DRAFT FORMULA TO DETERMINE THE QUANTUM OF COMPENSATION IN CASE OF CLINICAL TRIAL RELATED INJURY (OTHER THAN DEATH)

The Drugs and Cosmetics Rules, 1945 provides under Rule 122DAB that in the case of clinical trial related injury/death, the trial subject is entitled for the financial compensation. A committee was constituted under the Chairmanship of Shri R. K. Jain, AS & DG to deliberate and work out formula to be followed to determine the quantum of compensation in case of clinical trial related injury other than death.The committee after deliberations has devised a draft formula in this regard.

The report of the committee is annexed. The committee has desired that the formula suggested should be available to the stakeholders for at least 15 days for their suggestions.

The stakeholders are therefore requested to forward their comments and suggestions on the above formula within 15 days (i.e. by 16th May, 2014) forfurther consideration of the committee. The formula will then be finalized after taking into consideration the suggestions as received from the stakeholders.

ANNEXURE

REPORT OF THE COMMITTEE CONSTITUTED TO PREPARE FORMULA TO DETERMINE THE QUANTUM OF COMPENSATION IN CASE OF CLINICAL TRIAL RELATED INJURY (OTHER THAN DEATH)

As per Rule 122DAB of Drugs and Cosmetics Rules 1945, in case of clinical trial related injury/death, the trial subject is entitled for the financial compensation. The Sponsor or his representative is required to pay the compensation as per the order of DCG(I). The financial compensation will be over and above the expenses incurred on the medical management of the trial subject. The Appendix XII of schedule Y of the Drugs and Cosmetics Rules prescribes the procedure for processing the reports of Serious Adverse Events (SAEs) including death to arrive at the cause of death/injury to the subject and to decide the quantum of compensation.

As per the procedure, in case of SAE of death, the DCG(I) will determine the cause of death and decide the quantum of compensation after considering the recommendation of Independent Expert Committee constituted for the purpose. In case of SAE other than death, the DCGI will determine the cause of injury and decide the quantum of compensation considering the reports of the Investigator, Sponsor and Ethics Committee. However, there is an option to constitute expert Committee to advise the DCG(I) in the matter.

The Independent Expert Committee constituted for examination of SAE of deaths has already devised a formula being followed for determining the quantum of compensation in case of clinical trial related death which is as under.

Compensation = (B x F x R)/ 99.37

Where,

B = Base amount (i.e. 8 lacs)

F = Factor depending on the age of the subject as per Annexure 1 (based on Workmen Compensation Act)

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4 as under:

1 .0.50 terminally ill patient (expected survival not more than (NMT) 6 months)
2. 1.0 Patient with high risk (expected survival between 6 to 24 months)
3. 2.0 Patient with moderate risk
4. 3.0 Patient with mild risk
5 4.0 Healthy Volunteers or subject of no risk

However, in case of patients whose expected mortality is 90 % or more within 30 days, a fixed amount of Rs. 2 lacs should be given.

The Apex Committee and the Technical Committee in their 7th meeting held on 30.08.2013 and 23.08.2013 respectively, after detailed discussions agreed to the above formula for determining the quantum of compensation in cases of clinical trial related deaths. The Apex Committee in the said meeting recommended that a separate formula should also be worked out for determining the quantum of compensation in case of clinical trial related injury (other than death).

In view of the above, a committee was constituted under the Chairmanship of Shri R. K. Jain, AS & DG comprising following members to deliberate and work out a formula to be followed to determine the quantum of compensation in case of clinical trial related injury (other than death) in accordance with the provisions of the Drugs and Cosmetics Rules.

1. Dr. Y. K. Gupta, Head, Department of Pharmacology, AIIMS, Ansari Nagar, New Delhi – 110 029
2. Dr.Arun Agarwal, Professor of ENT, Maulana Azad Medical College,Bahadur Shah Zafar Marg New. Delhi
3. Dr. B. T. Kaul, Prof. of Law, Delhi University, Law Centre – II, DhaulaKaun, New Delhi – 110021
4. Dr Mira Shiva, Coordinator, Initiative for Health, Equity and Society, A-60, HauzKhas, New Delhi - 110 016

The Committee met and deliberated the matter in detail on 04-Apr-2014.The Committee discussed various criteria that could be considered for determination of quantum of compensation in case of clinical trial related injury other than death. The Committee opined that for calculation of quantum of compensation in such cases the guiding principle may be linked to the criteria considered for calculation of compensation in cases of death. The Committee also deliberated that the quantum of compensation in case of clinical related injury (not resulting in death) should not exceed the quantum of compensation which would have been due for payment in case of death of the subject since the loss of life is the maximum injury possible.

Considering the definition of SAE, the following sequelae other than death are possible in a clinical trial subject, in which the subject shall be entitled for compensation in case the SAE is related to clinical trial.

(i) A permanent disability
(ii) Congenital anomaly or birth defect

(iii) Chronic life-threatening disease or
(iv) Reversible SAE in case it is resolved.

The Committee considered that unlike clinical trial relatedSAE of death, the formula for determination of compensation in each of the above 4 sequelae may be different.

Accordingly, the committee deliberated separately the each of the above four situations and worked out the criteria to be followed as under:

(i) SAE causing permanent disability to the subject

In case of SAE causingpermanent disability to the subject, the Committee deliberated that so far as the quantum of compensation is concerned, 100% permanent disability to a subject may not be considered equivalent to the death of the subject. Therefore, even in case of 100% permanent disability, the quantum of compensation should be less than that for the death of the subject. After detailed deliberation the committee arrived at a decision that quantum of compensation in case of 100% disability should be 80% of the compensation which would have been due for payment to the nominee (s) in case of death of the subject. The quantum for less than 100% disability will be proportional to the actual percentage disability the subject has suffered.

Accordingly, committee arrived at the following formula:

Compensation =(Dx80 x C)/ (100x100)

Where,

D= Percentage disability the subject has suffered.
C= Quantum of Compensation which would have been due for payment to the subject's nominee(s) in case of death of the subject.

(ii) SAE causing congenital anomaly or birth defect

The committee opined that the congenital anomaly or birth defect in a baby may occur due to participation of any one or both the parent in clinical trial. Following situations may arise due to congenital anomaly or birth defect.

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

The Committee opined that the compensation in such cases should be a lumpsumamount such that if that amount is kept by way of fixed deposit or alike, it should bring a monthly interest amount which is approximately equivalent to half of minimum wage of the unskilled worker (in Delhi). The committee noted that this aspect was duly considered while fixing Rs. 8 lacs as base amount for determining the amount of compensation in case of SAE resulting into death. Hence, the Committee decided that quantum of compensation in such cases of SAE should be half of the base amount as per formula for determining the compensation for SAE resulting into death.

In case of birth defect leading to (c) &(d) above to any child, the medical management as long as required should be provided by the Sponsor or his representative which will be over and above the financial compensation.

(iii) SAE causing life-threatening disease

The committee deliberated that the quantum of compensation in such cases should be linked to the duration (in days) for which the subject remained under life-threatening situation and required medical care, irrespective of number of days of hospitalisation. The committee also considered that compensation per day in such cases should be equal to minimum wage of unskilled worker (of Delhi).

Accordingly, the Committee arrived at the following formula.

Compensation = N x W

Where,
N= Number of days for which the trial subjectremained under life-threatening situation requiring medical care, irrespective of number of days of hospitalisation.
W=Minimum wage per day of the unskilled worker (in Delhi)

(iv) Reversible SAE in case it is resolved

In case of clinical trial related SAE which was reversible and resolved, the quantum of compensation should be linked to the number of days of hospitalization of the subject. The compensation per day of hospitalization should be equal to the wage

loss. The wage loss per day should be calculated based upon the minimum wage of the unskilled worker (in Delhi)

Since, in case of hospitalization of any patient not only the patient loses his /her wage, there will be direct or indirect losses of various kind including inconvenience, wage loss of attendant. The Committee decided that the compensation per day of hospitalization in such case should be double the minimum wage.

Accordingly, the committee arrived at the following formula.

Compensation = 2 x W x N

Where,

W=Minimum wage per day of the unskilled worker (in Delhi)

N= Number of days of hospitalization.

The committee felt it necessary that the formulas suggested above should be considered as draft which should be available to the stakeholders for at least 15 days for their suggestions. The formula can be finalized after taking into consideration the suggestions of stakeholders.

****