

Harmonizing Diclofenac Regulation: A Call to Protect Public Health

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Description

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) have long played a crucial role in managing pain, inflammation, and fever, with diclofenac standing out as a widely used option. However, recent revelations about its safety profile necessitate a meticulous examination of the global regulatory landscape and the implementation of proactive measures to safeguard public health [1]. Diclofenac, classified as a non-selective NSAID, has been a mainstay in managing various inflammatory conditions due to its potent analgesic and anti-inflammatory properties. Its ubiquity is reflected in its availability, with prescription-only status in the USA and over-the-counter accessibility in certain countries, albeit at a lower 25 mg dose [2].

Despite its proven efficacy, diclofenac is not without its drawbacks. Well-documented side effects, including gastrointestinal bleeding and cardiovascular complications, have prompted recent studies that call for a reassessment of its safety profile. These findings raise pertinent questions about the adequacy of existing regulatory measures, signaling the need for a comprehensive examination to ensure patient safety [3,4]. Beyond concerns related to cardiovascular issues, experimental studies conducted on both *ex vivo* and *in vivo* models have consistently demonstrated the nephrotoxic effects of diclofenac. In human populations, prolonged and chronic usage of diclofenac has been linked to a heightened risk of Acute Kidney Injury (AKI), particularly evident in both the general population and those with Chronic Kidney Disease (CKD) [5,6].

Administration of Diclofenac (DCF) substantially elevated serum urea, creatinine, KIM-1, TNF- α , NF- κ B, and malondialdehyde levels. This heightened oxidative stress within renal tissue has the potential to adversely influence mitochondrial structure and function, leading to disruptions in antioxidant mechanisms, heightened inflammatory mediator production, histopathological alterations, cellular dysfunction, apoptosis, and ultimately, nephrotoxicity [7]. A meta-analysis showed that rofecoxib, etoricoxib, and diclofenac exhibited consistently elevated Cardiovascular Risks (RRs) compared to naproxen [8]. This association underscores the potential renal risks posed by sustained diclofenac use, emphasizing the importance of considering these findings in the context of human health.

The global regulatory landscape for diclofenac is intricate, marked by disparities in formulations and regulatory statuses. While the USA confines diclofenac to prescription-only status, other nations permit over-the-counter access. This divergence in regulatory approaches creates a complex and varied landscape of patient exposure and

regulatory standards, necessitating a harmonized global strategy. The recent suspension of diclofenac potassium 75 mg and 100 mg registrations by the Drug Regulatory Authority of Pakistan (DRAP) is a noteworthy regulatory response to concerns raised by the World Health Organization (WHO). This proactive step exemplifies a localized initiative to safeguard public health. However, achieving a global consensus on diclofenac's regulation remains a complex challenge that requires collaborative efforts among international regulatory bodies [9,10].

Addressing diclofenac's safety concerns demands immediate international collaboration and harmonization of regulatory standards. Swift actions should include the permanent suspension of manufacturing and importation of higher-strength diclofenac formulations. Simultaneously, a prompt withdrawal of existing stocks is imperative to prevent inadvertent exposure and potential harm to patients. A transparent and rigorous re-consider of diclofenac's safety profile is warranted. Collaborating with international experts, healthcare professionals, and pharmaceutical manufacturers will ensure that regulatory decisions are evidence-based and reflect a collective understanding of the risks and benefits associated with diclofenac use. A proactive public awareness campaign is pivotal to educating healthcare professionals and the public about the potential risks of diclofenac. Clear guidelines on the safe use of lower-strength formulations should be disseminated, empowering both prescribers and consumers to make informed decisions that prioritize patient safety.

Diclofenac's safety conundrum demands a comprehensive, global approach that involves regulatory harmonization, proactive measures, and robust public awareness initiatives. By recalibrating regulatory standards based on evolving evidence, implementing immediate actions, and prioritizing public education, the global healthcare community can effectively navigate the complexities of diclofenac's safety profile, ensuring the highest standards of safety and efficacy for patients worldwide.

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