**Ministry :** Ministry of Health and Family Welfare

**Department/Board :** Health

**Notification No. :** GSR53(E)

**Date of Notification :** 30.01.2013

# Drugs and Cosmetics (First Amendment) Rules, 2013

**G.S.R.53(E).--**Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India, Ministry of Health and Family Welfare (Department of Health), number G.S.R. 821(E), dated the 18th November, 2011, in the Gazette of India, Extraordinary, Part II, section 3 sub-section (i), dated the 18th November 2011, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette of the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on the 24th November, 2011;

And whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government;

Now therefore in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

**1.** (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2013.

(2) They shall come into force on the date of their publication in the Official Gazette.

**2.** In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules),-

(i) after rule 122DAA, the following rule shall be inserted, namely:-

**"122-DAB. -** Compensation in case of injury or death during clinical trial.-

(1) In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

(2) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(3) In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of such subject.

(4) The expenses on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

(5) Any injury or death of the subject occurring in clinical trial due to 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 injury or death:

(a) adverse effect of investigational product(s);

(b) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator;

(c) failure of investigational product to provide intended therapeutic effect;

(d) use of placebo in a placebo-controlled trial;

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

(f) for injury to a child in-utero because of the participation of parent in clinical trial;

(g) any clinical trial procedures involved in the study.

(6) The Sponsor, whether a pharmaceutical company or an institution shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled to compensation.

(7) In case the Sponsor fails to provide medical management for the injury to the subject and/or financial compensation to the trial subject for clinical trial related injury or financial compensation to the subject's nominee(s) in case of clinical trial related death of the subject, the Licensing Authority may after giving an opportunity to show cause why such an order should not be passed,

by an order in writing, stating the reasons thereof, suspend or cancel the clinical trial and/or restrict Sponsor including his representative(s) to conduct any further clinical trials in the country or take any other action deemed fit under the rules.

(ii) in the said rules, in Schedule Y, in paragraph 2 relating to Clinical Trial,

(a) in sub paragraph (2) relating to Responsibilities of Sponsor,-

(i) clause (iv) shall be substituted with the following, namely:-

"(iv) Any report of serious adverse event of death occurring in clinical trial, after due analysis shall be forwarded by the Sponsor to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority as defined under rule 21(b) under Appendix XII with a copy of the report to the Licensing Authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis, shall be forwarded by the Sponsor to the Licensing Authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.",

(b) after clause (iv), the following shall be inserted, namely:-

"(v) in case of injury or death occurring to the clinical trial subject, the Sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII;

(vi) the Sponsor (whether a pharmaceutical company or an Institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within thirty days of the receipt of the order of the Licensing Authority.";

(c) in sub paragraph (3) relating to Responsibilities' of the investigator(s),-

(i) the sub paragraph "(3)" shall be numbered as "(3)(i)";

(ii) in the so numbered, clause (i), the words and figures "Sponsor Within 24 hours and to the Ethics Committee that accorded approval to the study protocol within 7 working days of their occurrence" shall be substituted with the words, figures and brackets "Licensing Authority defined under clause (b) of rule 21, the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, and the Ethics Committee that accorded approval to the study protocol, within twenty four hours of their occurrence. The report of the serious adverse event of death, after due analysis shall be forwarded by the Investigator to Chairman of the Ethics Committee and Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII with a copy of the report to the Licensing Authority and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event of death. The report of the serious adverse event other than death, after due analysis shall be forwarded to the Licensing Authority, Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.";

(iii) after the so numbered clause (i), the following clause shall be inserted, namely:-

"(ii) The Investigator shall provide information to the clinical trial subject through informed consent process as provided in Appendix V about the essential elements of the clinical trial and the subject's right to claim compensation in case of trial related injury or death. He shall also inform the subject or his/her nominee(s) of their rights to contact the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial for the purpose of making claims in the case of trial related injury or death.";

(d) in clause (5) relating to Responsibilities of the Ethics Committee, after sub-clause (iii), the following sub-clause shall be inserted, namely:-

"(iv) In case of serious adverse event of death occurring to the clinical trial subject, the Ethics Committee shall forward it's report on the serious adverse event of death, after due analysis, along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee constituted by the Licensing Authority under Appendix XII

with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death. In case of serious adverse event, other than death occurring to the clinical trial subject, the Ethics Committee shall forward its report on the serious adverse event after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event."

(e) after sub paragraph (5), the following shall be inserted namely:-

"5(A). Serious Adverse Events

(1) A serious adverse event is an untoward medical occurrence during clinical trial that is associated with death, in patient hospitalisation (in case the study was being conducted on out-patient), prolongation of hospitalisation (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.

(2) The Investigator shall report alt serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, and the Ethics Committee that accorded approval to the study protocol, within twenty four hours of their occurrence as per Appendix XI, and the said Licensing Authority shall determine the cause of injury or death as per the procedure prescribed under Appendix XII and pass orders as deemed necessary.".

(iii) in APPENDIX V.

(A) in serial number 1, in sub serial number 1.1, the entries against item number 9 shall be substituted with the following, namely:-

"9. Statement describing the financial compensation and medical management as under:

(a) In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.

(b) In the event of a trial related injury or death, the Sponsor or his

representative, whosoever has obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation for the injury or death."

(B) in serial number 2, after the line "Date of Birth/Age....." the following shall be inserted, namely:-

"Address of the Subject.....

Qualification.....

Occupation: Student/Self-Employed/Service/Housewife/Others (Please tick as appropriate)

Annual Income of the subject.....

Name and address of the nominee(s) and his relation to the subject..... (for the purpose of compensation in case of trial related death).";

(C) after the words, "Name of the witness....." occurring at the end, the following shall be inserted, namely:-

"(Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject or his/her attendant).";

(iv) after APPENDIX XI, the following shall be inserted, namely:-

**"APPENDIX XII**

**Compensation in case of injury or death during clinical trial**

(1) In the case of an injury occurring to the clinical trial subject, he or she shall be given free medical management as long as required.

(2) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(3) In the case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation, as per the order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expenses incurred on the medical management of the subject.

(4) The financial compensation for clinical trial related injury or death could be in the form of:-

(a) payment for medical management;

(b) financial compensation for trial related injury;

(c) financial compensation to nominee(s) of the trial subject in case of death;

(d) financial compensation for the child injured in-utero because of the participation of parent in clinical trial.

(5) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall provide financial compensation, if the injury or death has occurred because of any of the following reasons, namely:-

(a) adverse effect of investigational product(s);

(b) any clinical trial procedures involved in the study;

(c) violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the Investigator;

(d) failure of investigational product to provide intended therapeutic effect;

(e) use of placebo in a placebo-controlled trial;

(f) adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol;

(g) injury to the child in-utero because of the participation of parent in clinical trial.

(6) Procedure for payment of financial compensation

(a) The Investigator shall report all serious and unexpected adverse events to the Licensing Authority as defined under clause (b) of rule 21, the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial and the Ethics Committer that accorded approval to the study protocol, within twenty four hours of their occurrence as per Appendix XI.

(b) (i) The cases of serious adverse events of death shall be examined as under:

(A) An independent Expert Committee shall be constituted by the licensing Authority as defined under rule 21(b) to examine the cases and recommend to the Licensing Authority for the purpose of arriving at the cause of death and quantum of compensation in case of clinical trial related death.

(B) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and the

Investigator shall forward their reports on serious adverse event of death after due analysis to Chairman of the Ethics Committee and Chairman of the Expert Committee with a copy of the report to the Licensing Authority as defined under rule 21(b) and the head of the Institution where the trial has been conducted, within ten calendar days of occurrence of the serious adverse event of death.

(C) The Ethics Committee shall forward its report on serious adverse event of death after due analysis along with its opinion on the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Chairman of the Expert Committee with a copy of the report to the Licensing Authority within twenty one calendar days of the occurrence of the serious adverse event of death.

(D) The Expert Committee shall examine the report of serious adverse event of death and give its recommendations to the Licensing Authority for the purpose of arriving at the cause of the adverse event within thirty days of receiving the report from the Ethics Committee, and the Expert Committee while examining the event, may take into consideration, the reports of the Investigator, Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and the Ethics Committee.

(E) In the case of clinical trial related death, the Expert Committee shall also recommend the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

(F) The Licensing Authority shall consider the recommendations of the Expert Committee and shall determine the cause of death and pass orders as deemed necessary.

(G) In case of clinical trial related death, the Licensing Authority, after considering the recommendations of the Expert Committee, shall decide the quantum of compensation to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

(ii) Cases of serious adverse events, other than deaths, shall be examined as under:

(A) The Sponsor or his representative, whosoever had obtained permission

from the Licensing Authority for conducting the clinical trial, and the Investigator shall forward their reports on serious adverse event, after due analysis, to the Licensing Authority as defined under rule 21(b), Chairman of the Ethics Committee and the head of the Institution where the trial has been conducted within ten calendar days of occurrence of the serious adverse event.

(B) The Ethics Committee shall forward its report on the serious adverse event, after due analysis, along with its opinion regarding the financial compensation, if any, to be paid by the Sponsor or his representative, whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial, to the Licensing Authority within twenty one calendar days of occurrence of the serious adverse event.

(C) The Licensing Authority shall determine the cause of injury and pass order as deemed necessary. The Licensing Authority shall have the option to constitute an independent Expert Committee, wherever considered necessary, to examine such serious adverse events of injury, which will recommend to the Licensing Authority for arriving at the cause of the injury and also the quantum of compensation in case of clinical trial related injury, to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority as defined under rule 21(b) for conducting the clinical trial.

(D) In case of clinical trial related injury, the Licensing Authority, shall decide the quantum of compensation to be paid by the Sponsor or his representative whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, and shall pass orders as deemed necessary within three months of receiving the report of the serious adverse event.

(c) The Sponsor or his representative, whosoever had obtained permission from the Licensing Authority for conducting the clinical trial, shall pay the compensation in case of clinical trial related injury or death as per the order of the Licensing Authority as defined under rule 21 (b) within thirty days of the receipt of such order.

**[F. No. X-11014/6/2011-DFQC]**

**ARUN K. PANDA, Jt. Secy.**

**Foot note:** The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated the 21st December, 1945 and last amended vide notification number G.S.R. 844(E), dated the 26th November, 2012.