



From AIMFA (Agrupación de Investigación y Marketing Farmacéutico), we gladly inform that the implementation of the Spanish Code of Good Practices for the Promotion of Medicines and Interaction with Healthcare Professionals of Farmaindustria (from now on the 'Code') is taking place in a normal and successful manner.

The market research practice in Spain occurs at the moment with absolute normality. Furthermore, the Code is aiding to raise the quality of our country's market studies.

As a general rule and in conformity with the international standards commonly accepted for the market research area, these kind of studies meet a series of requirements. Article 14.3 of the Code reminds what these requirements are:

- I. **Ignorance of the identity of the individuals participating in the study.** Pharmaceutical companies shall not be able to know before, during or after its conduct, the identity of the individuals who took part in the study.
- II. **Anonymous nature of the information collected.** Pharmaceutical companies shall not have the possibility of linking by name each of the study participants with the data or opinions obtained.
- III. **Pooled processing of the responses or data obtained.**
- IV. **Proportionality between the universe and the sample.** Quantitative market research studies pursue a level of representativeness of the universe. When calculating sample size, parameters are used other than those generally accepted in market research (simple random sample, a margin of error of 5%, 95% confidence and 50% heterogeneity level), prior authorization by the Code of Practice Surveillance Unit shall be required.
- V. **The individual who participates in the study does not know and has no opportunity to link its conduct with a pharmaceutical company or a specific product.** Therefore, the sales network of the pharmaceutical company cannot play any role in the conduct and implementation of study.
- VI. **The study results and the data obtained will not be advertised or used in promotional material.**

For those existing market research studies that exceptionally do not conform to the above mentioned requirements the Code establishes that:

Any exception to these requirements should have prior approval of the Code of Practice Surveillance Unit.

STUDIES COMMUNICATION PROCESS

Prior communication of studies to the Code of Practice Surveillance Unit constitutes a separate and different matter to the one mentioned above.

The Rulings of the Self-Regulation System Control Bodies in “Article 10 Studies Communication Procedure” specifies, among other aspects, those cases under which **COMMUNICATION IS NOT COMPULSORY**.

Communication shall **NOT** be mandatory when any of the following circumstances occurs:

- the sponsoring or the financing from the company shall not be in its majority (superior to 50%); or
- the company does not have access before, during or after study, to the identity of the participating healthcare professionals and has not intervened in their selection beyond defining participating group described in the study protocol; or
- The study does not imply the direct or indirect remuneration of the participating healthcare professionals; or
- The study involves paid participation of less than 20 healthcare professionals. It is not allowed to split a study into smaller units that share approach, objectives and methods.