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Review Article

A COMPARATIVE REVIEW OF HUMAN AND VETERINARY GENERIC DRUG APPROVAL SYSTEMS

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ABSTRACT

This review compares human and veterinary generics' regulatory regimes with respect to applicable similarities and differences between approval processes, dossier presentation, bioequivalence (BE) test protocols, and post-marketing control. Therapeutic equivalence is the aim of both industries, albeit under a regulatory regime, and there are enormous disparities in BE protocols, pharmacovigilance schemes, and ethical requirements. These differences lead to inefficiencies, cost increases in drug development, and potential negative effects on animal and human health, specifically antimicrobial resistance (AMR), and off-labeling. Global issues of new nature, including implications on AMR, controversy of data exclusivity, and animal welfare in clinical trials, are highlighted by the review. Efforts at harmonizing endeavors, for instance, through the International Council for Harmonisation and the veterinary international conference on harmonization, are framed as filling the regulation gap. They urge an international concerted effort to align intellectual property rights with the interests of public health and animal welfare, with prudent use of antimicrobials, in addition to promoting the one health approach.

Keywords: Generic drugs, Regulatory framework, Harmonization, Veterinary medicine, Human medicine, Bioequivalence, Pharmacovigilance, Antimicrobial resistance, One Health, Data exclusivity, Animal welfare.

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INTRODUCTION

Generic medicines are a mainstay of modern health-care systems by offering affordable alternatives for the innovator (brand-name) drugs, thereby enhancing access to required treatments [1,2]. These drugs are made to be bioequivalent to their comparator drugs in quality, safety, and efficacy, but usually, the generic versions are introduced into the market after the patent covering or the exclusivity rights of the originator products have lapsed [3]. The generics phenomenon has reduced the price of treatment in human and animal medicine by a significant amount, promoting widespread use in high-, middle-, and low-income nations [4,5].

In human pharmaceuticals, generic drug control and approval have evolved significantly in recent decades, spurred by international standards and harmonized processes through organizations such as the International Council for Harmonization (ICH) [6]. On the other hand, veterinary generics, though rooted in the same scientific logic, fall under more scattered regulatory control, often modified by species-related pharmacoparametric profiles, food safety, and environmental considerations [6]. Regulatory pathways such as human abbreviated new drug application (ANDA) and animal abbreviated new animal drug application (ANADA) highlight the structured divergence within dossier format, filing procedures, and post-approval regulations [7,8].

Despite the common goal of providing therapeutic equivalence, the animal and human pharmaceutical industries diverge dramatically in terms of regulation systems, bioequivalence (BE) testing strategies, pharmacovigilance systems, and labeling schemes [9]. Such divergences have the potential to yield inefficiencies, longer development periods, and greater manufacturer costs [10]. Compounding the issues is the challenge of antimicrobial resistance (AMR), off-label use, and ethical concerns regarding trial conduct, which add complexity to the approval process, most notably for veterinary generics [10].

This review contrasts critically the regulatory regimes for human and veterinary generic drugs, comparing and contrasting the routes to approval, dossier requirements, methods of BE, and mechanisms of post-market monitoring. It also touches on future international challenges – such as AMR, data exclusivity, and One Health requirement – that underscore the necessity for harmonization. By highlighting key differences, ethical issues, and the impact of digital innovations, this review aims to guide policy development and promote a more coordinated, internationally harmonized regulation of generic drugs across human and veterinary sectors.

FOUNDATIONS OF GENERIC DRUG APPROVAL

Generic drugs are drug products that are intended to be therapeutically similar to innovator (reference) drugs in terms of quality, safety, and efficacy. They have the same active ingredient, dosage form, route of administration, and strength as the branded equivalent but are sold following the patent and exclusivity right expiration [11]. They are mainly manufactured to reduce the cost of health care while offering an equivalent therapeutic benefit to patients and animals [11]. Both human and animal medicine benefit from generics by enhancing access to treatment without requiring the sponsor to replicate large clinical trials conducted by the originator [12].

One of the key regulatory requirements for generic approval is the demonstration of BE, the absence of clinically significant differences in the rate and extent to which the active ingredient is delivered to the site of action when administered under similar conditions [13]. In human generics, BE is usually established from pharmacokinetic (PK) assessments of area under the curve (AUC) and peak concentration (Cmax) between test and reference products [14]. For veterinary generics, BE determination could be species and formulation-dependent, which often requires *in vivo* testing in the target species or use of surrogate models [15]. Therapeutic equivalence also guarantees that the generic will produce the same clinical effect and safety profile when taken as directed by the label.

Despite the common scientific foundations, generic drug approval procedures differ between and within jurisdictions and between the

veterinary and human markets. These differences lead to inefficiencies, result in duplication of effort, and postpone market entry [16]. A global shift towards harmonization, such as through initiatives such as the ICH for human pharmaceuticals and the veterinary international conference on harmonization (VICH) for veterinary medicines, seeks to harmonize data submission requirements, BE testing protocols, and dossier format [17,18]. Alignment is not yet achieved, and coordinated regulatory systems that promote innovation, eliminate redundancy, and accelerate safe access to generics across species and geographies are a pressing need.

REGULATORY ARCHITECTURE: GLOBAL SNAPSHOTS

National and international regulatory bodies regulate generic drug approval and place some standards on dossier submission, BE testing, labeling, and pharmacovigilance. There are shared principles, but wide variations in the procedures, particularly between human and veterinary medicine (Tables 1 and 2).

APPROVAL PATHS: VETERINARY VERSUS HUMAN

Regulatory approval routes for generic medicines in human and veterinary medicine, while grounded on similar principles of BE and quality control, differ significantly in regulatory strategies, dossier organization, and post-approval controls. These differences are valuable information to scientists who manage both domains and policymakers interested in simplifying the efficiency of regulation without compromising safety and efficacy [39].

Submission requirements and dossier structure (ANDA vs. generic investigational new animal drug [JINAD]/ANADA)

In human drugs in the US, approval of generic drugs is predominantly controlled under the ANDA pathway by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research [19]. The filing allows applicants to be able to use safety and efficacy established data of the reference listed drug, but only where they can establish BE and pharmaceutical equivalence [40]. The dossier is in the format of a common technical document (CTD) and comprises modules for administrative information, quality, non-clinical overviews, and BE studies [41].

In animal drugs, the U.S. parallel regulatory system is the ANADA under the guidance of the FDA's Center for Veterinary Medicine (CVM) [20]. For study drugs, a JINAD file is established to allow pre-application consultation and submission of information [42]. While the ANADA process similarly relies on BE and waived safety/efficacy testing, the form tends to encompass additional target animal safety, species-specific PKs, and environmental specifications in food-producing species [43]. The international generic veterinary dossier form is less well standardized with some regional variations to data requirements and form (e.g., has Part I-IV format by Committee for Veterinary Medicinal Products [CVMP] within the European Union [EU]) (Table 3).

BE protocols and waiver conditions

Bioequivalence (BE) continues to be the foundation for generic drug approval in both markets, but methodology and waiver conditions differ. BE in human pharmaceuticals is most often established through comparative pharmacokinetic (PK) studies quantifying parameters such as AUC and Cmax in healthy subjects [44,45]. Waivers, more familiarly termed as biowaivers, are available for selected Biopharmaceutics Classification System Class I and III products, or selected dosage forms such as oral solutions [46].

In veterinary genetics, BE studies should be adjusted to address interspecies differences, and frequently, trials should be conducted in the species of interest. For example, systemic exposure in a cow could vary significantly from that in a pig or poultry and may demand specific study designs [47]. The FDA-CVM and the European Medicines Agency's-CVMP outline clear guidance regarding when *in vivo* BE studies can be waived, i.e., in the case of topical or parenteral solutions having the same excipients and concentration. Yet, in food-producing animals, further requirements such as residue depletion studies and withdrawal time validation are required, which complicates the waiver process [20,24].

Differences in pharmacovigilance expectations

Post-marketing safety surveillance (pharmacovigilance) grows stronger in both arenas but with variable structures. The manufacturers of human generics are required to set up pharmacovigilance systems in accordance with ICH E2E guidance and report Adverse Events through central databases such as the FDA Adverse Event Reporting System [48]. Generic sponsors are

Table 1: Comparative overview of regulatory authorities for generic drug approvals

Region	Authority (human drugs)	Authority (veterinary drugs)	Approval pathway	Bioequivalence requirement	Dossier format	Harmonization frameworks
USA	USFDA-CDER [19]	USFDA-CVM [20]	ANDA (505[j]) [21]	*In vivo* or waiver (BCS class I/III) [22]	CTD	ICH (human), VICH (vet)
EU	EMA-CHMP/ National Agencies [23]	EMA-CVMP/ National agencies [24]	Centralised/DCP/ MRP/National [25]	BE+*in vitro* dissolution [26]	eCTD	ICH (human), VICH (vet)
India	CDSCO (DCGI) [27]	DAHD/CDSCO (limited veterinary oversight) [28]	Abbreviated NDA/ Form 44 [29]	BE with PK data in humans/ animal studies (case-wise) [30]	CTD-like (Schedule Y)	No formal VICH adherence
Japan	PMDA [31]	MAFF [32]	Generic Approval (Japan NDA) [33]	Required; exemptions for certain generics [34]	Japanese CTD	ICH (human), VICH (vet)
Australia	TGA [35]	APVMA [36]	Generic Pathway/ Streamlined Assessments [37]	BE essential (*in vitro*/ *in vivo*) [38]	eCTD/ modular format	ICH and VICH
WHO (global guidance)	WHO pre-qualification	Not primary vet regulator, offers guidance	Not directly involved in national approvals	Biowaiver allowed (based on BCS, comparator)	WHO-CTD	WHO TRS guidance adopted globally

ANDA: Abbreviated new drug application, ICH: International Council for Harmonization, VICH: Veterinary International Conference on Harmonization, CVMP: Committee for Veterinary Medicinal Products, eCTD: Common Technical Document, TGA: Therapeutic Goods Administration, WHO: World Health Organization

Table 2: Visual matrix of regulatory alignment in human and veterinary generic drug approvals across key jurisdictions

Criteria	USFDA	EMA	India	Japan	Australia
Bioequivalence rigor	□ High	□ High	□ Medium	□ High	□ High
Veterinary regulatory maturity	□ High	□ High	□ Low	□ Moderate	□ High
Dossier format uniformity	□ High	□ High	□ Moderate	□ High	□ High
Harmonization (ICH/VICH)	□ Full	□ Full	□ Partial	□ Full	□ Full
Species-specific BE approach	□ Applied	□ Applied	□ Inconsistent	□ Applied	□ Applied

Legend: □: Fully aligned □: Partially aligned □: Not aligned

Table 3: Comparative overview of regulatory pathways for human and veterinary generics

Aspect	Human generics	Veterinary generics
Pathway (USFDA)	Abbreviated new drug application under section 505(j) of the FD and C Act [21]	Generic Investigational New Animal Drug followed by Abbreviated New Animal Drug Application
Core requirements	Bioequivalence, CMC data, labeling, patent certifications (Orange Book) [30]	Target animal safety, effectiveness data (when required), manufacturing data, and bioequivalence
Dossier format	CTD/eCTD (5 modules) [30]	Modified CTD or country-specific veterinary format
Regulatory oversight (India)	CDSCO, Schedule Y guidelines, Form 44 submission [27]	No standardized pathway; approval through DAHD or state-level boards; emerging alignment under CDSCO

Table 4: Labeling and packaging distinctions between human and veterinary drugs

Feature	Human drugs [19]	Veterinary drugs [20]
Labeling language	Must match RLD; patient-friendly inserts required	Often includes veterinary-specific precautions, withdrawal times (food animals)
Packaging	Must comply with tamper-evident and child-resistant norms	May vary by species and application method (oral, topical, and injectable)
Special disclosures	Pregnancy categories, excipient details, contraindications	Species-specific dosing, meat/milk withdrawal periods, and AMR warnings
Color coding/logos	Common branding regulations apply	May include symbols like "Not for Human Use" or "Prescription Animal Remedy"

obligated to keep identical labeling revisions and risk management mechanisms as the original innovator.

Pharmacovigilance is relatively less developed in veterinary medicine. The U.S. adverse drug experience reporting system receives voluntary and mandatory reports, but coverage of data is usually limited [48]. The EU's EudraVigilance Veterinary system is more mature, with periodic safety update reports even for generic products. Furthermore, variability of species, underreporting by field veterinarians, and absence of standardized causality assessment instruments present substantial challenges to signal detection and risk management [49] (Table 4).

CASE STUDIES (TABLE 5)

Real-world regulatory experiences with generic drug approvals reveal critical success factors and pitfalls across both human and veterinary sectors. For instance, a generic version of ciprofloxacin received FDA approval after successfully demonstrating bioequivalence to the reference product through pharmacokinetic studies. This facilitated broader access and cost savings, emphasizing the importance of strong bioequivalence data, early engagement with regulators, and vigilant post-marketing surveillance to monitor resistance trends [50].

In the veterinary domain, generic ivermectin for cattle gained EMA approval by providing comprehensive data on bioequivalence, target species safety, and environmental impact. This case underlined the need for thorough environmental risk assessments and species-specific safety documentation. It also highlighted how harmonized regulatory frameworks can ease international market entry [51].

Conversely, some applications failed to meet approval criteria. A generic linezolid product was rejected by the FDA due to inconsistent plasma concentration results that questioned its therapeutic equivalence. The case demonstrated that even small formulation differences could affect drug absorption, and underscored the necessity of optimizing formulations before submission [52].

Similarly, a generic fenbendazole product for dogs was denied approval by the FDA-CVM. The rejection was based on inadequate stability data, failure to show bioequivalence, and non-compliance with Good Manufacturing Practice (GMP) standards. This case illustrates the essential role of robust manufacturing documentation and the importance of early GMP compliance audits in ensuring regulatory success [53] [Table 5].

EMERGING CHALLENGES AND ETHICAL INTERSECTIONS

With generic drug development progressing in human and veterinary medicine, it faces an increasing number of scientific, regulatory, and ethical challenges. These new challenges cut across conventional regulatory boundaries, frequently taking place in controversial areas that intersect with public health, legal safeguards, and animal welfare. Resolving these intersections is essential to maintaining generic approval pathways as effective and ethically robust.

AMR implications

One of the most urgent international issues is the contribution of generic antimicrobials to the dissemination of AMR. Both in human and veterinary medicine, the widespread and frequently uncontrolled use of generic antibiotics have been associated with greater selection pressure, which has helped spread resistant strains [54]. In animal practice, particularly in food animals, generics tend to be applied prophylactically or as growth promoters, increasing the risk of cross-species transmission of resistant organisms [55]. International guidelines such as the World Health Organization (WHO) Global Action Plan on AMR call for stewardship and responsible use, yet generic markets in low- and middle-income countries tend to operate with little pharmacovigilance and weak prescription control. Therefore,

Table 5: Regulatory case studies on generic drug approvals and rejections: Insights from human and veterinary sectors

Case study	Drug	Regulatory outcome	Snapshot	Lessons learned
Generic antibiotic (human) [50]	Generic ciprofloxacin	Approved (FDA)	Demonstrated bioequivalence to branded Cipro through pharmacokinetic studies; approval enabled wider access and cost reduction.	Robust bioequivalence data are critical. Early regulatory engagement streamlines approval. Post-marketing surveillance is important for resistance monitoring.
Veterinary antiparasitic [51]	Generic ivermectin (Cattle)	Approved (EMA)	Submitted bioequivalence, safety, and environmental impact data; EMA confirmed efficacy, safety, and environmental safety.	Environmental risk assessments are essential. Safety for target species and food residues must be documented. Regulatory harmonization aids market access.
Generic antibiotic rejection [52]	Generic linezolid	Rejected (FDA)	Failed to demonstrate bioequivalence due to inconsistent plasma concentration profiles, raising therapeutic equivalence concerns.	Strict bioequivalence criteria must be met. Formulation differences affect absorption. Formulation optimization before submission is crucial.
Veterinary Antiparasitic Rejection [53]	Generic fenbendazole (Dogs)	Rejected (FDA-CVM)	Inadequate stability data and bioequivalence demonstration; the manufacturing process did not meet GMP standards.	Stability and manufacturing quality are critical. Comprehensive manufacturing documentation is required. Early GMP compliance audits prevent delays.

FDA: Food and drug administration, EMA: European medicines agency, CVM: Center for veterinary medicine

AMR not only challenges the clinical appropriateness of generics but also reveals regulatory vulnerabilities in post-marketing surveillance and enforcement in both industries [54].

Off-label use and species-cross prescribing

Off-label use of human generics (more so in the veterinary field) is a complicated, under-regulated practice. In the absence of species-specific generics, veterinarians tend to give human generics to animals, and more so exotic or companion species. This practice, although occasionally clinically indicated, is hazardous, with possible inaccuracies in dosing, unexpected side effects, and absence of proven withdrawal times in food-producing animals. Off-label generic use in human medicine occurs less frequently but is not unknown, especially in children and older people, where trial data may be unobtainable. Regulatory authorities generally have no clear, enforceable guidelines for tracking or limiting off-label use, particularly in the veterinary setting, where evidence generation is more difficult. Such practices make it harder to guarantee drug safety, traceability, and efficacy, and they require regulatory creativity to reduce risks while maintaining therapeutic flexibility [55,56].

Data exclusivity and patent linkage: Conflict zones

Data exclusivity and patent linkage are also highly controversial issues in the generic drug approval environment, especially in finding the right balance between innovation and access. In the human pharmaceutical industry, data exclusivity (typically lasting 5 to 10 years) can delay the entry of generics even after patent expiry. In contrast, the veterinary sector often lacks clearly defined data protection rules, leading to uncertainty for manufacturers and inconsistent enforcement across markets [56]. In the veterinary field, similar protections are not usually well established and hence result in uncertainty for manufacturers and varying enforcement across markets [56]. Patent linkage (where a regulatory agency must verify the patent status before approving a generic) further complicates timelines, especially in countries without robust patent dispute resolution mechanisms. While intended to incentivize innovation, these legal constructs can delay the entry of cost-effective generics and restrict market competition. In both fields, there is an urgent necessity to strike a balance between public health needs and intellectual property rights, especially with the international drive to enhance medicine affordability and access [57,58].

Animal welfare issues in trials versus human subject protection

Ethical control of clinical trials varies significantly between human and animal medicine, creating vital questions on the issue of equality in protection levels. In human generics, BE studies are subject to rigorous ethical regulations, such as informed consent, institutional review boards, and compliance with the Declaration of Helsinki [59]. In contrast, veterinary generic trials, especially residue depletion and target animal safety studies, have little or no harmonized welfare requirements, particularly in non-VICH nations [60]. The practice of using large animal numbers, often in the absence of adequate analgesia or long-term maintenance, has drawn increasing attention from animal welfare organizations. Where good laboratory practice regulations hold, enforcement of humane endpoints and ethical oversight is still patchy. Furthermore, failure to have a global veterinary clinical trial registry reflects inadequacies in transparency and accountability [61]. Closing the ethical gap between human and veterinary trial protocols is important to guarantee that approval procedures for generics are not only scientifically sound but also ethically justifiable.

HARMONIZATION AND DIVERGENCE: A REGULATORY DILEMMA

The more globalized character of the pharmaceutical supply chain and the expanded interdependence of human and veterinary medicine (most notably under the One Health model) have made regulatory harmonization a focal concern. Despite significant efforts at convergence, there remain substantial divergences between the human and veterinary regulatory environments. Whether and to what extent harmonizing approval processes for generics in each sector is possible or necessary relies on a range of factors such as species-specific safety profiles, therapeutic objectives' differences, and market access

Table 6: Comparative overview of ICH and VICH regulatory frameworks

Parameter	ICH (human) [6]	VICH (veterinary) [7]
Established	1990	1996
Participants	EU, USA, Japan+Global Observers	EU, USA, Japan (OIE as observer)
Focus	Quality, Safety, Efficacy, and Multidisciplinary (e.g., M4 CTD)	Quality, Safety, Efficacy, and PV
Implementation	Strong global uptake	Limited to a few regions
Regulatory binding	Adopted in legislation or regulation	Often remains guidance
Digital infrastructure	CTD/eCTD standards	No universal digital dossier system yet

imperatives [62].

Are convergence efforts biologically possible and required?

Regulatory standard convergence efforts between generic drug approvals for human and veterinary species are hindered by scientific as well as practical issues. Diversity of the species, metabolic pathway differences, and the alternative goals of treatment interventions (such as veterinary medicine's food safety versus therapeutic effectiveness per individual human) render biologic convergence in its entirety a complicated process [63]. Yet, partial harmonization is not just possible but necessary, particularly with regard to dossier organization, BE approaches, good manufacturing practice, and post-marketing monitoring [64]. The growing danger of AMR, fueled by antibiotic misuse in both industries, requires harmonized risk reduction measures. Further, for global regulators and manufacturers, harmonization can minimize duplication, facilitate streamlined dossier reviews, facilitate quicker market entry, and ensure continued product safety and efficacy [65].

VICH

The VICH is a trilateral initiative launched in 1996 by the EU, the United States of America, and Japan, in association with industry partners [66]. VICH seeks to establish harmonized technical specifications for veterinary medicinal products in terms of quality, safety, and efficacy. A number of guidelines produced under VICH (e.g., VICH GL52 [pharmacovigilance systems] and VICH GL27 [BE]) act as international points of reference for regulators [67]. These guidelines increase predictability in submissions and decrease the necessity of duplicate studies. Nevertheless, the scope of VICH is still geographically limited, with most low- and middle-income nations having indirect representation in the guideline-making process. Moreover, VICH documents are advisory and not legally binding, which restricts their enforceability and uniformity across jurisdictions [67].

ICH versus VICH-Similarities and disconnects (Table 6)

The International Council for Harmonisation (ICH) and the Veterinary International Conference on Harmonization (VICH) share similar goals but differ substantially in their scope, impact, and implementation across global regulatory environments.

ICH, established in 1990, involves regulatory authorities and industry from the EU, USA, and Japan, along with global observers. It focuses on the harmonization of quality, safety, efficacy, and multidisciplinary topics such as the Common Technical Document (CTD) and its electronic counterpart (eCTD). ICH guidelines have been widely adopted and integrated into national regulations, giving them strong regulatory binding and global uptake [6].

On the other hand, VICH, established in 1996 with the EU, USA, and Japan as core members and the OIE (World Organisation for Animal Health) as an observer, aims to harmonize regulatory requirements for veterinary medicinal products. VICH covers areas of quality, safety, efficacy, and pharmacovigilance (PV). However, its guidelines often remain non-binding and are adopted inconsistently, mainly limited to a few regions. Unlike ICH, VICH lacks a universal digital submission framework, which presents a significant gap in regulatory efficiency for veterinary products [7].

This contrast highlights the need for expanding the reach of VICH, improving digital infrastructure, and strengthening legal enforceability to parallel the success of ICH in human pharmaceuticals [Table 6].

Need for a harmonized digital submission system

One of the major obstacles in veterinary generic drug approvals is the absence of a standardized digital submission system, such as the eCTD platform commonly used in human medicine. A unified digital platform for veterinary medicines can standardize application forms, enhance cross-border data transfer, and support integrated pharmacovigilance reporting. Such a system would be particularly beneficial for multinational regulators and producers with large volumes of generic applications to manage. Elements of the proposed digital system would include modular templates specifically tailored for species-specific data, in-built tools for withdrawal period and residue limit reviews, and safety monitoring dashboards all in one location. The absence of such infrastructure is to blame for regulatory inefficiencies, redundant evaluations, and delays in entering the market. Developing a veterinary CTD model consistent with VICH principles but driven by ICH's digital advancements could greatly enhance regulatory harmony and capacity development in developed and developing areas.

FUTURE TRENDS: TOWARD A HOLISTIC APPROVAL LANDSCAPE

Regulation of generic drugs is evolving rapidly with the emergence of technology acceleration, evidence-based policy, and the building of integrated health paradigms such as One Health [68]. Problem alliances shared more broadly by human and veterinary disciplines (antibiotic resistance [AMR], regulatory complexity, and expedited approvals) drive convergence and innovation. Regulatory inspection is being transformed using artificial intelligence that is facilitating computerized dossier screening, PK prediction, and pharmacovigilance streamlining as ongoing endeavors in the industry [69]. E-labeling is being rapidly implemented in all over the globe since real-time dynamic product information facilitates enhanced access to current advice, with post-market surveillance and safety bolstered by real-world evidence (RWE) from integrated electronic and smart vet equipment records [70]. One Health promotes synergistic collaboration between sectors of human, animal, and environmental health with coordinated AMR programs, shared pharmacovigilance infrastructure, and harmonized public health practices, as promoted by WHO, Food and Agriculture Organization, World Organization for Animal Health, and United Nations Environment Programme [71]. As a global leader in generic human pharma, India can expand its veterinary pharma presence based on its manufacturing base, education network, and digital health competencies. To realize this potential, India must establish a centralized veterinary drug regulatory authority, apply CTD-based approvals with the same criteria, and bring in integrated, multispecies pharmacovigilance systems. With modernized regulation, multisector cooperation, and investment in research, India can emerge as the world leader in human as well as veterinary generics [69].

CONCLUSION

The regulatory regime behind generic medicines captures a multi-faceted equilibrium of harmonization efforts and sectoral divergences within and across human and veterinary medicine. Even as both industries overlap in the final imperative of offering safe, efficacious, and low-cost drugs, they dramatically diverge with regard to the design of regulation, paths of approval, BE regimes, pharmacovigilance, and

ethical control. These divergences engender inefficiencies, increase the cost of development, and represent risks to human and animal health, particularly AMR and off-label prescribing.

These challenges have to be addressed through a global-consistent strategy harmonizing intellectual property rights with public health concerns and animal welfare. Harmonization programs, such as those undertaken by the ICH and VICH, need to be stepped up and expanded evenly. In addition, the establishment of accurate, enforceable guidelines for off-label drug administration, robust pharmacovigilance systems, and ethical standards for animal trials are unavoidable. By closing the regulatory gap, we can maximize generic drug development, ensure therapeutic equivalence, and encourage proper antimicrobial use across species, ultimately advancing the One Health agenda.

AUTHOR'S CONTRIBUTIONS

- Karthikesavan Ponmurugesan: Literature review, data collection, and initial manuscript drafting.
- Vivek Reddy Murthannagari (Corresponding Author): Conceptualization, supervision, critical revision of the manuscript, and final approval.
- Hemalatha Devaraj: Support in literature analysis and formatting.
- Jeswanth Raj Nagarajan: Assistance in comparative table design and referencing.
- Dr. GNK Ganesh: Technical guidance, review, and manuscript structuring.

CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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