



HAUTE AUTORITÉ DE SANTÉ

**CERTIFICATION CRITERIA FOR
PHARMACEUTICAL AND MEDICAL
SALES REPRESENTATIVES'**

July 2006

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1 Scope

These certification criteria concern the practice of pharmaceutical and medical sales representatives, hereinafter called medical representatives, who either call on non-hospital medical practitioners at their surgery or contact them remotely, to promote reimbursable prescription medicines¹.

The criteria are intended for all pharmaceutical companies which market products and which have signed an agreement with CEPS². They are based on the "Medical sales representatives' Code of Practice", hereinafter called the "Code", which is a contract of undertaking between CEPS and representatives of the pharmaceutical industry (LEEM³) and which is specified by the National Health Insurance law of 13 August 2004.

2 Background

Certification of sales representatives' calls comes within the framework of the 13 August 2004 National Health Insurance law, specified in the following articles:

- *Article L162-17-8*: a Code of Practice concerning the quality of the professional practice of companies tasked with promoting pharmaceutical products by prospecting for business or by cold calling is agreed between CEPS and one or more associations representing pharmaceutical companies.
- *Article L162-17-4*: signatory companies must undertake to comply with the medical representatives' Code of Practice and must ensure that the quality of the calls they organise or commission and their compliance with the Code are assessed and certified by accredited organisations in accordance with a procedure established by HAS.

HAS has chosen to certify the company's technical qualification. The company must deploy the resources required to ensure that medical representatives' practice complies with the Code.

The present set of criteria has been developed from the medical representatives' Code of Practice. Under the certification process, application of the criteria will be assessed by independent organisations accredited by COFRAC. Accreditation will be in accordance with European Standard EN 45012, with additional accreditation criteria specific to the certification of medical representatives' practice .

Before a company can be certified, it must submit an application for certification to a certifying body accredited for this purpose. As a temporary measure, until 30 December 2007, certifying bodies that have submitted an application for accreditation to COFRAC between 30 September and 30 December 2006 will be allowed to carry out certifications.

¹ Only remote medical representatives' activity conducted via the telephone and Internet together comes within the scope of certification.

² CEPS: Committee for Pricing of Health Products. Law no. 2004-810 of 13 August 2004 relating to National Health Insurance – Article L162 – 17-4

³ LEEM: Association of pharmaceutical manufacturers

3 Certification: provisions and process

It is the company's responsibility to implement the Code and the requirements defined in the certification criteria for medical representatives' practice.

The Chief Executive determines the procedures with which the company will satisfy the requirements of the certification criteria, in line with their company culture and organisation. In particular, the involvement of divisions (marketing, sales, training, etc) and medical representatives' managers (regional directors, network directors, etc) is established.

It is essential that the company's Chief Executive commit to the certification process for effective implementation of the criteria.

3.1 Administrative provisions

The company uses its own internal organisation to implement the actions that will allow it to satisfy the requirements of the certification criteria and the procedure.

3.1.1 Defining the quality policy for medical representatives' practice

The company should have defined its quality policy concerning medical representatives' practice. The policy should be formally established, widely distributed and be familiar to all company staff involved.

For example, the quality policy may:

- define the company's commitments with regard to medical representatives' practice (notably the commitment of the company, etc).
- define the objectives to be achieved,
- define indicators,
- describe company procedures for discussing and/or providing information on the quality policy for medical representatives' practice,
- etc.

3.1.2 Defining responsibilities

It is the company's responsibility to implement the Code of Practice and the requirements defined in the certification criteria for medical representatives' practice.

The company's Chief Executive and the Chief Pharmacist organise the quality initiative concerning certification of medical representatives' practice within the company, taking account of its structure and organisation.

3.1.3 Document management for medical representatives' practice

The document system:

- supports and disseminates quality initiatives,
- ensures that the individuals concerned have essential, appropriate and up-to-date information,
- proves that the certification criteria are applied within the company.

3.1.4 Assessment and monitoring

- **Pre-audit before the certification audit**

It is recommended that a pre-audit be carried out before the initial certification audit in order to verify that:

- all requirements and criteria in the Code are being complied with,
- the tools used are effective and able to achieve the goals established.

The company is free to choose whether or not to carry out a pre-audit. If necessary, this audit can be incorporated into and interface with other audits carried out as part of the company's quality process.

The pre-audit is the subject of a report that highlights any nonconformities identified and specifies preventive and corrective actions to be implemented.

- **Assessment and monitoring tools**

The company should select and introduce assessment and monitoring tools for ensuring continued compliance with the requirements and criteria of the Code (continuous quality improvement process). These tools are essential to the dynamic process, in particular for the different audits carried out by the certifying body (initial, monitoring and renewal audits).

There should be a formal statement that these tools exist, and that the results are used (preventive and corrective actions implemented).

- **Quality indicators**

The company should establish, introduce and monitor quality indicators that can be used to ensure that *the certification criteria* are satisfied.

The quality indicators should be consistent with the company's quality policy concerning medical representatives' practice. Data collection procedures should be established.

- **Management of complaints about medical representatives' practice**

The company should facilitate the handling and recording of complaints about medical representatives' practice. Procedures for managing complaints should be established.

- **Implementation of preventive and corrective actions**

As part of the quality process, any nonconformities observed should be recorded and analysed, and should lead to corrective and preventive action.

3.2 The certification process

This section describes the certification initiative implemented by accredited certifying bodies to ensure standardisation of certification practices.

3.2.1 Application form

All companies applying for certification submit an application form to a certifying body.

The application form includes a commitment by the company to be aware of and comply with the procedures for certification at the time of the initial certification audit.

This commitment by the company concerns:

- **Compliance with legal obligations ("prerequisites")**

Compliance with the Public Health Code (PHC) governing pharmaceutical companies is controlled by AFSSAPS⁴ (regulation of advertising and inspection of facilities). The obligations (Annex 1) are not part of the Code (they are not the subject of a certification audit) but constitute the prerequisites⁵ of the Code. Compliance with these obligations is a preliminary to certification.

The company confirms that it complies with the prerequisites in the form of a letter of undertaking from the Chief Pharmacist.

- **Commitment by the company's Chief Executive to apply the criteria** for certification of medical representatives' practice for a period of at least 3 months before the initial audit.

Criteria 1.2 (simulation exercises) and 4.3 (monitoring of information distributed and quality of practice) may take longer to put into practice. In that case, the company should provide evidence that their implementation has been defined and scheduled.

In its application form, the company should also describe its procedures for using commissioned representatives to carry out its medical sales activities.

The table below summarises the information the certifying body asks a company to provide for examination of an application form.

Contents of an application form	
1	Administrative information (specific list drawn up by each certifying body)
2	Procedures for using service providers for medical sales activities
3	Letter of undertaking from the Chief Pharmacist
4	Organisation chart of the company that markets the medicinal products ⁶
5	List and identification of individuals who may be interviewed

3.2.2 Audit conditions

- **Initial certification audit**

The initial certification audit covers the following points:

- compliance with all certification requirements and criteria,
- implementation of assessment and monitoring tools to ensure compliance with the requirements and criteria.

The audit should not last more than 5 man-days, including a maximum of 3 man-days onsite.

The audit is carried out by an auditor approved by the certifying body. The auditor is not necessarily a specialist in the sector, but he or she must be trained by the certifying body in the field, sector and Code.

⁴ AFSSAPS: French health Products Safety Agency

⁵ See Annex 1 – "Prerequisites to certification"

⁶ The company's organisation chart should show the link between the individuals mentioned and the functions of the individuals to be interviewed as given in the certification criteria.

To carry out the audit, the auditor

- completes an audit checklist,
- interviews the Chief Pharmacist,
- interviews the individuals concerned (marketing manager, sales manager, regional director, medical sales representative, training manager, scientific and medical manager, human resources manager, etc.),
- checks that reference documents and records are available and that they comply with requirements and certification criteria,
- reviews the quality indicators used by the company to ensure constant compliance with the requirements and criteria, and the implementation of related corrective action.

At least one person should be interviewed for each job function that comes within the scope of the Code. There are no rules defining the maximum number of individuals who may be interviewed.

The company includes in its application form a list of individuals who may need to be interviewed because their job function is listed in the Code. However, the job functions identified can be adapted to the organisation and to the organisation chart of the company.

Moreover, the auditor may ask the Chief Pharmacist for permission to interview individuals other than those mentioned in the application form.

- **Conditions for issuing certification**

Before the contract is signed, the company is informed of the certifying body's procedures for issuing and renewing certification.

- The person responsible for the audit writes the audit report and then submits it to an independent decision-making body (expert group or certification committee) within the certifying body.
- The decision-making body examines the audit report and proposes a decision (approval or refusal of certification). The company may be asked to provide further details on a particular point.
- The certifying body sends the company a report on the audit results, which identifies any non-conformities to be cleared in order to satisfy all certification requirements. It invites the company to comment on this report and to describe the specific measures it has taken or plans to take within a fixed time to remedy these nonconformities.
- The responses made by the company may require a total or partial reassessment.
- The final audit report is sent to the applicant company by the certifying body.
- The company may distribute the report but in its final form only. The report should include the general conclusions of the audit and the conclusions for each requirement, including strong points, points to be improved and ways in which progress may be made. The company may decide whether or not to distribute the audit report.
- Certification is issued by the certifying body for a period of 3 years.
- All certifying bodies send HAS an updated quarterly list of certifications approved, according to procedures to be determined.

- **Monitoring procedures**

A compulsory monitoring audit is part of the certification procedure in order to maintain the initiative in motion and to ensure that the company is engaged in a continuous quality improvement process.

This audit is carried out at least once during the 3 years for which certification is issued in order to ensure that the certified company continues to comply with the requirements of the Code. It should take place between the end of the first and second years. It is shorter than

the initial audit, taking not less than one-third and not more than two-thirds of the time the initial audit took. It is carried out by an auditor approved by the certifying body, with the same profile as for the initial audit. It comprises an analysis of records and interviews with the individuals concerned, and focuses on items or documents that are likely to have changed since the previous audit.

After each monitoring audit, the certification maintenance file is examined by the certifying body on the basis of the audit report and the audit manager's proposal.

- ***Conditions of suspension and withdrawal***

Before entering into a contract with the certifying body, the company is informed of the certifying body's procedures for suspending or withdrawing certification.

The conditions for suspension and withdrawal are established by the certifying body. In any case, before any decision is taken to suspend or withdraw certification, the certifying body notifies the company of the reasons for any such decision, and invites it to comment before a given deadline on these reasons and/or describe the specific measures taken or that it plans to take to remedy its nonconformities with certification requirements.

The corrective measures carried out by the company may require a total or partial reassessment.

Suspension does not interrupt the initial certification process.

Certification of a company does not involve audit without notice.

- ***Company's methods of appeal***

Methods of appeal open to the company are laid down by the certifying body, in the event of its decisions being disputed. The company is informed of these methods of appeal before entering into any contract.

The certifying body should have a competent impartial committee to examine appeals submitted by applicants for certification or by companies who have been certified.

- ***Conditions under which certificates may be transferred***

The certified company may change certifying body during the period of validity of its certification.

After receiving a request from a certified company, the new certifying body examines the application form on the basis of the written records (stage in the certification cycle, status of unresolved minor or major nonconformities, etc).

If the result of this examination is judged satisfactory, the new certifying body may take over the previous certificate and issue a certificate with the same validity as the first.

Transfer of certificates classed as having been suspended or threatened with suspension should not be accepted by a new certifying body.

- ***Renewal audit***

At the end of the certification period the company must renew its certificate by submitting a new application form to the certifying body.

The company's audit plan schedules and describes its renewal audit. If necessary, the audit can be incorporated into and interface with other audits carried out as part of the company's quality initiative.

3.2.3 Announcement of company certification

Once certification has been granted, the company may announce its compliance with the requirements and criteria, being careful to use the same wording as that of the Code.

The wording of the certificate should be explicit and should specify the scope of certification, i.e.: "Pharmaceutical company marketing products + corporate name" is certified for its medical representatives' practice, as regards the promotion of reimbursable pharmaceutical products in the non-hospital sector, in accordance with the National Health Insurance law of 13 August 2004. The certifying body should be unambiguously identified.

Information, sales and advertising materials produced by the company that refer to certification of the company's technical qualification should:

- display the certification logo and the name of the Code of Practice criteria, with version number,
- comply with the rules for using the certifying body's logo.

3.2.4 Updating certification criteria

The medical representatives' certification criteria will be updated as necessary.

Procedures for including amendments to the certification process will be determined jointly with stakeholders, on a case-by-case basis, according to a framework defined by HAS.

4 Certification requirements and criteria

The medical representatives' Code states that:

"The main purpose of medical representatives' work is to promote medicines to health professionals and to contribute to the development of pharmaceutical companies. It should encourage quality of medical treatment, i.e. should avoid misuse of medicines and needless expense, and should help keep doctors informed.

A medical sales representative, exclusively and outside all commercial activity, presents pharmaceutical products in order to ensure their promotion in compliance with the company's strategic orientations, to ensure that members of the medical profession are aware of these products, and to ensure that products are used in compliance with the proper use of medicines."

The aims of this Code concern:

- **THE QUALITY OF INFORMATION DISTRIBUTED**

The pharmaceutical company is responsible for the quality of the information provided by its medical representatives. The company undertakes to transmit, via its medical representatives, reliable and clear information that complies with legal requirements, encourages the proper use of medicines and complies with public health goals. The company is accountable for: 1) the scientific, medical and economic quality of the promotional materials it makes available to its medical representatives; 2) the information given to doctors in their own premises.

- **QUALITY OF THE COMPANY'S MEDICAL REPRESENTATIVES' WORK**

A company should be committed to quality in its organisation and in the practice of its medical representatives in order to be able to provide high-quality information. This means that medical representatives' work should focus on its own missions of promotion of medicines and provision of medical information.

To do this, the company makes available the necessary resources to ensure that its medical representatives' work is of high quality and complies with ethical rules concerning doctors, patients, competing companies, and National Health Insurance.

Production of reference documents and recordings, definition of the related responsibilities and introduction of tools to monitor practice and to improve information quality should comply with all these aims.

How to read the requirements

Each **requirement** is accompanied by a note describing the context, indicating which items of the Code the requirement refers to.

Requirements are broken down into **criteria**. Each criterion is accompanied by a reference to the section of the Code from which it is derived.

Each criterion has response items with which the company must comply for certification. Responses other than those described are possible. It is for the company to demonstrate that their response satisfies the criterion. The sections in italics provide further guidance.

Monitoring actions are proposed for each criterion. These constitute evidence that the company is satisfying the requirements and criteria of the certification audit. They are:

- reference documents and records,
- interviews with the individuals concerned, useful as a guide for the certifying body (particularly when carrying out its audit plan). They ensure standardisation of practice between certifying bodies and illustrate the commitment of company staff. However, the job functions may differ according to the company set up and organisation chart (different job titles, other individuals carrying out these job functions in the company, delegation, etc).

REQUIREMENT 1**The company ensures that its medical representatives have the knowledge and skills needed to disseminate high-quality information**

The company must guarantee distribution of high-quality information through its written promotional materials, as well as in messages delivered verbally by a medical representative. The quality of training given to medical representatives by the company is one of the ways in which the quality of verbal information can be guaranteed.

The training of medical representatives includes initial training, continuing training and specific training for promotional campaigns:

- Initial training is confirmed by a diploma, title or certificate that is required to practice the profession.
- Continuing training consists of induction training for all new recruits and updating of knowledge. Continuing training sessions - and training carried out for promotional campaigns - help medical representatives deliver highly comprehensive information and strike a balance between presenting a medicine and presenting information on its proper use, when calling on a doctor.

Initial training and the organisation of continuing training are controlled by AFSSAPS' ⁷*Direction des Etablissements*.

The company assesses the quality of information delivered by its medical representatives by means of simulation exercises, which come under the responsibility of the Chief Pharmacist.

CRITERION 1.1**The company holds continuing training sessions for medical representatives in accordance with the Code**

§ I.1 - § I.2 - § I.3 - § II.2c - § III.5 Medical representatives' Code of Practice

Actions

Training for medical representatives on products (induction training, continuing training or training for promotional campaigns), should address not only legal, pharmacological and technical aspects, but also treatment strategies, proper use of medicines and health economics.

The content of the training should specify the place of the medicine within the recommended treatment strategy (guidelines, HAS, INCa⁸, etc.), and take account of any campaigns for the proper use of medicines and of any public health programmes.

Health economics aspects concern information about reimbursement of the cost of the medicine by National Health Insurance, i.e.:

- *reimbursable and non-reimbursable indications,*
- *the different packs according to cost; and particularly for treatment of long-term conditions, the most appropriate packs for the patient, and the most economical,*
- *whether the medicine is subject to a Tarif Forfaitaire de Responsabilité (TFR⁹).*

⁷ AFSSAPS: French Health Products Agency

⁸ INCa: National Cancer Institute

⁹ This is an additional fee paid by a patient when they want a specific branded medicine rather than a generic

Monitoring

Documents and records	Interviews
Training programme and materials in the context of the Code of Practice	Chief Pharmacist Training manager Human resources manager Medical sales representative

CRITERION 1.2

The company uses simulation exercises to assess the quality of information delivered by its medical representatives

§ II.2b - § III.5 Medical representatives' Code of Practice

Actions

- a. The company arranges simulation exercises for medical representatives using formal and appropriate methods.

The procedures for using simulation exercises for medical representatives, and their scope, are left to the company to determine. However, a few examples of such procedures are given below.

1. *A collective exercise: The scientific and medical manager checks that all prerequisites included in the assessment checklist have been completed during the session and hands the checklist with the signature sheet to the Chief Pharmacist. If there are any nonconformities with the prerequisites, another session must be arranged, accompanied by specific documentation which is also given to the Chief Pharmacist. This such collective validation by a working group, working groups should not exceed 20–30 people.*
2. *An exercise based on a 'circulating' sample of medical representatives. The scientific and medical manager uses a review checklist and simulation exercise rules that have been validated by the Chief Pharmacist.*
3. *An individual exercise during special training courses. This also uses an assessment checklist validated by the Chief Pharmacist. This arrangement may be limited by the size of the network and by the number of mandated scientific managers required.*

- b. The Chief Pharmacist gives a mandate in writing to a scientific and medical manager who verifies the quality of medical representatives' work during the simulation exercise.

The Chief Pharmacist defines the qualifications and skills required for the mandated individual. Several scientific and medical managers may be mandated by the Chief Pharmacist.

The scientific and medical manager is not necessarily a doctor. He or she may work inside or outside the company. If an external service provider is used, the mandate is issued on a personal basis.

During a simulation exercise for medical representatives, the scientific and medical manager verifies the following, using a checklist validated by the Chief Pharmacist:

- *consistency of the message delivered with legal requirements,*
- *compliance with comparative advertising rules,*
- *consistency of information delivered with the Transparency Committee Opinion (objective presentation of Actual Clinical Benefit (ACB)¹⁰ and Improvement in Actual Clinical Benefit (IACB)¹¹*

¹⁰ Service Médical Rendu (SMR) in French

¹¹ Amélioration du Service Médical Rendu (ASMR) in French

- the description of the medicine's reimbursement status and conditions, TFR, etc,
- information about the proper use of medicines.

c. The company arranges an assessment of medical representatives' simulation exercises.

Medical representatives' simulation exercises are assessed by the scientific and medical manager, based on criteria established by the Chief Pharmacist.

The company decides on any corrective action to be implemented on the basis of the results of the simulation exercise assessment.

All assessment results are made available to the Chief Pharmacist, in accordance with procedures established by the company.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures¹² for organising and assessing simulation exercises for medical representatives ▪ Simulation exercise checklist ▪ List of profiles (training, job function, etc) of scientific and medical managers ▪ Decision traceability system (planning, programmes and simulation exercise results) 	Chief Pharmacist Scientific and medical manager Training manager Sales manager Regional director Medical sales representative

REQUIREMENT 2

The company ensures that medical representatives have the information and resources they need to carry out their missions

According to the Code, the main mission of a medical representative is to distribute high-quality information on medicines and promote them to doctors, in order that the company may achieve its aims, i.e. improve patient care and reach financial targets.

The company should ensure that every medical representative has the supporting materials they need to carry out their missions:

- documents they must provide (SPC¹³, Transparency Committee opinion, price list, etc.),
- documents they must present and may provide (product sheets, good practice guidelines, etc).

The professional relations established between medical representative and doctor comply with the legal framework defined by the authorities¹⁴.

The Code tends to focus medical representative's activity on delivering information. Medical representatives may no longer give samples directly to doctors nor recruit doctors as clinical trial investigators.

¹² "Procedures" means any procedures, documents, recordings, tools for monitoring or ensuring traceability, and arrangements established by the company to provide a satisfactory response to the criterion.

¹³ SPC: Summary of Product Characteristics

¹⁴ The "DMOS" law referring to law no. 93-121 of 27 January 1993 ("anti-gift" law) and to article L4113-6 of the PHC.

CRITERION 2.1

The Chief Pharmacist ensures that medical representatives have and use any documents they need to carry out their missions

§ II.3 Medical representatives' Code of Practice

Actions

- a. The Chief Pharmacist keeps an up-to-date list of the documents that may and the documents that should be given out by medical representatives.

The Chief Pharmacist ensures that all medical sales representatives have all the documents they need.

These documents may be distributed in hard copy or on computer media.

- b. The Chief Pharmacist makes available to medical representatives the list of documents that they must show and provide.

Medical representatives must give a doctor the following documents:

- *the Summary of Product Characteristics (SPC),*
- *the medicine's prescription and supply category (e.g. médicament d'exception¹⁵, drugs subject to restricted prescription, etc),*
- *the legally approved maximum price for sale to the public and the cost of daily treatment,*
- *the medicine's reimbursement category and status regarding approval for use by hospitals,*
- *the Transparency Committee's Opinion,*
- *any documents judged by AFSSAPS, HAS or INCa to be necessary.*

When the medicine is the subject of a number of Transparency Committee Opinions because of extensions of therapeutic indications, the term 'Opinion' covers all the opinions making up an assessment of the actual clinical benefit in each of the therapeutic indications of the medicine.

These documents should always be sent to the doctor after every remote sales visit (by post or email).

- c. The Chief Pharmacist makes available to medical representatives the list of documents that they must show and give out.

It is compulsory for medical representatives to show doctors these documents, and they may give them out:

- *good practice guidelines,*
- *consensus conferences,*
- *other documents and standards issued or validated by HAS, AFSSAPS or INCa.*

These documents are sent to the doctor after a remote visit if they so wish (by post or email).

- d. The company sees that it has ways of verifying medical representatives' compliance with these obligations.

Managers responsible for medical representatives ensure that these obligations are being complied with when they accompany them on sales visits.

¹⁵ *Médicament d'exception*: drug available under strict conditions from local pharmacies and reimbursed by NHI

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Up-to-date list of documents made available to medical representatives ▪ Procedures for distributing or making available the documents that may be or should be given to doctors ▪ Procedures for removing out of date documents from circulation ▪ Procedures for monitoring compliance by medical representatives with their obligations ▪ Procedures for appraisal of medical representatives by their line manager 	Chief Pharmacist Regional manager/Network manager Medical sales representative

CRITERION 2.2

Medical representatives maintain a professional relationship with doctors, in compliance with the legal framework defined by article L. 4113-6¹⁶ of the PHC § III.2d Medical representatives' Code of Practice

Actions

a. Medical representatives are given training in the law and its amendments.

*Medical representatives may issue invitations to scientific conferences, promotional events and/or training sessions under an agreement sent to the Council of the *Ordre des médecins*¹⁷.*

b. Medical representatives only have gifts of negligible value to give to doctors.

Gifts that are advertising 'products' are submitted to AFSSAPS in accordance with the provisions of the PHC.

Medical representatives may not give gifts in cash or in kind unless they are of negligible value and are related to the practice of medicine and pharmacy.

Medical representatives should not respond to any unauthorised requests from health professionals.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for training and information on compliance with the legal framework defined in article L. 4113-6 of the PHC ▪ Procedures for declaring and monitoring agreements with the Council of the <i>Ordre des médecins</i>. 	Chief Pharmacist Marketing manager Sales manager Regional manager Legal affairs manager Medical sales representative

¹⁶ DMOS law, known as the "anti-gift" law

¹⁷ The *Ordre des Médecins* is the French Medical Association

CRITERION 2.3

The company establishes a procedure for providing samples, in compliance with the Code

§ III.2d Medical representatives' Code of Practice

Actions

- a. Medical representatives inform doctors of the rules relating to the giving out of samples.
Medical representatives may under no circumstances give samples to doctors. As a temporary measure, this prohibition does not apply in the overseas departments.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for giving out samples 	Chief Pharmacist Medical sales representative

CRITERION 2.4

Medical representatives may monitor clinical trials other than biomedical research covered by articles 88–97 of the Public Health law of 09 August 2004 and excluding recruitment of doctors

§ I.4 Medical representatives' Code of Practice

Actions

- a. The recruitment of doctors as investigators for the conduct of clinical trials complies with current regulations.
*The company does not ask medical representatives to recruit doctors.
Medical representatives may not recruit doctors (nor instigate a financial relationship) for pharmaco-economic, pharmacovigilance or observational studies.*
- b. A company may ask medical representatives to follow up clinical trials excluding biomedical research covered by articles 88--97 of the Public Health Law of 09 August 2004.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for recruiting doctors 	Chief Pharmacist Medical director Medical sales representative

REQUIREMENT 3**The company makes available to medical representatives and their managers the resources they need to comply with ethical rules**

The medical representatives' Code contains a chapter entirely devoted to the ethics of medical representatives' work. The ethical rules guide behaviour towards patients, doctors, the company, competing companies and National Health Insurance. Medical representatives and their managers undertake to comply with these rules.

The company commits to transparency towards doctors, as regards any data it collects and processes on them.

CRITERION 3.1**The company ensures that medical representatives and their managers have access to and apply ethical rules**

§ III.1 - § III.2a - § III.2b - § III.3 - § III. 5 Medical representatives' Code of Practice

Actions

- a. The company ensures the publication and raising of awareness by medical representatives and their managers of ethical rules, in accordance with the medical representatives' Code of Practice, i.e.:
- *Medical representatives are subject to professional confidentiality and must reveal nothing that they may have seen or heard in a doctor's premises.*
 - *Medical representatives behave with discretion in the waiting room out of respect for the doctor and their patients, and for the doctor's relationship with their patients.*
 - *Medical representatives obey the rules established by each doctor, particularly with regard to days, times and intervals between sales visits.*
 - *Medical representatives do not use any inducement to obtain permission to make a sales visit. No fee or compensation should be offered to obtain permission to make a sales visit.*
 - *Medical representatives ensure that doctors are well aware of their identity and also of the identity of the company or network they represent.*
 - *Medical representatives state the name of the marketing Authorisation holder and/or the company marketing the medicine presented.*
 - *The doctor's consent is obtained for visits at which the medical representative is accompanied (in particular, by the regional Director). An individual accompanying the medical representative should state their name and job function.*
 - *The information provided by medical representatives is not discrediting, and it is based mainly on opinions of the Transparency Committee, i.e.:*
 - *an objective presentation of the level of IACB¹⁸,*
 - *it does not denigrate medicines in the same group in the generic list as the medicine being presented,*
 - *no inducement to the prescriber to prevent a pharmacist replacing one medicine with another.*
- The application of these ethical rules does not challenge the company's own ethical code.*
- b. Medical representatives and their managers undertake to familiarise themselves with and comply with these ethical rules.
- c. The company verifies that ethical rules are being applied.

¹⁸ IACM = Improvement in Actual Clinical Benefit; *Amélioration du Service Médical Rendu, SMR*, in French

Managers responsible for medical representatives ensure that these obligations are being complied with when they accompany them on sales visits.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for informing medical representatives and their managers of the ethical rules ▪ Procedures for appraisal of medical representatives by their line manager 	Company chief executive Sales manager Regional director/Network director Medical sales representative

CRITERION 3.2

The company guarantees the quality of collection and use of data on doctors they have visited.

§ III.2c Medical representatives' Code of Practice

Actions

- a. The company establishes procedures for the collection and use of data collected by medical representatives on the doctors they have visited.

In accordance with the law¹⁹, the company declares the items collected to CNIL²⁰ and the doctor is informed of the database.

The company should inform doctors of their right of access to and correction of data that medical representatives have collected concerning them.

Information about doctors visited consists of professional and factual information only, and not value judgements or information of a subjective nature.

Medical representatives should inform doctors about data on them obtained during prescribing surveys or dispensing surveys carried out by the company. These are available to the doctor.

Special attention should be paid to this criterion and to the response actions for medical representatives' visits made remotely.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for collecting and analysing information ▪ Declarations to CNIL ▪ Procedures for keeping data secure 	Marketing manager Sales manager Regional director Legal affairs manager

¹⁹ French Data Protection law of 06 January 1978, amended by the law of 06 August 2004 – Articles 34--38

²⁰ CNIL: French Data Protection and Civil Rights Commission

REQUIREMENT 4

The company makes available the resources needed to ensure the quality of its medical representatives' work

The success of certification of medical representatives' work depends on the commitment of the Board, of the whole company and of all the stakeholders in the certification process.

The company implements a continuous quality improvement initiative concerning information given out and medical representatives' work. This is a dynamic process allowing the company to maintain its results or improve them if necessary.

CRITERION 4.1

The company undertakes to comply with the principles stated in the medical representatives' Code

§ IV. 3 Medical representatives' Code of Practice

Actions

- a. The company ensures that the Code is distributed to the individuals concerned, particularly the Board, medical representatives' managers and medical representatives.
- b. The company establishes procedures ensuring the personal commitment of top management, medical representatives' managers and the representatives themselves, to complying with the principles stated in the Code.

It is the company's responsibility to apply the Code. Procedures for implementing the personal commitment of representatives to the Code are left to the company to determine.

- c. The company ensures that the Code is applied if it uses third parties (service providers, another pharmaceutical company, etc.)

A company using service providers or another pharmaceutical company ensures that their practice complies with the Code. Pending the drafting of certification criteria specific to service providers, temporary procedures to ensure their compliance with the Code are given in chapter 5 of the present certification criteria.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures implemented to ensure the personal commitment of top management, managers of medical representatives and the medical representatives themselves ▪ Procedures and provisions for arranging the use of subcontractors ▪ Procedures for assessing the compliance of service providers with the requirements (inserting into the contract undertakings to be complied with by service providers, auditing of service providers by the company, monitoring of requirements by service providers, etc.). 	Top management Chief Pharmacist Human resources manager Sales manager Marketing manager Regional manager/Network manager Medical sales representative

CRITERION 4.2

The company measures its medical representatives' work

§ IV.2c Medical representatives' Code of Practice

Actions

- a. The company defines procedures for collecting and analysing quantitative data (appointments).

These procedures comply with methods for collecting quantitative data, thus ensuring that the data:

- *are organised, known and exhaustive,*
- *are shared with the Chief Pharmacist,*
- *reliable.*

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for collecting and monitoring quantitative data about medical representatives' work ▪ Procedure for making these data available to the Chief Pharmacist 	Top management Chief Pharmacist Sales manager Marketing manager

CRITERION 4.3

The company monitors the quality of information given to doctors and the quality of medical representatives' work

§ III.2a - IV.2b Medical representatives' Code of Practice

Actions

- a. The company arranges for feedback from doctors visited.

To ensure that medical representatives' work complies with the Code, the company measures various elements with the doctors visited, particularly the quality of information provided (side effects, contraindications, role in the treatment strategy, etc) and the arranging and frequency of calls.

- b. The Chief Pharmacist defines a procedure for analysing qualitative data

Monitoring of qualitative data is one of the elements required by the Board for monitoring application of the Code within the company and taking relevant decisions.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Procedures for collecting information from doctors visited ▪ Data analysis procedures ▪ Summary of results 	Top management Chief Pharmacist

CRITERION 4.4

The company has a continuous quality improvement process concerning information distributed and medical representatives' work

Actions

- a. The company takes account of qualitative assessments when implementing quality improvement actions.

Monitoring

Documents and records	Interviews
<ul style="list-style-type: none"> ▪ Internal control procedures ▪ Monitoring the improvement plan 	Top management Chief Pharmacist

5 Temporary procedures concerning service providers²¹

These procedures concern all service providers working within the field of application covered by the Code (sales visits carried out in doctors' surgeries and remotely). They define the criteria that apply to the work carried out by service providers, that is, what the company requires of the work. The company must ensure that service providers comply with the requirements listed below.

The company is free to choose which method it will use to assess how service providers fulfil their commitments, for example by including these commitments in the contract, auditing, monitoring, etc.

- 1. The company ensures that a service provider's medical representatives have received continuing training that complies with criterion 1.1 – [Criterion 1.1]

The company provides proof that it has verified:

- that the documents and training materials used by service providers are those that have been validated and sent by the Chief Pharmacist of the company,
- procedures for assessing the knowledge of service providers.

- 2. The company ensures that the service provider has assessed the quality of information delivered by their medical representatives, using simulation exercises – [Criterion 1.2]

The company provides proof that it has verified the procedures for arranging and assessing the simulation exercise intended for the service provider.

- 3. The company ensures that the service provider's medical representatives have and use the documents required for carrying out their missions, which have been validated and sent by the company's Chief Pharmacist - [Criterion 2.1]

The company provides proof that it has verified service providers' document management processes.

²¹ These temporary procedures to ensure service provider compliance with the Code of Practice are given pending the drafting of specific certification criteria for service providers. Should it be possible to establish specific criteria, companies will be able to make use of certified service providers while remaining responsible for the sections that concern them (compliance with prerequisites, content of training, etc.).

4. The company ensures that the service provider's medical representatives maintain professional relationships with doctors in compliance with the legal framework defined by article L. 4113-6 of the PHC - [\[Criterion 2.2\]](#)

The company provides proof that it has verified the procedures for training and information on compliance with the legal framework defined by article L. 4113-6 of the PHC by the service provider's medical representatives.

5. The company ensures that the service provider's medical representatives and their managers have access to the ethical rules and that they apply them - [\[Criterion 3.1\]](#)

The company provides proof that it has verified:

- the procedures for informing the service provider's medical representatives and their managers about the ethical rules,
- the procedures for appraisal of the service provider's medical representatives by their line manager.

6. The company ensures that service providers have undertaken to comply with the principles laid down in the medical representatives' Code - [\[Criterion 4.1\]](#)

The company provides proof that it has verified the procedures implemented by the service provider to ensure the personal commitment of top management, medical representatives' managers and the medical representatives themselves.

Annex 1 - Prerequisites for certification

As in any certification process, irrespective of sector and mode of certification chosen, a company applying for certification must comply with legal obligations.

In the context of medical representatives' work, compliance with legal obligations is regarded as a pre-requisite as, unlike AFSSAPS' inspections of facilities, certification does not control compliance with legal obligations. In fact, inspection and certification have different aims: inspection aims to verify compliance with legal requirements, while certification aims to ensure that the company organisation makes it possible to satisfy the requirements of the Code of Practice.

The legal obligations contained in the Code of Practice are:

1. The company undertakes to deliver reliable and high-quality information on its pharmaceutical products. Its medical representatives use promotional materials which comply with the legal provisions and which are controlled by AFSSAPS' advertising regulation department.
2. The way in which the company controls advertising, training and pharmacovigilance complies with the Public Health Code (PHC). This is checked from time to time by AFSSAPS' *Direction des Etablissements* and, on formal request, where necessary.

Compliance with the prerequisite is established when the certifying body examines the application form. Compliance is compulsory before the application for certification can be accepted. The company confirms compliance in a letter of undertaking from the Chief Pharmacist. In the absence of compliance, the application form will not be accepted, which means there will be no certification audit.

1. The company undertakes to deliver reliable and high-quality information on its pharmaceutical products. Its medical representatives use promotional materials which comply with the legal provisions.

In carrying out their missions of promotion and disseminating medical information, medical representatives base their work, amongst other things, on the promotional materials produced by their company. By law, "*All promotional materials must be submitted within 8 days of their distribution to AFSSAPS*"^{22, 23}. If this is not complied with, AFSSAPS may:

- order the advertising to be suspended,
- require it to be changed,
- prohibit it and, if necessary, require a correction to be published.

The promotional documents made available to medical representatives are produced by the company in accordance with legislation

§ II. 1a Medical representatives' Code of Practice

The company submits to AFSSAPS all the promotional documents it uses.

Promotional documents bear the date on which the information was produced or updated in compliance with current regulations, i.e.:

²² Advertising Control Department for retrospective monitoring" – Articles L.5122–L.5122-16, R.51221–R.5122-26 of the PHC and articles L.121-8–121-14 of the Consumers' Code amended by order no. 2001-741 of 23 August 2001.

²³ This concerns promotional materials satisfying the definition of advertising for medicines for human use in accordance with article L 5122-1 of the PHC.

- Advertising must not be misleading and should not lead to error or harm the protection of public health.
- Advertising must be objective, encourage the proper use of products, and comply with the provisions of the Marketing Authorisation.

The company keeps a copy of each advertising material submitted to AFSSAPS for 3 years from last publication, together with a descriptive sheet giving the recipients, method of distribution and date of first distribution.

The company complies with the conditions required for using in its promotional documents studies carried out after the granting of a Marketing Authorisation and/or not examined by the Transparency Committee

§ II.1c Medical representatives' Code of Practice

When using promotional documents that contain results from studies carried out after the granting of the Marketing Authorisation and/or not examined by the Transparency Committee, the company refers only to studies which are:

- properly designed and conducted,
- published in a peer reviewed journal,
- conducted under the conditions of use of the medicine defined by the Marketing Authorisation and by other existing standards (Transparency Committee opinion, clinical practice guidelines).

In its promotional documents, the company uses only conference abstracts which:

- comply with the Summary of Product Characteristics (SPC) and existing specifications,
- are less than 12 months old,
- have been published in a peer-reviewed journal

These studies are presented objectively.

The company ensures that the information delivered in its promotional documents comply with the rules of competitive advertising

§ II.1d Medical representatives' Code of Practice

This means that advertising that compares medicines by implicitly or explicitly identifying medicines marketed by a competitor may not be used unless:

- it complies with the basic rules of advertising (compliance with Marketing Authorisation, objectivity, encouraging proper use, not harming public health),
- it concerns medicines satisfying the same needs or having the same therapeutic aim,
- it objectively compares one or more essential, relevant, verifiable and representative characteristics of these medicines. This may include price.

2. The way in which the company controls advertising, training and pharmacovigilance complies with the Public Health Code (PHC).

The legal provisions referred to in the prerequisites concern:

- validation of promotional documents used by medical representatives in their activity, the updating of these materials, their traceability and how and to whom they are made available²⁴;
- verification of sales representatives' initial training, the organisation of continuing training and pharmacovigilance²⁵.

²⁴ Articles L.5122-1–L.5122-8 and R.5122-1–R.5122-16 of the PHC

²⁵ Article L.5122-11 of the PHC.

The Chief Pharmacist, in the name of the company, defines the procedures required to validate and monitor the promotional documents used by medical representatives

§ IV.1a Medical representatives' Code of Practice

The Chief Pharmacist validates the quality of the scientific and economic information contained in promotional documents (printed materials, audiovisual aids, etc) used by medical representatives.

The Chief Pharmacist dates and endorses promotional documents in the name of the company and in his or her own name before they are duplicated or distributed for the first time.

The Chief Pharmacist, in the name of the company, establishes all procedures required to monitor files submitted and reasons for sanctions

§ IV.1a Medical representatives' Code of Practice

For all documents submitted to AFSSAPS, the company provides itself with tools for monitoring and analysing any nonconformities leading to sanctions (requirement for further information, prohibitions) and implements any corrective action.

The company updates the scientific medical and regulatory information in promotional documents used by medical representatives

§ II.1b Medical representatives' Code of Practice

The company makes available to its medical representatives updated promotional documents which comply with the SPC, and takes account of recently published data satisfying the quality criteria of the prerequisites or issued by the health authorities.

The company arranges for scientific information and published documents to be monitored.

The responsibilities and skills of individuals in charge of the monitoring of scientific information and published documents, and of updating promotional documents, are defined.

The Chief Pharmacist organises and supervises the traceability of promotional documents used by medical representatives, and access to them

§ IV.2a Medical representatives' Code of Practice

The Chief Pharmacist ensures that documents made available to medical representatives are those that he or she has dated and guaranteed by his or her signature to be in compliance with scientific, medical, regulatory and economic information.

The Chief Pharmacist puts in place a procedure for managing stocks of promotional documents. In particular, this procedure incorporates rules for the return and destruction of obsolete promotional documents held by medical representatives.

The Chief Pharmacist establishes a procedure for monitoring all available promotional documents and their history.

All medical representatives must use the most recent promotional documents made available to them.

The company ensures that the medical representatives it employs can substantiate the knowledge required for carrying out their work

§ II.2a - § IV.5 Medical representatives' Code of Practice

At the time of recruitment, the company ensures that medical representatives have received training, and that this is confirmed by diploma, title or certificate.

This information is made available to the Chief Pharmacist according to procedures defined by the company.

Medical representatives have a professional card allocated by LEEM through the *Association pour la Gestion de la Visite Médicale* (AGVM²⁶).

The company arranges continuing training for medical representatives under the control of the Chief Pharmacist

§ II.2a - § II.2b - § IV. 1b Medical representatives' Code of Practice

The company ensures that induction training for each new recruit in particular concerns regulatory aspects, diseases and disorders, treatment strategies, the company's products and the competition's products.

The knowledge acquired is assessed. This information is made available to the Chief Pharmacist according to procedures defined by the company.

The company provides its medical representatives with continuing training to update their knowledge and to ensure that their professional skills are maintained and developed.

The company establishes a procedure for arranging continuing training for its medical representatives. In particular, this organisation includes:

- defining the requirements of scientific and regulatory training for each medical representative,
- producing training materials,
- scheduling continuing training,
- assessing medical representatives' knowledge at the end of each training course.

All training materials are archived.

The Chief Pharmacist guarantees the scientific quality of information delivered during continuing training, and of promotional campaigns and product information. To this end, he or she validates training materials on the product or of a scientific nature, particularly compliance with legal aspects and pharmacological and technical aspects.

In particular, the legal and pharmacological and technical aspects concern:

- indications in the Marketing Authorisation (AMM)
- doses
- treatment duration
- undesirable effects
- precautions for use
- drug interactions
- treatment monitoring
- prescribing restrictions
- reimbursement categories (i.e. indications in which product costs are reimbursed to people with National Health Insurance, and level of reimbursement),
- paediatric dosage, when appropriate.

The Chief Pharmacist establishes procedures for ensuring that all medical representatives receive appropriate continuing training.

All documents (training plan, monitoring, definition of needs, etc.) are made available to the Chief Pharmacist in accordance with procedures defined by the company.

The Chief Pharmacist ensures that all medical representatives have sufficient scientific knowledge and product knowledge to carry out their work. To this end, the Chief Pharmacist ensures that all medical representatives receive and take part in training.

The Chief Pharmacist monitors the application of the procedures for arranging continuing training and decides on corrective action if necessary.

²⁶ AGVM: Association for the management of medical sales activity

The Chief Pharmacist establishes any procedures needed to collect pharmacovigilance data without delay

§ III.4 Medical representatives' Code of Practice

The Chief Pharmacist sets up a programme for collecting pharmacovigilance information.

Medical representatives bring to the Chief Pharmacist's immediate attention any information obtained concerning pharmacovigilance for the pharmaceutical products marketed by the company.

Medical representatives are made aware of and trained in the need for feedback concerning information about pharmacovigilance data.

Good pharmacovigilance practice states that all medical representatives, including service providers' networks, should receive regular training on the legal provisions, methods and aims of pharmacovigilance, as well as on their role in communicating information.

Annex 2 - Abbreviations

ABBREVIATION	HEADING
ACB (= SMR)	Actual Clinical Benefit (<i>Service Médical Rendu</i>)
AFSSAPS	<i>Agence Française de Sécurité Sanitaire des Produits de Santé</i> (French Health Products Safety Agency)
AGVM	<i>Association pour la Gestion de la Visite Médicale</i> (Association for the management of medical sales activity)
AMM	Marketing Authorisation
ASMR (IACB)	<i>Amélioration du Service Médical Rendu</i> (Improvement in actual clinical benefit)
CEPS	<i>Comité Economique des Produits de Santé</i> (Healthcare Products Pricing Committee)
CNIL	<i>Commission Nationale de l'Informatique et des Libertés</i> (French Data Protection and Civil Rights Commission)
COFRAC	French Accreditation Committee
CSP (PHC)	Public Health Code
DMOS	<i>Diverses Mesures d'Ordre Social</i> (Various social measures)
DOM	<i>Département d'Outre Mer</i> (French overseas <i>départements</i>)
HAS	<i>Haute Autorité de Santé</i> (French National Authority for Health)
IAB (= ASMR)	Improvement in actual benefit
INCa	<i>Institut National du Cancer</i> (National Cancer Institute)
LEEM	<i>LEs Entreprises du Médicament</i> (Association of Pharmaceutical Manufacturers)
SPC	Summary of Product Characteristics
SMR (AB)	<i>Service Médical Rendu</i> (Actual Benefit)
TFR	<i>Tarif Forfaitaire de Responsabilité</i> – An additional fee paid by a patient when they want a specific branded medicine rather than a generic

Annex 3 – References

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Law no. 93-121 of 27 January 1993 introducing various social measures ("anti-gift" law). *Journal Officiel*; 30 January 1993

Law no. 2004-801 of 06 August 2004 relating to the protection of natural persons with regard to the processing of personal data and amending law no. 78-17 of 06 January 1978 relating to computer processing, files and liberties. *Journal Officiel*; 07 August 2004

Articles L.5122-1--L.5122-16 of the Public Health Code

Articles R.5122-1--R.5122-26 of the Public Health Code

Articles L.121-8--124-14 of the Consumer Code, amended by order no. 2001-741 of 23 August 2001 transposing Community directives and adaptation of Community law relating to Consumer rights. *Journal Officiel*; 25 August 2001

Annex 4: Method used to produce these criteria

▪ Drafting the criteria, procedure and rules for certification

HAS set up 2 working groups:

1. A "*certification criteria*" working group tasked with
 - translating the medical representatives' Code of Practice into a set of certification assessment criteria (set of quality criteria),
 - defining monitoring methods (to check that the criteria are applied),
 - encouraging effective interfacing with AFSSAPS' control of advertising and inspection.

This group was made up of medical representatives, Chief Pharmacists, sales directors, training managers, a representative of LEEM, representatives of AFSSAPS, quality specialists and independent doctors working

2. A "*certifying bodies*" working group" tasked with
 - validating the method of certification,
 - validating the method of monitoring,
 - establishing the certification procedure and the criteria for accrediting certifying bodies.

The group was made up of certifying bodies²⁷, a representative of COFRAC²⁸, a Chief Pharmacist, a representative of LEEM and quality specialists.

▪ Pilot-testing the criteria and procedure

The test phase consisted of:

- consulting peer reviewers for their opinion on the content and clarity of the criteria,
- carrying out a feasibility study in order to test "in situ" whether it was possible to carry out an audit of the quality criteria, monitoring, and the certification procedure (conduct of the audit, deadline, audit duration, etc).

Certifying bodies and the pharmaceutical companies taking part in the feasibility study did so voluntarily. Companies were allocated to certifying bodies by drawing lots.

²⁷ In July 2005, HAS published a call for applicants aimed at certifying bodies interested in participating in our work.

²⁸ French Accreditation Committee

Annex 5 - Working group members and peer reviewers

This document was produced by Carole Micheneau and Marie Erbault, HAS project managers, under the supervision of Dr Bertrand Xerri, and then of Hervé Nabarette, Heads of Department:

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Dr Natacha Todorovski, general practitioner, Toulouse

Frédéric Van Roekeghem, chief executive, UNCAM, Paris

Gérard Vincent, general representative, *Fédération Hospitalière de France*, Paris

Feasibility study

Certifying bodies

AFAQ – AFNOR

Bureau Veritas Certification (BVC)

SGS - ICS

Pharmaceutical companies

Bristol-Myers Squibb

Cephalon

Grunenthal

Sanofi Aventis