ECONOMIC COMMITTEE
FOR HEALTH PRODUCTS (CEPS)

CHARTER ON INFORMATION PROVIDED FOR THE PROMOTION OF MEDICINES THROUGH PROSPECTING AND CANVASSING

The purpose of this charter is to set forth the conditions under which information is provided, anywhere, on pharmaceutical products through prospecting or canvassing for promotional purposes.

Included within the scope of the charter is information in all its forms, regardless of medium, provided through canvassing, prospecting or incentives designed to encourage the prescribing, supply or use of pharmaceutical products by any professionals licensed to prescribe, dispense and use such products.

In accordance with the law, the aim of this charter is to improve the quality of information provided in the promotion of medicines to ensure their proper use among healthcare providers.

The aim of delivering information based on regulated and validated scientific information is to promote medicines among healthcare professionals. Information provided in this setting must promote the quality of medical treatment in an effort to prevent misuse of the product, avert unnecessary costs and raise healthcare professionals' awareness.

I- DUTIES OF PERSONS ENGAGED IN INFORMATION ACTIVITIES THROUGH CANVASSING OR PROSPECTING FOR PROMOTIONAL PURPOSES

1- Persons engaged in information activities through canvassing or prospecting shall present the medicinal products to healthcare professionals in compliance with the legal provisions, this charter and the guidelines set out by the company which they represent. This promotional activity involves imparting high-quality medical information on the presented medicine in strict compliance with the marketing authorisation and ensuring its proper use among healthcare professionals.

Such information shall comprise the role of the medicine in the recommended therapeutic strategy, its treatment of the disease in question, approved by the French Transparency Commission and in accordance with the recommendations issued by the National Authority for Health, ANSM (National Agency for Medicines Safety) and the National Cancer Institute, and with the consensus meetings approved by the National Authority for Health. This role must take account of campaigns to promote proper use and public health programmes. The information shall also include data on safety and monitoring of the medicine. Persons engaged in information activities through canvassing or prospecting shall present and offer to submit all risk minimisation documents provided for by the risk management plans or the risk minimisation plans.

Information may not be provided through canvassing or prospecting for the promotion of a medicine which is subject to a benefit/risk reassessment following a pharmacovigilance alert until this procedure is completed.

2- The activity of providing information through canvassing or prospecting shall involve informing healthcare professionals of all the regulatory, pharmacotherapeutic and health economic aspects of the presented medicine:

- therapeutic indications specified in the marketing authorisation;

- dosage (especially paediatric dosages if any);

- treatment duration;

- adverse reactions;

- contraindications;

- drug interactions and monitoring;
- prescribing conditions;

- price and funding arrangements (indications reimbursed to patients covered by national health insurance and reimbursement rates);

- Inclusion on the list of expensive medicines apart from diagnosis-related groups for internal-use medication and medicines sold by the health facility's pharmacy to outpatients.

Under the regulations, information may not be provided through prospecting or canvassing for promotional purposes on medicines granted temporary authorisation for use (ATU) status.

In addition, information may be presented on the existence of a temporary recommendation for use (RTU) and its updates provided that it is separated from all promotional activities, is approved by ANSM, and involves the delivery of documents intended to systematically gather information on such RTU.

3- In accordance with the laws in force (including art. L162-17-4-1 Social Security Code), if prescriptions are found not to comply with the marketing authorisation, the administrative authority may ask the company concerned to contact healthcare professionals to draw attention to the prescribing context set out in the marketing authorisation and, where appropriate, to disseminate such corrective statements as it deems necessary. These information actions specifically targeted at prescribers by the company or group of companies may be devolved to persons engaged in information activities through canvassing or prospecting. CEPS may request notification thereof.

These persons thus contribute to limiting the observed off-label use of medicines where such use is inconsistent with the recommendations of the competent health authorities.

When a company finds that a prescription does not comply with the proper use of a medicinal product, it may ask the persons engaged in information activities through canvassing or prospecting for promotional purposes to convey the appropriate information measures to the healthcare professionals and shall notify ANSM immediately thereof.

These persons shall inform the company fully on the use of medicines which they advertise, with particular regard to any adverse reactions and off-label uses which are brought to their attention.

4- The implementation (recruitment of and financial relations with professionals licensed to prescribe, dispense and use the medicines) of pharmacoeconomic analyses and clinical studies, including Phase IV and observational studies, does not fall within the remit of persons engaged in promotional information activities through canvassing or prospecting. They may however monitor such analyses and studies.

5- Information on apprenticeship schemes presented by persons engaged in information activities through canvassing or prospecting should be separated from any promotional activities relating to the medicinal product involved in the scheme.

II- THE QUALITY OF THE INFORMATION PROVIDED

1- Preparation of the information by the company

a) Preparation of documentation and training materials

Promotional materials made available to persons engaged in information activities through canvassing or prospecting must be drawn up in accordance with the provisions of the CSP (Public Health Code) and with the recommendations of ANSM. These documents shall bear the date on which the information was produced or updated. They must include a valid visa issued by the ANSM.
Information related to the use of the medicine, especially adverse reactions, precautions and contraindications shall be clearly stated in such a way as to highlight their relationship with the indication and the proposed benefit.

b) *Updating of promotional materials*

The company shall take steps to ensure that the scientific, medical and regulatory content of the promotional documents is kept up to date.

c) *Post-marketing studies*

Studies which may be used are peer-reviewed published studies conducted under the conditions of use of the medicine as set out in its marketing authorisation and other existing reference standards (opinion of the Transparency Committee, good practice guidelines). Moreover, in an effort to fully inform recipients and to comply with the recommendations of ANSM on the advertising of medicinal products, advertising must specify whether the publication relates to a study included in the transparency dossier and/or in the marketing authorisation dossier.

When a company uses such studies, it shall present them in a comprehensive and impartial manner.

d) *Comparative advertising*

Information provided on a medicinal product and on competing products having the same therapeutic aim falling within the therapeutic strategy defined by the Transparency Commission, must meet the following criteria defined for comparative advertising:

Any advertising that compares medicinal products by identifying, implicitly or explicitly, medicines marketed by a competitor may only be used if:

1º It is not misleading or likely to mislead;
2ºIt relates to medicines which meet the same needs or have the same therapeutic indication;
3º It objectively compares one or more essential, relevant, verifiable and representative characteristics of these medicines, of which price may be one.

Comparative advertising may not:

1º Take unfair advantage of the reputation of a trade mark, trade name, or other distinguishing signs of a competitor;
2º Discredit or denigrate the trade marks, trade names, other distinguishing signs, or circumstances of a competitor;
3º Generate confusion between the advertiser and a competitor or between the advertiser's trade marks, trade names or other distinguishing signs and those of a competitor;
4º Subject to the provisions governing generic medicines, present medicines as an imitation or reproduction of another medicine possessing a brand or protected trade name.

2- Training for persons engaged in information activities through canvassing or prospecting for promotional purposes

a) Initial training

In accordance with legal, regulatory and contractual requirements, persons engaged in information activities through canvassing or prospecting for promotional purposes shall receive adequate initial training, as evidenced by a certificate, diploma or other formal qualification, including prior experience accreditation or an equivalence awarded to the prior experience accreditation pursuant to Article L.335-5 of the Code of Education.

b) Continuing training

In addition to the induction training given to each new recruit, the company shall provide as a matter of course the necessary training to update its recruit on regulatory and scientific developments and to maintain and further their professional skills, including preparation for oral presentations.
Training in knowledge of regulatory requirements shall cover the following topics:

a. The medicine: classes of medicines, prescribing and dispensing rules, proper use of the medicine;
b. The funding arrangements for the medicine;
c. Pharmacovigilance and "product" complaints;
d. Code of conduct: DMOS anti-gift act and transparency of company links;
e. Advertising;
f. The Charter and certification;
g. Organisation of the healthcare system.

The training should allow persons engaged in information activities through canvassing or prospecting to know and comply with the regulations governing the medicine so they may be a source of information and answers to healthcare professionals. Each training topic shall relate to the training objectives that determine the content of the training.

Training on scientific knowledge shall cover:

a. The medicinal product and/or one or more diseases for which the presented medicine may be used;
b. The treatment strategy for the medicinal product and/or disease concerned, or the state of the art;

For each training programme attended by a person engaged in information activities through canvassing or prospecting, the company shall conduct an annual assessment to certify that the employee has the knowledge to deliver high-quality information. The company shall establish the procedures and period for the assessment. This assessment shall be conducted as a matter of course prior to meeting with healthcare professionals whenever a new indication or new product is introduced. It shall also establish training validation thresholds so that the required level can be set and corrective actions taken in the event of non-validation. The assessment procedures must comply with the following principles:

- Knowledge is assessed on the basis of the content of the training given;
- The company must demonstrate the randomness of the assessment process and its traceability;
- The company must have a sufficient database of assessment items to ensure compliance with the random assessment principle.

c) Certificate of initial and continuing training via the professional card

Persons engaged in information activities through canvassing or prospecting for promotional purposes shall be in possession of a professional card awarded by Leem through the AGVM

(Association for the Management of Medical Sales Visits). The award of this card ensures that the employee's level of regulatory and scientific knowledge meets the requirements of Article L.5122-11 CSP and the continued training requirement described above.

To this end, the company shall provide the AGVM each year with an individual report on the training given and the overall assessment outcomes. The AGVM may ask the company for additional information related to the assessment.
This information shall be available for inspection by the certification authorities.

See Chapter III Code of Conduct

3 Documents used by persons engaged in information activities through canvassing or prospecting for promotional purposes

These documents are all subject to prior oversight by ANSM and must therefore include a valid visa.

Persons engaged in information activities through canvassing or prospecting shall perform their duties exclusively by means of dated documents made available to them by the company, approved by the responsible pharmacist (name and signature) and for which an advertising permit has been issued by ANSM. When a document has been updated by the company, only the most recent may be used.

No exemption from delivery of the documents listed below may be sought as a result of using of audio, video or interactive materials.

Pursuant to Article R.5122-11 CSP, healthcare professionals must receive without fail:

- The summary of product characteristics referred to in Article R.5121-21 CSP;

- The product's prescribing and dispensing classification as stated in the marketing authorisation;

- The retail price ceiling, the reference rate or the transfer price where such price or rate is set by the laws and regulations in force, together, in this case, with the cost of daily treatment;

- The medicine's status in terms of its reimbursement by health insurance providers or its approval for public authorities pursuant to Article L. 5123-2;

- The opinion delivered pursuant to Article R. 163-4 of the Social Security Code by the Transparency Committee referred to in Article R. 163-15 of the selfsame Code and most recently published in the conditions laid down in the last paragraph of section III of Article R. 163-16 of this Code (where the medicine has received several opinions due to an extension of the treatment indications, the concept of opinion refers to all opinions involving an assessment of the medical benefit provided for each of the treatment indications of the medicine in question);

- Ministerial order(s) to include it on the supplementary list and/or on the list of medicines sold on through hospital pharmacies, if applicable.

Healthcare professionals must also receive without fail any documents deemed necessary by the French National Authority for Health, ANSM, the National Cancer Institute, or CEPS.

These documents must be fully legible and include the date on which they were created or last revised.

The following documents must be presented and may be delivered by persons engaged in information activities through canvassing or prospecting:

- Proper use of medicines leaflets;
- Prescribing information;
- Good practice guidelines;
- Consensus meetings;
- The opinions of the High Council for Public Health (Technical Committee on Vaccinations)
- or other reference standards issued or validated by the National Authority for Health, ANSM, or the National Cancer Institute;
- As well as risk minimisation documents provided for by the risk management plans or the risk minimisation plans.

III CODE OF CONDUCT

1- In respect of patients

Persons engaged in information activities through canvassing or prospecting for promotional purposes are bound by professional secrecy and may disclose nothing which they may have heard or seen in the places where they operate.

They should behave discreetly in the waiting areas and not hinder the delivery of care (limited conversations with professionals and mobile phone use, proper dress attire).

2- In respect of healthcare professionals met

Persons engaged in information activities through canvassing or prospecting shall be supervised to ensure that organisation, planning and frequency of visits are optimised.

In terms of professional ethics, persons engaged in information activities through canvassing or prospecting may not use incentives to secure a visit nor offer any remuneration or compensation to this end.

a) Organising visits

α- In any place where healthcare professionals practise

Persons engaged in information activities through canvassing or prospecting for promotional purposes shall endeavour not to disturb the smooth operation of the medical practice or health facility visited. Accordingly, they are required to comply with the following organisational procedures:

- They must ensure that their interlocutors are fully aware of their identity, their function, the name of the company and/or network being represented and, where applicable, the marketing authorisation holder of the medicinal product being presented.

- They must adhere to the timetables, the conditions of access and circulation within the various practice settings where the meeting takes place, as well as the duration and the venue decided by the healthcare professional or facility.

Accompanied visits (for example, with the regional director of the company or network) must be approved by the healthcare professionals visited. Accompanying persons must state their identity and position.

β- Within healthcare facilities

In healthcare facilities, persons engaged in information activities through canvassing or prospecting for promotional purposes are required to comply not only with the general rules set out in this charter but also the facilities' own internal rules of organisation and practice, including:

- Wearing a professional badge (e.g., business card worn as a badge, etc.);

- The conditions of access to the facility, to internal structures and to healthcare professionals regardless of their mode of practice within the facility;

- The rules governing identification and circulation within the facility as defined by its rules of procedure;

- The collective character or otherwise of the visit.

In all events, in healthcare facilities:

- Access to restricted facilities (operating theatres, sterile areas, intensive care, etc.) is prohibited without the prior approval, at each visit, of the heads of the facilities in question.

- Meetings shall be arranged in advance.

- Persons engaged in information activities through canvassing or prospecting may only meet staff undergoing training if given the prior approval of the facility's senior administrator or supervisory staff.

- Persons engaged in information activities through canvassing or prospecting may only meet interns in the presence, or with the prior approval, of their supervising practitioner.

- Persons engaged in information activities through canvassing or prospecting may not seek data (consumption, costs, etc.) specific to the internal facilities or prescribers.

b) Information gathering and compliance with the French Data Protection Act

Persons engaged in information activities through canvassing or prospecting shall gather information in relation to professionals licensed to prescribe, dispense and use medicines in accordance with the French Data Protection Act (Law No. 78-17 of 6 January 1978).

This information is gathered in order to reach a better understanding of the professionals' expectations with regard to the medicine and its use, or with regard to the therapeutic class concerned, to provide them with information tailored to their needs, and to streamline the work of persons engaged in promotional information activities through canvassing or prospecting.

Accordingly, information stored in databases must incorporate only professional and factual elements, to the exclusion of value judgements or information of a subjective nature.

The database in which this information is stored shall be notified to the CNIL (National Data Protection Agency). In accordance with the law, professionals licensed to prescribe, dispense and use medicines shall be notified that information concerning them is held in a computerised data base. Persons engaged in promotional information activities through canvassing or prospecting must notify professionals licensed to prescribe, dispense and use medicines of the data gained about them during individual or departmental prescribing or dispensing surveys, and that this information is available to them.

Upon written request of healthcare professionals, persons engaged in information activities through canvassing or prospecting may send them the personal data concerning them.

c) Professional relations - Congresses

Invitations to scientific congresses and/or to promotional events, as well as participation in research or scientific evaluation activities, must be subject to an agreement sent in advance to the

relevant professional association. Such agreements may allow for the receipt by healthcare professionals of the benefits referred to in Article L. 4113-6 of the Public Health Code. These benefits must be made public by the companies awarding them, pursuant to Article L. 1453-1 of the Public Health Code, in accordance with the procedures set out in Articles D. 1453-1 and R. 1453-2 et seq. of the Public Health Code.

d) Samples

Persons engaged in information activities through canvassing or prospecting are not allowed to hand out samples of pharmaceutical products.

This prohibition also applies to the giving of samples of cosmetics, dietary supplements and medical devices by persons engaged in promotional information activities through canvassing or prospecting when they are presenting a pharmaceutical product, without prejudice to the application of the 4th paragraph of Article L5122-10 CSP.

Samples of medical devices may, however, be used for demonstration purposes, subject to the provisions of Chapter III, Title 1, Book II, Part 5 of the Public Health Code.

e) Gifts

Persons engaged in promotional information activities through canvassing or prospecting may not offer healthcare professionals gifts in kind or in cash, whether or not covered by an agreement, nor respond to any requests in this respect.

This prohibition also applies to offering or facilitating the provision of a benefit covered by the exceptions made in the second paragraph of Article L. 4113-6 of the Public Health Code.

f) Meals

Meals offered to healthcare professionals by persons engaged in information activities through canvassing or prospecting may constitute benefits within the meaning of Article L. 4113-6 of the Public Health Code.

In order to be exempted from an agreement, meals must in all instances be of an impromptu character and be linked to the visit made to the healthcare professional. They shall be made public, where applicable, pursuant to the provisions of Section II of Article L. 1453-1 and Articles D. 1453-1 and R. 1453-2 et seq. of the same Code.

3- In respect of competitors

The information provided by persons engaged in information activities through canvassing or prospecting in respect of the pharmaceutical product being promoted and in respect of competing pharmaceutical products having the same therapeutic aim and featured in the therapeutic strategy defined by the Transparency Committee, must not be disparaging and must be based principally on the opinions of the Transparency Committee. The ASMR (improvement of the medical benefit provided) level set by the HAS must be faithfully presented.

Persons engaged in information activities through canvassing or prospecting shall refrain from disparaging the pharmaceutical products of competitors, including generic and biosimilar medicines.

4- In respect of their own company

In accordance with the law, persons engaged in information activities through canvassing or prospecting shall immediately advise the responsible pharmacist or their pharmacovigilance

department of any information received from healthcare professionals concerning pharmacovigilance and/or the improper use of their medicines.

5 In respect of medical insurance

Persons engaged in information activities through canvassing or prospecting shall set out the reimbursable and non-reimbursable indications of the medicinal products being presented.

They shall present the different packaging options in terms of their health insurance cost and, with particular regard to chronic treatments, those that are most economical and best suited to the patient, especially where practitioners prescribing in a non-hospital setting are concerned.

They shall specify whether the medicinal product being presented is covered by a reference rate.

I- OVERSIGHT OF THE ACTIVITIES OF PERSONS ENGAGED IN INFORMATION ACTIVITIES THROUGH CANVASSING OR PROSPECTING FOR PROMOTIONAL PURPOSES

1- Responsibility of the Responsible Pharmacist

a) On content

The responsible pharmacist shall set up a quality control system that guarantees the scientific and economic content of the promotional materials used in the information activities through canvassing or prospecting and more generally shall ensure compliance with section II-1 of the charter. He/she shall approve these materials.

The responsible pharmacist shall ensure that the lists of materials that can and should be delivered by the persons engaged in information activities through canvassing or prospecting are kept up to date.

He/she is responsible for the content of the messages delivered by the persons engaged in information activities through canvassing or prospecting.

b) On training

The responsible pharmacist shall ensure that the persons engaged in information activities through canvassing or prospecting possess the necessary knowledge for the exercise of their profession and that they receive regular continuous training designed to update their knowledge and prepare for promotional campaigns.

c) On procedures

The responsible pharmacist shall ensure the proper development and implementation of information-related procedures within the company.

2- Procedures

a) Document traceability

The responsible pharmacist shall ensure that only those documents whose scientific, medical and economic quality is guaranteed by his/her signature and date are used at all times for medical sales visits.

b) Feedback

The healthcare professionals visited are regularly given the opportunity to provide the company, without cost to themselves, with their assessment of the scientific quality of the information, its objectivity and its compliance with laws, regulations and this charter.

The assessments sent to the company by the healthcare professionals are recorded and reviewed by the responsible pharmacist.

The company shall also provide itself with the resources to measure its contribution to proper medicinal use, to the detection of prescriptions that deviate from such use, and to steps aimed at correcting them (L5121-14-3 CSP).

c) Follow-up of contacts

The company shall provide itself with the resources to regularly measure its information activity through soliciting or canvassing.

These data shall be made available to the Joint Monitoring Committee referred to section V of this charter, which may request that they be submitted in the event that the quality of the promotional information is identified by the national observatory as having deteriorated and/or in case of an alert by ANSM or the HAS.

3- Certification and audits

Pursuant to Article L. 162-17-4 of the Social Security Code, a certification standard shall be established, subject to conditions to be determined by the National Authority for Health, guaranteeing compliance by the certified companies with the provisions of this charter.

This standard also sets out the procedures according to which company executives, supervisory staff and persons engaged in information activities through canvassing or prospecting adhere personally to the charter.

When, for the purposes of promoting its medicines through canvassing or prospecting, a company enlists a service provider or another pharmaceutical company, it shall be responsible for ensuring

that the practices adopted by such service provider or such pharmaceutical company are in compliance with the Charter.

4- Implementation of Articles L162-17-4 and L162-17-8 CSS

The company shall prioritise the content of medical sales visits by persons engaged in information activities through canvassing or prospecting over their frequency in order to ensure that the information provided is as comprehensive and objective as possible and, in particular, that the time needed to instruct healthcare professionals on the proper use of the medication is sufficient.

To this end, CEPS and LEEM have decided to establish a national observatory for promotional information. The aim of this observatory is to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

The observatory will be used as a non-exclusive reference tool for the signatories to this charter and as a source of shared information between the parties to this charter. Pharmaceutical companies that fall within the scope of this charter shall conduct a survey once a year among healthcare professionals to measure the quality of their promotional practices on their most promoted medicine and on any other medicines, at the reasoned request of CEPS, totalling up to 3 products. The investigation method and criteria applicable to all companies shall be defined jointly by CEPS and LEEM. They are contained in the annex to this charter.

Once collected, the data shall be forwarded to a trusted third party able to aggregate and analyse them. This work will give rise to an annual report to be sent each year to the signatories to this charter. In addition, the trusted third party must be able to alert the charter's signatories to any quality practices that fall short of the requirements set out herein. The trusted third party shall be selected jointly by CEPS and LEEM.

A CEPS-Leem Joint Monitoring Committee shall be established. It shall meet at the request of either party. It shall analyse primarily the evidence forwarded by the national observatory showing deterioration in the quality of the promotional information and any other relevant findings (alert sent by the health authorities, evidence available to CEPS, etc.). The Committee shall meet at least once a year to review the national observatory's annual report drawn up by the trusted third party. At the meeting, it shall prepare its own annual report which it will make public. It shall serve as a forum for discussion, allowing manufacturers to explain their promotional practices and, where applicable, to provide answers to CEPS and/or the health authorities.

CEPS may set quantified annual targets for the development of promotional practices, if necessary for certain pharmacotherapeutic classes or products pursuant to Article L.162-17-8 of the Social Security Code. To do so, CEPS shall base itself on a body of evidence pointing to commercial and promotional practices which may affect the quality of care.

In light of the evidence gathered, if CEPS wishes to set quantified targets, it shall meet with the companies concerned. Following this exchange and such additional evidence as may be submitted by the companies, CEPS may, by agreement or by its own decision in the absence of an agreement within two months, set these quantified annual targets for the development of promotional practices.

If these targets are not met, CEPS may impose a financial penalty on the company, pursuant to Article L162-17-8 CSS, once the company has been given the opportunity to submit its observations.

V - JOINT MONITORING OF THE CHARTER

The parties agree to establish a joint committee to monitor the implementation of this charter and the attainment of the objectives pursued. This monitoring committee shall consult, as necessary, the relevant professional associations on the rules of professional conduct, as well as ANSM and HAS. It shall meet at the request of either party and in particular each year on receipt of the national observatory's annual report. It shall review the issues raised by each party.

VI- TERM AND TERMINATION

This agreement shall enter into force upon signature.
It shall be renewed annually by tacit agreement and may be amended by an additional agreement.
It may be terminated by either party.
In case of termination, the effective date of termination is 12 months following notice by one party to the other, such period allowing for the adoption of appropriate regulatory measures.

Made in Paris, on 15 October 2014, in duplicate

On behalf of CEPS	On behalf of Leem
Mr Dominique GIORGI Chairman	Mr Patrick ERRARD Chairman

ANNEX TO THE CHARTER ON INFORMATION PROVIDED FOR THE PROMOTION OF MEDICINES THROUGH PROSPECTING AND CANVASSING

ESTABLISHMENT AND OPERATION OF THE NATIONAL OBSERVATORY FOR THE MONITORING OF PROMOTIONAL INFORMATION

1) General framework

As part of the charter on information provided for the promotion of medicines through prospecting and canvassing, CEPS and LEEM have decided to set up a national observatory to measure the quality of promotional practices based on objective, verifiable and transparent criteria.

This observatory is provided each year with data collected from healthcare professionals by the pharmaceutical companies falling within the scope of the charter. These companies shall conduct a survey each year to measure the quality of their promotional practices on their most promoted medicine and on any other medicines, at the reasoned request of CEPS, totalling up to of 3 products.

Once collected, the data shall be forwarded to a trusted third party responsible for aggregating and analysing them. If significant deviations in practice are found, the trusted third party shall inform Leem and CEPS thereof.

The trusted third party shall be selected jointly by CEPS and LEEM following a competitive bidding process. The cost of the trusted third party's services shall be borne equally by CEPS and LEEM.

The signatories to this charter shall draw up the specifications for selecting the service provider in the month following the signing of the charter and shall establish a scoring chart for selection purposes. Responses should be sent separately to CEPS and LEEM within two months from the date on which the specifications were sent out.

The signatories to this charter shall meet in the ensuing 15 days to review the candidates' responses. At this meeting, the signatories to the charter may decide to interview the candidates.

2) Survey methodology

Companies shall conduct surveys among healthcare professionals by electronic questionnaire, the panel recruitment criteria for which shall be identical for all companies and established by the trusted third party.

Each questionnaire shall include questions set by the trusted third party on the following 4 topics:

Identification of the healthcare professional

- Specialism
- Place of practice
- Acceptance of the medical sales visit
- Frequency of visits

Description of the visit

- Identification of the medical sales representative and/or accompanying person
- Compliance with the visiting rules laid down by the healthcare professionals
- Place of the visit
- Sample distribution (medical devices)
- Number of products presented

Content of information provided for the products presented

Therapeutic indications

- Clinical data on the benefit of the medicine
- Role of the medicine in the therapeutic management of the patient
- Proper use: adverse reactions - contraindications
- Pharmacovigilance alert or Risk Minimisation Plan/Risk Management Plan
- Official recommendation (HAS, etc.)
- Submission of the SPC
- Submission of the opinion of the Transparency Commission
- Economic aspects (reimbursable and non-reimbursable indications, reference price, packaging, etc.).

Satisfaction of healthcare professionals

- Objectivity of the presentation
- Usefulness of the visit
- Appropriate frequency of visits

The questions proposed by the trusted third party will be validated in advance by the signatories to the charter during the course of a dedicated working group session.

The answers to the questions on the 4 listed topics shall be sent to the trusted third party in the month following completion of the survey and in all events before the end of each year.

This survey is implemented for the first time in 2014.