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THE DRAFT DRUGS AND COSMETICS (AMENDMENT) BILL, 2015

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

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About Vidhi

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EXECUTIVE SUMMARY

The draft Drugs and Cosmetics (Amendment) Bill, 2015 ('the Bill'), which amends the Drugs and Cosmetics Act, 1940 ('the Act') seeks to bring about some positive changes to the law in this area. It introduces the regulation of medical devices, reconstitutes the Drugs Technical Advisory Board and attempts to reform the law on clinical trials. It is this last aspect that these submissions are concerned with. The main thrust of these submissions is that the Bill does not go far enough in giving the regulatory framework on clinical trials the complete overhaul that it needs. The existing framework is messy and complex because of the piecemeal amendments to the law attempted in the past. This implies that the rights of clinical trial participants as well as the obligations of sponsors, investigators and ethics committees remain unclear. This in turn is a violation of the right to health and life of the participants besides discouraging clinical trial research in India. Clarity and certainty will only be introduced by a far more comprehensive code than the 2015 Bill. These submissions suggest the following three ways in which this may be achieved.

First, the draft Bill must simultaneously be accompanied by a thorough review and re-enactment of the Drugs and Cosmetics Rules, 1945 ('the Rules'). One of the positive changes introduced by the Bill is the inclusion of provisions on clinical trials in the main body of the Act. However, most of these provisions are framed in basic language, leaving the details to be worked out in the Rules. If these provisions are to be effective, a review of the secondary legislation must occur side by side. This could either take the form of amendments to the existing rules or the drafting of a new set of rules. The first part of these submissions will argue that the latter option is preferable given the uncertain nature of the existing law which is itself a result of frequent amendment.

Second, the draft Bill must consider a more comprehensive reorganisation of Schedule Y. The existing Schedule is a disorganised mix of primary obligations and secondary, more detail-specific rules. The former kind of obligations ought to be transferred to the main text of the Act in keeping with the other basic obligations introduced in the parent statute by the Bill. The secondary details in Schedule Y may be reviewed along with the comprehensive re-enactment of the Rules recommended above. Thus, the second part of these submissions outlines those provisions of the Schedule that are a better fit as part of the main text of the Act.

The third part of these submissions deals with specific clauses of the Bill. As already stated, the Bill in its current form does not do enough to constitute a complete, stand-alone code on the subject. The third part therefore recommends key terms that also ought to be defined in the Bill, along with the draft definitions themselves. Some of these definitions draw on the United Kingdom Medicines for Human Use (Clinical Trials) Regulations 2004. This part of the submissions also points out deficiencies in the drafting of the other clauses of the Bill.

The state of the law on clinical trials in India is highly fragmented, with negative consequences for participant safety and the progress of scientific research. The 2015 Bill represents an ideal opportunity to tackle this comprehensively; it must not be squandered for yet another patchwork attempt at reform.

I. SIMULTANEOUS REVIEW AND RE-ENACTMENT OF THE RULES

This part of the submission is divided into two sections. The first section points to key provisions of the Bill that create obligations for sponsors, investigators and ethics committees, leaving the manner of carrying out these obligations to secondary legislation. This makes it evident that a draft Bill must also be accompanied by draft Rules for the provisions of the Bill to have any effect. The second section provides some examples of how the provisions proposed to be covered by the Bill are already governed by the existing secondary legislation. The aim of this exercise is to demonstrate the confusing state of the law presented by the Rules, as amended by several individual circulars, notices, office orders and guidelines. These examples in turn make a strong case for the Bill to be accompanied by a wholly new set of Rules, rather than amending the existing ones.

A. Provisions of the Bill requiring Secondary Legislation

Chapter IA of the Bill, which introduces a separate chapter on clinical trials leaves the following provisions to be worked out through secondary legislation:

Clause 4A (1): Form and manner in which permission to conduct a clinical trial must be furnished by the Central Licensing Authority

Clause 4A (2): Manner in which Ethics Committees must be constituted

Clause 4A(3): Period for which a new drug shall be considered to be new

Clause 4B: Determination of the cause of injury or death of a participant in a clinical trial

Clause 4C(1): Manner in which the sponsor must provide medical treatment and compensation to an injured or disabled participant

Clause 4C (2): Manner in which the sponsor must provide compensation to the legal heir of a participant whose death is caused by the clinical trial

Clause 4E: Manner of registration of Ethics Committees

Clause 4F(1): Manner in which the Ethics Committee shall grant approval to the clinical trial protocol

Clause 4E(3): Manner in which the Ethics Committee shall periodically review the trial, monitor internal audit reports furnished by the sponsor and visit study sites

Clause 4E(5): Other functions and responsibilities of Ethics Committees

Clause 4G(2): Manner in which the Central Licensing Authority shall review approval granted by an Ethics Committee whose registration has been suspended or cancelled

Clause 4U of the Bill also specifically empowers the Central Government to make rules in respect of the abovementioned provisions.

These provisions are integral to the conduct of clinical trials and the existing Rules and Schedule Y already do provide in some measure for most of these matters. However, as the next section demonstrates, they do so in a confusing and incomplete manner. It is therefore recommended that a fresh set of Rules be enacted simultaneously with the Bill to ensure that there is no legal vacuum and to create a clearer set of rights and obligations in relation to clinical trials.

B. State of Existing Secondary Legislation

In this section, some of the provisions listed in the previous section which are proposed to be introduced by the Bill are set out along with the manner in which they are already covered by the existing Rules and Schedule Y. This exercise will demonstrate the three kinds of problems that would arise if the existing secondary legislation was intended to govern the provisions of the Bill. These problems are:

(a) It is unclear

(b) It is contradictory to the provisions of the Bill

(c) It exists only in draft form or does not provide for the matters proposed to be introduced by the Bill.

The provisions of the Bill and corresponding provisions in the existing secondary legislation are set out below.

1. New Drug

Provision in the Bill: Clause 4A(3) states that a new drug shall be considered a new drug for such period as may be prescribed.

Provision in the Existing Secondary Legislation: The Explanation to Rule 122E states that a new drug shall be considered new for a period of four years from the date of its first approval or inclusion in the Indian Pharmacopoeia, whichever is earlier.

Problem: This provision in the existing Rules is clearly contradictory to the Bill. The latter does away with the four-year time period and introduces flexibility regarding the definition of a new drug.

2. Medical Management and Compensation for Clinical Trial Related Injuries or Deaths

Provision in the Bill: Clauses 4B and 4C of the Bill state that the determination of the cause of injury or death as well as the manner of payment of compensation shall be such as may be prescribed.

Provisions in the Existing Secondary Legislation:

Rule 122DAB of the Rules currently provides that participants or their legal heirs, as the case may be, are entitled to financial compensation for a clinical trial related injury or death as per the order of the Licensing Authority.

Schedule Y requires the Ethics Committee to forward its report on a serious adverse event or death, along with its opinion on financial compensation to an Expert Committee constituted under Appendix XII as well as to the Licensing Authority.

Appendix XII sets out separate procedures to determine the cause in the case of serious adverse events on the one hand, and death on the other. The Licensing Authority is to determine the cause in case of the former, while an independent Expert Committee is to be set up to determine the cause in case of the latter.

In addition to these, an office order dated 3rd July 2014 states that compensation is also to be provided for drug-related anomalies discovered at a

later stage and accepted to be drug-related. However, it does not specify the authority that is to determine whether it is drug-related or not.

Another office order of the same date states that sponsors are obliged to provide 'ancillary care to patients suffering from any other illness during the trial' without specifying whether such illness must be caused by the clinical trial or not.

Problem:

This combination of rules and office orders is confusing because it is inconsistent and contradictory in the following manner.

First, the terms 'injury' and 'serious adverse event' are used interchangeably. Serious adverse events are a narrower group of events than clinical trial related injuries, with financial compensation required to be paid for the broader group of injuries. However, Appendix XII only sets out the procedure for determining the cause in cases of serious adverse events and deaths. It is unclear which authority is to determine the cause in case of a clinical trial related injury which is not a serious adverse event.

Second, different timelines are prescribed in different provisions of the secondary legislation regarding the submission of reports regarding a serious adverse event or death by the sponsor and the Ethics Committee to the Licensing Authority. This confusion has been compounded by a different set of timelines prescribed in the notification dated 12th December 2014 which seeks to amend the existing Rules.

Third, the 12th December notification is also at odds with the 3rd July office order that requires the provision of ancillary care to clinical trial participants. The 12th December notification seeks to restrict the provision of medical management by the sponsor to participants only when the injury or illness is related to the clinical trial. However, the notification on ancillary care (which does not define the term) seems to suggest that medical care is to be provided irrespective of whether the illness is related to the trial.

These anomalies demonstrate that the existing system lacks a principled approach and a uniform procedure to determine compensation.

3. Medical Management and Compensation for Clinical Trial Related Injuries or Deaths

Provision in the Bill: Clause 4G(2) of the Bill states that the manner in which the Central Licensing Authority shall review approval granted by an Ethics Committee whose registration has been suspended or cancelled shall be as may be prescribed.

Provision in the Existing Secondary Legislation: None

Problem:

A notification dated 8th February 2013 which amended the existing Rules to require the registration of Ethics Committees also empowered the Licensing Authority to suspend or cancel such registration. However, there is no provision requiring such authority to review prior approvals granted by such Committees. A new provision to this effect will therefore have to be enacted to give effect to Clause 4G(2) of the Bill.

The examples above are only illustrative of the uncertainty caused by the existing secondary legislation. Given the extent of changes proposed to be introduced by the Bill, it is therefore recommended that a thorough review of the Rules, including Schedule Y, and the various notifications, circulars and orders be undertaken, a task which is better accomplished by the consolidation and re-enactment of these provisions, rather than their amendment. One of the key components of this consolidation ought to be a reorganisation of this body of secondary legislation according to an appropriate hierarchy. More fundamental obligations ought to find their place in the parent Act, while the details ought to be left to be worked out in the Rules. A potential reorganisation of Schedule Y is suggested in the second part of these submissions.

II. REORGANISATION OF SCHEDULE Y

The Bill transfers important provisions from the status of secondary legislation in the Rules and Schedule Y to the main body of the Act, presumably to create certainty and to signal the expressive commitment of the legislature to the importance of these obligations. However, there is no principled distinction between provisions that already exist in the Act, provisions that are proposed to be introduced by the Bill, and those that remain in the Rules and Schedule Y. The first section of this part sets out provisions in the Act and Bill, while the second section compares these with provisions of a similar character in Schedule Y that also ought to be included in the Bill (and eventually, the Act) by comparison.

A. Relevant Statutory Provisions

The relevant provisions of the Act are the following:

Section 10 (c): Prohibits the import of a drug other than in accordance with a licence

Section 10 (f): Prohibits the import of a drug which is prohibited under the Rules

Section 10A: Empowers the Central Government to prohibit the import of drugs in the public interest, especially if it is likely to involve any risk to human beings or animals or does not have the therapeutic value claimed

Section 13: Prescribes penalties for the contravention of the above provisions

Sections 18, 26A and 27 contain the same provisions, but with respect to manufacture, not import.

These provisions of the Act are not directly related to clinical trials, but must be read with Part XA of the Rules which require clinical trials to be conducted before a licence may be granted for the import or manufacture of a new drug.

These prohibitions in the Act have been made more explicit under the Bill, which introduces a separate chapter on clinical trials in the Act. The provisions that have been elevated to the status of statutory provisions are set out below, classifying them according to the entity on which they impose an obligation or confer powers and rights.

4. Sponsors

Clause 4A: No clinical trial may be initiated without obtaining the permission of the Central Licensing Authority or the Ethics Committee. This is also applicable to investigators and clinical research organisations.

Clause 4C: Medical treatment and compensation must be provided for any injury or death that occurs as a result of the clinical trial.

Clauses 4-I and 4J: Disclosure of details of clinical trial participants to Drugs Control Officers and maintaining records, data and other documents related to the clinical trial. Also applicable to investigators and clinical research organisations.

5. Central Licensing Authority

Clause 4D: Power to waive or defer pre-clinical and clinical data requirements in the case of life-threatening diseases or diseases of special relevance to the country.

Clause 4G: May suspend or cancel the registration of an Ethics Committee when it is satisfied that it has become incapable of discharging its functions and responsibilities under the Act, in which case it shall also review the approval granted to a clinical trial protocol by such committee.

6. Ethics Committee

Clause 4E: Must obtain registration with the Central Licensing Authority before granting approval to clinical trial protocols.

Clause 4F: Must be responsible for the safety and well-being of clinical trial participants, and to this end, must undertake periodic review of the trial, monitor internal audit reports and visit study sites. It also has the power to revoke permission granted to a clinical trial protocol.

The above provisions of the Bill are integral to the ethical conduct of a clinical trial and have therefore been deemed fit for inclusion in the parent statute. Specific penalties have also been described for the breach of these provisions. The common feature of these provisions is that all of them set out certain basic obligations for the different entities involved in a clinical trial, leaving the details to be worked out in the secondary legislation ie these provisions

constitute the minimum threshold that must be met before a clinical trial may be conducted. While this is a positive step, it is not comprehensive.

The existing Rules, including Schedule Y, contain obligations of the same character as the provisions in the existing Act and those proposed to be introduced by the Bill. By comparison, such obligations also ought to be transferred from Schedule Y to the parent statute. For example, the Bill recognises the power of the Ethics Committee to revoke permission granted to a clinical trial protocol for reasons to be communicated in writing to the investigator and the Central Licensing Authority. The existing Schedule Y confers a similar power to revoke on the Licensing Authority after giving a hearing to the sponsor or the investigator. There is no principled reason why the power of the Ethics Committee to revoke ought to be included in the parent statute, while the same power of the Licensing Authority is confined to secondary legislation.

The next section points out other similar obligations that are currently in the secondary legislation, but which ought to be in the main Act by virtue of comparison with the provisions set out in this section.

B. Provisions in existing Secondary Legislation that ought to be included in the Act

1. Registration of Clinical Trials

Rule 122 DAC of the Rules states that all clinical trials must be registered with the Clinical Trials Registry of India before enrolling the first participant. This is a similar threshold obligation to the provision in the Bill that requires the approval of the Central Licensing Authority and the Ethics Committee to conduct a clinical trial, and therefore ought also to be included in the Act.

2. Conditions under which Clinical Trials may be waived

Rules 122A and 122 B of the Rules allow the Licensing Authority to waive the requirement of local clinical trial results in the public interest and on the basis of data from other countries. Similarly, data requirements related to animal toxicology studies, mutagenicity studies and carcinogenicity may be modified if there is evidence of the drug having been safely marketed in other countries.

Schedule Y specifies the different kinds of phases for which clinical trials must be conducted eg Phase I trials need not necessarily be conducted in the case of new drug substances discovered outside India. It also sets out instances in which bioavailability and bioequivalence studies are to be conducted.

The Report of the Professor Ranjit Roy Chaudhury Committee also makes certain recommendations regarding instances in which requirements for clinical trials may be relaxed. Some of these have been implemented through office orders dated 3rd July 2014. Thus, one of the orders recommends abbreviated trials for generics and biosimilars that have been marketed with a satisfactory report in well-regulated countries like the United States of America for more than four years. The other order recommends that clinical trials be waived in Indian populations for national emergencies, cases of extreme urgency or for rare or orphan diseases for which no therapy is indicated. These office orders thus appear to modify the conditions of waiver set out in Rules 122 A and B above.

Whether or not a clinical trial is required to be conducted at all is a base-level provision that ought to be clearly articulated in the parent statute. One of the most basic functions of a statute is that it defines its own applicability. Currently, the law in this regard is unclear especially given the office orders that have been issued to implement the recommendations of the Professor Ranjit Roy Chaudhury Expert Committee. The law would therefore be much improved if the Bill were also to define conditions under which clinical trials are required to be conducted, may be conducted with abbreviated requirements, or may be waived.

3. Obligation to Obtain Informed Consent and Report Serious Adverse Events

The Bill recognises the seriousness of injuries and deaths caused by clinical trials and thus ensures that the provision of medical treatment and financial compensation is a statutory obligation. This obligation is particularly crucial to safeguard the rights of clinical trial participants. However, there are two other equally important obligations related to participant safety that have also been

of particular concern to the courts and public interest organisations- obtaining informed consent and reporting serious adverse events. Technically, the Bill covers these two obligations in as much as it penalises sponsors and investigators for failing to conduct a clinical trial in accordance with the protocol or in violation of the conditions that might have been imposed while granting permission for the conduct of the trial (These conditions will inevitably include the duty to obtain informed consent and to duly report serious adverse events). Nevertheless, it is recommended that these obligations be explicitly included in the parent statute for two reasons- one, to emphasise the seriousness of their breach and second, to impose a primary obligation on sponsors and investigators, independent of conditions that may be imposed by the Central Licensing Authority or Ethics Committees.

4. Obligation to Furnish Periodic Safety Update Reports

Schedule Y contains a section titled Post Marketing Surveillance that imposes certain obligations on sponsors after having obtained approval for a new drug. Sponsors are required to furnish Periodic Safety Update Reports (PSURs) that provide more information to the Licensing Authority about the effects of the drug in a larger population. The reports are also required to summarise the market authorisation status in different countries and to indicate whether any changes are required to the product information to optimise the safety and effectiveness of the drug. Specific timelines are set out for the submission of such safety data, with cases involving serious unexpected adverse reactions requiring to be reported to the Licensing Authority within fifteen days of the sponsor having obtained information.

PSURs are an important component of pharmacovigilance and are crucial in allowing the Licensing Authority to determine whether or not the drug in question be permitted to remain on the market. In this sense, a requirement to submit PSURs is the same kind of obligation as the submission of pre-clinical trial data requirements before approval to conduct clinical trials may be granted. Thus, this is another example of a base-level obligation, moreover, one which is particularly important in ensuring the removal of unsafe and

ineffective drugs from the market. Given the poor record on pharmacovigilance in the country (59th Report of the Department-Related Standing Committee on Health and Family Welfare on the Functioning of the Central Drugs Standard Control Organisation), it is recommended that a separate provision requiring the submission of PSURs be included in the parent Act. Failure to submit these reports ought to attract a penalty and be accompanied by a revoking of the marketing authorisation.

III. SUGGESTED DEFINITIONS AND PROVISIONS

The first two parts of these submissions made broader points about the structure of the Bill in general. This part addresses more specific aspects. The first section recommends the definition of key terms that have not been defined in the Bill and also sets out draft definitions. The second section suggests some amendments to the clauses of the Bill in their current form.

A. Definitions

The Bill takes a welcome step by defining terms like 'clinical trial', 'clinical trial protocol', 'investigator' and 'sponsor.' However, there are other terms that routinely form the vocabulary of clinical trials, such as 'serious adverse event' and 'good clinical practices' that find no mention in the Bill. The inclusion of these definitions is important because it has legal consequences for the investigator, sponsor and ethics committee. The definition of these terms in the parent legislation will add more clarity to the obligations imposed on these entities. Listed below are a set of terms that ought to be defined in the Bill along with suggested definitions and Explanatory Notes wherever applicable.

'adverse event' means any untoward medical occurrence during a clinical trial which is not a serious adverse event;

Explanatory Notes: It is important to include a definition of 'adverse event' in the parent Act because Schedule Y imposes an obligation on the investigator to provide medical care to any participant who suffers an adverse event. It has deliberately been defined to include events that are not caused by the clinical trial. The duty of the investigator to provide immediate care in such an event is paramount; it is a different question from the liability of the sponsor to provide medical management and compensation. It is only the latter that ought to be restricted to injuries caused by the clinical trial.

'clinical research organisation' means any person or organisation to which the sponsor has contracted out one or more of its clinical trial-related duties and functions;

Explanatory Notes: This is similar to the definition of 'contract research organisation in the guidelines issued by the International

Conference on Harmonisation. It is important to define this term since Clause 4A of the Bill prohibits, among others, clinical research organisations from conducting clinical trials without obtaining the permission of the Central Licensing Authority. Depending upon the extent to which a sponsor contracts out its clinical-trial related duties, there are several obligations, such as reporting serious adverse events or furnishing periodic reports that ought to be equally applicable to clinical research organisations as well. This makes it important to include a definition of clinical research organisations in the text of the Act.

'clinical trial-related injury or death' means an injury or death of a subject, including an injury or death of a child in-utero of such subject, when such injury or death is caused, whether wholly or partially, by the participation of the subject in such trial, as determined by the appropriate authority, and includes an injury or death caused by:

(a) the adverse effect of an investigational new drug or an investigational medical device;
(b) the adverse effect of concomitant medication, excluding the standard of care, as required by an approved clinical trial protocol;
(c) the adverse effect of any clinical trial procedures required by an approved clinical trial protocol;
(d) the violation of the clinical trial protocol, including the standard of care, by the sponsor, investigator or any person acting on their behalf;
(e) the violation of the conditions imposed by the Central Licensing Authority or ethics committee on the sponsor or investigator while approving a clinical trial protocol;
(f) an act of negligence or scientific misconduct by the sponsor, investigator or any person acting on their behalf;

Explanatory Notes: This is similar to the manner in which a clinical trial-related injury or death is defined under Rule 122DAB of the Drugs and Cosmetics Rules, 1945 ('the Rules'). However, the definition set out above excludes two kinds of trial-related injuries or deaths that are included under Rule 122 DAB: (i) failure of the investigational new drug to have its intended therapeutic effect and (ii) the use of a placebo. This is in keeping with the notification dated 12th December, 2014, which has modified Rule 122 DAB to exclude compensation in these two cases, except when the standard of care

was not provided. Since the definition suggested above recognises failure to provide the standard of care as capable of causing a trial-related injury or death, it is in keeping with the most recent statement of the law on the issue, as well as in consonance with the recommendations of the Professor Ranjit Roy Chaudhury Expert Committee.

The definition also specifies that a clinical trial-related injury or death will be considered such only when the determination of the cause has been made by the appropriate authority. (Specifying this authority is an exercise that will have to be undertaken when the Rules and Schedule Y are simultaneously reviewed).

'compensation' means the amount payable by the sponsor to a subject or his or her legal heir, as the case may be, when such subject suffers from a clinical trial-related injury or death, but does not include the expenses borne by the sponsor while providing medical management to such subject;

Explanatory Notes: This definition clearly imposes the obligation of paying compensation on the sponsor. It also clarifies the distinction between the medical expenses that are incurred by the sponsor while providing treatment to a subject who has suffered a clinical trial related injury, and the compensation that such subject or his legal heir is entitled to in case of a clinical trial-related injury or death. Moreover, it also specifies that compensation is not to be paid for all adverse events, only those that result in a clinical trial related injury.

'good clinical practices' mean the Good Clinical Practices for Clinical Research in India as framed by the Expert Committee set up by the Central Drugs Standard Control Organisation;

Explanatory Notes: Schedule Y makes reference to the responsibilities of the sponsor and the investigator to adhere to the Good Clinical Practices; it is therefore useful to define them and preferably include them in a Schedule or Annex to the Rules. However, before defining this term to mean the Indian version of the Practices as framed by the CDSCO, a review should be undertaken to ensure that these practices are not inconsistent with existing provisions in the Rules and Schedule Y.

'informed consent' means the free and voluntary consent given by a subject or his or her legal representative, as the case may be, to participate in a clinical

trial after having been made to understand the clinical trial protocol and the risks and benefits of such participation in such manner as may be prescribed;

Explanatory Notes: The existing Rules do not contain any definition of informed consent. One of the most important obligations of the investigator is to ensure that informed consent is obtained from a subject before he or she is enrolled in a clinical trial. One of the previous recommendations in these submissions suggested that obtaining informed consent be made a statutory obligation. This would require that the term 'informed consent' also be appropriately defined.

'legal representative' means the person lawfully capable of giving consent to participate in a clinical trial on behalf of a subject who is incapable of giving such consent because he or she has not attained the age of eighteen or is mentally incapacitated;

'medical management' means the provision of medical care at the expense of the sponsor to a subject for any adverse event or serious adverse event till as long as may be required or until such time as it is proved that the adverse event or serious adverse event was not caused by the participation of such subject in the trial, whichever is earlier;

Explanatory Notes: This is in keeping with the 12th December Notification mentioned above which seeks to limit the liability of the sponsor to provide medical management and compensation only to those injuries that are caused by participation in the clinical trial.

'serious adverse event' means an untoward medical occurrence during clinical trials that is associated with death, in-patient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life-threatening

Explanatory Notes: This is the same as the definition in Schedule Y to the Rules and is modelled on the definition of 'serious adverse event' in the United Kingdom Medicines for Human Use (Clinical Trials) Regulations 2004.

'subject' means a person participating in any phase of a clinical trial, irrespective of his/her age or mental capacity.

B. Other Provisions

In addition to creating a more comprehensive definitions section in the Bill, the following specific changes are recommended:

1. Clause 4G

Clause 4G of the Bill empowers the Central Licensing Authority to suspend or cancel the registration of an Ethics Committee that is found to be incapable of discharging its functions and responsibilities under the Act. When such suspension or cancellation occurs, every member of the Ethics Committee is disqualified from being a member any other such Committee for the next two years.

It is submitted that this disqualification is unduly harsh. An Ethics Committee may be found to be incapable of discharging its functions and responsibilities merely because it does not have the adequate supporting infrastructure, without impeaching the integrity of its members. In the absence of any personal oversight, negligence, incompetence, or demonstration of bad faith by the members, they ought not to be *automatically* disqualified from serving on other committees when the registration of their own committee has been suspended or cancelled. Discretion to this effect ought to be vested in the Central Licensing Authority. In this regard, more weight should also be given to the recommendation of the Professor Ranjit Roy Chaudhury Committee which suggested the accreditation of Ethics Committees.

2. Clause 4R

This clause prescribes a penalty of not less than fifty thousand rupees for whoever conducts clinical trials in contravention of the provisions of the Chapter, exclusive of Sections 4A -4-I. However, the only provision that is left in the Chapter is the obligation on sponsors, clinical research organisations and investigators under Clause 4J to maintain such data, record, registers and other documents as may be prescribed and to be furnish such information as may be required by the Central Licensing Authority. Rather than describe Clause 4R as

'Penalty for contravention of any provision of this chapter', it should instead be described as 'Penalty for failure to maintain data and furnish information'.

3. Disqualification of Investigators and Sponsors

The Bill is very rigorous about prescribing penalties for different kinds of offences that may be committed by sponsors, investigators and clinical research organisations. However, monetary penalties may not necessarily be the most effective deterrent; in addition to imposing fines and imprisonment, the Bill should also disqualify those investigators and sponsors who have been convicted of offences from conducting clinical trials at least for a limited period of years. The Bill introduces disqualification of members of Ethics Committees, as mentioned above, but a more pressing need for disqualification/blacklisting exists in the case of investigators and sponsors.

4. Cognisance of Offences

Clause 4T of the Bill states that no prosecution shall be instituted except on a complaint made by a duly authorised Drugs Control Officer or Gazetted Officer, an aggrieved person or a recognised consumer association. An important entity to include this list is an Ethics Committee or an individual member of such Ethics Committees. These committees are responsible for periodically reviewing the conduct of clinical trials and visiting the trial sites; therefore, they are in the best possible position to observe violations of the clinical trial protocol or any other condition imposed on the conduct of the trial. Clause 4T should therefore be modified to allow complaints to be made by members of Ethics Committees in respect of offences under the Bill.

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