ORIGINAL ARTICLE

Judicial Medicine: How the Ivermectin Ruling Redefined Doctors' Responsibilities in Drug Governance

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ABSTRACT

INTRODUCTION: Ivermectin, a tropical medicine recognised with the 2015 Nobel Prize, is safe at approved doses but in Malaysia remains registered solely for veterinary use under the Poisons Act, raising complex legal and regulatory issues when dispensed to humans. This paper critically analyses the Federal Court decision in Dr Vijaendreh a/l Subramaniam, situating it within Malaysia's drug dispensing framework and assessing implications for medication safety and patient protection. **MATERIALS & METHODS:** Using a doctrinal legal research approach, statutory interpretation and case law analysis were applied to the Poisons Act, Sale of Drugs Act, Control of Drugs and Cosmetics Regulations, and appellate decisions, highlighting tensions between medical practice and pharmaceutical governance. **RESULTS:** The Federal Court affirmed that section 19 of the Poisons Act grants registered doctors' statutory authority to dispense Group B poisons, including ivermectin, regardless of whether products are registered for human or veterinary use, and that this right cannot be curtailed by subsidiary legislation under the Sale of Drugs Act. The Poisons Act was deemed a complete code for practitioners, while the Sale of Drugs Act governs commercial trade. This interpretation exposes regulatory gaps: the Poisons List lacks human–veterinary distinction, NPRA's product control may be undermined, and safeguards remain reactive, leaving no proactive mechanism to prevent unsafe prescribing. **CONCLUSION:** Legislative reform is urgently needed to distinguish human and veterinary medicines, ensuring safe prescribing, protecting patients, and modernising Malaysia's regulatory framework for public trust.

Keywords
Ivermectin, Drug Control, Pharmaceutical Policy, Legal Case, Poisons

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INTRODUCTION

Ivermectin, a macrocyclic lactone derived from *Streptomyces avermitilis*, was first discovered in Japan in the late 1970s[1] and later commercialised by Merck & Co.[2] as a broad-spectrum antiparasitic drug. It revolutionised the treatment of parasitic diseases such as onchocerciasis, strongyloidiasis, and scabies, earning its discoverers the 2015 Nobel Prize in Physiology or Medicine. Pharmacologically, Ivermectin acts on glutamate-gated chloride channels in invertebrate nerve and muscle cells, leading to paralysis and death of the parasite while maintaining a wide safety margin in humans at approved doses. Adverse effects are usually mild, though misuse or overdose may cause hypotension, neurotoxicity, or hepatotoxicity.[3] In Malaysia, Ivermectin is registered solely for veterinary use under the Poisons Act 1952 and has never been authorised for human consumption.[4]

The COVID-19 pandemic brought Ivermectin into controversy. An early in vitro study suggested inhibition of SARS-CoV-2 replication within 48 hours,[5] generating significant public and professional interest. However, subsequent pharmacokinetic data showed that effective antiviral concentrations in humans would require toxic dosing,[6] yet global misinformation and advocacy groups

promoted ivermectin as a "miracle cure".[7] During Malaysia's 2021 Delta wave, public pressure led the Ministry of Health to convene the Drug Expert Task Force for Ivermectin (DETF-Ivermectin)[8] and to initiate the I-TECH randomised clinical trial,[9] which found no significant benefit in preventing COVID-19 progression or death. By 2022, the Ministry reaffirmed that ivermectin should not be used for COVID-19 treatment outside clinical trials,[10] but unregulated sales and off-label prescribing persisted, prompting enforcement under the Poisons Act 1952 (Act 366) and Sale of Drugs Act 1952 (Act 368).

These tensions culminated in *Kerajaan Malaysia & Anor v Dr Vijaendreh a/l Subramaniam & Anor* [2025] 2 MLJ 209. Following the seizure of ivermectin from the second appellant's clinic in June 2021, the appellants sought judicial declarations on whether registered medical practitioners were legally entitled to dispense ivermectin under the Poisons Act and its regulations. The High Court dismissed the application, but the Court of Appeal (2024) allowed the appeal, holding that both appellants had a statutory right to supply Group B poisons, including Ivermectin, in accordance with section 19 of Act 366. Crucially, the Court held that this right could not be curtailed by subsidiary legislation such as the Control of Drugs and Cosmetics Regulations 1984. The Federal Court upheld this reasoning in 2025, affirming that declaratory relief was appropriate and that Act 366 constitutes a complete code governing the handling, sale, and dispensation of poisons by medical practitioners. Because Ivermectin is listed as a Group B poison, section 19(1)(a) expressly authorises registered medical practitioners to dispense it for treatment. The Court further clarified that Act 368 governs the commercial trade of drugs and does not override the clinical dispensing rights conferred by Act 366.

Malaysia's regulation of the manufacture, sale, distribution, and use of medicines are grounded in four principal statutes: the Poisons Act 1952 (Act 366), the Sale of Drugs Act 1952 (Act 368), the Dangerous Drugs Act 1952 (Act 234), and the Medicine (Advertisement and Sale) Act 1956 (Act 290). Together, they form an interdependent regulation that is central in controlling hazardous substances. Under First Schedule of the Poison Act, the Poisons List, classifies substances into Groups A to F based on their level of restriction. Group A poisons, often highly toxic or narcotic, may only be supplied by licensed wholesalers to pharmacists or authorised dealers. Group B poisons, which include most therapeutic agents such as antibiotics and Ivermectin, may be dispensed by registered medical practitioners, dentists, veterinary officers, or licensed pharmacists under sections 19 and 21. Groups C to F encompass substances with progressively fewer controls. Section 6 empowers the Minister of Health to amend the Poisons List via Gazette order, ensuring regulatory adaptability. Importantly, the Act does not distinguish between human and veterinary formulations of the same active ingredient. The Sale of Drugs Act 1952 (Act 368) regulates the commercial sale of pharmaceutical products and forms the basis of the Control of Drugs and Cosmetics Regulations 1984, under which the Drug Control Authority (DCA) and National Pharmaceutical Regulation Authority (NPRA) require all human medicines to be registered for safety, efficacy, and quality. The Dangerous Drugs Act 1952 (Act 234) criminalises the manufacture, possession, and trafficking of narcotics and psychotropic substances, while still permitting limited medical use under strict controls. The Medicine (Advertisement and Sale) Act 1956 (Act 290) governs public advertising of medicines, prohibiting misleading claims and requiring Ministry of Health approval for treatment claims involving serious diseases.

MATERIALS & METHODS

This article adopts a doctrinal legal research methodology, supported by socio-legal and regulatory analysis, to examine the implications of the ivermectin litigation for Malaysia's drug control framework. No empirical data were collected; instead, the study relied on systematic examination of legislation, case law, regulatory instruments, and policy documents. Primary statutes, including the Poisons Act 1952, Sale of Drugs Act 1952, Dangerous Drugs Act 1952, and Medicine (Advertisement and Sale) Act 1956, were analysed alongside the Control of Drugs and Cosmetics Regulations 1984, with attention to statutory definitions,

ministerial powers, classification mechanisms such as the Poisons List, and enforcement provisions. The Federal Court decision in *Kerajaan Malaysia & Anor v Dr Vijaendreh a/l Subramaniam & Anor* [2025] 2 MLJ 209 was examined through close reading of the judgment particularly on the Court's reasoning on statutory interpretation and the relationship between primary and subsidiary legislation. Professional regulatory sources, including the Medical Act 1971 and the Malaysian Medical Council Code of Professional Conduct (2019), were reviewed to situate the ruling within the broader framework of medical accountability. Policy documents, such as Ministry of Health advisories, the DETF-Ivermectin report, and the I-TECH trial findings, were consulted to contextualise regulatory intent. The analysis adopts a purposive, harmonising approach to assess the implications for regulatory oversight, practitioner autonomy, and patient safety.

RESULTS

When the Federal Court affirmed that registered medical practitioners possess a statutory right under section 19 of the Poisons Act to dispense Group B poisons, including Ivermectin, the decision was widely perceived as a significant challenge on the Ministry of Health's regulatory authority in matters of public health. Despite the findings of the Drug Expert Task Force for Ivermectin (DETF-Ivermectin) advising against its use for COVID-19, Chief Justice Tengku Maimun Tuan Mat clarified that the Court's focus was not on Ivermectin's clinical efficacy, but solely on the substantive right of medical practitioners to dispense Group B poisons for patient treatment in compliance with the Act. The judgment also effectively invalidated the reliance on Regulations 7 and 15 of the Control of Drugs and Cosmetics Regulations 1984, which stipulate that no person shall manufacture, sell, supply, import, possess, or administer any product unless it is a registered product and the person holds the appropriate licence issued under the Regulations. The court held that interpreting these provisions as a regulatory prohibition on the use of ivermectin was misconceived, since the subsidiary legislation could not override or remove a vested statutory right expressly granted under the Poisons Act 1952. In simple terms, the ruling means that once a drug is classified as a Group B poison, any registered doctor is legally entitled to prescribe or dispense it, even if the product was originally approved for veterinary rather than human use and did not go through the safety monitoring by NPRA.

DISCUSSION

This legal development raises important regulatory questions, particularly whether a medical doctor may lawfully prescribe or dispense a drug approved only for veterinary use. Medicines for human use in Malaysia fall under the Sale of Drugs Act 1952 (Act 368) and the Control of Drugs and Cosmetics Regulations (CDCR) 1984, which establish the Drug Control Authority (DCA) and its operational arm, the National Pharmaceutical Regulatory Agency (NPRA). Regulation 7(1) of the CDCR 1984 prohibits the manufacture, sale, supply, import, possession, or administration of any product unless it is registered with the DCA and the person holds the appropriate licence. This ensures that only authorised, quality-assured medicines reach human patients. However, both human- and veterinary-approved substances appear collectively in the Poisons List under the Poisons Act 1952 (Act 366), which classifies active ingredients into Groups A–F without distinguishing between human, dental, or veterinary applications. Traditionally, Regulation 7 would prevent doctors from dispensing unregistered products. However, the court in the case of *Dr Vijaendreh a/l Subramaniam* held that Act 368 governs commercial trade, not clinical dispensation by registered medical practitioners. The Court affirmed that section 19 of Act 366 grants doctors a statutory right to dispense Group B poisons, regardless of whether the formulation is registered for human or veterinary use, and that subsidiary legislation cannot override this primary statutory right. Thus, a medical practitioner may lawfully dispense a veterinary-approved substance classified as a Group B poison regardless of its registration. However, this legal entitlement sits within a narrow statutory framework and does not shield practitioners from civil or professional liability should harm occur.

A doctor who prescribes a substance irresponsibly or

outside accepted medical standards remains answerable under tort law and professional ethics. In civil jurisprudence, liability would still arise through the doctrine of medical negligence, guided by the Bolam principle (*Bolam v Friern Hospital Management Committee*, 1957) and refined by the Bolitho test (*Bolitho v City and Hackney Health Authority*, 1998). These principles hold that a practitioner is not negligent if the treatment adopted is supported by a responsible body of medical opinion, provided that such opinion is logically defensible and scientifically sound. Thus, if the prevailing consensus among competent Malaysian or international experts maintains that ivermectin lacks proven efficacy against COVID-19, a doctor prescribing it could be found negligent. Conversely, if a substantial body of qualified professionals reasonably supports its use based on credible scientific evidence, the doctor may rely on Bolam protection. Yet, under Bolitho, courts retain the discretion to reject any medical opinion that is illogical, outdated, or contrary to established science. Applied to Ivermectin, judicial scrutiny would likely assess whether medical advocacy for its use during the pandemic was grounded in rigorous empirical evidence rather than conjecture or anecdote. In Malaysia, professional opinion on ivermectin remains divided, some clinicians endorse its use while others firmly reject it.

This divergence presents a judicial challenge in determining what constitutes an *accepted standard of care.* In such cases, courts may refer to authoritative sources, such as the Drug Expert Task Force for Ivermectin (DETF-Ivermectin) technical report, as persuasive (though not binding) guidance on medical consensus. Ultimately, the court must exercise judicial realism by evaluating not only the law in theory but also the realities of medical practice, social context, and evolving scientific understanding. From a sociological jurisprudence perspective, such adjudication reflects the law's adaptive function, balancing the professional autonomy of physicians with the broader societal duty to protect patients from harm. Hence, a doctor's liability depends not merely on peer agreement but on whether that consensus is rational, evidence-based, and aligned with the community's legitimate expectation of safe and ethical medical practice.

Outside the courtroom, the conduct of medical practitioners continues to fall under the regulatory supervision of the Malaysian Medical Council (MMC) and related statutory bodies. The Medical Act 1971 and the Malaysian Medical Council (MMC) Code of Professional Conduct (2019) empower the Council to initiate action against any practitioner who prescribes unregistered, unsafe, or veterinary-only products to human patients. Under Section 1.1 of the Code, it constitutes professional misconduct when a practitioner "endangers the welfare of a patient by persisting in independent practice of a branch of medicine in which he does not have the appropriate knowledge and skill and has not acquired the experience which is necessary." In this context, prescribing veterinary formulations or unapproved medicines for human use could be construed as practising beyond one's competence and, consequently, a breach of professional standards. Disciplinary sanctions under the Medical Act 1971 may include formal censure, suspension, or removal from the medical register, even in the absence of a civil negligence claim. However, as the MMC functions on a complaint-driven process, an inquiry can only be initiated once a formal complaint has been lodged. Although the complainant need not be limited to the patient concerned, any individual, including a colleague, member of the public, or regulatory authority, who becomes aware of such professional misconduct may file a report with the MMC to trigger an investigation, the complaint can only arise after harm or damage has already occurred.

Second, if a drug approved for animals falls within Group B poisons, must it still undergo human clinical trials before being used in patients? In current practice, any attempt to repurpose a veterinary drug for human treatment must involve toxicological studies, Phase I–III clinical trials, and registration with the NPRA. These steps ensure compliance with international standards of Good Clinical Practice (GCP) and pharmacovigilance, protecting patients from untested or unsafe therapies. However, following this case, pharmaceutical companies may exploit this ambiguity, seeking approval solely for animal use while allowing practitioners to rely on section 19 of the Poisons Act to administer the drug to humans.

Although the Federal Court clarified that Act 368 governs commercial sale rather than clinical dispensation, and that subsidiary legislation cannot override rights conferred under the Poisons Act, this interpretation should not negate the need for scientific validation when a substance transitions from animal to human use.

Third, while the NPRA still retains its regulatory role, the problem stems from a structural conflict in the law. Ivermectin is *not approved by the NPRA for human use*, yet it appears in the Poisons List under the Poisons Act 1952, a principal Act. Since the NPRA's authority comes from subsidiary legislation, it cannot override what is permitted under the principal Act. As a result, doctors may rely on the Poisons List to justify dispensing a substance that the NPRA has not authorised for human consumption. By reinforcing broad dispensing rights, the court's interpretation of section 19 further exposes this gap and weakens the practical effectiveness of NPRA oversight. Hence, while the Federal Court affirmed the legal rights of medical practitioners, the decision also exposes significant regulatory gaps that require urgent legislative clarification. The Poisons Act 1952 should be improvised to include distinct, clearly defined schedules that differentiate medicines authorised for human use from those approved for veterinary purposes. Such differentiation is crucial not only to guide prescribers but also to support enforcement authorities in monitoring and controlling the circulation of regulated substances.

In addition, amendments should aim to harmonise professional prescribing rights with robust regulatory safeguards, ensuring that statutory protection for doctors does not inadvertently create loopholes that undermine patient safety. This includes establishing clearer prescribing boundaries, defining cross-species prescribing exceptions, and ensuring that any expanded clinical discretion is matched by appropriate accountability measures. Strengthening the Poisons Act in this manner would help maintain the integrity of Malaysia's drug control system, prevent misuse or inappropriate access to veterinary medications, and reinforce public trust in clinical and regulatory institutions. Ultimately, a balanced and updated legislative framework is essential to safeguard both the professional autonomy of medical practitioners and the safety and wellbeing of the patients they serve. Because the Poisons List determines which substances are controlled and who may handle them, regular regulatory oversight is essential to keep the list scientifically current and aligned with therapeutic practice. Section 6 of the Act empowers the Minister of Health, after consultation with the Poisons Board, to amend the list dynamically in response to new pharmaceutical developments, emerging safety data, or public-health threats. Yet, in practice, updates have lagged behind rapid advances in pharmacology, leaving outdated classifications and gaps that create uncertainty for enforcement officers and healthcare practitioners alike.

Alternatively, the Ministry of Health could restrict the use of ivermectin in private healthcare settings by issuing a directive or guideline under section 76 of the Private Healthcare Facilities and Services Act 1998 (Act 586), which empowers the Director General to prescribe any quality or standards requirements for private healthcare facilities as he considers necessary. Such a guideline would automatically bind all private facilities, and non-compliance may trigger enforcement action. Under section 43, read together with section 44(d) of Act 586, the Director General may issue a show-cause notice with the intention to suspend, cancel, or refuse renewal of a facility's licence where any directive, order, or guideline issued by the Minister or Director General is not complied with. Yet, this mechanism may still create uncertainty, as ivermectin remains listed under the Poisons List, which could further obscure its lawful use. This reflects a deeper structural gap in Malaysia's regulatory ecosystem: a haphazard mosaic of overlapping laws and authorities.

CONCLUSION

The ivermectin litigation culminating in the Federal Court's 2025 decision revealed a critical tension in Malaysia's regulatory framework: broad statutory dispensing rights under the Poisons Act 1952 coexist uneasily with product-based controls under the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984. While the Court clarified that

registered medical practitioners may dispense any Group B poison, including ivermectin, this interpretation exposed structural gaps in a system designed for a different era. Outdated statutory language, the absence of human–veterinary differentiation in the Poisons List, and limitations of subsidiary legislation have created ambiguity over safe and defensible prescribing.

The ruling should not diminish the need for rigorous scientific evaluation, NPRA registration, or adherence to Good Clinical Practice when medicines transition from animal to human use. Nor does it shield practitioners from civil liability or disciplinary scrutiny. Instead, it highlights the haphazard mosaic of Malaysia's healthcare regulatory system, characterised by overlapping laws and authorities that urgently require reform. Legislative reform of the Poisons Act is urgently required. Introducing distinct schedules, clarifying cross-species prescribing boundaries, and aligning statutory rights with regulatory safeguards would restore coherence, protect patients, and preserve public trust. Modernisation is essential to balance professional autonomy with robust oversight in an evolving clinical landscape.

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