

~~support healthcare professionals embarking on participating in clinical trials by serving as a resource that identifies stakeholders which are able to offer funding, facilities like medical clinics, and services like laboratory services. The rationale for aspects in the new EU legislation regulating clinical trials intended to ensure patient safety are highlighted so that healthcare professionals are empowered to navigate the process through proper management and good governance.~~

## Regulation of food supplements

Isaac Yakubu Akogu<sup>1</sup>, Anthony Serracino Inglott<sup>1</sup>

<sup>1</sup>Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

**Introduction:** Food supplements, which deliver essential nutrients like vitamins, minerals, and probiotics, face inconsistent global regulation. Jurisdictions classify them differently—some as pharmaceuticals (requiring rigorous safety evaluations) and others as food products (with laxer standards). These disparities in definitions, labeling, analytical methods, and oversight create challenges for market access, consumer trust, and safety. Harmonizing regulations is critical to address these gaps and ensure efficacy, safety, and transparency.

This study evaluates global regulatory frameworks for food supplements to identify inconsistencies and propose strategies for harmonization. It addresses the lack of a universal definition and examines how divergent approaches (e.g. pharmaceutical-grade standards vs. flexible food regulations) impact safety assessments, labeling accuracy, and consumer confidence.

**Method:** A systematic review followed the PRISMA framework, analysing peer-reviewed literature, policy documents, and industry reports from PubMed and Google Scholar (2013–2023). Inclusion criteria focused on studies addressing regulations, safety, or harmonization. Thematic analysis identified trends in regional regulatory approaches.

**Results:** Key findings illustrate clear divides across jurisdictions EU and Canada prioritize safety via precautionary principles, enforcing strict manufacturing controls and pre-market approvals. US and Asia favour market accessibility, permitting supplements with minimal oversight if labeled correctly. While medicines and medical devices are regulated by established statutory bodies such as the European Medicines Agency in Europe, food supplements are regulated haphazardly. The Food Drug Agency in the US takes a more pragmatic approach. Community pharmacists are in a position to guide patients in rationale and appropriate informed selection of food supplements.

**Conclusion:** Global regulatory misalignment in food supplement oversight undermines equity. This study advocates for harmonized standards to balance precautionary safeguards with market flexibility. Collaboration among policymakers, industry leaders, and health authorities is critical to establish unified definitions, testing protocols, and labeling requirements. Such alignment would enhance consumer protection, reduce disparities, and support sustainable market growth. While challenges like jurisdictional resistance persist, cohesive international efforts can bridge gaps, ensuring supplements meet consistent safety benchmarks without stifling accessibility or innovation.

## Extended stability evaluation of dexrazoxane solutions: implications for prolonged clinical administration

Dong Wang<sup>1</sup>, Lifeng Han<sup>2</sup>, Mengrong Li<sup>1</sup>

<sup>1</sup>Tianjin Cancer Hospital Airport Hospital, Tianjin, China

<sup>2</sup>Instrumental analysis & Research Center, Tianjin University of Traditional Chinese Medicine, Tianjin, China

**Introduction:** Dexrazoxane, a cardioprotective adjunct in oncology, is clinically employed to mitigate anthracycline-induced cardiotoxicity. Currently, five manufacturers have obtained regulatory approval for dexrazoxane injections in China. However, stringent usage window ( $\leq 4$  hour, diluted in sodium lactate Ringer's solution or 0.9% NaCl) imposes significant operational constraints. This limitation persists despite centralized preparation through Pharmacy Intravenous Admixture Services (PIVAS), necessitating evidence-based protocol revisions. This study combines physicochemical properties with pharmacokinetic parameters to systematically evaluate the stability of dexrazoxane solution, and establish scientific rationale for extending clinical usage windows.

**Methods:** Dexrazoxane solutions were prepared according to manufacturer guidelines and stored in infusion bags under two conditions: ambient temperature ( $25 \pm 2$  °C) and refrigeration ( $4 \pm 2$  °C) for 24 hours. Throughout the observation period, solutions were monitored for changes in appearance, pH, particulate matter, and concentration using visual inspection, a pH meter, a particle analyzer, and high-performance liquid chromatography at various intervals. Triplicate samples were analyzed to ensure statistical robustness. A liquid chromatography-tandem mass spectrometry method was established to quantify dexrazoxane and doxorubicin in plasma. Pharmacokinetic parameters were compared in Sprague-Dawley rats ( $n=6$ ) administered fresh versus 12-hour refrigerated dexrazoxane solutions, combined with doxorubicin at clinically translatable doses.