

Rules For Compensation

in Clinical Trials Related
Injury, Death Notified

February 2013

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1. Rules For Compensation in Clinical Trials Related Injury, Death Notified

On November 31, 2011, the Ministry of Health and Family Welfare (“**the Ministry**”) had proposed certain draft amendments to the Drugs and Cosmetic Rules, 1945 (“**Proposed Amendment**”) to ensure payment of compensation to the study subject (“**Subject**”) for clinical trial related injury or death. These draft amendments were proposed as it was felt that the existing law did not protect the interests of the study subjects adequately. The Government had invited suggestions and objections in relation to the proposed amendments by December 31, 2011. Readers may remember that Nishith Desai Associates had provided its recommendations on the Proposed Amendment which can be found here. After more than a year, the final amendments have been notified, to be effective from January 30, 2013 (“**Amendment**”). The Amendment seems to have taken into account some of the recommendations made by the stakeholders.

The salient features of the Amendment have been captured below:

- i. Subjects are entitled to free medical management as long as required, and also are entitled to financial compensation for clinical trial related injury or death. In case of death of the Subject, the compensation is payable to the nominee(s) of the Subject.
- ii. What constitutes ‘clinical trial related injury or death’ has been laid out. Some of the provisions such as “failure of investigational product to provide intended therapeutic effect” have raised concerns.
- iii. The Sponsor or his representative (“**Sponsor Representative**”), whosoever has obtained permission to conduct the clinical trial in India, is obligated to bear the expenses of the Subject’s medical management and provide financial compensation. With respect to the compensation, the Sponsor, whether a pharmaceutical company or an institution, is also required to give an undertaking to the Drugs Controller General of India (“**DCGI**”) stating that it will provide compensation in case of clinical trial related injury or death.
- iv. ‘Serious Adverse Event’ has now been defined for the purpose of Schedule Y (brought in from the definitions of ‘Adverse Event’ and ‘Serious Adverse Event’ set out in the Good Clinical Practice Guidelines).
- v. A definite procedure for reporting serious adverse events and processing of incidental claims of financial compensation has been put in place. The Sponsor, Investigator and Ethics Committee have to submit their report with an analysis on the cause of the adverse event to the Expert Committee (in case of death and in case of injury, if the DCGI, i.e., the Licensing Authority, appoints such Committee) and the DCGI within a stipulated time. The Expert Committee to be set up by DCGI, would investigate the cause of death or injury (if required by DCGI), and recommend financial compensation, if applicable, to the DCGI.
- vi. The DCGI has been authorised to decide the cause of the serious adverse event as well as pass an order on payment of compensation, if applicable, taking into account recommendations of the Expert Committee.
- vii. The time frame for determination of the cause of serious adverse event and order of financial compensation is 3 months from the date of report of the serious adverse event by the Investigator.
- viii. The Sponsor or Sponsor Representative has been given a time frame of 30 days from receipt of the order of the DCGI to provide compensation to the Subject.
- ix. Failure of the Sponsor or Sponsor Representative to provide free medical management and/or financial compensation, as ordered, may lead to suspension or cancellation of the existing and further clinical trials in India.

The Informed Consent Form has been modified to include relevant details for the purpose of determination of compensation such as qualification, occupation and annual income of the Subject. It is now obligatory to hand over a copy of the informed consent sheet and duly filled informed consent form to the Subject or his/her attendant.

We will now discuss the amendment in detail and provide our insights and recommendations:

I. Entitlement of Trial Subjects

A. Free Medical Management

This requirement of FMM is new to both law and industry practice. Prior to the amendment, under Schedule Y (2) Para III of the Drugs & Cosmetics Rules, 1945 (“**Rules**”), the Investigator was required to “ensure that adequate care is provided to participants for any adverse event”. Correspondingly, all clinical trial agreements put an obligation on the Investigator and the clinical trial site to provide medical services in case of an adverse event, and on Sponsor to pay for expenses incurred by the Investigator and the Site in doing so.

Post Amendment, all Subjects have been given a right to ‘free medical management as long as required’ for injury occurring during the clinical trial. The language suggests that this right accrues, irrespective of whether the injury is trial related or not i.e., arising out of the trial or not. Now, the protection has been extended from adverse events to any injury arising during a clinical trial, whether it is a serious adverse event or not. This means that the entitlement of the Subject for free medical management (“**FMM**”) will be applicable for any injury which has occurred up to the time the individual was a Subject, irrespective of when it is discovered. The Subject would not be entitled for medical management for an injury which occurred after the clinical trial got over. If the injury occurs during the clinical trial and subsists beyond the term of the clinical trial, the

entitlement of the Subject to get FMM would continue as long as the injury is cured or as long as is required. The question that arises here is what happens in instances where the Subject has incurred the expenses. Determining what expenses are related to the clinical trial and the amount that the Sponsor may need to reimburse to the Subject may, perhaps, vary on a case to case basis, depending on the facts and circumstances of each case.

Unfortunately, it is not clear who will decide whether medical management is required and if required, what would be the length of any such medical management. In our view, since the Investigator was hitherto responsible for ensuring adequate care of the Subject, and is also in charge of patient care, the decision to provide medical management and duration of such medical management should be of the Investigator.

Since the obligation to pay for medical management is on the Sponsor (discussed later), it is recommended that the Sponsors should revisit their clinical trial agreements and impose additional obligations on the Investigator to provide such ‘medical management’. If the Sponsor does not appoint a suitable person to provide medical management, it may find itself in breach of law.

B. Financial Compensation

The Amendment provides that the financial compensation would be provided to the Subject in case of ‘clinical trial related injury’ and would be provided to the nominee(s) of the subject in the case of ‘clinical trial related death’. The financial compensation would be over and above any expenses incurred in medical management of the Subject. The Amendment does not specify that the remedy of financial compensation for injury or death is an exclusive remedy available to the Subject or nominees, as the case may be. In the absence of such a provision, it is not clear whether a separate civil remedy for seeking compensation may still lie, in the event the Subject/nominee is

not satisfied with the amount already provided. In the revised Informed Consent Form, the Subject is required to provide the names of the nominees for the purpose of compensation in case of trial related death. If the Subject nominates individuals, who are not legal heirs as per the applicable inheritance law, then, a dispute may arise between nominees as per the Informed Consent Form and legal heirs.

C. Liability to Bear Expenses for FMM and Financial Compensation

Under the main Rule, it is stated that the Sponsor is required to bear these expenses. However, in other parts of the Amendment, the obligation has been put upon the 'Sponsor or Sponsor Representative'. It appears that the regulator may hold the local Sponsor Representative liable to bear the expenses. The Sponsor and Sponsor Representative will be required to agree contractually as to who will be liable in the first instance, and accordingly protect their respective interests through such contracts.

At the time of making the application for a clinical trial, the Sponsor is required to give an undertaking that he will provide compensation in the case of clinical trial related injury or death for which Subjects are entitled to compensation. Since the reference to a Sponsor Representative to give the undertaking does not appear, it is unclear if there has been a drafting error in this provision. This aspect may need some more clarity as limiting it to the Sponsor only would, then, seem contrary to the other provisions which require either the Sponsor or the Sponsor Representative (whosoever has obtained the permission from the DCGI) to bear the expenses for financial compensation.

II. Changes in the Informed Consent Form (ICF) and Other Documents

Prior to the commencement of the trial, the Sponsor is required to provide a statement to the Subject describing its obligation to provide

free medical management to the subject as long as required and financial compensation in case of clinical trial related injury or death. Certain fields such as address of the subject, qualification, occupation, annual income of the subject, name and address of the nominee etc. have been added to the ICF in order to facilitate the payment of financial compensation. This copy of the ICF and the patient information sheet is required to be provided to the Subject or his/her attendant. The requirement to state the quantum of minimum compensation for trial related injury or death in the ICF that was included in the Proposed Amendment has not been retained in the Amendment.

The Amendment obligates the Investigator to provide information about essential elements of the clinical trial and the Subject's right to claim compensation through the informed consent process provided in Appendix V of Schedule Y of the Rules. The Investigator is also obligated to inform the Subject and his/her nominee about their right to contact the Sponsor or the Sponsor Representative, whosoever had obtained permission for conducting clinical trial, for the purpose of making claims in case of trial related injury or death.

It is surprising that the Amendment has not mandated a requirement to submit proof of income along with the ICF and other documents. Since income is one of the most essential criteria for determining compensation, it goes without saying that proof on income would be a critical aspect for determination of the financial compensation. In the absence of such a legal requirement, we recommend all existing and prospective Sponsors make appropriate inclusions in the contract entered into between the Sponsor and the Investigator to ensure the Investigator obtains such documents from the Subject.

III. Definition of Clinical Trial Related Injury or Death

The Amendment specifies that a clinical trial

related injury or death is any injury or death occurring in a clinical trial due to the following reasons:

- i. Adverse effect of investigational product(s)
- ii. Violation of the approved protocols, scientific misconduct or negligence by the Sponsor or the Sponsor Representative or the Investigator
- iii. Failure of investigational product to provide the intended therapeutic effect
- iv. Use of placebo in a placebo-controlled trial
- v. Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol
- vi. For injury to a child in-utero because of participation of the parent in the clinical trial
- vii. Any clinical trial procedures involved in the study

The list of reasons is exhaustive and to an extent overlapping. We have examined the seven reasons, *seriatim*:

A. Adverse Effect of Investigational Products

The expression ‘adverse effect’ is not defined in the Amendment. For the sake of better understanding, it may be worthwhile to try and define what an adverse effect could mean. One secondary source suggests this definition “*An adverse effect is an adverse reaction which can be attributable to some action of a drug.*”¹

B. Violation of the Approved Protocols, Scientific Misconduct or Negligence by the Sponsor or the Sponsor Representative or the Investigator

This appears to cover those injuries which are not related to the use of the investigational product, but may have occurred due to violation of the approved protocols, scientific misconduct or negligence by the Sponsor or the Sponsor Representative or the Investigator. It is important that in the contracts with the Sponsor Representatives and Investigators, the Sponsor

obtains adequate indemnity from them. E.g. in a clinical trial agreement, the Sponsor should seek an indemnity from the Investigator for any liability arising due to injury or death arising out of the negligence, scientific misconduct or a breach of the approved protocol by the Investigator. Similar indemnity should be obtained from the Contract Research Organization (“CRO”) as well.

C. Failure of the Investigational Product to Provide the Intended Therapeutic Effect

The intention behind the inclusion of this provision appears to avoid the possibility of luring patients for clinical trial with the promise of cure. Typically, the informed consent document makes it clear to the Subject that the investigational product may not have any benefit. It is not clear as to how this provision will be interpreted when the informed consent document does convey any intended therapeutic effect. In our view, such a requirement would be triggered only when the Sponsor or the Investigator hold out that the investigational drug will have a certain therapeutic effect, instead of stating that the investigational drug may or may not have any therapeutic effect.

The Sponsors should ensure that the clinical trial protocol and the ICF is strictly worded in order to prevent the Investigators from recruiting Subjects on the promise of a proposed therapeutic effect. The Sponsors would also require indemnity from the Investigators in case the Investigators make any representations which are not warranted by the protocol or the ICF.

In any case, this appears to be an onerous clause. Even the drugs that have been approved are not subjected to such a requirement.

D. Use of Placebo in a Placebo Controlled Trial

Compensation for this reason would be payable

1. R. Edwards et al., “Adverse Drug Reaction: Definitions, Diagnosis and Management” 356 *The Lancet* 1255 at 1255- 1256.

when an injury is caused due to the placebo in a placebo-controlled trial. It appears that this provision is included with a view to cover all extreme possibilities of injuries and providing compensation for the same.

E. Adverse Effects Due to Concomitant Medication Excluding Standard Care, Necessitated as a Part of the Approved Protocol

In a situation where an adverse effect has taken place due to the administration of a drug other than the trial drug, then such injury or death would entitle the Subject for medical management and financial compensation.

It is important here to emphasize on the expression 'necessitated as a part of the approved protocol'. The liability to pay compensation for adverse effect of concomitant medication arises only when the concomitant medication was endorsed (necessitated) by the protocol. If the medication was not necessitated by the protocol, and was administered by the Investigator in good faith to the Subject, then injury or death caused by adverse effect of such concomitant drug would not lead to financial liability on the Sponsor.

The Investigator must be careful to maintain records of concomitant medication administered during a clinical trial, in order to manage risk on grounds of breach of protocol. In addition, it may also be prudent to have the relevant protocols legally vetted in order to ensure there is no undue liability on the Sponsor as a result of what might be stated/missing in the protocol.

F. For Injury to a Child In-utero Because of Participation of the Parent in the Clinical Trial

Though death does not seem to have been covered in the Amendment, it appears to have been a drafting error as going by the intent of the provision when read in entirety, death would have been covered as well. There may be two interpretations of this reason: 1) compensation payable for injury or death of the Subject due to injury to child in-utero owing to participation of

the patient in clinical trial, and 2) compensation payable for injury or death to a child in-utero because of participation of the parent in the clinical trial. Schedule Y, Appendix XII (4)(d) inserted by the Amendment (discussed later) does provide that financial compensation payable to the Subject would include financial compensation for the child injured in-utero because of participation of the parent in the clinical trial.

G. Any Clinical Trial Procedures Involved in the Study

In this provision, unlike in relation to concomitant medication, the clinical trial procedure is not linked to the protocol. The expression clinical trial procedure is not defined. Hence, it may lend itself to broad interpretation, unless the DCGI provides further guidance of its interpretation.

IV. Insertion of Definition of Serious Adverse Event

Serious Adverse Event has been defined as "an untoward medical occurrence during clinical trial that is associated with death, in-patient hospitalization (in case the study was being conducted on out-patient), prolongation of hospitalization (in case the study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life threatening" This is a standard insertion. This definition appears to have been borrowed from the terms 'Adverse Event' and 'Serious Adverse Event' as set out in the Good Clinical Practice Guidelines issued by the Central Drugs Standard Control Organization.

V. Procedure For Determination of the Financial Compensation

A. Insertion of New Appendix XII

A new appendix 'Compensation in case of injury or death during clinical trial' (Appendix XII) has been inserted under Schedule Y of the Rules, in

the Amendment. It reiterates the compensation entitlement of the Subject and his/her nominee (discussed above), discusses forms of financial compensation obligations of the Sponsor or the Sponsor Representative, as the case may be, and lays out the procedure for determination and payment of compensation. Since the entitlement of the Subject has already been discussed earlier, this section will only discuss the forms of compensation and the procedure related to determination and payment of compensation.

Appendix XII provides that the financial compensation for clinical trial related injury or death could be in the following form:

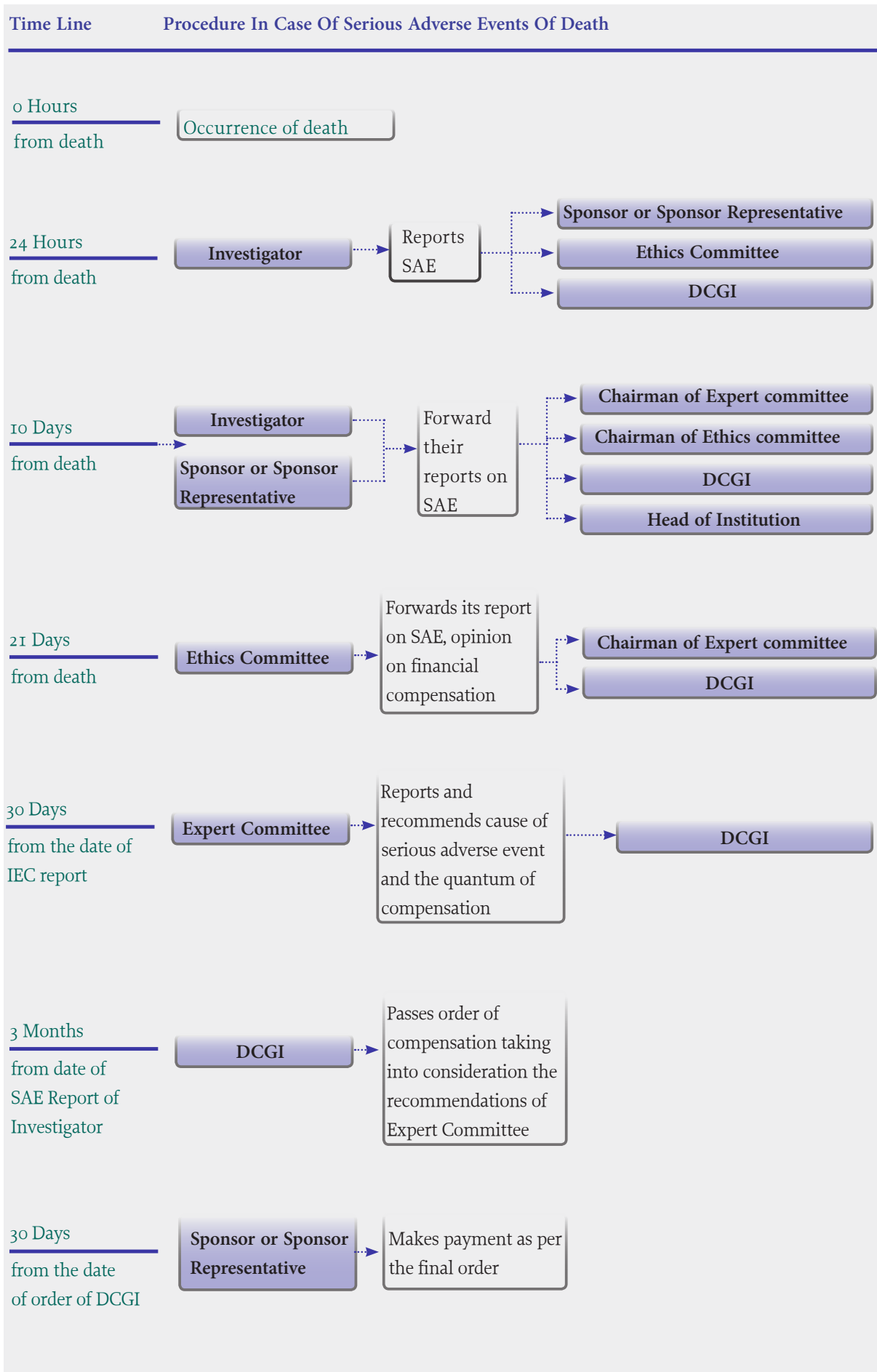
- i. Payment of medical management
- ii. Financial compensation for trial related injury
- iii. Financial compensation to the nominee(s) of the Subject in case of death
- iv. Financial compensation for the child in-utero because of the participation of the parent in the clinical trial.

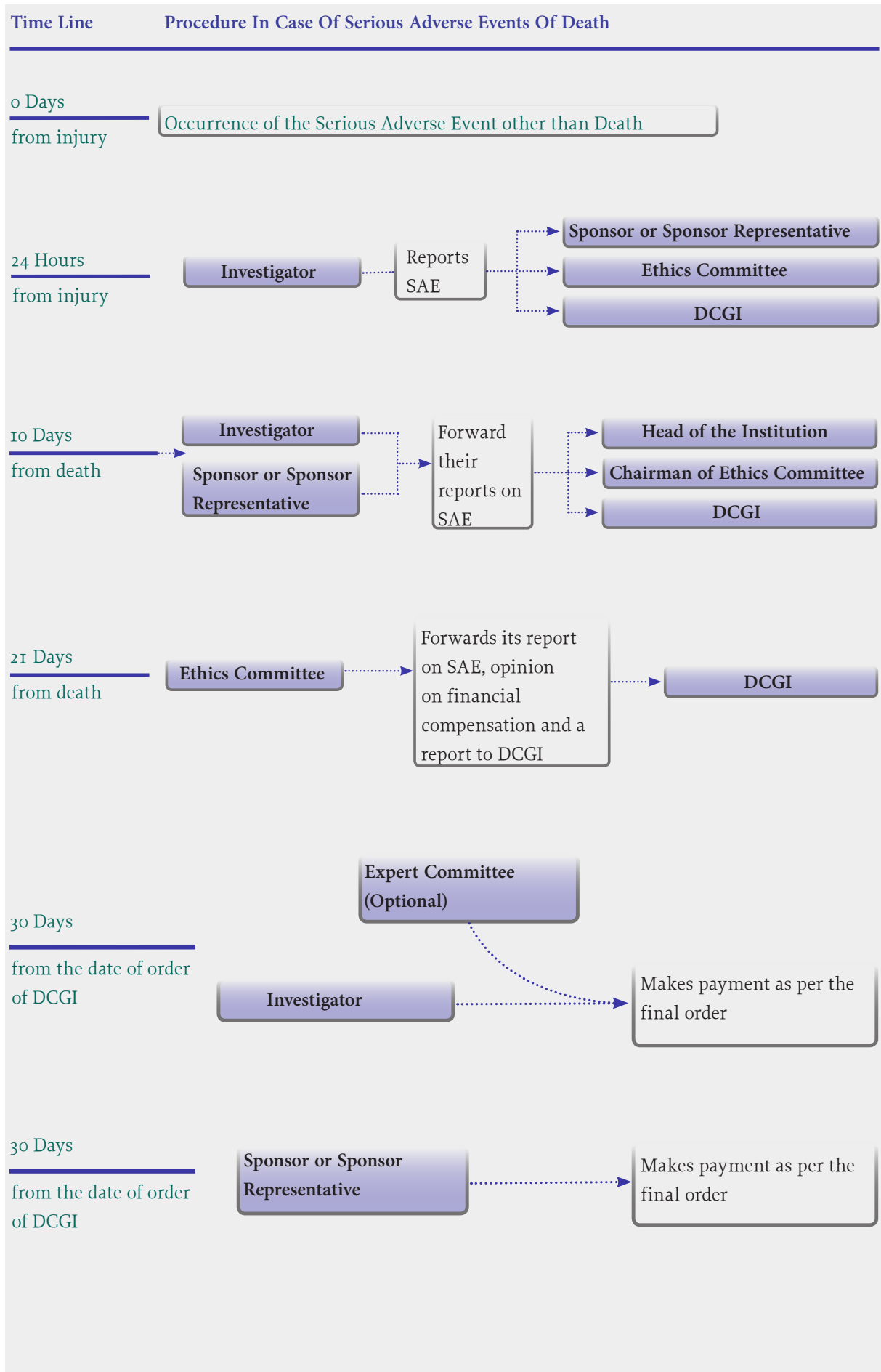
There are two things to note here. First, the list of forms of financial compensation is not exhaustive. However, there are very few forms of payments other than those envisaged in the list which can be provided. One situation is when a pregnant Subject dies post-delivery of the child because of her participation in the clinical trial and it is also found that the new-born has suffered injury in-utero, again because of the participation of the parent in the clinical trial. In such a case, the financial compensation payable to the father (or a

nominee) would be for death of the Subject as well as financial compensation for the child.

Second, and more important, payment of medical management has been added as a form of financial compensation. This is a padding provision for the Sponsors and would come in handy when the Subject suffers a clinical trial related injury which is not of a serious nature. In such a case, the DCGI need not direct the Sponsor to provide financial compensation directly to the Subject. It may only order the Sponsor to pay for the Subject's medical management. If compensation for clinical trial related injury could not be given in the form of medical management, then occurrence of all adverse events and corresponding injuries would have resulted in payment of one or the other quantum of compensation.

The flow charts below describe the process and timelines for determination of the financial compensation. We have, thereafter, described the obligation of each stakeholder in the said process. It is noteworthy that after the Notification dt. February 1, 2013 (related to the Amendment) issued by the Ministry of Health and Family Welfare ("**Second Amendment**"), non-performance of the below-mentioned obligations may lead to the debarment of the Investigator/Sponsor from conducting clinical trials in India..





B. Investigator's Obligations

The Investigator has the following obligations:

- To report unexpected and serious adverse events to the Sponsor, Ethics Committee and DCGI within 24 hours of occurrence of the event.
- To prepare a report with due analysis on the serious adverse event and submit the report within 10 calendar days of occurrence of the serious adverse event -
 - » in case of death, to the Chairman of the Ethics Committee, Chairman of the Expert Committee (constituted by the DCGI), the DCGI and Head of the Institution where the trial was conducted; and
 - » in case of any serious adverse event other than death, to the Chairman of the Ethics Committee, DCGI and the Head of the Institution where the trial has been conducted.

In view of this, it appears that contractually, the Investigator would want to require the Sponsor to bear the cost of preparing the report. It may be advisable that the agreement between the Sponsor, CRO and/or Investigator, as the case may be, includes a specific provision on whose liability it will be to cover the expenses in preparing the report.

C. Sponsor's Obligations

The Sponsor has the following obligations:

- To prepare a report with due analysis on the serious adverse event and submit the report within 10 calendar days of occurrence of the adverse event:
 - » In case of death, to the Chairman of the Ethics Committee, Chairman of the Expert Committee constituted by the DCGI (discussed later) and the DCGI
 - » In case of serious adverse event other than death, to the Chairman of the Ethics Committee, DCGI and the Head of the Institution where the trial has been conducted

- Time-frame for payment of compensation: A Sponsor or Sponsor Representative is required to pay the compensation and submit details of such payment within 30 days of the receipt of the order of the DCGI.

The obligation to prepare the report with due analysis is a new requirement. The earlier requirement was to simply communicate such serious adverse event to the DCGI and other Investigators within 14 calendar days of occurrence of the adverse event. Since, now, there is no requirement on the Sponsor to communicate to other Investigators, it is expected that the DCGI would do so. It is recommended that the prospective Sponsors must enter into a multi-party clinical trial agreement with Investigators/investigation agencies for investigation into such deaths (or injuries, as discussed next) and preparation of a report containing due analysis of the event. Existing Sponsors should enter into bi-partite contracts with Investigators/investigation agencies with the same agenda.

It is to be noted that the time line for submission of the report is extremely tight. Also, the Amendment does not provide any guidance about the scope of the expression 'due analysis'.

D. Ethics Committee's Obligations

The Ethics Committee has the following obligations:

- to prepare a report on the serious adverse event (of death/other than death) containing due analysis along with its opinion on financial compensation, if any, and submit the report within 21 calendar days of occurrence of the event:
 - » in case of death, to the Chairman of the Expert Committee (constituted by the DCGI) and the DCGI, and
 - » in case of any adverse event other than death, to the DCGI [A copy of the of the report will have to be forwarded to the Chairman of the Expert Committee if it is constituted].

E. Independent Expert Committee's Obligations

The Amendment obligates the DCGI to constitute an independent Expert Committee to “*examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of the death and quantum of compensation in case of clinical trial related death.*” That is, all cases of serious adverse event of death would, henceforth, be examined by an independent Expert Committee, and its recommendation on cause of death and quantum of financial compensation will be taken into consideration by the DCGI at the time of determination of cause of death and compensation. Unlike in a case of death in case of adverse event other than death, the DCGI may or may not refer the case to the Expert Committee.

The insertion of the provision of constitution of Expert Committee will raise a couple of issues. First of all, it is uncertain if the Expert committee would be constituted on a case by case basis at the site or would be a permanent central body. The relevant provision (Schedule Y, Appendix XII, 6(a)) makes it clear that the Expert Committee would be a permanent body since it says that ‘An’ independent Expert Committee shall be constituted to examine the ‘cases’ (that is, more than one case). However, another provision states that in case of an adverse event other than death, the DCGI “shall have the option to constitute an independent Expert Committee, wherever considered necessary”. The other issue is absence of clarity on constitution of the Expert Committee. The industry would like to see balance in the Expert Committee with involvement of the experts from the clinical trial industry on the Committee. Finally, it remains to be seen what kind of powers can be exercised by the Expert Committee - whether it can summon for documents, issue interrogatories, take evidence etc. All these issues will be resolved over time by issuance of appropriate regulations on the constitution and working of the Expert Committee by the Ministry.

F. DCGI's Obligations

The DCGI has been given power to determine the cause of death and decide the financial compensation, if applicable. In doing so, the DCGI may consider the recommendations of the Expert Committee (as applicable) and the opinion of the Ethics Committee (in case of adverse event other than death). The DCGI is obligated to pass an order of payment of financial compensation within 3 months from the date of receipt of the report of the serious adverse event from the Investigator. Hence, the entire process, as stated above, will have to be completed accordingly.

The blanket power given to the DCGI to determine the cause of death or injury is, in our view, an excess. The Amendment does not talk about the requirement of passing a reasoned order; neither does it speak of any specific appeal provisions. Unfortunately, the Amendment gives power to the DCGI to disregard the recommendations/opinion (though it may rarely happen in practice) of the Expert Committee. In our view, the DCGI should be bound by the recommendations/opinion of the relevant body unless there is an allegation of bias or malpractice against the body or its members. In such cases, the DCGI should be allowed to decide on the allegation of malpractice or bias on the basis of evidence.

VI. Failure to Pay For Medical Management or Pay Compensation

If the Sponsor or Sponsor Representative fails to pay for medical management or provide financial compensation, the DCGI may, after giving an opportunity of being heard, suspend or cancel clinical the trial or restrict the Sponsor or Sponsor Representative from conducting any further clinical trials in India or take such action that it deems fit under the Amendment Rules. The order of the DCGI must be a written reasoned order.

The penalty of suspension or cancellation of any further clinical trials may be harsh on a CRO, in

case trials of different Sponsor(s) are ongoing. It would be prejudicial to the interests of the CRO if, due to failure to pay for the trial of one Sponsor, it is stopped from conducting trials for other Sponsors. It is expected that the DCGI may exercise its power in a sagacious manner.

122 DC of the Rules) will apply. Under the said provision, an appeal from the order of the DCGI either by the Subject/nominee or by the Sponsor can lie before the Central Government and the same should be filed within 60 days of the date of such order.

VII. Absence of Specific Appeal Provision










The Amendment does not provide for a specific process of appeal. In the absence of a specific provision, the general provision (under Rule

2. Conclusion

Though, with the Amendment in place, there might appear clarity and certainty on some specific aspects, the industry is, yet, bound to feel that some of the provisions are unfair (such as failure of the investigational product to provide the intended therapeutic effect), impractical (such as the requirement to submit a report on the cause of the adverse event with due analysis within 10 days), burdensome (such as the obligation to pay for medical management for injury arising during the course of the clinical trial and later as well in certain cases) and unclear (such as the constitution and working of the

Expert Committee). The process of determination of compensation has not taken into account the principles of natural justice. The right of the Sponsor to receive the copies of the reports filed by the Investigator, Ethics Committee or to be heard before the order is passed is not recognized. We believe the industry can split the burden imposed by the Amendment amongst the players involved using various legal devices and in a fair manner and portray a confident picture to the world.

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	E-Commerce in India January 2013		Cloud Computing Risks/Challenges- Legal & Tax Issues March 2013		Private Equity in Real Estate February 2013

NDA Insights

TITLE	TYPE	DATE
File Foreign Application Prosecution History With Indian Patent Office	IP Lab	02 April 2013
Warburg - Future Capital - Deal Dissected	M&A Lab	01 January 2013
Public M&A's in India: Takeover Code Dissected	M&A Lab	26 November 2012
Copyright Amendment Bill 2012 receives Indian Parliament's assent	IP Lab	25 May 2012
Real Financing - Onshore and Offshore Debt Funding Realty in India	Realty Check	01 May 2012
Pharma Patent Case Study	IP Lab	21 March 2012
Patni plays to iGate's tunes	M&A Lab	04 January 2012
Vedanta Acquires Control Over Cairn India	M&A Lab	03 January 2012
Corporate Citizenry in the face of Corruption	Yes, Governance Matters!	15 September 2011
Funding Real Estate Projects - Exit Challenges	Realty Check	28 April 2011
Real Estate in India - A Practical Insight	Realty Check	22 March 2011
Hero to ride without its 'Pillion Rider'	M&A Lab	15 March 2011
Piramal - Abbott Deal: The Great Indian Pharma Story	M&A Lab	05 August 2010
Bharti connects with Zain after two missed calls with MTN	M&A Lab	17 May 2010
The Battle For Fame - Part I	M&A Lab	01 April 2010
Great Offshore Takeover Saga - Bharati Shipyard v/s ABG Shipyard	M&A Lab	16 December 2009
Second missed call: Bharti Airtel fails to reconnect with MTN	M&A Lab	09 October 2009

Research @ NDA

Research is the DNA of NDA. In early 1980s, our firm emerged from an extensive, and then pioneering, research by Nishith M. Desai on the taxation of cross-border transactions. The research book written by him provided the foundation for our international tax practice. Since then, we have relied upon research to be the cornerstone of our practice development. Today, research is fully ingrained in the firm's culture.

Research has offered us the way to create thought leadership in various areas of law and public policy. Through research, we discover new thinking, approaches, skills, reflections on jurisprudence, and ultimately deliver superior value to our clients.

Over the years, we have produced some outstanding research papers, reports and articles. Almost on a daily basis, we analyze and offer our perspective on latest legal developments through our *"Hotlines"*. These *Hotlines* provide immediate awareness and quick reference, and have been eagerly received. We also provide expanded commentary on issues through detailed articles for publication in newspapers and periodicals for dissemination to wider audience. Our *NDA Insights* dissect and analyze a published, distinctive legal transaction using multiple lenses and offer various perspectives, including some even overlooked by the executors of the transaction. We regularly write extensive research papers and disseminate them through our website. Although we invest heavily in terms of associates' time and expenses in our research activities, we are happy to provide unlimited access to our research to our clients and the community for greater good.

Our research has also contributed to public policy discourse, helped state and central governments in drafting statutes, and provided regulators with a much needed comparative base for rule making. Our *ThinkTank* discourses on Taxation of eCommerce, Arbitration, and Direct Tax Code have been widely acknowledged.

As we continue to grow through our research-based approach, we are now in the second phase of establishing a four-acre, state-of-the-art research center, just a 45-minute ferry ride from Mumbai but in the middle of verdant hills of reclusive Alibaug-Raigadh district. The center will become the hub for research activities involving our own associates as well as legal and tax researchers from world over. It will also provide the platform to internationally renowned professionals to share their expertise and experience with our associates and select clients.

We would love to hear from you about any suggestions you may have on our research reports. Please feel free to contact us at research@nishithdesai.com

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