European Federation of Pharmaceutical Industries and Associations

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EFPIA Japan

Principle Relevant to Contract-Based Funding to Investigator Sponsored Study (ISS)

1. Objective

For the purpose of assuring that a fund supplied by a pharmaceutical company to an Investigator Sponsored Study (ISS) does not become a means to unfairly induce a deal of ethical drugs and is used appropriately for academic research and also for the purpose of securing the transparency of such fund, this principle is prepared to approve contract-based funding as one of cooperation forms other than donation and specify the relevant rules that have been unclear.

2. Definition

ISS is a study sponsored by a physician instead of a pharmaceutical company. Here, the "Investigator Sponsored Study" refers to a study, regardless of whether a clinical study or a non-clinical study, in which an investigator (including a medical institution and an incorporated non-profit organization etc. and hereinafter referred to as "investigator") takes legal and ethical responsibilities for all of planning, conduct, management, safety and, as necessary, fundraising. The "Guidelines on Medical Research" established by Health, Labor and Welfare Ministry will be applied to ISS. Meanwhile, investigator-sponsored clinical trials for drug application will be excluded from ISS.

3. Scope of application of this principle

(1) Studies included in the scope of application

ISS to which a pharmaceutical company supplies a contract-based fund instead of one-sided support by donation

Especially, the funding of an ISS in clinical disciplines conducted by a company using the company's own products will be contract-based and this Principle will be applied.

(2) Studies excluded from the scope of application

Studies not applicable to the definition of ISS including examples below

A) Commissioned studies taken legal and ethical responsibilities by a pharmaceutical company

B) Joint studies taken legal and ethical responsibilities jointly by an

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investigator and a pharmaceutical company

C) Investigator-sponsored clinical trials

Even the studies applicable to the definition of ISS will be excluded from the scope of application of this principle when conducted with a donation etc. from a pharmaceutical company.

4. Requirements

(1) On supplying a contract-based fund to ISS, the pharmaceutical company concerned shall comply with Japanese laws/regulations, industry standards and the following requirements.

A) The ISS to which a fund is supplied shall be specified, and a written contract specifying the supply contents shall be concluded with the investigator concerned.

B) Purchase or prescription of current or future one's own products of the pharmaceutical company concerned shall not be a condition for fund supply.

C) The pharmaceutical company concerned shall not induce planning of ISS. It is acceptable for the pharmaceutical company concerned to respond to the investigator's inquiry about whether a fund can be supplied to ISS or to disclose a study field or type to which a fund can be supplied.

D) The pharmaceutical company concerned shall not be proactively involved in ISS protocol preparation itself. It is acceptable for the pharmaceutical company concerned to review the protocol or to give a scientific comment to the investigator concerned.

E) The pharmaceutical company concerned shall not be proactively involved in ISS planning, conduct or management itself. It is acceptable for the pharmaceutical company concerned to provide the investigator concerned with information on the safety of one's own compound or product or to respond to an inquiry from the investigator concerned.

F) The pharmaceutical company concerned shall not make any scientific, technical or administrative support which may be suspected of infringement of the independence of the ISS investigator.

G) The pharmaceutical company concerned shall avoid supplying a fund which can be used by the investigator concerned for purposes other than the study specified by the written contract in the provision A). If the fund supplied has not been used completely for the target ISS, the remaining

fund should be returned from the investigator concerned to the pharmaceutical company concerned.

H) The pharmaceutical company concerned shall arrange the in-house advance review system and shall supply a fund only to ISS judged as scientifically worth conducting. Also, it shall be confirmed that the budget of ISS is appropriate and reasonable, and the supply content shall fit the budget concerned. In addition, the pharmaceutical company concerned shall not supply a fund which may be suspected of compensation for the investigator concerned and expenses which may be deemed to be private expenses such as wining and dining expenses at a meeting.

I) In principle, a fund to ISS shall not be paid at once but shall be paid considering the progress of the study.

J) Before the results of ISS are published, the pharmaceutical company concerned should be given an opportunity by the investigator concerned to review the draft or make a comment.

K) The protocol and outcome document of ISS should appropriately describe the fact that the ISS concerned is funded by the pharmaceutical company concerned. In addition, on using the outcome document of the ISS concerned for a third party, the pharmaceutical company concerned shall disclose the fact of fund supply.

L) The right relevant to the ISS outcome shall belong to the investigator concerned in principle. However, it is acceptable to state in the written contract in the provision A) that the pharmaceutical company concerned has the right to use the outcome concerned, or that the right relevant to the outcome concerned belongs to the pharmaceutical company concerned when a compound or product of the pharmaceutical company concerned has been used in the ISS.

End