

# SAFS ANNEX to the Code of Conduct of Pharmaceutical Industry in Slovakia

**Valid for SAFS members only from 17 April, 2008**

## 1. Article 8 - Research

**Article 8.1.1 shall be amended and shall read as follows:**

“The aim of NCT is to acquire scientific and professional information defined in NCT protocol. The objective of NCT shall be to answer a scientific question that has not been answered yet.”

**Explanatory notes related to Article 8.1.3 e) shall be amended and shall read as follows:**

*"e) Study design*

*It should contain at least the following data:*

- *number of centres,*
- *number of patients,*
- *number of physicians,*
- *evaluation form (e. g. questionnaire),*
- *statistical evaluation of the NTC.*

*The number of patients and physicians must not be higher than absolutely necessary to answer the question in NCT objective.”*

**Article 8.1.5 shall be amended and shall read as follows:**

“The distribution of drug samples must not be a part of NCT. Encourage initiation or switch of therapy to the drug of the NCT sponsor shall not be allowed.”

**Article 8.1.8 shall be supplemented by the following sentence:**

“NCT related visit by the Medical Representative to the physician involved must be free of any promotional activities.”

**Article 8.1.9 shall be amended and shall read as follows:**

“Any NCT must be notified at the office of the Member home association before its implementation. Notification of NCT to Member home association is with full documentation.

In the event there is submitted complaint, the Ethical Committee shall ask the office of the Member association for the complete trial documentation.

The compulsory notification must contain the following:

- the name and the goal of the trial,
- identification of the organisation or sponsor who organises and/or performs NCT,
- time schedule - expected commencement date and completion date of data collection,
- number of patients / centres involved,
- planned date and form of publication of results,

- the complete trial documentation and the protocol including approval of the competent Ethical Committee according to Sec. 2 par. 12 and Sec. 5 of the Act No. 576/2004 Coll. on Health Care, as later amended, and financial conditions under the trial is run including draft of financial agreement with the doctor. “

Following documentation must be published on the Member home association intranet and available for all member companies:

- Protocol outline
- Financial conditions under which the trial is run

## **2. Article 9 - Relations with Healthcare Professionals**

**Article 9 shall be supplemented by new Article 9.5 - Donations which shall read as follows:**

“Both cash and non-cash donations must be limited to non-for-profit organisations and state hospitals. Private healthcare providers (individuals and entities) must be excluded from such donations. Healthcare professionals who are employees of the state hospitals may receive donations only through their employers. Healthcare professionals who are employees of the private healthcare providers may not receive any donations provided by pharmaceutical companies\*.”

### *EXPLANATORY NOTES*

*Determination of status of an organisation as non-for-profit shall be always be made with respect to the objective which the organisation pursues and which is usually set fort at the moment of its establishment. The legal form of the organisation shall be of a secondary interest (for example a joint stock company [a.s.] and a limited liability company [s.r.o.] can be under the Commercial Code established and incorporated also as non-profit-making companies).*

*\*Support of medical education, such as sponsorship of national and international congresses and symposia, provision of scientific literature are not included and regarded as donations.*

**Article 9 shall be supplemented by new Article 9.6 - No Rentals which shall read as follows:**

“Fake or counterfeited rental of the space on the health care provider’s venue for free or for a symbolic price shall be prohibited.”