

## Pharma & Healthcare Update

June 12, 2014

### DRAFT COMPENSATION FORMULA FOR CLINICAL TRIAL RELATED INJURY PROPOSED

- Formula is 'consequence based', addresses four major consequences of injury - permanent disability, birth defect, life - threatening disease and reversible injury.
- In case of permanent disability, compensation payable is a percentage of compensation in case of death.
- In case of birth defect, compensation is fixed at INR 400,000 along with medial management of the child as long as required.
- In case of life - threatening disease and reversible injury, compensation will depend on loss of wage caused by the injury. The wage is not the actual wage, but minimum wage for unskilled labour already fixed by the Government (INR 329 per day).

The office of the Drugs Controller General of India ("DCGI"), India's apex drug regulator, has published a draft formula for calculating compensation payable to a clinical trial participant ('subject') when the subject suffers an injury owing to his or her participation in a clinical trial. The publication of the formula is good news for the sponsors of clinical trials in India as well as for the subjects because it brings objectivity to the process of compensation and also adds to the credibility of clinical trials in the mind of the common man. Readers may recollect that irregularity in the payment of compensation to clinical trial subjects is one of the central themes of the ongoing litigation against the Ministry of Health and Family Welfare in the Supreme Court. To learn more about the ongoing litigation, you may refer to our hotline on the subject by clicking [here](#). Readers may also recollect that prior to publication of a formula to calculate compensation payable for clinical trial related injury, the DCGI had published a formula to calculate compensation payable for clinical trial related death. To learn more about that formula, you may read another hotline by clicking [here](#).

### BACKGROUND

In early 2013, under the instructions from the Supreme Court, the Ministry of Health and Family Welfare ("Ministry") amended the Drugs and Cosmetics Rules, 1945 ("Drug Rules") three times in a span of 9 days which took the entire clinical trial industry by surprise. The amendments crystallized the obligation on the sponsor of a clinical trial, or its legal representative who had obtained permission to conduct clinical trial, to pay for compensation in case of clinical trial related injury or death to the trial subject or nominee. One of these amendments gave DCGI the powder to determine compensation in cases of clinical trial related injury as well as death. Our firm had provided feedback on the amendment on numerous issues, one of the foremost issues being that the DCGI may act arbitrarily and therefore should not be given the final say in deciding compensation. To read our analysis and other criticisms of the amendment, click [here](#).

Realizing the need for objectivity in the process of arriving at the compensation, the DCGI had commissioned two separate committees with the task of arriving at a formula to determine compensation in cases of death and injury respectively. The committee commissioned to arrive at a formula for determining compensation in case of death was constituted in March of 2013 and the consequently the formula got published first. The other committee was commissioned much later (no date provided), and hence, the formula got finalized and published only recently, though in draft form. We have described and analyzed the draft formula in the following paragraphs.

### SALIENT FEATURES OF THE FORMULA

In order to fully understand the salient features of the formula, it is important to understand the concept of a 'serious adverse event'. In medical jargon, an adverse event is understood as any undesirable experience associated with the use of a medical product in a patient.<sup>1</sup> The adverse event takes form of a 'serious adverse event' ("SAE") in context of clinical trials when it leads to one of the following outcomes<sup>2</sup>:

- Death
- in patient hospitalization (in case study was being conducted out-patient)
- prolongation of hospitalization (in case study was being conducted in-patient)
- persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- any life threatening outcome

For arriving at the formula, it appears that the Committee assumed that the compensation for clinical trial injury is payable only in case of SAE, and closely analyzed the definition of SAE (described immediately above). The Committee then took cognizance of the above outcomes (excepting death since it was dealt with by another

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committee), and decided that a single formula that will apply to all outcomes which constitute SAE may not be possible due to inherent differences in nature of various outcomes. Therefore, the Committee decided to club various outcomes for which a single formula would apply. After such clubbing, the Committee arrived at the following heads:

- Permanent disability
- Congenital anomaly or birth defect
- Chronic life-threatening disease or
- Reversible SAE in case it is resolved.

The Committee then examined all factors which should be considered for arriving at the compensation under each head, and came up with unique formula to cover a situation falling under each head. The formulas are discussed below:

**SAE causing permanent disability to the subject**

The Committee decided that in case of 100% disability, the quantum of compensation should be 80% of the amount payable in case of death. In case of disability which is less than 100%, the compensation payable will be proportional to the actual percentage disability the subject has suffered. The rationale provided for keeping the compensation as a percentage of the amount payable in case of death *is that the quantum of compensation should not exceed the compensation in case of death.*

Thus, the formula arrived at is:

$$Compensation = (D \times 80 \times C) / (100 \times 100)$$

Where,

D = Percentage disability the subject has suffered

C = Compensation which would have been due in case of death of the subject (for details of the formula to calculate compensation in case of death, please see our previous hotline [here](#).)

**SAE causing congenital anomaly/ birth defect**

The Committee analyzed the scope of the expression 'congenital anomaly' and 'birth defect' and came to the conclusion that the following situations would constitute a 'congenital anomaly' or 'birth defect' due to one or both parents participating in a clinical trial:

- Still birth
- Early death due to anomaly
- No death but deformity which can be fully corrected through appropriate intervention
- Permanent disability (mental or physical)

The Committee was of the opinion that the compensation for congenital anomalies or birth defects should be approximately half the base amount payable for compensation in case of death (i.e. INR 800,000). Thus, the committee decided that in cases of for congenital anomalies or birth defects as specified above, a lump sum of INR 400,000 will be payable as compensation.

The Committee also decided that in cases of correctable deformity and permanent disability, the Sponsor or his representative must also take care of medical management of the child as long as required.

**SAE causing life - threatening disease**

According to the Committee, the cases falling under this head should be compensated in terms of the number of days that the subject remained in a life-threatening situation and required medical care, irrespective of the number of days of hospitalisation. The Committee decided that the amount of compensation payable will have to be calculated on a per day basis, which amount will be equivalent to the minimum wage per day of an unskilled worker (in Delhi). Thus, the formula arrived at the Committee is:

$$Compensation = N \times W$$

Where,

N = Number of days that the subject remained in a life threatening situation

W = Minimum Wage

**Reversible SAE in case it is resolved**

The Committee has clarified that by reversible SAE it means an SAE which was reversible and got resolved. As per the Committee, the compensation for such SAE should be linked to the number of days that the subject was hospitalized. The subject would, thus, be paid compensation calculated on a per-day basis. The Committee decided that the compensation payable per day should be equivalent of the minimum wage payable to an unskilled worker (in Delhi). The Committee also acknowledged that since the subject would be attended by somebody during his hospitalization, the attendant would undergo loss of wage. Such loss of wage should also be accounted for in the compensation. Hence, the Committee decided that the compensation should be doubled to factor in the wage lost by the attendant. Accordingly, the formula arrived at by the Committee is:

$$Compensation = 2 \times N \times W$$

Where,

N = Number of days that the subject was hospitalised

W = Minimum Wage

**ANALYSIS**

The publication of the draft formula is a step in the right direction. However, there is a lot of ground that remains to be

covered. The draft formula omits to cover numerous situations. The most obvious situation is when the subject suffers temporary disability due to which he/she is not hospitalized but the injury leads to loss of wages. The other situation is when the subject is already hospitalized (in-patient) and suffers an injury, but the suffering does not lead to prolongation of the subject's hospitalization and is of a nature which cannot be considered life threatening. The draft formula is vague too, and leaves much room for interpretation. For example, it does not clarify who will determine percentage of disability in cases of permanent disability. A small variation in the figure of percentage of disability can make a substantial difference in compensation amount because percentage of disability is the only variable in the formula. Hence, the subject would like to have option to get his or her injury assessed by a medical practitioner of choice. Whether this will be possible is not clear. Similarly, in relation to a child born with birth defect, the formula provides that medical management should be provided to such child for as long as required. In this specific context, the scope of expression 'medical management' may be given a wide interpretation and be made onerous for the Sponsor. Further, with due respect to the views of the Committee, it appears that the draft formula has unnecessarily encumbered the Sponsors by adding loss of wages of the attendant to the compensation amount. Under the present law, a Sponsor is required to pay for the entire medical management of the subject in the event of clinical trial related injury, and medical management includes medical supervision of the subject through a medical practitioner. Thus, when the Sponsor is already required to pay for medical supervision of the subject, it seems unfair to require the sponsor to pay for personal supervision of the subject through the attendant as well. In any case, one fails to understand why provision for payment of wages of the attendant is made applicable in case of reversible SAE, but it is not made in case when the subject suffers from a life threatening injury.

It is also arguable that the Committee has started on the wrong foot. The formulae provided by the Committee have been premised on the definition serious adverse event as indicated above. In other words, the formulae imply that compensation is payable in cases of serious adverse event only. However, under law, compensation is payable for all adverse events, and not just 'serious' adverse event.<sup>3</sup> Thus, there seems to be a gap left open by the Committee.

## CONCLUSION

We expect the final formula to treat the subject exhaustively and address all the shortcomings. Needless to say, we will analyze the final formula in detail and provide our views when it is published.

– The Pharmaceutical and Life Sciences Team

You can direct your queries or comments to the authors

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<sup>1</sup> As per a US FDA note, available on <http://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm>(last accessed June 9, 2014).

<sup>2</sup> Schedule Y(2)(5A) of the Drug Rules.

<sup>3</sup> Rule 122-DAB(5) of the Drug Rules states as follows: *Any injury or death of the subject occurring in clinical trial due to the following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee(s), as the case may be, are entitled for financial compensation for such an injury or death:*

*(a) adverse effect of the investigational product;*

*(e) adverse effect due to concomitant medication excluding standard care, necessitated as part of the approved protocol;*

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