated the presence and regulatory status of novel food ingredients in dietary supplements available on the market of the Republic of Srpska (RS).

Method: A review of official European Commission documentation was conducted in order to identify authorised novel food ingredients and their conditions of use. Commercially available dietary supplements distributed on the market of the RS were analysed. Ingredients classified as novel foods were compared with the Union List of Novel Foods. Declared daily intakes were compared with the maximum authorised values and regulatory requirements defined by EU legislation.

Results: Ten dietary supplements were analysed. Eight products (80%) contained novel food ingredients authorised in the European Union, including chromium picolinate, zeaxanthin, galactooligosaccharides, citicoline, fermented soy extract, chondroitin sulphate and Antarctic krill oil. In all of these products, the declared daily doses were within the maximum recommended intake levels and complied with the prescribed conditions of use. Two products (20%) contained ingredients that are not included in the Union List of Novel Foods, namely serrapeptase and nicotinamide mononucleotide. These substances are not authorised as novel foods in the EU; however, they were identified in products that are freely marketed on the market of the Republic of Srpska. The findings indicate the presence of non-authorised ingredients within the analysed market segment.

Conclusion: Although the majority of the analysed dietary supplements were compliant with EU requirements regarding authorisation and recommended maximum intake levels, the identification of non-authorised substances indicates potential regulatory differences between the EU framework and markets outside the Union. Strengthening market surveillance and aligning national regulations with European standards may contribute to improved consumer protection and safer use of novel food ingredients in dietary supplements. The results provide relevant information for regulatory authorities and support the further development of harmonised approaches in the regulation of dietary supplements. These findings highlight the importance of continuous monitoring of dietary supplements and may contribute to improved regulatory practices in markets outside the EU.

12 years of Cannabis market regulation in Uruguay: A case study

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In December 2013, Uruguay became the first country in the world to fully regulate the cannabis market through Law 19.172. This study analyses twelve years of implementation of this regulatory framework, examining its structure, governance model, and main public policy outcomes.

The regulatory model adopted by Uruguay is an integrated approach encompassing non-medical, medical, and industrial uses of cannabis. This model is a specific exception within the national drug control legislation (Decree-Law 14.294 of 1974), which otherwise regulates substances subject to international control. Importantly, Uruguayan legislation has historically not criminalised personal drug consumption, providing a distinctive legal context for the implementation of this policy.

Law 19.172 created the Institute for the Regulation and Control of Cannabis (IRCCA), an autonomous public institution responsible for licensing, registry management, and market oversight. The regulatory framework is operationalised through three main decrees regulating the different cannabis markets.

Decree 120/014 (May 2014) establishes that Uruguayan citizens and legal residents aged over 18 may legally access cannabis for non-medical use, defined as the flowering tops of the female Cannabis plant (with or without fruit), excluding seeds and leaves separated from the stem, with a tetrahydrocannabinol (THC) content equal to or greater than 1% by weight. People can access cannabis through three mutually exclusive mechanisms: home cultivation, cannabis social clubs, and controlled sales through community pharmacies. The system requires user registration and establishes quantitative limits to prevent diversion. Private companies with state licenses produce cannabis for pharmacy sale.

Decree 372/014 (2014) regulates industrial hemp production, defined as Cannabis plants containing no more than 1% THC. The Ministry of Livestock, Agriculture and Fisheries supervise this sector and has enabled the development of value chains, including food products and other industrial derivatives.

Decree 246/021 (2021), which replaced earlier regulations, governs medical cannabis and scientific research activities. This framework promotes pharmaceutical development and clinical research under the supervision of IRCCA and the Ministry of Public Health.

After twelve years of implementation, the policy has relevant outcomes.

In the non-medical market, the registers account for approximately 46% of users who obtain cannabis through legal channels, indicating partial but significant migration from the illegal market. Furthermore, problematic cannabis use has not significantly increased during this period. However, challenges remain, including the persistence of illegal supply channels and the emergence of grey-market dynamics involving diversion of legally produced cannabis.

In the industrial sector, regulation has facilitated the development of domestic production capacities, particularly in hemp-derived food products.

In parallel, the medical cannabis framework has enabled the establishment of pharmaceutical production facilities, the development of cannabis-based medicinal products, and a measurable increase in scientific research activities, including clinical trials.

Uruguay's experience demonstrates the feasibility of a state-regulated cannabis market that attends to public health objectives, harm reduction, security considerations, and economic development. The case provides relevant evidence for countries considering alternative approaches to cannabis public policy, highlighting both the achievements and the regulatory challenges inherent to pioneering models of legal market regulation.

Implementing regulatory flexibilities to enhance compliance and patient access: A practice-based initiative

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Background: Regulatory frameworks serve an essential role to safeguard public health, notwithstanding this, they may hinder timely access to pharmaceutical care and create additional administrative burden for pharmacists. During routine inspections of community and hospital pharmacies in Malta, several recurring operational challenges were identified that contributed to inefficiencies in service delivery and documentation processes. In response, the Malta Medicines Authority (MMA) sought to introduce proportionate regulatory flexibilities that maintained compliance while supporting pharmacists in delivering efficient and patient-centred services. The aim of this study is to develop, validate and implement regulatory flexibilities which may reduce administrative burden for pharmacists and improve timely access to pharmaceutical care.

Method: Regulatory flexibilities were identified through a combined approach involving a review of relevant legislation, regulatory guidance and international best practices, together with insights gathered during routine pharmacy inspections conducted by MMA inspectors. A focus group discussion consisting of a Pharmacist, Pharmacy Inspector, Senior head of pharmacy inspections and the director was held to assess regulatory soundness, risk implications, feasibility of implementation and to evaluate their potential

impact on patient safety, compliance and operational efficiency. Regulatory flexibilities demonstrated through evaluation to yield a positive impact were formally adopted and incorporated into subsequent inspection cycles. Implementation was monitored through inspectors' feedback, follow-up inspections and ongoing communication with pharmacists to ensure consistency, clarity and continued adherence to regulatory standards.

Results: Five (5) regulatory flexibilities were implemented to streamline processes and support pharmacists in meeting compliance requirements. First, the use of online sources in place of printed physical copies was permitted, enabling timely access to up-to-date reference information and reducing the need for maintaining extensive printed materials. Second, statutory registers were allowed to be stored in secure online formats, improving accessibility, reducing physical storage demands and supporting more efficient record management. Third, a standardised process for the disposal of Dangerous Drug of Abuse (DDAs) was developed to ensure safe and consistent handling of DDAs across pharmacy settings. Fourth, the use of photographs of prescriptions for the daily register was authorised, allowing accurate documentation while reducing administrative workload and minimising transcription errors. Finally, the storage of medicinal products within doctors' clinics was permitted, if products were kept under lock and key and secured from unauthorised access. Collectively, these flexibilities reduced administrative burden and improved workflow efficiency. Inspectors reported fewer recurrent non-compliances and pharmacists noted improved practicality in meeting regulatory expectations. No safety concerns or adverse regulatory outcomes were observed following implementation.

Conclusion: The introduction of targeted regulatory flexibilities demonstrated that regulatory systems may remain robust while adapting to operational realities in pharmacy practice. These measures supported improved compliance, reduced bureaucratic burden and facilitated more efficient patient access to pharmaceutical care. Continued evaluation will assess the long-term impact of these flexibilities and identify further opportunities to optimise regulatory processes within the regulatory framework.

Consumer behaviour and perceptions of medicines from unlicensed vendors

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Background: Medicine peddling, the illegal sale and distribution of pharmaceuticals outside licensed channels, remains a significant public health challenge in Ghana. Despite regulatory frameworks such as the Pharmacy Act (Act 489) and oversight by the Food and Drugs Authority enforcement gaps that exist allow this practice to persist. The practice exposes the public to substandard and counterfeit medicines, inappropriate dosing, adverse drug reactions, treatment failure, and antimicrobial resistance among others.

Purpose: To assess factors driving medicine purchases from unlicensed vendors and evaluate consumer knowledge and perceptions.

Method: A cross-sectional quantitative survey was conducted among 384 participants at a busy bus terminal in the Kumasi metropolis. Data was collected using a well-structured pre-tested questionnaire from traders, artisans, students, and other members of the traveling public. Informed consent was obtained and participants assured of confidentiality. Data were analyzed using descriptive and inferential statistics.

Results: Among respondents, 30.5% purchased medicines from peddlers monthly, 16.7% weekly, 7% daily, 34.6% occasionally, and 11.2% rarely. The majority were female (56%), aged 36–45 years (36.5%) and had attained secondary education (47.1%). Medicines frequently purchased from peddlers included pain relievers (25.2%), antihypertensives (24.4%), antibiotics (21.2%), and antimalarials (21.2%). The key reasons for patronage were the lack of prescription requirements (44%), ease of accessibility (33.3%), lower cost (26%), and trust in vendors (13.5%). Knowledge gaps were evident, 55.6% were unsure if medicine peddling is illegal, and 44.8% did not know whether medicines sold were approved by regulatory authorities. Adverse outcomes were common, with 59.4% reporting side effects and 37.2% experiencing hospitalization which they linked to peddled medicines. Regarding willingness to change behavior, 42.7% would stop buying if health risks are emphasized, 39.3% if pharmacy prices are reduced, 12% if pharmacies are more accessible, 45.8% expressed readiness to attend health education programs
Statistical analysis showed that knowledge of illegality was not significantly associated with education level ($p = 0.437$), challenging the perception that medicine peddling is confined to the uneducated.

Conclusion: The study reveals that socioeconomic pressures, limited access to licensed pharmacies, and inadequate public awareness sustain reliance on unlicensed medicine vendors. Consumers often prioritize affordability, convenience, and lack of prescription requirements over safety, despite experiencing adverse health outcomes. Strengthening public health education, improving affordability and geographic access to legitimate pharmaceutical services, and enhancing regulatory enforcement are necessary to curb illegal medicine sales and safeguarding the health of the public.

Ten years of safety signal assessment by the European Medicines Agency

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Background: According to the European Medicines Agency (EMA), a safety signal is information regarding an adverse event potentially caused by a drug that necessitates further investigation. To identify any previously unknown risks associated with drugs after marketing authorisation, routine assessment of these signals is crucial in pharmacovigilance. In 2012, the EMA established the Pharmacovigilance Risk Assessment Committee (PRAC) to improve drug safety surveillance activities in Europe, including safety signal assessment and recommendations for regulatory actions. A comprehensive understanding of the evaluated safety signals may help stakeholders to further develop pharmacovigilance measures.

Purpose: The objective of this analysis was to describe the safety signals assessed by the PRAC, the involved drugs, and the subsequent recommendations for regulatory actions.

Method: Data on all safety signals from September 2012 to June 2023 were extracted from PRAC meeting agendas, minutes, and recommendations and systematically collected in a Structured Query Language (SQL) database for descriptive statistics. Safety signals were classified as potential adverse drug reactions or others (e.g., drug interactions or medication errors) and Anatomical Therapeutic Chemical (ATC) codes were assigned to all drugs involved in the safety signals.

Results: A total of 752 safety signals were assessed by the PRAC during the evaluated period. Most of these signals (507 [67 %]) originated from European Union (EU) spontaneous reporting systems, and 245 (33 %) originated from other sources, such as scientific literature. Out of all the assessed safety signals, 463 (62 %) were related to Centrally Authorised Products (CAPs), 196 (26 %) to Nationally Authorised Products (NAPs), and 93 (12 %) to both types of authorisation procedures (CAP/NAP). The majority of the safety signals (699 [93 %]) were potential adverse drug reactions, whereas only 53 (7 %) were classified as others. Drugs involved in the safety signals covered all ATC classes. In total, 778 ATC codes were assigned to the 752 safety signals. Of these, the three most frequent drug classes were antineoplastic and immunomodulating agents (ATC class L; 280 [36 %]), antiinfectives for systemic use (ATC class J; 123 [16 %]), and drugs affecting the nervous system (ATC class N; 108 [14 %]). The safety signal assessments resulted in 890 final PRAC recommendations, the most common being variations/ product information updates (303 [34 %]) and cumulative reviews in the upcoming Periodic Safety Update Report (PSUR) (301 [34 %]) followed by no regulatory action (151 [17 %]).

Conclusion: EU spontaneous reporting systems constituted the main source for the detection of safety signals in European pharmacovigilance. The affected drugs represented a heterogeneous spectrum, highlighting the importance of routine periodic monitoring of every marketed drug. For most safety signals, the PRAC recommended moderate regulatory actions, such as product information updates and systematic safety reviews in the next PSUR.

The Approval of the acupuncture law and the performance of the working group on traditional Chinese medicine and acupuncture of the federal council of pharmacy

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The regulation of acupuncture in Brazil constitutes one of the most complex scenarios in Sanitary Law and public health policy management. The debate centers on the nature of the practice: whether it is an exclusive medical act or a multiprofessional activity. In this conflict, the performance of the Federal Council of Pharmacy (CFF), through its Working Group (WG) on Traditional Chinese Medicine (TCM) and Acupuncture, has been fundamental to the technical-scientific and legal substantiation of the pharmaceutical acupuncturist's autonomy.

Legal Paradigm and the Defense of Multiprofessionalism The process of approving regulatory frameworks for acupuncture has faced decades of judicialization, especially following the enactment of Law No. 12.842/2013 (the "Medical Act Law"). The CFF, through its WG, played a strategic political role by maintaining that acupuncture—as

an ancient and transdisciplinary knowledge—is not restricted to medical nosological diagnosis. The group's actions were decisive in upholding specific regulations (such as CFF Resolution No. 516/2009), which establish the criteria for the exercise of the specialty by pharmacists, aligning with the guidelines of the World Health Organization (WHO).

Technical Attributes of the Working Group

The CFF's TCM and Acupuncture Working Group acts as a consultative and deliberative body aiming to:

Curricular Standardization: Defining postgraduate standards and minimum hourly requirements to ensure the pharmacist's clinical proficiency.

Sanitary and Clinical Safety: Establishing biosafety protocols and rigorous criteria for the application of needles and other associated techniques (moxibustion, cupping therapy), merging pharmacotherapeutic rigor with the logic of TCM.

Legislative Support: Producing technical notes and opinions that guide parliamentarians during the processing of bills, aiming to prevent the monopoly of the technique and guarantee the constitutional right to free professional exercise.

Impacts on Collective Health

The consolidation of pharmaceutical acupuncture, driven by the WG, is directly reflected in the expansion of Integrative and Complementary Practices (PICS) within the Unified Health System (SUS). The inclusion of the pharmaceutical acupuncturist increases resolutivity in primary care, offering effective alternatives for pain management and chronic disorders, reducing excessive dependence on synthetic drugs, and optimizing integral care.

Conclusion: In summary, the approval of legislation and standards that legitimize acupuncture in Brazil is inseparable from the institutional resistance of the CFF. The performance of the Working Group ensures that Traditional Chinese Medicine is practiced with academic rigor, ethics, and safety, consolidating the pharmacist as an essential agent in the promotion of public health and the democratization of access to high-efficacy complementary therapies.

Strengthening regulatory frameworks and professional capacity for clinical trials in Portuguese-speaking African Countries: progress of the CT-Luso project

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Background: Africa offers important opportunities for conducting clinical trials (CTs) due to its epidemiological and genetic diversity. However, only a very limited proportion of global clinical trials currently take place on the continent. Several barriers continue to hinder the development of CTs and the attraction of international research investment. These include regulatory gaps, fragmented ethical frameworks, limited training opportunities for professionals involved in research governance, linguistic barriers related to the scarcity of training and educational resources in Portuguese, and institutional constraints associated with less robust research and governance structures. These challenges need to be addressed to enable the sustainable development of clinical research capacity in the region.

Method: CT-Luso is a capacity-building project focused on clinical trials in Portuguese-speaking African countries (PSAC): Angola, Cape Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe, in partnership with Portugal. The project involves 24 institutions, including national regulatory authorities, ethics committees, research centres, and universities, and is funded by the Global Health EDCTP3 programme supported by the European Union. CT-Luso is structured into eight work packages (WP): coordination and management (WP1), scientific leadership (WP2), analysis of legislative gaps and recommendations (WP3), training programs (covering WP 4, 5, 6, and 7), and communication (WP8). The project addresses three complementary domains: legislative, institutional and professional. The work packages are designed to respond to these areas in an integrated manner.

Currently, activities related to the legislative and institutional domains are in advanced or near-completion stages, while the professional capacity-building component remains ongoing.

Results: The legislative and institutional mapping has been completed, including the analysis of legal frameworks in force or under development and of competent authorities responsible for clinical trials. This enabled the identification of key regulatory gaps and areas requiring alignment with international standards and informed the development of country-specific recommendations and a targeted roadmap with priority actions, currently underway. In parallel, the first interdisciplinary training programme was successfully implemented, with 234 professionals completing the course. Participants included ethics committee members, regulatory authorities, researchers, project managers, and academics from across the PSAC. More than 90% of participants achieved final grades of "Good" or higher and reported a positive impact on their professional activities.

Conclusion: These results demonstrate the strong demand for capacity-building initiatives and highlight the importance of combining legislative development with professional training to strengthen clinical trial ecosystems. By advancing regulatory analysis and successfully delivering a large-scale training programme, CT-Luso contributes to reinforcing ethical governance and promoting sustainable development of clinical research capacity in PSAC. Such initiatives are essential to foster more equitable global health research partnerships and to enable greater participation of African countries in international clinical trials.

Risk factors for medicine shortages in the Netherlands: a cross-sectional study of ten high-use pharmaceuticals

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Background: Medicine shortages are structural and increasing globally. They are mainly caused by manufacturing and quality issues in upstream supply chains.

Method: A cross-sectional study on medicinal products containing ten pharmaceutical substances with the highest number of outpatients in the Netherlands (July 2022). We identified the marketing authorisation holders (MAHs), finished pharmaceutical product (FFP) and active pharmaceutical ingredient (API) manufacturers, indicated the commercial availability and occurrence of shortages and mapped the upstream pharmaceutical supply chains. Each pharmaceutical substance was examined for the presence of cascading shortages. Commercially available products were analysed to identify differences in supply chains, economic, and product characteristics between products with and without shortages. Products with a shortage were compared according to the cause of the shortage being manufacturing issues versus increased demand.

Results: Of 407 authorised medicinal products, 216 were commercially available, of which 59 faced a shortage in the Netherlands. Most shortages were part of a cascade. Some pharmaceutical substances faced a meaningful decrease in supply, involving products with a cumulative market share of 39 to 95% and affected 25 to 100% of the MAHs with a commercially available product. Products with shortages more often had multiple FPP sources (51% vs. 27%, p = 0.001). Products with shortages due to manufacturing problems had multiple API manufacturers (79% vs. 54%; p = 0.034) and FPP manufacturing location in Europe (& other continents) (95% vs. 81%; p = 0.050). Products with shortages were more frequently subject to maximum pricing (58% vs. 39%, p =0.014), mainly driven by shortages due to manufacturing problems.

Conclusion: Effectively preventing and mitigating medicine shortages requires minimising risks on the micro-level of a product (such as sourcing and price policies) and on the macro-level of a substance (such as preventing cascading effects).

Development of an educational training curriculum for quality assurance signal Management in pharmaceutical regulatory sciences

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Background: The complexity of pharmaceutical regulatory environments necessitates progressive approaches to Quality Assurance (QA) that extend beyond procedural compliance and retrospective quality control. QA signals embedded within organisational quality records yield significant QA signals related to system performance, best practices, emerging challenges, and operational dynamics. Yet, to date, structured educational resources and competency-based training frameworks supporting QA signal management remain underdeveloped. This study addresses the identified gap through the development and validation of a specialised

educational training curriculum presented in the format of an Educational Training Information Leaflet (ETIL). The initiative aims at cultivating a culture of continuous learning and a competency-based approach to strengthening expertise in the specified and emerging science.

Method: In response to the limited availability of expertise within the specific research area, a training needs assessment form (TNAF) was developed and duly completed by the researcher, based on preceding methodological insights. The TNAF facilitated an understanding of the knowledge and competencies required to identify, develop, and pursue professional development opportunities. The TNAF informed the design and development of the training topics by establishing the corresponding (i) prospective titles, (ii) target audience, (iii) descriptions, (iv) aims, (v) objectives and main content, (vi) learning outcomes categorised as knowledge, skills and competences, (vi) learning formats, and (vii) assessment methods. The ETIL criteria were subjected to a two-round content validation assessment through a structured expert focus group (N=7) consultation. Iterative refinements led to the development of the consolidated framework.

Results: A technical training curriculum was designed and developed as a consolidated ETIL. The leaflet emerged as a pedagogical tool focusing on a target audience proficient in quality management systems and actively engaged in quality management activities. The premeditated technical curriculum streamlined the conceptual, methodological, and practical operational dimensions of QA signal management. The approach undertaken equipped professionals with the proficient capability to keep abreast of evolving trends, best practices and challenges within the specialised niche of QA signal management in pharmaceutical regulatory sciences. The technical curriculum structure was segmented into three topics to effectively translate the complex of analytical frameworks, operational tools, and the emergent signalomics terminology. Indeed, Topic I focused on the contextual sources of quality assurance signals in pharmaceutical regulatory sciences; Topic II focused on the application of the Quality Assurance Signal Analytics Framework (QASAF) and on the introduction of novel terminological constructs; and Topic III focused on the practical-orientated understanding of the application of the User Guidance document for the QASAF and the Work Instruction Manual for the Quality Assurance Signal Optimisation Cycle.

Conclusion: The ETIL holds an innovative educational intervention potential, as it supports competency development in QA signal management within pharmaceutical regulatory sciences. Through the integration of analytical frameworks, operational tools, and structured terminology, the curriculum stimulates scientific knowledge dissemination, methodological consistency, and organisational QA intellect. It is aspired that such an initiative serves to strengthen professional capacity-building and sustain systematic implementation of QA signal management as a proactive, intelligence-driven component of regulatory quality systems in dynamic healthcare and medical technology environments.