INFORMATION RELATED TO ARTICLE 14.3 – MARKET RESEARCH STUDIES

All Market Research studies are subject to Article 14.3 if they are conducted at a company's initiative, the initiative of several companies that share business strategies for a product or when a pharmaceutical company hands the study to a third party (research institute, scientific society, etc.) that has undertaken the work at its own initiative.

Market research (including social and opinion research) consists of the systematic compilation and interpretation of information on individuals and organizations using statistical and analytical methods and social science techniques that are applied in order to obtain new perceptions or to provide elements that support decision-making.

In these studies, the identities of the interviewees are not revealed to the user of the information without their expressed consent, nor are interviewees contacted for sales activities that result from the information they provide.

Notwithstanding applicable legislation, there is a general ethical framework within which market research must be conducted, as shown in the ICC/ESOMAR International Code for the Practice of Social and Market Research from the European Society of Marketing and Opinion Research (ESOMAR). In the specific case of the pharmaceutical industry, the self-regulation framework on this material consists of the European Pharmaceutical Market Research Association (EphMRA) Code of Conduct.

This regulation does not presume to replace the EphMRA Code, but instead establishes certain mechanisms that guarantee the appropriate execution of these studies in the application of this Code. The EphMRA Code will be of subsidiary application for the appropriate interpretation of this Code.

Market research studies must meet the following requirements:

i) Blinding of the identity of the persons participating in the study. The pharmaceutical company will not have the ability to learn before, during or after the study, the identity of the individuals participating in the study.

ii) Anonymous nature of the information collected. The pharmaceutical company will not have the ability to associate the data or opinions obtained with the names of the participants.

iii) Aggregate handling of the responses or data obtained.

iv) Proportionality between the universe and the sample. Quantitative market research studies pursue a level that is representative of the universe. When calculating sample size, if parameters other than those generally used in market research studies (simple random sample, 5% margin of error, 95% confidence level and 50% level of heterogeneity), the prior approval of the Code of Practice Surveillance Unit will be necessary.

v) The individual who participates in the study does not know and does not have the opportunity to link the study with the pharmaceutical company or with a specific product. Therefore, the pharmaceutical company's sales network cannot play any role in developing and conducting the study.

vi) The results of the study and the data obtained will not be published or used in promotional materials.

Any exception to these requirements must receive prior approval of the Code of Practice Surveillance Unit. In particular, the requirements of i, ii and v are included in the Supplementary Rules for market research studies associated with a product.

In addition, in order to guarantee that the marketing research studies do not represent an inducement to prescribe, or may contain an incentive that is prohibited under the Code, pharmaceutical companies undertake to:

i) Communicate the study prior to its commencement, in accordance with the provisions of Title II Rules of Procedure for the Control Bodies.

ii) Ensure that the study does not modify the physician's prescribing habits or the pharmacist´s dispensing habits.

iii) To have a written protocol that clearly establishes the objectives, methodology, anticipated results and use. In this regard, written agreements will be formalized with the professionals and/or entities with whom the studies will be conducted on the one hand and the company sponsoring the study on the other, specifying the nature of the services to be rendered, the conditions for participation and remuneration to the professionals, etc.

iv) Remuneration to participating professionals must follow market criteria and be in accordance with the time spent, the work performed and the responsibilities assumed. In addition, it must be appropriately formalized. Remuneration must be monetary. In exceptional cases and with the prior authorization of the Code of Practice Surveillance Unit, remuneration may be provided in kind.

v) Guarantee that the conduction of the study does not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer medicines.

vi) Be approved, prior to execution, by the company's scientific department or by the Compliance Officer stipulated in article 12.11 of the Code.

These requirements will be applicable regardless of the methodologies, sources or techniques applied to implement them, for example: survey method, observation, experimental designs, ethnographic techniques, expert groups, qualitative techniques, etc.

Failure to communicate studies referred to in this article 14.3 that are required to be reported will constitute a violation of this Code.

SUPPLEMENTARY RULES FOR MARKET RESEARCH STUDIES

In compliance with the conditions stipulated in the ESOMAR Code, companies may only **access the identity of participants** for the purpose of supervising and controlling the quality of the study. For this purpose, access to this data will be temporary while quality control activities are being conducted and no record of data from participants may remain in the possession of the company.

There are market research studies that have the objective of learning the opinion of Healthcare Professionals on a specific medicine, to study interest in a product based on its strong or weak points, or, for example, to analyze materials that will be used to provide information about the product's characteristics, etc. In these cases, the Healthcare Professional who participates knows, or may know, the pharmaceutical company that is developing said study and, in addition, when the aim is to test the content, comprehension, design, ease of presentation or interest in the materials used by companies to promote their medicines, personnel from the company's marketing or sales departments may also be involved.

Because of their nature, **market research studies on a product** will only be remunerated when strictly necessary and must be conducted on very small sample sizes. When in doubt, companies must take the ruling of the Code of Practice Surveillance Unit on this matter into account.

Regardless of the study being undertaken, when **remuneration** is provided, this must be of an ancillary nature. Therefore, not only should market criteria and the time used, the work performed and the responsibilities assumed by the professional be taken into account, it should also be proportional to the aims of the study.

The purpose of communicating studies is to facilitate the monitoring work of the Code of Practice Surveillance Unit. In no case should this be understood as implying authorization. The companies continue to be solely responsible for compliance with the Code in these studies, regardless of whether or not they are communicated previously to the Code of Practice Surveillance Unit.

FAQ - PROCEDURE FOR COMMUNICATING STUDIES

WHO should communicate these studies?

Pharmaceutical companies. Each company will designate through their legal representative one or two persons responsible for communicating studies who shall be the intermediary in these matters and who shall be assigned personal passwords for communicating studies via Internet/electronic mail.

WHEN is communication mandatory?

Such communication SHALL NOT BE MANDATORY when any of the following circumstances occurs:

- the sponsorship or funding provided by the company does not represent the majority of the financial resources; or
- the company does not have access, prior to, during or after the study, to the identities of the participating Healthcare Professionals, nor has it intervened in the selection beyond defining the participating group in the study protocol; or
- the study involves the remunerated participation of less than 20 Healthcare Professionals practicing in Spain. The subdivision of a study into smaller units when such units share the same focus.

WHEN should the communication be submitted?

Communication shall be addressed to the Code of Practice Surveillance Unit at least ten working days before the beginning of the study or exceptional access to the identity of the participants for reasons of quality control.

HOW should the communication be submitted?

A procedure will be put in place to present these communications through electronic media that ensure the agility of the process, its efficacy and the confidentiality of data. The electronic communication procedure was implemented on January 1st 2009.

WHICH INFORMATION should be provided? (*)

- Company reporting the study
- Name of the sponsor: company, scientific society, healthcare institution, other.
- Title of the study.
- Objective of the study.
- Methodology being applied.
- Planned times of execution.
- Approximate number of Healthcare Professionals participating in the study.
- Specialty to which the Healthcare Professionals belong.
- Geographical scope of the study (international, national, regional, local).
- Planned remuneration of the participating Healthcare Professionals.
- Other individuals or legal entities involved in the execution or sponsorship of the study (scientific societies, healthcare institutions, third-party service providers, etc.).
- In the case of exceptional access to the identity of the participants for reasons of quality control, position in the company of the persons with said access.

(*) A detailed standard communication form (in Spanish) will be provided.

HOW CAN I CONTACT THE SPANISH CODE OF PRACTICE SURVEILLANCE UNIT (SCPSU) FROM FARMAINDUSTRIA?

Email: usd@codigo.farmaindustria.es
Address: María de Molina 54, 7ª; 28006 Madrid, Spain
Website www.codigofarmaindustria.es

We encourage companies to contact their Spanish subsidiary representatives to clarify any aspect related with these instructions.