Comments on the Drugs, Medical Devices and Cosmetics Bill, 2022

Submission to the Ministry of Health and Family Welfare, Government of India

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Executive Summary

Pharmaceutical product regulation in India needs a fundamental overhaul. The draft Drugs, Medical Devices and Cosmetics Bill, 2022 does not go far enough in making the changes that are needed to protect the health and safety of Indian citizens and to make the Indian pharmaceutical and medical device industry a truly global competitor.

The key reason for this is the absence of an independent, statutory regulator. Most developed jurisdictions around the world, in line with World Health Organisation Recommendations on the regulation of pharmaceutical products, have a dedicated, statutory regulator for drugs and medical devices that has a certain degree of autonomy from the government.

The Drugs Technical Advisory Board and the Medical Devices Technical Advisory Board that are proposed under the Draft Bill are not sufficient to allow for the modern, dynamic regulation of pharmaceutical products. The existing regulatory architecture is outdated and will not be responsive to the needs of citizens or the industry. Therefore, our main recommendations are:

- Create separate legal regimes for drugs and medical devices
- Create separate, independent regulators for drugs and medical devices, with the autonomy to take their own decisions and with appropriate, specialised expertise to carry out different functions – standard setting, licensing, quality control, post-market surveillance, and enforcement

Specifically in relation to the Draft Bill, our main recommendations are:

- Create centralised regulators that have oversight over state drug authorities or regulatory agencies
- Lay down clear functions for central and state drug regulatory authorities and provide mechanisms to audit their functioning
- Centralise the process of issuing manufacturing licences
- Provide a clearer regulatory pathway for emergency use authorisation of drugs
- Provide legislative guidance for the compounding of offences
- Create standard operating procedures for coordinated enforcement actions
- Clarify rules for the recruitment of Drugs Control Officers
- Lay down substantive provisions regarding the approval of clinical trial protocols
- Publish justifications for the approval or rejection of clinical trial protocols
- Make information about serious adverse events during clinical trials, and the action taken thereon, available in the public domain, while ensuring the protection of personal health information
- Specifically in the context of medical devices, create dedicated registries to track and monitor medical devices and to issue advisories, alerts or warnings in case of malfunction or otherwise
- Permit medical devices to demonstrate substantial equivalence with predicate devices only on the basis of certain safeguards, especially for high-risk medical devices

I. Regulatory Architecture

A. Current Position under the Bill

As far as the regulatory architecture goes, the Draft Bill[1] continues to follow the same arrangement as its predecessor – the Drugs and Cosmetics Act, 1940 (D&C Act).[2] It does not provide for the constitution of an independent statutory drug regulatory body. The regulatory functions are divided between the Central and State governments, including prescribing rules for implementing the Act. However, it has taken a step ahead from the D&C Act by providing for the appointment of regulatory officers – the Drugs Controller General (DCGI) and State Drugs Controllers - under the Act itself.[3] They have been assigned certain regulatory functions under the Act including licensing, and compounding of offences among others.

Further, the Bill duplicates the D&C Act's provisions regarding the constitution of the Drugs Technical Advisory Board, with certain changes in the composition.[4] It additionally provides for the constitution of the Medical Devices Technical Advisory Board.[5] The role of the two technical advisory boards is to advise the Central and State Governments on technical matters pertaining to drugs and cosmetics and medical devices respectively arising out of the administration of this Act. Similar to the D&C Act, the Bill also constitutes the Drugs, Medical Devices and Cosmetics Consultative Committee (DMDCCC) to advise the Central Government, the State Governments, the Drugs Technical Advisory Board and the Medical Devices Technical Advisory Board on any matter tending to secure uniformity in the country in the administration of this Act and the rules made thereunder.[6]

B. Vidhi's comments

We have analysed the existing/proposed regulatory model against the parameters of independence, federalism, autonomy, transparency, accountability, and excessive delegation. We have identified the following issues with it:

1. *Lack of Independence and autonomy*: The Central Drugs Standards Control Organisation (CDSCO) headed by the DCGI is a non-statutory body housed under the Directorate General of Health Services (DGHS) under the Ministry of Health and Family Welfare (MoHFW). Similarly, the State Drug Regulatory Authorities (SDRAs) headed by State Drug Controllers are housed under the respective State Health Departments.

   Thus, unlike other modern regulatory models like the Food Safety and Standards Authority of India (FSSAI) or the Telecom Regulatory Authority of India (TRAI), the CDSCO is neither established under statute nor does it have an independent regulatory existence separate from

[1] Ministry of Health and Family Welfare, The Drugs, Medical Devices and Cosmetics Bill, 2022 (Draft Bill for Circulation and Comment), <https://main.mohfw.gov.in/sites/default/files/Drugs%2C%20Medical%20Devices%20and%20Cosmetics%20Bill.pdf> accessed 16 Aug 2022 (hereinafter "Draft Bill").
[2] Drugs and Cosmetics Act, 1940 (hereinafter 'D&C Act').
[3] Draft Bill, cl 161.
[4] Draft Bill, cl 5.
[5] Draft Bill, cl 6.
[6] Draft Bill, cl 11.

the Central Government. Due to this, it does not have the autonomy to make its own recruitment and procedural rules or financial powers. Further, it is under the superintendence of the Central Government and can be overruled as the Bill provides for appeals against its decisions to the Central Government.[7]

2. *Fragmented regulation*: The current regulatory architecture is fragmented between the CDSCO and 36 different SDRAs that function independently of each other. These SDRAs are not regional or state extensions of the CDSCO, and the CDSCO does not function as the oversight or coordinating body for the SDRAs. This is the only regulatory model in India that aims to regulate the quality of products marketed across India through multiple regulators functioning independently. The lack of hierarchy between the CDSCO and the SDRAs leads to fragmentation as they are legally entitled to function autonomously. This leads to a huge gap concerning overall coordination between the Centre and states, eventually leading to ineffective regulation.

   The WHO multi-country Study on Effective Drug Regulation observed that when drug regulatory functions are assigned to two or more agencies, at either the same or different levels of government, regulatory effectiveness is usually impeded by fragmentation and uncoordinated delegation. In this type of organisational structure, since the command and control of drug regulatory functions needs to flow across different government agencies, it becomes hard to coordinate a multitude of functions. In the context of federal structures like India, where some drug regulatory activities are delegated to States, a concerted effort is required across agencies at all levels to attain the same regulatory objectives for the whole country. This type of organisational structure eventually lacks unity of command over drug regulatory functions, which undermines the overall effectiveness of regulation.[8]

   This leads to non-uniformity in the quality of drugs marketed across India. One of the recent investigations conducted on the drug Remdesivir revealed stark variations in testing standards and actions taken by SDRAs with regard to its tainted batches manufactured by the pharmaceutical giant Zydus Cadila.[9] While the Draft Bill duplicates the D&C Act regarding the constitution of the DMDCCC for dealing with matters related to uniformity in the administration of the Act, it has not necessarily proved to be an effective mechanism as the directions of this Committee do not have any legal or binding effect.

3. *Lack of accountability and transparency*: A drug regulatory law should be seen as a law for the protection and promotion of public health rather than a law for the promotion of business and investment in the drug industry. A law focused on public health needs to lay down clear duties and functions for regulatory authorities, grant certain powers to perform those functions, and restraints to prevent the authorities from overreaching the powers assigned.[10]

   Neither the D&C Act nor the Draft Bill makes any attempts towards laying down clear duties and powers for the drug regulatory authorities. Most of the regulatory functions have been

[7] Draft Bill, cl 165.
[8] Saowakon Ratanawijitrasin and Eshetu Wondemagegnehu, *Effective drug regulation: A multicountry study* (World Health Organisation 2002).
[9] Priyanka Pulla, 'The dangerous failure to stop tainted remdesivir' *Mint* (23 December 2021) <https://www.livemint.com/science/health/the-dangerous-failure-to-stop-tainted-remdesivir-11640197634967.html> accessed 21 August 2022.
[10] Lawrence O Gostin, 'Public Health Law Reform' (2001) 81 American Journal of Public Health 1365-1368.

excessively delegated to the Central Government to be prescribed by the rules.[11] In the absence of clear duties and powers, there is no accountability on the part of the regulatory authorities to act as per prescribed norms. Further, the Bill does not provide any guiding principles for the performance of regulatory functions by the authorities, such as transparency. For example, there are no provisions in the law mandating the regulator to make the rationale behind its decisions public. Additionally, there are no independent mechanisms under the law to hold the regulator accountable except for appeals against the decisions of the CDSCO and SDRAs to the Central and State Governments respectively.

Recommendations

1. *Establish a Central Drug Regulatory Authority under the Act*: The new law should constitute a Central Drug Regulatory Authority (CDRA) with clear duties, powers and functions laid down under the Act. Practically, the CDSCO can be upgraded to be the CDRA with centralised regulatory functions. It may continue to be housed under the MoHFW, but as a statutory authority with an independent existence. This is in line with the recommendations given by the Mashelkar Committee in 2003, which proposed strengthening the existing CDSCO and giving it the status of a Central Drug Authority reporting directly to the MoHFW as an independent office, as is the case in most countries.[12] This was also the model suggested under the Drugs and Cosmetics Amendment Bill, 2013.

2. *Promote a cooperative regulatory model between the Centre and States*: Instead of fragmented regulation between the Centre and 36 independent SDRAs, the law should provide for a centralised administration under the CDSCO, with the SDRAs acting as its counterparts at the state level for the enforcement of the provisions of the Act. The CDSCO should be the oversight authority of the SDRAs.

3. *Ensure Transparency and Accountability*: A clear set of powers, functions and restraints need to be laid down under the new law without delegating essential functions. The law also needs to lay down the guiding principles for the regulator to carry out its functions, with the central duty being to ensure the availability of safe and effective drugs in the interests of public health. This will provide a clear standard against which to review the performance of the drug regulator. Further, the law should make it mandatory for the regulator to make public the rationale behind its regulatory decisions in order to inspire confidence in its ability to protect the health of the public.

   In its current form, the Bill does not provide for any monitoring and accountability mechanisms that can hold the regulator to account. In the United States, the role of legislative oversight of the regulator is key — the House Energy and Commerce Committee, which has oversight of the USFDA, and routinely conducts transparent hearings into the functioning of the regulator. The Indian law also needs to provide for a parallel mechanism for seeking accountability from the regulator in addition to the Parliamentary Standing Committees' oversight, which is not so regular and frequent. Further, the law should provide for independent audits of the CDSCO and SDRAs to monitor and evaluate their functioning.

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[11] Draft Bill, cls 26, 83

[12] Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs, Ministry of Health & Family Welfare (2003) available at <https://pharmaceuticals.gov.in/sites/default/files/MashelkarCommitteeReport.pdf>

II. Licensing for Import and Manufacture of Drugs including New Drugs

A. Current Position under the Bill

Under the D&C Act, in principle, the Central Government had the power to prescribe the authority to issue licenses to import and manufacture drugs. Exercising this power,, it prescribed under the Drugs and Cosmetics Rules, 1945– the Central Licensing Authority (CLA) to be the authority to grant licenses to import drugs and to manufacture new drugs, certain biological and special products specified under Schedule C and C1 of the Rules, and such drugs as might be notified by the Central government from time to time. For the manufacture, sale and distribution of all other drugs, the Central Government, sub-delegated the power to appoint an authority to issue licences to the state governments. As a result, State Licensing Authorities (SLAs), are responsible for issuing manufacturing licences.

The Draft Bill continues to replicate the old scheme of licensing, which is split between the CLA and SLA; however, it has taken a step ahead by assigning respective licensing powers to the CLA[13] and SLA [14] under the Act itself. It has further added clauses related to the licensing of new drugs for both import and manufacturing. It provides that any new drug can be imported into India only in accordance with the permission or approval issued by the CLA.[15] It has also specified the CLA to be the authority for issuing licences to manufacture new drugs.[16] However, it has not specified the authority to grant licences to import drugs other than new drugs. This has to be prescribed by the Central Government under the Rules.[17]

For the manufacture, sale and distribution of other drugs, the power to issue licences rests with the SLA, as specified in the Act.[18] However, for issuing licences to manufacture drugs specified under the Third Schedule of the Act, the SLA has to take the approval of the CLA in such manner as may be prescribed under the Rules. The Proviso to this Clause adds that the Central Licence Approving Authority (CLAA) may issue directions to the State Licensing Authority in respect of any of the drugs included in the Third Schedule and such directions shall be binding. Effectively, the DCGI is both the CLA and the CLAA for this purpose as appointed under Clause 161. The Third Schedule contains some of the drugs that were part of Schedule C of the 1945 Rules, for which, the CLA has the sole authority to issue manufacturing licences under the existing scheme.

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[13] Draft Bill, cl 3(f) ("Central Licensing Authority" for the purposes of this Act means the Drugs Controller General, India appointed under sub-section (1) of section 161).
[14] Draft Bill, cl 3(zr) ("State Licensing Authority" for the purposes of this Act means the State Drugs Controller, by whatever name called, under section 161).
[15] Draft Bill, cl 22(h).
[16] Draft Bill, cl 41(3).
[17] Draft Bill, cls 22(c), 26(2)(r).
[18] Draft Bill, cl 41(c).

The Draft Bill allows the Central Government to regulate or restrict the import as well as manufacturing of a drug if it is essential to meet the requirements of emergency situations arising due to epidemic or natural calamities and in the public interest.[19] Under the D&C Act, this provision was applicable to regulating or restricting only the manufacture, sale and distribution of such drugs.[20] Further, now the Bill has a substantive provision allowing the CLA to abbreviate, defer or waive off such pre-clinical and clinical data requirements for approval of a new drug, which relates to life-threatening or serious diseases or rare diseases or diseases of special relevance to the country in the manner prescribed.

The Draft Bill has also added a substantive provision on the suspension and cancellation of manufacturing licences to manufacture,[21] but has left it to the Rules to lay down provisions related to the suspension and cancellation of import licences.[22]

B. Vidhi's Comments

We analysed the system of licensing of drugs including new drugs under the Draft Bill against the parameters of federalism, transparency and uniformity. We have identified the following issues with the existing licensing mechanisms:

1. *A fragmented system of licensing*: The Draft Bill has divided substantive powers regarding the import of new drugs and manufacturing of new drugs and other drugs between the CLA and SLA. However, the power to issue licences to import drugs other than new drugs has not been granted either to the CLA or to the SLA under the Act. The Bill has left it to the Central Government to prescribe it under the Rules, duplicating the D&C Act. This is a case of bad drafting.

   Further, the power to issue manufacturing licences is fragmented across different SDRAs. While the standards are set centrally by the CDSCO, their interpretation and implementation lie with the states while issuing manufacturing licences. This leads to non-uniformity in the quality of drugs manufactured across different states. Further, if one state is stringent with implementing the provisions of the Act and determining the conditions of licences while issuing them, the manufacturer may always approach another state, which is not as stringent. Competition between states to attract investments in the pharmaceutical industry means that some states often interpret central standards with laxity. This leads to forum shopping since once a drug is approved in one state, it can be marketed across India.

   This is not in the interest of public health because the drug manufacturers in different states do not go through the same amount of regulatory checks and balances. This eventually has an impact on the quality of drugs as they are approved by applying the standards of quality non-uniformly.

2. *Power to suspend/cancel licences only rests with the licence issuing authority*: The Draft Bill gives the power to suspend or cancel manufacturing licences only to the issuing SLA. So if a drug is reported to be substandard or spurious in any other state, the reporting SDRA has to rely on

[19] Draft Bill, cls 24, 55.
[20] D&C Act, s 26B.
[21] Draft Bill, cl 68.
[22] Draft Bill, cl 26.

the SDRAs which issued the manufacturing licence to suspend or cancel it. This does not work smoothly on the ground as often the licence issuing SDRA does not take necessary actions and the reporting SDRA has to then resort to only criminal prosecutions, which has it own issues discussed in the inext section.

3. *Opacity in licensing of new drugs:* As pointed out in the 59th Report of the Parliamentary Standing Committee on the functioning of the CDSCO, the process of approval of new drugs is completely opaque and is left to the absolute discretion of the CDSCO.[23] There are no guiding principles in the existing or proposed law to check on these approvals. While the establishment of subject expert committees (SECs) to provide recommendations to the Drugs Controller on whether or not to approve a new drug was a step in the right direction, the functioning of SECs is opaque too. Neither the composition of these committees is made public nor their deliberations are available in detail to understand the rationale behind them. Only a summary of these recommendations is available. This is in contrast with the regulators in the United States and Europe, where long assessment reports of new drug applications are released by them.

   Further, the addition of a substantial provision related to waiving off clinical data requirements in emergency circumstances gives unchecked powers to the DCGI to grant such approvals. The COVID-19 pandemic highlighted a glaring gap with respect to this. While granting approvals to new drugs including vaccines, the CDSCO relied on a makeshift framework under the New Drugs and Clinical Trials Rules, 2019, which provides for accelerated approval of drugs under special circumstances, without any conditions regarding their administration post-approval. These approvals coined terminologies which were not defined anywhere under the law.[24] They were granted by the CDSCO to new drugs and vaccines in an opaque manner. This Bill completely misses the opportunity to lay down a detailed framework on this like in the United States and Europe. Instead, it confers more discretionary powers on the CDSCO to waive off clinical data requirements in the absence of any guiding principles and accountability mechanisms, and leaves it up to the Central Government to prescribe the details in the Rules.

Recommendations

1. *Centralise the Manufacturing Licence Process:* The power to issue manufacturing licences should be centralised with the CDSCO. Several attempts have been made in the past to centralise the process of drug licensing, including the one in 1955,[25] when the power to appoint an authority to issue manufacturing licences was granted to the Central Government under Section 33 until it was diluted by amending the 1945 Rules in 1960 to sub-delegate this Authority to the State Governments. The Draft Bill has taken another step in the reverse direction by substantially granting this power to the SLAs under the Act. This should be reversed, and the power to grant all kinds of licences to manufacturers should be with the CDSCO as upgraded to a statutory

[23] Parliamentary Standing Committee on Health & Family Welfare, *The Functioning of the Central Drugs Standard Control Organisation* (RS 2012-05 59) <http://164.100.47.5/newcommittee/reports/englishcommittees/committee%20on%20health%20and%20family%20welfare/59.pdf> accessed 22 August 2022.
[24] Shreya Shrivastava, 'It's time to have a clear regulatory framework for emergency approval of drugs in India' *Economic Times* (31 January 2022) <https://economictimes.indiatimes.com/opinion/et-commentary/its-time-to-have-a-clear-regulatory-framework-for-emergency-approval-of-drugs-in-india/articleshow/89229641.cms> accessed 21 August 2022.
[25] Drugs and Cosmetics (Amendment) Act, 1955.

Central Drug Regulatory Authority. The Mashelkar Committee too recommended there should be a single agency to regulate the manufacture and quality control of drugs in the country and it should be done centrally.

2. *A clear framework for thje approval of new drugs and their Emergency Use Authorisations:* The Draft Bill needs to account for a clear framework for the emergency use authorisation of drugs and clear substantive provisions in the law to guide the emergency approvals of drugs by the CDSCO. It should also make it mandatory for the CDSCO to make public the rationale behind such approvals as well all the documents that support its decisions. This should be applicable to the approval of all new drugs.

III. Enforcement

A. *Current Position under the Bill*

The Bill's provisions on the powers and procedures of enforcement officials[26] are, in substance, almost identical to those in the D&C Act,[27] aside from the fact that the Bill renames Drugs Inspectors under the D&C Act, and makes them "Drugs Control Officers" or DCOs.[28]

Further, the Bill replicates the D&C Act's provisions, and limits the autonomy of State Governments with respect to designating the officer in charge of DCOs. The Drugs and Cosmetics Rules, 1945 mandate that all Inspectors appointed by the Central Government "shall be under the control of an officer appointed in this behalf by the Central Government." The expression "as prescribed" means "as prescribed by Rules made under the Statute."[29] While the recruitment qualifications for drug inspectors and the authorities in charge of them are already in the purview of the Central Government's rulemaking power,[30] Clause 46(5) of the Bill: (i) adds the term "controlling authority", referring to the authority under whom DCOs shall function; (ii) states that such authority shall be designated by the Central Government or the State Government; and (iii) states that the Controlling Authority shall have such qualifications and experience "as may be prescribed." Aside from the change in terminology, these changes have the same effect as the relevant provisions under the D&C Act and the Drugs and Cosmetics Rules, 1945.

The Bill also replicates the structure followed by the D&C Act with regard to criminal penalties. *Prima facie*, the Bill appears to enhance existing penalties.[31] However, the Bill also creates a new class of offences, under Clause 56(e), which deals with the manufacture or sale of "not of standard quality" (NSQ) or misbranded drugs, where the defects of such drugs are enumerated in the Fourth Schedule. For these violations, Clause 56(e) prescribes imprisonment of up to one year and a fine that is not less than two lakh rupees, which is among the lowest penalties available under the Act for a manufacturing-related violation. In effect, Clause 56(e) reduces the penalty for manufacturing NSQ drugs, if they are listed in the Fourth Schedule.

The Bill goes even further. Offences under Clause 56(e) are compoundable at the discretion of the DCGI or the State Drugs Controller, as the case may be.[32] The power to compound offences is also delegable to officers under the DCGI or the SDRAs.[33] Unlike the D&C Act which does not permit the compounding of subsequent offences, the Bill permits the compounding of subsequent offences under various provisions, including Clause 56(e).[34]

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[26] Draft Bill, cls. 46-48.
[27] D&C Act, ss 21-23.
[28] cf D&C Act, s 21.
[29] *Nidhi Pandey v UPSC and Anr.* (Central Administrative Tribunal, 22 March 2018) para 12, <https://catjudgements.nic.in/bitstream/123456789/53549/1/110720055012016_1.pdf>
[30] See D&C Act, § 33(2)(b)
[31] *See* cl 27, 56.
[32] Draft Bill, cl 71(1).
[33] Draft Bill, cl 71(3).
[34] Draft Bill, cl 71(1), Proviso 2.

B. *Vidhi's Comments*

While most of the scheme of penalties is duplicated from the D&C Act, the draft Bill presented an opportunity to reexamine persistent issues in the enforcement regime. The Bill does not appear to recognise the serious and multivariate challenge to public health. Existing processes around enforcement - from the structure of the authorities, to the conduct of the investigations, to the effectiveness of drug inspectors - are deeply flawed and require urgent reform. Existing issues on drug quality require political focus, an end-to-end focus on Good Manufacturing Practices (GMPs), and an independent, modern, and autonomous enforcement authority that operates in a coordinated and effective manner. Instead of acknowledging the problem, addressing these issues, and pursuing long-overdue reform, this Bill dilutes existing penalties and grants unguided discretion to authorities which are often uncoordinated, if not at odds with each other.

We highlight some of these issues below:

1. *Negation of penal provisions*: As it exists, the Bill lacks an internally consistent framework of penalties. While the enhancement of existing penalties, the addition of improvement notices, and more liberal sentencing provisions may create an impression of reform, Clauses 56(e) and 71 of the Bill, read together, defeat that impression. The Bill allows the executive to compound (without legislative guidance), a growing catena of quality violations, effectively creating "acquittals." In addition, the compounding of subsequent quality violations, as long as they are listed in the Fourth Schedule, imposes no serious cost. If lenient enforcement were the stated and appropriate objective of the Bill, it would at least attempt to create real consequences for quality violations where there are subsequent offences. However, this Bill does not do this. Further, the Fourth Schedule's criteria (categories of defects) are irrelevant to the appropriateness of criminal penalties. In granting the executive the authority to amend the Fourth Schedule at will, the Bill converts an expert decision, properly made by the Indian Pharmacopoeia Commission, into a bureaucratic and political one that is unguided by statute. In doing so, the Bill establishes a serious and permanent risk of regulatory capture over enforcement mechanisms.

2. *Investigative process*: Investigations under the D&C Act are characterised by a failure to abide by basic documentation requirements, charge offenders under the correct statutory provisions,[35] or prosecute cases effectively.[36] These issues are not limited to SDRAs, but extend to investigations and inspections conducted by CDSCO officials. There has been a reported lack of documentation during enforcement and inspection visits by the CDSCO.[37] Lack of documentation during inspections and enforcement actions diminishes public and industry trust in the regulator. This has the added effect of making accountability provisions toothless[38] in preventing malicious searches and seizures and instead prevents legitimate searches and seizures in the course of normal investigations.[39]

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[35] Dinesh Thakur & Prashant Reddy, 'A report on fixing India's broken drug regulatory framework' (2016) 73 <https://spicyip.com/wp-content/uploads/2016/06/Report_India-Drug-Regulatory-Framework_June-2016.pdf > accessed 19 August 2022.
[36] ibid 53 et seq.
[37] Priyanka Pulla, 'What do CDSCO officials do during vaccine-manufacturing site inspections?' (*In Sickness and in Health*, 7 July 2022) <https://insicknessandinhealth.in/2022/07/07/what-do-cdsco-officials-do-during-vaccine-manufacturing-site-inspections/> accessed 22 August 2022.
[38] Draft Bill, cl 168.
[39] Thakur & Reddy (n 35) 72.

3. *Shortage of enforcement officers*: Most enforcement happens through SDRAs. But almost every state has a shortage of drug inspectors.[40] This is not merely an administrative decision not to allocate funds or create posts; most states could not find qualified applicants in the first place. States have tried to get around the lack of qualified applicants by lowering recruitment requirements and interfering with the recruitment rules set by the Central Government,[41] leading to onerous litigation in almost every High Court and administrative tribunal in India. Partly, this litigation stems from the fact that generally, States are empowered to frame recruitment rules under Article 309 of the Constitution. However, they are constrained in this case by Rules made under the Act itself. Once they are recruited, drug inspectors receive different levels of training, which result in different levels of competence and efficiency of work.[42]

4. *Differential enforcement*: The prosecution of offenders varies significantly from state to state. As a ministerial response shows, in multiple states, no prosecutions were launched despite a large number of samples being found to be substandard/spurious.[43] In other states, a large number of prosecutions were launched, raids conducted, and arrests made.[44] Whether a drug manufacturer is prosecuted for a GMP violation or not should not depend on which state they happen to be operating from. This creates opportunities for crude regulatory arbitrage.

5. *Lack of Coordination*: Investigations under the D&C Act, as many have pointed out, are conducted on the basis of very limited (if any) coordination and cooperation between drugs inspectors "within the same state or between different states and also between the drugs inspectors at the state and centre."[45] Not only is there little cooperation, states have been sufficiently obstructionist that SDRA officials have attempted to use the criminal law to force the sharing of information by their counterparts in other states. In fact, this practice has been endorsed by the DCC as a measure of last resort.[46]

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[40] *See, e.g.*, AS Jayanth, 'Kerala's Drugs Control Dept. in the grip of staff shortage' *The Hindu* (Kozhikode, 4 September 2021) <https://www.thehindu.com/news/national/kerala/keralas-drugs-control-dept-in-the-grip-of-staff-shortage/article36293697.ece> accessed 22 Aug 2022 ("The Kerala Drugs Control Department, for example, had only 47 officials across the entire state, and no new posts for drug inspectors have been established for the last 22 years, while the number of institutions in the state requiring drug licences went from 12000 to 24000 between 2008 and 2020"); Peethaambaran Kunnathoor, 'Two senior drug inspectors suspended in TN for dereliction of duty' *PharmaBiz* (Chennai, 20 August 2009) <http://test.pharmabiz.com/news/two-senior-drug-inspectors-suspended-in-tn-for-dereliction-of-duty-52060> accessed 22 Aug 2022 ("As of now, the total strength of the drug inspectors is only 74. It is facing a shortage of 40 percent drug inspectors post"); J Umamaheshwara Rao, 'Andhra Pradesh: Staff shortage at drug control body' *Deccan Chronicle* (Visakhapatnam, 22 August 2022) <https://www.deccanchronicle.com/nation/current-affairs/090716/andhra-pradesh-staff-shortage-at-drug-control-body.html> available 22 Aug 2022.

[41] *See, for e.g.*, P Elango v State of Tamil Nadu (where the Government diluted the work experience requirement as there was a "dire need" to fill up vacant posts). *See also* Vinod Kumar Gupta v State of Uttar Pradesh and Ors., [2010 (79) ALR 879].

[42] Thakur & Reddy (n 35) 21.

[43] Rajya Sabha Unstarred Question No 3634, Monitoring Mechanisms for Quality of Drugs (answered on 27 March 2018).

[44] ibid.

[45] Thakur & Reddy (n 35) 70.

[46] 43rd DCC Meeting, Agenda No. 4, cited in forthcoming chapter on drug regulation and federalism.

Recommendations

We emphasise that these issues are inseparable from problems associated with the structure, independence, and functioning of the regulators, and that the following set of recommendations cannot, on their own, address issues like a lack of enforcement capacity, or the ability of those officials to operate in an independent and autonomous manner. However, neither does a new institutional structure necessarily address ground-level issues relating to enforcement actions, such as a lack of accountability or documentation, or even larger issues, such as coordination between SDRAs. We make the following recommendations to specifically address issues with penalties, inspections, enforcement actions, and monitoring:

1. *Remove the Fourth Schedule and refocus penalties around GMPs*: As a general approach, however, an effective system of criminal penalties must necessarily be internally consistent, adapted to ground realities, and create a deterrent effect. Criminal penalties must be proportional, and must account for the possible risk to public health, the value of the goods involved (if any), the gravity of the offence, and the state's interest in deterrence. While the penal provisions must not apply to bona fide errors, they must not actively create the environment for violations either. As others have suggested, a system of process-oriented penalties could revolve around GMP violations instead, in addition to various other approaches that could be taken.[47]

2. *Guide discretion on compounding and create safeguards*: The Prosecuting Agency should not have complete discretion on compounding. The CDSCO has claimed that they have a "fiduciary relationship" with the pharmaceutical companies they regulate.[48] This is not the agency that should have the power to compound a vast variety of quality violations. Therefore, we recommend that the draft Bill be amended to: (i) add provisions that clearly guide discretion on the compounding of offences; and (ii) require the approval of a court for compounding any subsequent offences.

3. *Clarify the recruitment rules for DCOs.* Evaluate existing recruitment mechanisms by SDRAs and attempt to create a consistent set of guidelines on recruitment in order to avoid litigation and delay. Make appropriate amendments clarifying the work experience qualifications for drug control officers, and issue model notifications to guide recruitment rules made by States under Article 309 of the Constitution.

4. *Prescribe Standard Operating Procedures (SOPs)*: We recommend that the draft be revised to permit the Central Government to prescribe binding Standard Operating Procedures for coordinated enforcement actions. The SOPs must:
    a. require comprehensive and proper documentation during inspections.
    b. encourage coordination between enforcement officials:
    c. encourage joint audits and cooperation between SDRAs
    d. ensure inter-state transparency on enforcement actions
    e. create effective mechanisms for continuous information sharing, the airing of agency views, and the resolution of differences in interpretation and approach

[47] Citizens for Affordable, Safe & Effective Medicine, 'Comments on Draft of New Drugs, Medical Devices and Cosmetics Bill, 2022' (20 August 2022) 19-20 <https://casemindia.org/wp-content/uploads/2022/08/CASEM-FInal-Comments-on-DC-Amendment-2022.pdf >accessed 22 Aug 2022.

[48] *See Amresh Chandra Mathur v CPIO, Directorate General of Health Services* (Central Information Commission, 10 April 2019).

f. encourage the effective adoption of software solutions to enable transparency and assist in the coordination of enforcement actions and prosecutions across state lines

5. *Establish a periodic, independent audit system for compliance with SOPs and the Act*: The Bill should provide for periodic independent audits of enforcement agencies, including SDRAs, which must involve "an extensive review of process and technical approach" that uses subsequent "training, advice, revision of job description, legal proceedings, and dismissal" to correct observed weaknesses.[49] Information gathered from these audits must continuously be used to guide executive rulemaking.

[49] Saowakon Ratanawijitrasin and Eshetu Wondemagegnehu, *Effective drug regulation: A multicountry study* (World Health Organisation 2002) 75.

IV. Regulatory Framework for Clinical Trials

A. *Current Position under the Bill*

The Draft Bill takes a step in the right direction by including substantive provisions on clinical trials (in the case of new drugs) and clinical investigations (in the case of new medical devices). These provisions include the obligation to obtain the permission of the CLA to conduct clinical trials and clinical investigations (Clauses 72 and 139 respectively), to provide medical management and compensation for injury or death related to a clinical trial or investigation (Clauses 73 and 140 respective) and provisions relating to the constitution and functions of ethics committees (Clause 74).

These changes are similar to those that have been proposed through previous draft amendments, such as the Drugs and Cosmetics (Amendment) Bill, 2015, and are presumed to be read in conjunction with the New Drugs and Clinical Trials Rules, 2019.

B. *Vidhi's Comments*

Clinical trials in India are carried out in a climate of distrust. There is a lack of confidence in the ability of ethics committees to protect participants, and a perception that pharmaceutical companies use Indian participants as 'guinea' pigs, especially since clinical trial participants are often recruited from vulnerable groups and lack awareness of their rights.[50] This distrust was channelised into a public interest petition filed by the Swasthya Adhikar Manch, that ultimately resulted in a series of unreasonable restrictions on the conduct of clinical trials.[51] Some of these changes have been rolled back since then, and the provisions on clinical trials themselves consolidated in the New Drugs and Clinical Trials Rules, 2019, but the atmosphere of distrust lingers on. The Covid-19 pandemic exacerbated this, with questions being raised about the reliability of data generated during clinical trials.

Like the rest of the Act, the provisions on clinical trials continue to leave too much to delegated legislation, and are not informed by the levels of transparency and accountability that are needed to regulate an activity that carries a great risk to the life and health of participants. Some of the key issues are listed below:

Permission for Clinical Trials by the Central Licensing Authority

Clause 72 of the Bill leaves it to the Central Licensing Authority to grant permission for the conduct of a clinical trial subject to such conditions and in such form and manner as may be prescribed. This leaves too much to the discretion of the Drugs Controller General, India, who does not, in any case,

[50] Neha Dixit, 'Churu Drug Trials: Four months on, Dalit victims report severe damage to health and caste-based harassment' *The Caravan* (11 September 2018), <https://caravanmagazine.in/health-and-education/churu-drug-trials-four-months-on-dalit-victims-report-severe-damage-to-health-and-caste-based-harassment> accessed 22 August 2022.
[51] *Swasthya Adhikar Manch , Indore v Union of India & Ors*, Writ Petition (Civil) No. 33 of 2012.

have specialised expertise concerning the conduct of clinical trials. In practice, and following the directions of the Supreme Court, clinical trial protocols for 'new chemical entities' and for 'global clinical trials', in addition to being approved by the relevant ethics committees, must also pass the scrutiny of Subject Expert Committees, appointed by the Central Drugs Standard Control Organisation. Subject Expert Committees are to evaluate these according to three criteria: assessment of risk versus benefit to the patient; innovation versus existing therapeutic options, and unmet medical need in India.

Neither the constitution of these expert committees nor the manner in which they are expected to perform these important functions currently find mention in the Draft Bill or in the New Drugs and Clinical Trials Rules, 2019. This leads to uncertainty for the person seeking permission for the conduct of the clinical trial, as well as a lack of accountability towards clinical trial and clinical investigation participants, who have a right to know that their interests and well-being are appropriately safeguarded. In light of this, we make the following recommendations:

Recommendations

1. *Statute to lay down the process for granting permission to clinical trials:* The Draft Bill set out the process for the approval of clinical trials in more detail by designating the persons who are responsible for the review of clinical trial and clinical investigation protocols.

2. *Independent experts to review clinical trial protocols:* These persons should be appropriately qualified experts who should be appointed or empanelled by a dedicated wing of the independent, central drug regulator that we have proposed earlier. This dedicated wing should have charge of the approval of new drugs and devices and should be capable of assessing the scientific validity of clinical trial and clinical investigation proposals submitted to it as well as the data that is generated from such trials and investigations or submitted as part of the application for the approval of a new drug or device.

3. *Transparency in decisions about clinical trials:* Decisions approving or rejecting clinical trial protocols, and their supporting reasons should be made available in the public domain.

Information about Clinical Trials in the Public Domain

Under the New Drugs and Clinical Trials Rules, 2019, all clinical trials as well as bioavailability and bioequivalence studies of new drugs should be registered with the Clinical Trial Registry of India. This is an important source of information about the clinical trial protocol, the sponsors and investigators, including the recruitment status of participants. There have been reports that suggest that this Registry is not being maintained properly and that there are several gaps and inconsistencies in the information that is recorded.[52] While this is an issue that must be addressed, there is other information about clinical trials that is not currently required to be made available in the public domain, which is crucial to addressing the lack of confidence in the way in which clinical trials are run. These include details about the adverse events and serious adverse events that take place during a clinical trial, and the manner in which the relevant ethics committee as well as the CLA responded to reports of these events.

[52] Rema Nagarajan, 'Clinical trial registry 'doesn't exist', 'ghost staff' runs tests' *The Times of India* (12 August 2022) <http://timesofindia.indiatimes.com/articleshow/93502120.cms> accessed 21 August 2022.

Recommendation

Make available information about action taken on adverse events and serious adverse events: In light of this, we recommend that anonymised information about the number and nature of such events, and the action taken in response to them, ought to be made available to the public, while ensuring that sensitive, personal, identifying health information is protected.

V. Regulatory Framework for Medical Devices

A. Current Position under the Bill

The Draft Bill contains dedicated provisions on medical devices, including a definition of medical devices that is separate from the definition of drugs, as was the case under the D&C Act. It also creates a Medical Devices Technical Advisory Board to advise the Central and State Governments on technical matters relating to medical devices, along the lines of the Drugs Technical Advisory Board. Finally, the Bill also contains separate provisions on the import, manufacture, licensing and conduct of clinical investigation of medical devices, all of which largely mirror the provisions in the D&C Act relating to drugs. It is presumed that this Bill will operate in conjunction with the Medical Devices Rules, 2017.

B. Vidhi's Comments

This is a serious missed opportunity to create a dedicated regime for the regulation of medical devices, which are wholly different in nature from drugs and require specialised expertise. Although medical devices have traditionally been regulated as an afterthought to drugs, they present very different regulatory challenges. Unlike drugs, they do not have active ingredients (although there are devices like pain control pumps that might deliver agents that have pharmacological action). While many devices might require complex surgery before they can be implanted, the standards that apply to surgical procedures are not meaningful in regulating the manufacture of the devices themselves. With the increasing use of artificial intelligence in the prediction and prognosis of medical conditions, solely medical expertise is no longer relevant in judging the effectiveness of medical devices. Again, unlike drugs, they do not disappear when they are used, instead, an important aspect of their safety depends on the manner in which they are maintained and serviced. Finally, the sheer range of products that fall within the scope of medical devices makes it difficult to think of them as a single regulatory class. Although sputum containers and pacemakers might notionally fall under the same law, it is evident that both these products present very different kinds of risk, which might require different regulatory approaches.

Medical devices have been at the eye of a global storm, following the revelations of the Investigative Consortium of Investigative Journalists ("ICIJ") in late December 2018,[53] although in India, their regulation came under scrutiny in the wake of the problems uncovered with Johnson & Johnson's hip implants. These investigations have highlighted weaknesses in the regulation of medical devices the world over. Some of these are peculiar to the nature of medical devices, while others are symptomatic of regulatory failure in other sectors as well. At the heart of the Implant Files, as the findings of the ICIJ have been dubbed, is the worryingly large number of devices that have had a devastating impact on the health and lives of millions of people around the globe.

In some instances, like the French PIP breast implants (which used industrial-grade silicone instead of medical silicone, causing inflammation, scarring and necessitating the precautionary removal of implants),[54] regulators failed to catch the sub-standard products that the manufacturer was placing on

[53] 'Implant Files', <https://www.icij.org/investigations/implant-files/> accessed 14 January 2019.
[54] Sasha Chavkin, 'Breast Implant Injuries Kept Hidden as New Health Threats Surface' *Implant Files, International Consortium of Investigative Journalists* (26 November 2018)

the market in time. In other instances, such as devices like metal-on-metal hip implants and implantable contraceptive devices, the key problem appears to be that devices have simply not undergone adequate testing to prove their safety and efficacy. The predicate-device approval route or 501(k), as it is known within the United States Food and Drug Administration ("US FDA") system means that devices with a high potential of risk have been approved merely on the basis of their "substantial equivalence" to previously approved devices, without manufacturers having to carry out clinical investigations in humans.

The unique characteristics of medical devices present regulatory challenges which regulatory regimes across different jurisdictions have found difficult to tackle, as the Implant Files suggest. In Europe, for example, adopting the same regulatory approach for medical devices as other 'products' like food or toys through the use of notified bodies that certify that medical devices adhere to certain quality standards has allowed risky devices to enter the market without being adequately tested.[55] In the US, although the FDA has stricter processes in place for pre-market approval, the 501(k) route, which allows devices to be approved without testing in humans, on the basis of predicate devices, has been exploited, so much so that nearly 80% of all devices are approved through this process.[56] This regulatory pathway was intended to be the exception, rather than the rule, when it was first introduced, but this has been reversed. In several cases, the predicate devices on the basis of which new devices are used have themselves been recalled from the market because of the harm that they have caused.

The most important regulatory challenge that all regimes will have to address is putting in place safeguards to ensure that devices are appropriately tested, so that only safe and effective devices enter the market. This may require regulators to modify their approach to the classification of devices into different categories of risk. It may also require regulators to expand the base of scientific evidence that must be submitted to prove the safety and efficacy of devices. This will have to be counterbalanced against the potential risks presented by the testing of devices in humans. The speed with which the medical device industry is growing and innovating also makes it difficult for regulators to keep up, as they strike a balance between preventing harm and responding to medical need.

There is, however, a limit to the extent to which pre-market testing will provide accurate information about the safety and efficacy of devices. Post-marketing surveillance and adverse event reporting have an important role to play in removing harmful devices from the market. Another important finding of the Implant Files investigation has been the failure of the adverse event reporting system.[57] Too much discretion has been vested in manufacturers to determine the seriousness of an adverse event, doctors have been slow to file voluntary adverse event reports, regulators have appeared to struggle to analyse the information received, and most importantly, information on adverse event reports is not made sufficiently public. In a regime that imposes the primary responsibility for making informed decisions on individuals (the US FDA website flatly warns that persons contemplating silicone breast implants should assume that they will have additional surgeries as a consequence of the implants), it becomes imperative that the information necessary to make such decisions is made available. While

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<https://www.icij.org/investigations/implant-files/breast-implant-injuries-kept-hidden-as-new-health-threats-surface/> accessed 16 January 2019.

[55] Simon Bowers, 'How Lobbying Blocked European Safety Checks for Dangerous Medical Implants' *Implant Files*, *International Consortium of Investigative Journalists* (25 November 2018).

[56] The Bleeding Edge, A Netflix Documentary (27 July 2018).

[57] Sasha Chavkin, 'How Medical Device Harm is Concealed' *Implant Files*, *International Consortium of Investigative Journalists* (19 December 2018) <https://www.icij.org/investigations/implant-files/how-medical-device-harm-is-concealed/> accessed 16 January 2019.

some of the solutions to these problems require innovative, technological solutions, such as the creation of joint clinical registries to record and share information about medical devices, or a unique identification number to track medical devices, legal changes are also required to create obligations regarding the reporting of adverse events and communicating such information to the public.

The Implant Files make out a strong case for the need for a separate law to govern medical devices in India. The Johnson & Johnson hip implants case highlights other weaknesses: the lack of capacity and expertise within the CDSCO, the reluctance of doctors to report adverse events for fear of legal consequences,[58] the nexus between doctors and device manufacturers and the failure of professional regulation,[59] and the difficulty of tracking down patients with faulty devices. Other problems that the Implant Files investigations have highlighted in India are the high proportion of private clinics and hospitals that use pre-owned or secondhand equipment that has not been tested for safety or accuracy,[60] that only 2 percent of diagnostic laboratories in India are accredited by the National Accreditation Board for Testing and Calibration Laboratories, that surgeries to implant medical devices are being conducted in unregistered establishments, and that clinical establishments themselves are not subject to the same code of medical ethics as doctors.[61]

The following are key regulatory challenges for medical devices in India:

1. An outdated legal framework
2. A weak regulatory authority
3. A defunct professional regulatory system
4. Ineffective mechanisms to track and provide information on medical devices

Unfortunately, none of these challenges are addressed by the Draft Bill in its current form. A necessary precondition for the successful implementation of any regulatory framework is the establishment of a regulatory body or agency to oversee and enforce the provisions of the law. The WHO Global Model Regulatory Framework for Medical Devices recommends that any law related to the regulation of medical devices should (i) delineate the responsibilities of the regulatory authority; (ii) establish its enforcement powers, including powers to remove products from the market as well as imposing penalties; and (iii) define the powers and functions of any decentralised subunits, that are set up, to function under the central authority.[62]

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[58] Ritu Sarin, '#ImplantFiles-First Official Red Flags: over 500 adverse events' *The Indian Express* (26 November 2018) <https://indianexpress.com/article/india/implant-files-first-official-red-flags-over-500-adverse-events-5463990/> accessed 21 August 2022.

[59] Shah Alam Khan, 'Implant Files: Who should own up to what' *The Indian Express* (22 December 2018) <https://indianexpress.com/article/opinion/columns/implant-files-who-should-own-up-to-what-hip-implants-express-investigation-johnson-and-johnson-5504634/> accessed 21 August 2022.

[60] Jay Mazoomdar, '#ImplantFiles: Diagnostic labs buy used machines; no checks by regulator, testing is voluntary' *The Indian Express* (4 December 2018) <https://indianexpress.com/article/india/implant-files-fault-medical-equipment-nabl-5477175/> 21 August 2022.

[61] Jay Mazoomdar, Kaunain Sheriff M, '#ImplantFiles; Pharma majors gave freebies to doctors, claimed tax benefits' *The Indian Express* (1 December 2018) <https://indianexpress.com/article/india/implant-files-pharma-majors-gave-freebies-to-doctors-claimed-tax-benefits-5473545/> accessed 21 August 2022

[62] *WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices* (World Health Organization 2017) <http://apps.who.int/iris/bitstream/handle/10665/255177/9789241512350-eng.pdf> accessed 21 August 2022.

Recommendations

1. *Enact a dedicated law for medical devices*

2. *Create a separate regulator for medical devices:* The regulator should have independence in functioning and should comprise of directorates with specialised, distinct functions, such as standard setting, licensing and quality control, safety and enforcement.

3. *Set out detailed obligations for adverse event reporting:* Obligations related to adverse event reporting should be extended from manufacturers, distributors and importers of medical devices to healthcare establishments as well. The regulator should issue periodic advisories to the public on the basis of information received through the adverse event reporting system. Registries should also be set up to track medical devices and allow the manufacturer as well as the regulator to issue alerts in case of device malfunction.

4. *Use substantial equivalence as a means of approval with caution:* Given the many problems with the assessment of substantial equivalence pointed out above, we recommend that claims for substantial equivalence on the basis of predicate devices that are older than a certain period should not be permitted. Substantial equivalence may not be permitted for medical devices that are high-risk, or may be permitted subject to strict conditions.