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THE DRAFT MEDICAL DEVICES RULES 2016

SUBMISSIONS TO THE MINISTRY OF HEALTH AND FAMILY WELFARE, GOVERNMENT OF INDIA

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November 2016

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The authors would like to thank Shalini Seetharam for her inputs.

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EXECUTIVE SUMMARY

The notification of draft rules on medical devices by the Ministry of Health and Family Welfare is a welcome move. There has been considerable uncertainty regarding the regulation of these devices, with the Ministry issuing circulars and guidelines that extended only to a limited number of devices, while most devices were marketed without any standards regarding their safety or effectiveness. The draft rules on medical devices are therefore a positive step, but will prove to be effective only if the following concerns are taken into account.

First, the notification of the rules ought to be harmonised with the drafting of the new Drugs and Cosmetics Act. The Ministry has declared its intentions to replace the existing Drugs and Cosmetics Act, 1940. However, several provisions in the proposed rules on medical devices have been drafted on the basis of the existing Act. If these rules are notified before the new Act enters into force, they will have to be amended extensively to match the new provisions. This will involve unnecessary duplication of legislative drafting.

Second, the rules rely on the existing regulatory architecture under the Drugs and Cosmetics Act, 1940, an architecture that has proved to be ineffective in ensuring the Act's successful implementation. These rules on medical devices are unlikely to be prove successful unless this regulatory architecture is substantially overhauled. We recommend that the Food Safety and Standards Authority of India be used as a model for creating a new regulator under the Drugs and Cosmetics Act. This will involve providing statutory backing to the powers and functions of the regulatory, which does not adequately exist under the current statutory scheme. We also recommend that the CDSCO be given limited powers of enforcement to reduce the existing near-complete reliance on the criminal justice system.

Third, we recommend that the provisions of the rules be reviewed thoroughly to separate provisions that are primary obligations and those that are secondary ones. We have identified several provisions in the rules that ought to find place in a primary statute—these include key definitions and provisions that set out the powers and functions of regulatory authorities and the obligations of private actors. The rules should be reserved for more detail-specific provisions. This will ensure appropriate legislative hierarchy, and give a firmer legal foundation to the regulatory provisions of the parent Act.

We have also identified some substantive issues with the draft rules. Two important issues are: one, the applicability of these rules to devices like e-cigarettes and healthcare apps, and two, the off-label use of these devices as well as the regulation of refurbished medical devices. The existing rules are ambiguous about both these issues.

Finally, we have also conducted a clause-by-clause critique of the provisions of the rules, pointing out drafting errors and inconsistencies and suggesting changes where appropriate. In particular, an important issue is the harmonisation of the provisions of the rules on medical management and compensation for serious adverse events during clinical investigations or clinical performance evaluations with similar provisions in the existing Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945.

The Ministry of Health and Family Welfare ("**MoHFW**") first issued draft rules on medical devices on 12 July, 2016. A revised draft was subsequently issued on 17 October, 2016, inviting objections and suggestions. We offer comments on these revised rules in two ways: first, by highlighting broader, structural issues with the rules; second, by undertaking a clause-by-clause analysis of the rules that points out errors in drafting and suggests ways in which the rules can be strengthened.

I. GENERAL COMMENTS

A. Harmonising the Rules with the Proposed New Drugs and Cosmetics Act

In June, 2016, the Cabinet announced that it was withdrawing the Drugs and Cosmetics (Amendment) Bill, 2013 which had been introduced in the Rajya Sabha on 29 August, 2013. The MoHFW subsequently invited public comments on a new law to replace the existing Drugs and Cosmetics Act, 1940. Naturally, this will also require the replacement of the existing Drugs and Cosmetics Rules, 1945. We understand that work is currently in progress to create this new law, although a draft has not yet been made available to the public.

It is commendable that the MoHFW has also recognised the need to address the regulation of medical devices in a systematic manner and has framed a separate set of Medical Devices Rules, 2016 in this regard. However, it will be premature to notify these rules without taking into account the process of drafting a new Drugs and Cosmetics Act that is currently underway. Ideally, it is this Act that ought to be drafted first, followed by general rules under the Act as well as specific rules on medical devices. This sequence of legislative drafting is necessary and desirable for the following reasons.

First, through the notification of draft rules, the MoHFW has expressed its intention to regulate medical devices through subordinate legislation, not a primary statute. The parent Act for these rules on medical devices continues to be the Drugs and Cosmetics

Act. Subordinate legislation cannot exist without a parent Act. The executive derives its power to frame rules only from primary legislation; there is no stand-alone power to frame rules, independent of this primary legislation. Under the existing scheme, the MoHFW has the power to frame rules for medical devices under s 33 of the Drugs and Cosmetics Act. However, if the rules on medical devices are notified under the existing Drugs and Cosmetics Act, and the Act is then repealed (as appears to be the intention of the MoHFW), the legal status of the rules on medical devices will be unclear.

Second, even if the MoHFW is able to ensure the continuing validity of the rules on medical devices despite the repeal of the parent Drugs and Cosmetics Act, it ought to be immediately apparent that this sequence (rules first, Act second) is not practical and will involve unnecessary duplication of legislative drafting. There are several provisions in the draft rules that refer to the parent Act. For instance, s 2 of the draft rules, which sets out their applicability refers to devices (substances used for *in vitro* diagnosis, substances in the nature of mechanical devices) that are defined in s 3 of the Drugs and Cosmetics Act. The definition of medical devices under clause (zc) of s 3 of the draft rules similarly refers to s 3 of the Drugs and Cosmetics Act. Chapter VII of the draft rules refers to specific provisions in the Drugs and Cosmetics Rules, 1945 that govern the conduct of clinical trials.

Once the existing Act and rules are repealed, and new ones are enacted, the above provisions in the draft rules will have to be correspondingly amended. These may only be technical amendments (for example, a reference in the draft rules to one provision in the Act will be substituted with reference to another), but it would still make for a more efficient process to ensure that the Act is in place before notifying the rules on medical devices.

In any case, there are other, more substantive provisions in the draft rules that are bound to overlap with issues that will also be covered by the parent Act. For example, the draft rules on medical devices define key terms related to clinical investigations ("clinical research organisation", "serious adverse event"), while Part VII sets out the conditions under which clinical investigations of medical devices are to be conducted. It is expected that the new Drugs and Cosmetics Act that is proposed, like the existing 1940 Act, will have provisions on the conduct of clinical trials for drugs.

It is desirable that provisions in the draft rules on the clinical investigation of medical devices and provisions in the new Act on clinical trials of drugs be harmonised, especially

with regard to provisions relating to ethics committees, medical management and compensation for injury or death. Again, this harmonisation requires at the very least, simultaneous drafting of the draft rules on medical devices and the new Drugs and Cosmetics Act. At the moment, the draft rules, for the most part, incorporate provisions on clinical trials in the existing Act, and rules. However, if the provisions on clinical trials in the Drugs and Cosmetics Act are revised (as we have earlier argued they should be[1]), this is bound to require corresponding amendment to the draft rules on medical devices if these rules are notified before the revised Act is in place.

The draft rules on medical devices also rely on the existing regulatory architecture, in the form of the Central Licensing Authority and State Drugs Controllers. It is likely that this architecture will change with the enactment of a new Drugs and Cosmetics Act (In fact, we argue in the next section, that this regulatory architecture *should* be changed). Like the example above, this change would also require subsequent amendment to the draft rules on medical devices if these rules were to be notified before the proposed new Act enters into force.

In both cases, this would unnecessarily lengthen the process of introducing a new and coherent legal and regulatory framework, and would be an inefficient use of drafting resources. **We therefore recommend that the rules on medical devices be notified only *after* the new Drugs and Cosmetics Act is in place and the rules have been modified to reflect the changes made to the parent statute. Measures necessary to regulate medical devices in the interim may be introduced through the existing Drugs and Cosmetics Rules. However, even these measures ought to be introduced only after taking into account the changes that will be introduced through the new Drugs and Cosmetics Act.**

Even though this recommendation might delay the process of putting in place a new regulatory framework for medical devices, ensuring that it is harmonised with the new Drugs and Cosmetics Act will mean a clearer and more robust framework in the long run.

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[1] Vidhi Centre for Legal Policy, 'Comments on the Drugs and Cosmetics (Amendment) Bill, 2015' (January 2015) <http://vidhilegalpolicy.in/reports-1/2015/4/6/the-draft-drugs-and-cosmetics-amendment-bill-2015-submissions-to-the-ministry-of-health-and-family-welfare-government-of-india> accessed> accessed 18 November 2016 ("Vidhi Comments").

B. Creating a Robust Regulatory Architecture

As mentioned in the previous section, the draft rules on medical devices rely on the regulatory architecture under the existing Drugs and Cosmetics Act, 1940. However, there are two problems with this architecture: for one, several regulatory powers that are exercised by the Central Drugs Standard Control Organisation ("**CDSCO**") do not have statutuory backing; second, the actual working of this regulatory architecture has been unsatisfactory, with a Parliamentary report criticising the weak enforcement of the Drugs and Cosmetics Act.[2]

The new rules on medical devices are unlikely to be effective if they continue to rely on this existing architecture for their implementation. Regulators in areas like electricity, food safety and telecommunications are all set up under statutes that clearly define their powers and functions. Although the CDSCO performs similar regulatory functions, provisions in the Drugs and Cosmetics Act that govern its establishment, limit its powers, and define its duties, are missing.

The Supreme Court, through obiter observations in several judgments, provides some guidance for what constitutes a 'regulatory function'. These include making regulations, overlooking the implementation and enforcement of these regulations[3] and taking measures in the interests of consumers.[4] The Court has also stated that regulators must function 'in total consonance' with statutory provisions. When the functions of the CDSCO are considered in light of this judicial guidance, it is evident that they are regulatory functions. However, the body still remains one of the few regulators in the country not set up through a statutory enactment.

The CDSCO is the authority is responsible for the approval of New Drugs, Clinical Trials, for laying down the standards for drugs, ensuring that only good quality drugs are

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[2] Department-Related Parliamentary Standing Committee on Health and Family Welfare, '59th Report on the Functioning of the Central Drugs Standard Control Organisation' (2012).

[3] *U.P. Power Corporation Ltd. v. National Thermal Power Corporation Ltd. and Ors*., [2011] Insc 964 ("A regulatory Commission not only makes Regulations but in view of its extensive powers but also in-charge of implementation thereof… A regulation may provide for cost, supply of service on non-discriminatory basis, the mode and manner of supply making provisions for fair competition providing for a level playing field, protection of consumers' interest, prevention of monopoly")

[4] *Hotel and Restaurant Association & Ors. v. Star India Pvt. Ltd.*, Appeal (Civil) No. 2061 of 2006. ("A regulation may provide for cost, supply of service on non-discriminatory basis, the mode and manner of supply making provisions for fair competition providing for a level playing field, protection of consumers' interest, prevention of monopoly.")

imported into the country, coordinating the activities of State Drug Licensing Authorities and providing expert advice to ensure uniformity in the enforcement of the Act. However, as the table below demonstrates, the Drugs and Cosmetics Act, 1940 makes only limited provision for the setting up of authorities to carry out these functions. The manner of appointment, composition, tenure, powers and functions, and procedure to be observed by these authorities are not set out in the Act in a systematic manner.

Authority	**Procedure for appointment of members**	**Composition**	**Tenure of Members**	**Powers and Functions**	**Procedure**	**Conflict of Interest**
Drug Technical Advisory Board	✓	✓	✓	✓	×	×
Central Drugs Laboratory	✓	×	×	✓ (Rules)	✓ (Rules)	×
Drugs Consultative Committee	✓	✓	×	✓	✓ (Rules)	×
Government Analysts	✓	✓ (Rules)	×	×	×	✓
Inspectors	✓	✓ (Rules)	×	✓	✓	✓

The absence of a firm statutory basis for such an important regulatory function has meant that the CDSCO has worked in an *ad hoc* manner, without the stability and predictability that is expected of a body of its stature. There has also been confusion about the scope of its powers, with the result that drug regulation has remained ineffective. In particular, the regulatory machinery has failed at ensuring that only drugs of standard quality, that are safe and efficacious, are sold in the market.

Apart from weak statutory backing for the CDSCO and its various functions, one of the primary reasons for the failure of enforcement is complete reliance on the judicial system

to impose criminal penalties on defaulters. The regulator itself cannot take any significant meausures to penalise those who violate the requirements of the Drugs and Cosmetics Act. Although the Act does provide for the setting up of separate Drug Courts or the designation of certain courts as Drug Courts, these have not been set up in most instances and cases related to drug offences are often litigated in overburdened sessions courts.

The procedure for reporting offences, prosecution and enforcement is also currently scattered and needs to be streamlined. Additionally, there is a need to set up a system for the systematic and scientific sampling of drugs and medical devices, testing, analysis and enforcement. The obligations of manufacturers and pharmacists need to be clearly outlined and there is a need for independence and accountability on the part of the regulator.

Similar problems with the enforcement of the Prevention of Food Adulteration Act, 1954 resulted in the creation of the Food Safety and Standards Authority of India ("**FSSAI**"), which unifies licensing and enforcement functions. The Food Safety and Standards Act, 2006, provides the statutory basis for setting up the FSSAI as a body corporate. The Act sets out the body's composition, qualifications for appointment, terms of office, salary of its members and Chairman. The appointment and functions of various other personnel and advisory committees are also provided for. The duties, functions and procedures of the FSSAI are also clearly laid out. The Act provides for a comprehensive enforcement mechanism, with the duties and responsibilities of each actor clearly outlined.

A similar model ought to be followed in setting up the CDSCO. By conferring limited powers of enforcement on the CDSCO, some of the burden on the criminal justice system will be lifted. These powers of enforcement could include (but are not limited to) civil penalties, suspension, blacklisting or revocation (de-registration) of licenses. However, these powers must be conferred through a strong statutory mechanism that clearly defines the penalties to be awarded (including their quantum, duration), and which imposes suitable checks on the exercise of discretion by the regulator. In cases where imprisonment is recommended, cases may be referred to the courts.

However, the regulatory architecture cannot be overhauled in this manner without simultaneously restructuring the existing Drugs and Cosmetics Act. **It is advisable that significant changes to the licensing and enforcement functions of the regulator be**

introduced through the parent Act, rather than through subordinate legislation. As the next section demonstrates, there are several provisions in the draft rules on medical devices that would have been a better fit in a primary statute than in secondary rules.

C. Ensuring the Hierarchy of Primary and Secondary Legislation

In previous submissions[5] to the MoHFW on the Drugs and Cosmetics Act and rules, we emphasised the importance of distinguishing between primary obligations that ought to find place in a statute, and secondary, detail-specific obligations that more appropriately formed part of the rules. A similar principle applies to the draft rules on medical devices. There are several provisions in the draft rules that are more suited to a primary statute; in fact, their inclusion in a primary statute is essential to ensure firmer legal authority for the powers conferred on regulatory authorities under the rules.

We have identified the following list of provisions in the draft rules that ought to form part of the parent Act instead:

- **Key definitions**, such as 'academic clinical study', 'active diagnostic medical device', 'active medical device', 'active therapeutic medical device', 'clinical investigation', 'clinical investigation plan', 'clinical performance evaluation, 'clinical research organisation', 'conformity assessment', 'custom made medical device, 'intended use, 'invasive device, 'investigational medical device', 'long term use', 'manufacture', 'manufacturer', 'medical device', 'new *in vitro* diagnostic medical device', 'Post Marketing Surveillance', 'predicate device', 'recall', 'serious adverse event', and 'sponsor'.
- **Provisions that confer powers, rights and obligations**, such as clause 7 (requiring manufacturers to follow Essential Principles for manufacturing Medical Devices), Chapter III (setting out the powers and functions of various authorities, officers and bodies), Clause 18 (requiring audit or inspection before licences for manufacture are granted), Clause 20 (conferring power on the State or Central Licensing Authority to grant a licence for manufacture), Clause 21 (setting out the conditions for grant of a manufacturing or loan licence), Clause 25 (providing for the suspension or cancellation of manufacturing licence), Clause 26 (requiring medical devices to conform to product standards), Clause 34

[5] Vidhi Comments (n 1).

(setting out the conditions to be complied with by import licence holders), Clause 38 (permitting the import of medical devices for personal use), Clause 46 (requiring compliance with conditions while conducting clinical investigations), Clause 47 (suspending or cancelling permission to carry out clinical investigation), Clauses 48 and 55 (requiring medical management and compensation to be provided for injuries or deaths during clinical investigations and clinical performance evaluations respectively).

- **Provisions that already have a parallel in the existing Drugs and Cosmetics Act**, such as Clauses 50 and 51 of the draft rules that require the maintenance of records and the disclosure of persons involved in clinical investigation/performance evaluations respectively. These are mirrored in Sections 18B and 18A of the Act, which impose similar obligations on the manufacturers of drugs. Similarly, some of the provisions in Chapter IX of the draft rules that set out the duties and powers of Medical Device Officers, Medical Device Testing Officers and Notified Bodies. These provisions are mirrored in the powers of Inspectors set out under Section 22 of the Drugs and Cosmetics Act.

The above provisions are not exhaustive—**we recommend that the draft rules be reviewed thoroughly to separate primary and secondary obligations, and that the new Act and rules be re-drafted accordingly. Provisions that define key terms, enabling provisions that confer powers and set out obligations, and those that define offences and prescribe penalties, ought to form part of the parent Act.**

D. Substantive Issues

In this section, we list out some of the content-based problems with the rules. These are related to the scope of the definition of 'medical device', the inconsistency of the definition of 'manufacturer' with the definition under the Drugs and Cosmetics Act, and the off-label use and use of refurbished medical devices.

1. Definition of 'Medical Device':

The current definition of medical devices under sub-clause (zc) of clause 3 of the draft rules includes devices that are *intended* to inter alia diagnose, monitor or treat a disorder. However, linking the categorisation of the medical device to the *intention* of the manufacturer has had the unintended effect of excluding devices that operate like medical devices but are not approved or marketed for the purposes specified under the

rules. A recent example of such devices is Electronic Nicotine Delivery Systems (ENDS) which are also known as e-cigarettes. While some manufacturers may market them as nicotine cessation devices (thus having an *intended* therapeutic effect), they may also be marketed simply as nicotine products. From the definition of 'medical device' under the draft rules, it is not clear whether they would be regulated under these rules in such a case.

This has led to legal and regulatory uncertainty, with the State Drug Regulatory Authorities in Punjab and Maharashtra categorising them as an "unapproved drug" under the Drugs and Cosmetics Act, 1940 while Punjab has also declared them a "poison" under the Poisons Act, 1919. Subsequently, people have been convicted and jailed[6] under the Drugs and Cosmetics Act, 1940 and e-commerce portals have received notices[7] from State Tobacco Control Cells for selling e-cigarettes. It is thus imperative that the CDSCO clarifies whether ENDS are regulated under the draft rules.

Another emerging technology that might be affected by similar regulatory uncertainty is healthcare apps.[8] These apps may range from simple trackers of vital statistics to actually providing therapeutic information. Recognising the potential public health impact and the need to regulate such apps, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom has released guidance to determine which health apps are classified as 'medical devices' and would be regulated by them.[9] With the use of health apps growing exponentially in India, there is a need for some oversight on their use.

It is thus recommended that the categorisation of medical devices be de-linked from the intended use of the device and determined instead from the potential public health impact of the device. Alternatively, the meaning of the term

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[6] Tribune News Service, 'E-cigarette seller gets 3 year jail in Mohali', 15 April, 2016 available at <http://www.tribuneindia.com/news/chandigarh/e-cigarette-seller-gets-3-year-jail-in-mohali/222736.html> accessed 6 September, 2016.

[7] PTI, 'E-commerce portals get notice for selling e-cigarettes in Punjab', 24 January, 2016 available at <http://www.deccanchronicle.com/in-other-news/240116/e-commerce-portals-get-notice-for-selling-e-cigarettes-in-punjab.html> accessed 6 September, 2016.

[8] IANS, 'Rise of Healthcare apps making it simpler for the patients to seek healthcare in India,' 5 September, 2016 available at <http://health.economictimes.indiatimes.com/news/health-it/rise-of-healthcare-apps-making-it-simpler-for-the-patients-to-seek-care-in-india/54016887> accessed 6 September, 2016

[9] Medicines and Healthcare products Regulatory Agency (Government of the United Kingdom), Guidance: Medical device stand-alone software including apps, 8 Aug 2014 available at <https://www.gov.uk/government/publications/medical-devices-software-applications-apps> accessed 6 September, 2016.

'intended' under Rule 3(zc) must be clarified further. The intended use of the medical device must not simply be gauged from the approved uses of the device by the CDSCO or from the approved information on the label. Such 'intended use' must also be gauged from the ways in which the device is commonly used by people and its potential public health impact.

2. Need to account for off-label use, re-use, refurbished and donated medical devices:

Often, adverse events from medical devices arise not out of defects in manufacturing or maintenance but from use by the ultimate consumers themselves. Unlike drugs, medical devices are complex, expensive and are often intended for multiple use. There is thus a higher probability that they administered incorrectly or used for purposes for which they are not approved. This leads to various practices like off-label use and the re-use of devices meant only for a single use. **It is thus crucial that the CDSCO issue regular alerts on the use of these devices and on issues and adverse events arising from common off-label uses.**

The draft rules also do not account for refurbished medical devices (which may or may not be imported) as well as donated devices, both of which may help to meet the critical shortfall of certain medical devices in the country. The import of refurbished medical devices is currently banned in the country, though news reports suggest that the government is considering relaxing this ban.[10] **In such case, the draft rules must contain provisions to regulate such devices and ensure that they safe and efficacious to use.**

The World Health Organisation, in its publication *Medical Device Regulations: Global overview and guiding principles* (2003) ("**WHO Principles**"), also **recommends that regulators ensure that companies supplying refurbished equipment fulfil after-sale obligations including the continued availability of technical support and maintenance services.**

The next part provides a clause-by clause critique of the provisions of the draft rules.

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[10] PTI, 'Govt may bring new law on medical devices: Ananth Kumar', 2 September, 2016 available at <http://health.economictimes.indiatimes.com/news/medical-devices/govt-may-bring-new-law-on-medical-devices-ananth-kumar/53979193> accessed 6 September, 2016.

II. CLAUSE-BY-CLAUSE CRITIQUE

Rule No.	Rule Text	Comments	Suggestions for Alternative Provision
2(1)	These rules shall be applicable in respect of,- (i) substances covered under sub-clause (i) used for *in vitro* diagnosis; (ii) substances that are in the nature of mechanical devices covered under sub-clause (ii); and (iii) devices specified from time to time by the Central Government by notification in the Official Gazette under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).	This provision specifies the subject matter applicability of the Draft Medical Devices Rules, 2016 (hereinafter "**Rules**"). However, the provisions under the Rules have been made applicable to 'medical devices', a term that has been defined in Rule 3(zc). The definition under Rule 3(zc), in fact, is more exhaustive than the one provided here. It is thus recommended that this provision be deleted. The definition of 'medical device' must also be amended so that it is linked to the Drugs and Cosmetics Act, 1940 (hereinafter "**Act**") (*see* comment on clause 3(zc)).	It is recommended that Rule 2(1) be deleted.
2(5)	Medical devices already notified under sub-clause (iv) of clause (b)	This provision specifies the process of transition from the old rules applicable to medical devices	To remove ambiguity, it is recommended that the eighteen month

	of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and marketed in India prior to the commencement of these rules shall continue to be marketed as hitherto before, till the expiry of eighteen months or the current validity of the licence, whichever is later, from the commencement of these rules.	to the Rules. However, for medical devices that have already been notified under section 3(b)(iv) of the Act, it allows for a minimum period of eighteen months after the commencement of the Rules for them to be applicable. However, it isn't clear whether the old rules continue to be applicable to notified medical devices till their license expires or whether the new Rules become applicable to these devices from the date on which they come into effect and the application of the old rules is limited to the validity of the license itself. Further, there is no rationale for the eighteen month relaxation period for notified devices that are already being marketed. The benefits accruing from the new Rules ought to be applicable to all medical devices once they come into effect. Thus, the relaxation period should be removed and once the license for a medical device expires, applications for new licenses ought to be made under the new Rules.	relaxation period be removed and the rule be re-drafted as follows: "*Medical devices already notified under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and marketed in India prior to the commencement of these rules shall continue to be marketed as hitherto before, till the expiry of the validity of the current licence."*

3(za)	"manufacture" in relation to,- (i) medical device includes any process for designing, making, assembling, configuring, finishing, packing, sterilizing, labelling or adapting with a view to sell or distribute or stock but does not include a custom made device; (ii) *in vitro* diagnostic medical device includes any process for designing, making, assembling, configuring, labelling or packing with a view to sell or distribute or stock;	The definition in this provision is currently under-inclusive, and should include both processing and refurbishing of medical devices. Further, the authority to prescribe legal liability for any actions can only be derived from primary legislation. This includes (i) the category of persons to whom such liability is attracted (in this case the manufacturer or authorised agent), (ii) the prescribed offences and (iii) the penalty prescribed for these offences. Under the current draft rules, both (i) and (ii) are provided for under secondary legislation, which is legally suspect. This is evident from the fact that the terms 'manufacture' and 'manufacturer' for drugs are defined under the parent Act while for medical devices these are defined under the draft rules. It is thus recommended that the definitions and offences under the draft rules are passed as primary legislation under the new Drugs and Cosmetics Act, as already mentioned in Part II (C).	It is recommended that Rule 3(za) be replaced with the following: "manufacture" in relation to,- (i) medical device includes any process for designing, making, assembling, configuring, finishing, **processing, refurbishing**, packing, sterilizing, labelling or adapting with a view to sell or distribute or stock but does not include a custom made device; (ii) *in vitro* diagnostic medical device includes any process for designing, making, assembling, configuring, labelling or packing with a view to sell or distribute or stock;
3(zc)(A)	"medical device" means,- (A) an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a	While sub rules 3(zc)(B) and 3(zc)(C) have been linked to the definition of "drug" under section 3(b) of the Act, sub rules 3(zc)(A) is a stand-alone definition.	It is recommended that sub rule 3(zc)(A) be replaced with the following: "medical device" means,-

	software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means for one or more of the specific purposes of,- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; or (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; or (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; or (iv) supporting or sustaining life; or (v) disinfection of medical devices; or	Section 3(b)(iv) of the Act states that it is applicable only to devices that have been notified by the Central Government. However, the definition of "medical device" in sub-rule 3(zc)(A) is much broader and will cover a larger category of devices. Thus, it is not clear whether the Rules are intended to apply only to medical devices notified under the Act or to all medical devices that would fall under the definition in Rule 3(zc)(A). Unless an amendment is made to the Act, the Rules can only be applicable to notified devices. Thus, it is recommended that sub-rule 3(zc)(A) be amended and linked to section 3(b)(iv) of the Act. However, these Rules ought to be ideally applicable to all medical devices envisaged in this definition, and not just to the narrower category of notified devices under section 3(b)(iv) of the Act. Alternatively, it is thus recommended that this definition of 'medical devices' be incorporated in the Act itself through an amendment.	(A) an instrument, apparatus, appliance, implant, material or other article **notified under sub-clause (iv) clause (b) section 3 of the Act**, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means for one or more of the specific purposes of,- (i) diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; or (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; or (iii) investigation, replacement or modification or support of the anatomy or of a physiological process; or (iv) supporting or sustaining life; or

	(vi) control of conception;		(v) disinfection of medical devices; or (vi) control of conception;
3(zc) Exp.	*Explanation:* For the purposes of these rules "accessory" means an article that is intended specifically by the manufacturer to enable a medical device to be used in accordance with its intended use;	The term "accessory" has already been defined under Rule 3(b) and is superfluous in this provision.	It is recommended that the explanation to Rule 2(zc) be deleted.
3(zl)	"predicate device" means a device, first time and first of its kind, approved for manufacture for sale or for import by the Central Licensing Authority and has the similar intended use, and design characteristics as the device which is proposed for licence in India;	It is not necessary that a predicate device is being used for the "first time" or that it is the "first of its kind". The current definition of predicate devices is very restrictive and ought to be expanded to any device that has already been approved for manufacture, sale or import by the Central Licensing Authority. Reference may be made to 21 CFR 807.92(a)(3) of the United States which defines a "predicate device" as a legally marketed device that: "*was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process*".	It is recommended that the provision be replaced with the following: *""predicate device" means a device approved for manufacture, sale, or import by the Central Licensing Authority and has the similar intended use, and design characteristics as the device which is proposed for licence in India;*"

		The US Food and Drug Administration maintains a 510(k) database which contains all devices cleared under the 510(k). This database may be searched to determine the most appropriate predicate device for a new license being sought. A similar searchable database of approved devices ought to be instituted in India as well for the effective implementation of these Rules.	
3(zp)	"serious adverse event" means an untoward medical occurrence that leads to- (i) a death; (ii) a serious deterioration in the health of the subject that either- (A) resulted in a life-threatening illness or injury; or (B) resulted in a permanent impairment of a body structure or a body function; or (C) required in-patient hospitalisation or prolongation of existing hospitalisation, or (D) resulted in medical or surgical	The current definition of 'serious adverse event' is under-inclusive when compared to the same definition under Rule 2(5)(A) of Schedule Y of the Drugs and Cosmetics Rules, 1945. It excludes the category of "persistent or significant disability or incapacity" and would this limit the ability of persons to seek medical management and compensation for adverse effects caused by a medical device.	It is recommended that the provision be amended as follows: *"serious adverse event" means an untoward medical occurrence that leads to-* *(i) a death;* *(ii) a serious deterioration in the health of the subject that either-* *(A) resulted in a life-threatening illness or injury; or* *(B) resulted in a permanent impairment of a body structure or a body function; or* *(C) required in-patient hospitalisation or prolongation of existing hospitalisation,*

	intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; (iii) foetal distress, foetal death or a congenital abnormality or birth defect		*or* *(D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or* ***(E) is associated with persistent or significant disability or incapacity*** *(iii) foetal distress, foetal death or a congenital abnormality or birth defect*
15(6)	The Central Licensing Authority may, wherever required, in case of Class C or Class D medical device, use the services of experts for matters relating to inspection or review of the documents:	The provision permits the Licensing Authority to consult experts when assessing applications for manufacture, sale and distribution of a medical device. However, safeguards must be incorporated in the Rules to ensure that there are no conflicts of interest and that these experts are chosen in a transparent manner. It is thus recommended that a panel of experts be set up through notification, at the State and Central levels, from which experts may be consulted when the application documents are being reviewed.	It is recommended that the provision be replaced with the following: *"(6)(i) The Central Licensing Authority shall, by notification, appoint experts with such qualifications as may be prescribed;* *(ii) The Central Licensing Authority may, wherever required, in case of Class C or Class D medical device, use the services of experts for matters relating to inspection or review of the documents*:"
21(vi)	After the grant of licence or loan	This provision requires the license holder to	It is recommended that the provisions

	licence, the licence holder shall comply with the following conditions, namely:- (vi) the manufacturer shall submit the confirmation that no changes in specification, labelling or technical staff has been made;	submit confirmation that there have been no changes in specification, labelling or technical staff. It does not clarify *when* such confirmation is to be submitted, although it appears that such confirmation is required when there is change in constitution of the manufacturer or when there is a 'major change', as is evident from a reading of clause (v) of clause 21. There is no clarity on what constitutes a major or a minor change either.	be redrafted as follows: *"(vi) In addition to the requirements under sub-rule (v), the manufacturer shall also submit the confirmation that no changes in specification, labelling or technical staff has been made;*" The format for such a submission ought to be provided for under the Schedule.
21(xiii)	if the manufacturer has stopped the manufacturing activity or closed down the manufacturing site for reasonable time, the same shall be intimated to the Central Licensing Authority or State Licensing Authority as the case may be.	It isn't clear what a reasonable amount of time is. This provision should specify an exact period of time after which a manufacturer must inform the Licensing Authority about the closure of manufacturing activity.	The provision ought to be amended and 'reasonable time' replaced with an exact time period as considered appropriate.
23	The State Licensing Authority shall have at least two per cent of the cases of licence recommended by every Notified Body annually, audited by its officers, and such cases shall be selected on a random	This provision states that the officers of the State Licensing Authority shall audit licenses granted on a random basis. However, a procedure must be specified to ensure that this selection is done in a statistically and scientifically sound manner to minimise sampling errors such that the licenses audited are representative of the larger sample	Such a process may be outlined in the employee guidelines and manuals of the Licensing Authorities.

	basis.	size.	
25(5)	The State Licensing Authority or the Central Licensing Authority, as the case may be, based on the level of risk may order destruction of such stock of medical device in the presence of a Medical Device Officer, if in its opinion, the licence holder has failed to comply with any of the conditions of the licence or loan licence or with any provisions of the Act or rules made thereunder.	The Licensing Authorities cannot take measures that they are not empowered to take explicitly under the parent Act. A power such as ordering the destruction of stocks of medical devices cannot be vested in the Authorities under the Rules. There is a possibility that actions taken under this provision may not stand scrutiny in a court of law. It is thus recommended that the Act would have to be amended to empower the Licensing Authorities to take a measure such as ordering the destruction of stocks of medical devices.	The Act ought to be suitably amended to empower the Licensing Authorities to take measures in the public interest.
30(7)	Where the original licence is defaced, damaged or lost, the authorised agent may make an application accompanied with fees as specified under the *Second Schedule* for a duplicate copy of such licence.	Since this provision is in Chapter V, it is only applicable to licenses for the import of medical devices. However, a similar facility should also be available for licenses for manufacture, sale, distribution, test licenses, permit for personal use etc. It is thus recommended that this provision be expanded and made applicable to licenses obtained for all these purposes. It might also be suitably shifted to Chapter XI (Miscellaneous).	
31	The Central Licensing Authority may cause an inspection of the overseas manufacturing site either by itself or by any other person to	Given the territorial application of law, national authorities cannot vest themselves with jurisdiction over foreign nationals or their assets. The local laws of the country where the overseas	This provision ought to be deleted and incorporated in the Act, keeping in mind the jurisdictional limits on the powers of the Central Licensing Authority.

	whom the power has been delegated for the purpose and the applicant shall be liable to pay a fee as specified under the *Second Schedule* in respect of expenditure required in connection with the visit to the overseas manufacturing site.	manufacturing site is located would be applicable in such a case and officials attempting to inspect such facilities might be understood to be committing trespass. Organisations like the US FDA ordinarily request inspections in foreign countries, and have been vested with the power to conduct these inspections once such permission has been granted by the overseas facility. If foreign firms refuse to permit such inspection and there is the appearance of a violation, the FDA has the option of not granting approval of the application and refusing entry of those products when offered for import. Further, they may enter memorandums of understanding with the heads of other Federal agencies to conduct such examinations through the officers and employees of the other Agency. [Section 702 of the Food, Drug and Cosmetics Act]. In any case, such a power cannot be vested in the authority under delegated legislation and can only be incorporated in the primary Act.	
34(1)(ii)	authorised agent shall inform the licensing authority forthwith in the event of any administrative action taken due to adverse reaction, viz.	This provision requires the authorised agent to inform the licensing authority in the event that the medical device for which they possess a license is subject to administrative action in the	

	Market withdrawal, regulatory restrictions, cancellation of authorisation or not of standards quality report of any medical device pertaining to this licence declared by the regulatory authority of the country of origin or by any regulatory authority of any other country, where the medical device is marketed, sold or distributed;	country of origin. However, it must also specify the time period within which such information must be communicated to the licensing authorities. The provision ought to be amended accordingly.	
38(3)	On receipt of an application under sub-rule (2), the Central Licensing Authority shall, on being satisfied about the information and the documents enclosed with the application, grant permission in Form MD19.	This provision empowers the Central Licensing Authority to permit the import of medical devices for personal use. However, given that such applications will usually be made by patients suffering from health issues, it is desirable that the process be made time bound and a provision for appeal to the State/Central Government be added.	Rule 38(3) ought to be numbered as 38(3)(i) and the following provisions added after it: *"(ii) The Central Licensing Authority shall communicate its decision granting or denying permission for import of medical devices within 60 days after the application is made.* *(iii) Any person who is aggrieved by the order passed under sub-rule (i), may, within thirty days from the date of receipt of such order, prefer an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as is considered necessary*

			and after giving an opportunity of being heard, pass such order in relation thereto as, it thinks fit."
46(v)	information about any report of suspected unexpected serious adverse event occurring during clinical investigation on the subject, shall, after due analysis, be submitted to the Central Licensing Authority within fifteen days of the sponsor coming to know about its occurrence as specified in the *Seventh Schedule* and in compliance with the procedure specified in these rules;	The inclusion of the words 'unexpected' before serious adverse events dilutes the import of the provision and ought to be deleted. These words may lead to persons who have experienced serious adverse events being deprived of medical management and compensation.	The provision ought to be replaced with the following: *"information about any report of suspected serious adverse event occurring during clinical investigation on the subject, shall, after due analysis, be submitted to the Central Licensing Authority within fifteen days of the sponsor coming to know about its occurrence as specified in the Seventh Schedule and in compliance with the procedure specified in these rules;"*
46(vi)	in case of an injury or death during clinical investigation of the subject of a clinical investigation, the applicant shall provide complete medical management or compensation in accordance with these rules;	The provision states that the applicant of a clinical investigation shall provide complete medical management **or** compensation to volunteers. This is contrary to the orders of the Supreme Court in *Swasthya Adhikar Manch v. Union of India* which requires that both medical management **and** compensation must be provided to volunteers who have experienced serious adverse events in a clinical investigation.	The provision ought to be replaced with the following: *"in case of an injury or death during clinical investigation of the subject of a clinical investigation, the applicant shall provide complete medical management and compensation in accordance with these rules;"*

46(ix)	the Central Licensing Authority may impose any other condition while granting permission in respect of specific clinical investigations, if considered necessary, regarding the objective, design, subject population, subject eligibility, assessment, conduct and treatment of clinical investigation.	The provision currently provides an exhaustive list of conditions that might be imposed by the Central Licensing Authority while granting permission for a clinical investigation. However, this provision should be re-worded to make it an illustrative list. This would allow the licensing authority to impose any such additional conditions as it sees fit. This might be particularly important to ensure that medical devices with respect to which clinical investigations are conducted in India are subsequently also marketed here.	The provision ought to be replaced with the following: "*the Central Licensing Authority may impose any condition while granting permission in respect of specific clinical investigations, if considered necessary, regarding the objective, design, subject population, subject eligibility, assessment, conduct, treatment of clinical investigation or any other condition in the public interest."*
48(1)	Where any participant is injured on account of participation of such participant in the clinical investigation, the sponsor permitted under rule 45 shall provide medical management to that participant.	Since the Rules don't define an 'injury' but a 'serious adverse event', this provision ought to be modified accordingly.	It is recommended that the provision be replaced with the following: "*Where any participant experiences a serious adverse event on account of participation of such participant in the clinical investigation, the sponsor permitted under rule 45 shall provide medical management to that participant.*"
48(2)	Where an injury is caused to the participant in a clinical investigation of any investigational	See comment for Rule 48(1).	It is recommended that the word 'injury' be replaced with 'serious adverse event'.

	medical device and such injury is attributable to the use of investigational medical device, the sponsor permitted under rule 45 shall provide to that participant, medical management and such compensation in such manner as specified under rule 122DAB of the Drugs and Cosmetics Rules, 1945 and shall be applicable *mutatis mutandis,* for the purpose of medical management and such compensation in case of clinical investigation and clinical performance evaluation under this Chapter.		
51	Every person, sponsor, clinical research organisation, any other organisation or investigator conducting a clinical investigation or clinical performance evaluation or his agent, as the case may be, shall, if so required, disclose to the Medical Device Officer or any other officer authorised by the Central	The provision does not make it clear who a 'person involved' in a clinical investigation or clinical performance evaluation is. More clarity must be provided on what categories of persons this includes.	

	Licensing Authority, the names, addresses and other particulars of persons involved in clinical investigation or clinical performance evaluation.		
55	Where any participant is injured on account of his participation in the clinical performance evaluation, the sponsor permitted under rule 52 shall provide medical management to that participant.	As explained above, the word 'serious adverse event' should be used instead of 'injured'. Further, the sponsor ought to provide **free and complete** medical management as well as compensation. The provisions in schedule Y of the Drugs and Cosmetics Rules 1945 should be made applicable *mutatis mutandis* for the purposes of determining and giving medical management and compensation in case of a serious adverse event.	The provision should be replaced with the following: "*Where any participant experiences a serious adverse event on account of his/her participation in the clinical performance evaluation, the sponsor permitted under rule 52 shall provide:* *(i) free and complete medical management to that participant.* (ii) *Such compensation in such manner as specified under rule 122DAB of the Drugs and Cosmetics Rules, 1945, which shall be applicable mutatis mutandis for the purpose of medical management and compensation in case of clinical performance evaluation.*"

59(c)	the permission holder shall inform the date of launch of medical device in the market to the Central Licensing Authority;	There is need for more accountability in case a permission holder does not actually launch the medical device in the country. Not just informing the Central Licensing Authority about the date of launch of the medical device, but actually marketing the device in the country should be made a condition for the grant of permission to import or manufacture a medical device. Such conditions are already imposed by the three-tier approval committee in the context of pharmaceutical drugs. However, their recommendations do not have binding force and thus there have been instances where clinical trials have been conducted for drugs in India but they have not been subsequently launched here. It is thus necessary that this condition be incorporated in the Rules and non-compliance with this condition is legally actionable. In case a permission holder fails to market the device within the two year period, the Central Licensing Authority ought to issue notice to them asking them to explain why their license should not be revoked. In the absence of a satisfactory answer, the license of the permission holder	After Rule 59(c), the following provision should be added: *"(d) the permission holder shall market the medical device in India within a period of two years from the grant of permission."* The following provisions are numbered (e), (f) and so forth.

		should be revoked.	
62	For the purpose of these rules, an application from a purchaser for test or evaluation of a medical device or portion of medical device under section 26 of the Act shall be made in Form MD29 and the report of such test or evaluation of the medical device which is prepared on such application shall be supplied to the applicant in Form MD28.	The provision allows a purchaser to make an application for test or evaluation of a medical device. However, it does not define who a purchaser is. It also does not take into account the 1986 amendment to section 26 of the Act, which allows a recognised consumer association to make an application under this section. If the provision is limited to a person who *actually pays* for the medical device, it may limit the ability of people affected by a malfunctioning or underperforming medical device from seeking recourse under the Rules. It is recommended that the word 'purchaser' be given the same meaning as understood under the Consumer Protection Act, 1986. This legislation provides an expansive definition of 'consumer' as follows: *"(d) "consumer" means any person who—* *(i) buys any goods for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any user of such goods other than the*	It is recommended that the provision be replaced with the following: "*For the purpose of these rules, an application from a purchaser or recognised consumer association for test or evaluation of a medical device or portion of medical device under section 26 of the Act shall be made in Form MD29 and the report of such test or evaluation of the medical device which is prepared on such application shall be supplied to the applicant in Form MD28.* *Explanation: The term 'purchaser' shall have the same meaning as that of a 'consumer' in section 2(d) of the Consumer Protection Act, 1986.*"

		person who buys such goods for consideration paid or promised or partly paid or partly promised, or under any system of deferred payment when such use is made with the approval of such person, but does not include a person who obtains such goods for resale or for any commercial purpose; or *(ii) hires or avails of any services for a consideration which has been paid or promised or partly paid and partly promised, or under any system of deferred payment and includes any beneficiary of such services other than the person who 'hires or avails of the services for consideration paid or promised, or partly paid and partly promised, or under any system of deferred payment, when such services are availed of with the approval of the first mentioned person* ***but does not include a person who avails of such services for any commercial purposes****;* *Explanation.— For the purposes of this clause, "commercial purpose" does not include use by a person of goods bought and used by him and services availed by him exclusively for the purposes of earning his livelihood by means of self-employment;"*	
72(2)	Where any person has been	The provision specifies the situations in which a	The provision ought to be re-drafted as

	convicted for manufacturing any medical device notified under sub clause (iv) of clause (b) of section 3 of the Act, which is deemed to be misbranded, adulterated or spurious, for sale, stocking or exhibiting for sale or distribution without a valid licence or licence, any implements or machinery used in such manufacture, sale or distribution and any receptacle, package or covering in which such medical device is contained and the animals, vehicles, vessels or other conveyances used in carrying such medical device shall be liable to confiscation.	medical device may be confiscated. However, it has been worded such that a person would have to be convicted for manufacturing a misbranded, adulterated or spurious medical device **and** for sale or distribution without a license before their medical devices can be confiscated. This appears to be contrary to the intention of the executive. It is recommended that the provision be re-drafted for clarity.	follows: Where any person has been convicted for manufacturing any medical device notified under sub clause (iv) of clause (b) of section 3 of the Act, which is: (i) deemed to be misbranded, adulterated or spurious; or (ii) for sale, stocking or exhibiting for sale or distribution without a valid licence or licence, any implements or machinery used in such manufacture, sale or distribution and any receptacle, package or covering in which such medical device is contained and the animals, vehicles, vessels or other conveyances used in carrying such medical device shall be liable to confiscation.
77(2)	The Central Licensing Authority shall audit the Notified Bodies at least once in two years or as may be considered necessary, by the Central Licensing Authority.	Rule 11(d) states that the National Accreditation Body shall audit the Notified Bodies periodically to assess conformance with the Rules and the norms laid down by it. It must be clarified what the difference in scope of the audits by the Central	After this provision, the following provision should be added: *"(3) The Audit Reports for the Notified*

		Licensing Authority and National Accreditation Body will be. Further, it is necessary that the Rules specify the frequency with which these audits will happen and that the Audit Reports will be publicly available on the website of the Central Licensing Authority and on request.	*Bodies shall be made publicly available on the website of the Central Licensing Authority and on request*."
81(1)	If a manufacturer or authorised agent, as the case may be, considers or has reasons to believe that a medical device which he has imported, manufactured, sold or distributed is not in compliance with the Act, or these rules, he shall immediately initiate procedures to withdraw the medical device in question from the market and patients, indicating reasons for its withdrawal and inform the competent authorities details thereof.	The provision currently requires the manufacturer or authorised agent to recall the medical devices from the market if she considers or has reasons to believe that they are not in compliance with the Act or the Rules. However, under Rule 3(zo), recall is mandated if the device is hazardous to health or if it fails to conform to any claims made related to its quality, safety or efficacy. For this, it is necessary that the manufacturer is constantly monitoring the performance of the devices. Reference may be made to Rule 3.1 of the EU Directive concerning medical devices 93/42/EEC, which requires: "*an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase, including the provisions referred*	The Rules must incorporate an obligation on the part of the license holder to constantly monitor the performance of the medical device and any reports of adverse reactions stemming from the use of the device.

		to in Annex X, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of the following incidents immediately on learning of them: *(i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;* *(ii) any technical or medical reason connected with the characteristics or performance of a device leading for the reasons referred to in subparagraph (i) to systematic recall of devices of the same type by the manufacturer."*	
87	The provisions of these rules shall have effect, notwithstanding anything inconsistent therewith contained in the Drugs and Cosmetics Rules, 1945.	This savings provision does not account for all the transitional issues that may arise when the new Rules are implemented. It is recommended that the savings provision from the previous notified draft Rules be retained.	After Rule 87, the following proviso should be added: *"Provided that such repeal shall not affect:-* *(i) the previous operations of the permission, licence, registration*

			certificate, no objection certificate under so repealed rules or anything duly done or suffered there under; or *(ii) any right, privilege, obligation or liability acquired, accrued or incurred under any of the rules under repeal; or* *(iii) any penalty, forfeiture or punishment incurred in respect of any offences committed against rules under repeal:"*

Vidhi

Centre For Legal Policy

BETTER LAWS. BETTER GOVERNANCE

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