Welcome to section B
Pharmacists in the medication and health care products industry

December 2013

Editorial

It is your job to ensure the observance of the Public Health Code (CSP: Code de la Santé Publique) within your company, and more generally the safety of medications: in terms of quality, registration, advertising and information, pharmacovigilance, batch monitoring and recalls.

This booklet can be downloaded from the website of the National Council of Pharmacists:
www.ordre.pharmacien.fr

Welcome to section B of the National Council of Pharmacists

The purpose of this booklet is to introduce you to the institution to which you are connected and the main aspects linked to your mission as a pharmacist working in the pharmaceutical industry. It is your job to ensure the observance of the Public Health Code (CSP) within your company, and more generally the safety of medications: in terms of quality, registration, advertising and information, pharmacovigilance, batch monitoring and recalls.

The chief pharmaceutical officer is, like a company representative or a director, a legal representative of the company. He is also the acknowledged contact person for the health authorities. He contributes to the role as a public health actor and to the image of the company. You will find in this booklet information about the role and the missions of the National Council of Pharmacists, the role of section B, a reminder of the main legislative and regulatory texts of the CSP that apply to you, the contact information for the supervisory bodies and some information that will be useful in carrying out your work as a chief pharmaceutical officer, deputy chief pharmaceutical officer, delegated pharmacist, deputy delegated pharmacist or assistant pharmacist.

It is also an opportunity to reinforce the links that connect all pharmacists: We are often the first professional contact for our colleagues.

We wish you every success.

Confraternally yours,

The President and the members of B Central Council
Vademecum of the pharmacists in the medication and health care products industry

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A- THE NATIONAL COUNCIL AND THE CENTRAL COUNCILS

The National Council is gathered members elected by the Central Councils and also of appointed members.

All of the sections are represented on it.
The Central Councils of the various sections (A; B; C; D; E; G; H) are gathered of elected members and appointed members and have permanent administrative personnel to assist them in carrying out their tasks.
The National Council of Pharmacists also has common services, under the authority of the President of the National Council, which provide their support to all of the sections:

> Legal Affairs Department
> Communications Department
> Professional Activity Department
> Human Resources Department
> Administrative and Financial Department
> Organization and Information Systems Department
> Health Technologies Department
> Gespharm: (Comité d’Education Sanitaire et Sociale de la Pharmacie française / Health Education and Social Committee of French Pharmacy)

Section B:
Breakdown by activity of pharmacists in industry

Dark: exclusive activity
Light: multiple activity
Source: 2013 demographic elements of the National Council of Pharmacists
**B-THE B CENTRAL COUNCIL**

**Main missions:**
Taking part in the drawing up of draft laws, exercising disciplinary authority, deciding on applications for registration from pharmacists and giving an opinion regarding the authorizations for the opening of pharmaceutical establishments covered by the section.

**B.1 Organization**

Section B includes chief pharmaceutical officers and deputy chief pharmaceutical officers, delegate pharmacists, deputy delegate pharmacists and assistant pharmacists working in establishments devoted to the manufacturing, operating ("exploitant" status in France), importing and exporting of medications or products mentioned in articles L. 5124-1 and L. 5142-1 (vet.) of the CSP.

All of the members of section B elect council members: a council member is elected for six years and the elections are for half of the council members (every three years).

**B.2 Organization of the Council**

Its composition is governed by article L. 4232-7 of the CSP.

In addition to the twelve main members (and their substitutes) elected from among the pharmacists listed in the table of section B, the Council includes members appointed by the Minister in charge of health:

- Two professors or assistant professors of pharmacy.
- An inspector of the ANSM representing the General Director of this agency.
- A public health pharmacy inspector representing the minister in charge of health.

The main elected officials of section B elect an executive board composed of a president, a vice-president, a treasurer, a member-secretary and three members.

**B.3 The Missions of the Council**

- Takes part in drawing up draft laws, decrees, rulings and circulars that involve the pharmaceutical industry.
- Ensures the observance of the professional and ethics rules that are specific to industrial pharmacy.
- Exercises disciplinary authority: examines, seeks conciliation and handles complaints against pharmacists registered in section B; the chamber of discipline of the National Council of Pharmacists which can impose penalties.
- Decides on the applications for registration of pharmacists in section B, decides on their possible registration and keeps up-to-date the table of section B of the National Council of Pharmacists.
- Issues an opinion on authorizations for the opening of pharmaceutical establishments involved in manufacturing, importing, exporting or operating.
B.4 The Other Activities of the Council

- Manages ad hoc groups on subjects relating to the profession. For example:
  > Certification of Medical Representative’s calls
  > Implementation of the Batch Recall procedure through the Pharmaceutical dedicated software
  > Recommendations concerning the transport of health care products
  > Inquiry about the chief pharmaceutical officer/deputy chief pharmaceutical officer, etc.
- Draws up recommendations (example: archiving, cold chain, etc.)
- Advises pharmacists who encounter difficulties in carrying out their job.
  In case of a crisis, it is useful to be able to get to an impartial and disinterested opinion. Any chief pharmaceutical officer facing a complex situation in which he must make a documented decision, and who is hesitating regarding the course of action to take or is facing various pressures, can contact a member of the B Central Council to receive its advice and/or help. This will be done in full confidentiality.
- Organizes information and/or training days on subjects involving the profession (example: day event for batch recalls)
- Sponsors new registrants in section B: any pharmacist, particularly a chief pharmaceutical officer or deputy chief pharmaceutical officer, who has recently registered in section B or who is about to request registration can contact section B in National Council of Pharmacists to obtain clarifications regarding their mission.
  They will be offered the possibility of meeting with an elected council member who will answer their questions.
  For a (deputy) chief pharmaceutical officer, during the meeting, the council member will mention the key points of the mission:
  > Article R. 5124-36 or 5142-35 (vet.) of the CSP: as a reference.
  > His role in the company: the responsibilities, the constraints, the risks.
  > His role and his participation on his company’s executive board of directors.
  > What he must do in the event of difficulties to fully carry out his mission within his company.
  > Then the council member will stress the importance of the split between his role as a pharmacist and the work contract linked to an activity that is well-defined in the job description (Quality Control, Quality Assurance, Regulatory Affairs, etc.), and what a chief pharmaceutical officer must do, with respect to his professional status, in the event of the termination of his work contract, whether decided by him or by his company. The council member may ask him questions regarding his place in the organizational chart and the compatibility of his mission with his position.
C-THE ARTICLES OF THE PUBLIC HEALTH CODE (CSP) TO KNOW

C.1 Code of ethics

category > Our-missions > Ensuring the respecting of professional obligations > Code-of-ethics.

NB: The CSP is constantly changing. We recommend you to consult the official website www.legifrance.gouv.fr to access the latest update.

Section 1
General provisions
"[The Code]…imposes on all pharmacists…"

Section 2
Provisions common to all pharmacists
Sub-section 1> General duties
Article R. 4235-11
"Pharmacists have the duty of keeping their knowledge up to date."

Sub-section 4> Duties of fellowship
Article R. 4235-34
"All pharmacists registered with the National Council of Pharmacists must help and assist each other in the carrying out of their professional duties. In all circumstances, they must demonstrate loyalty and solidarity amongst themselves."
Article R. 4235-39
"A pharmacist must not make any denunciation that is unjustified or intended to hurt a colleague."
Article R. 4235-40
"Pharmacists who have a disagreement of a professional nature between them must try to resolve it. If they do not succeed, they must notify the President of the appropriate …. Central Council of the National Council of Pharmacists."

Section 3
Provisions specific to various modes of working

Sub-section 2> Duties of pharmacists working in pharmaceutical establishments
Article R. 4235-68 – Ethics and Good Practices
"The chief pharmaceutical officer mentioned in articles L. 5124-2, L. 5124-7 and L. 5142-1 must try to ensure the observance of professional ethics and all rules set in the interest of public health. He must also make every effort to precisely define the attributions of the pharmacists and the personnel placed under his authority. He must train the personnel in the rules of good practices. The delegated pharmacist is bound, within the limits of his delegation, by the same obligations."
Article R. 4235-69 – Fairness, information and advertising
"The chief pharmaceutical officer and the pharmacists placed under his authority must not discredit any colleagues or competing firms. The chief pharmaceutical officer must ensure the accuracy of the scientific, medical and pharmaceutical information and the advertising, as well as the fairness of their use. He makes sure that the advertising for the medications is done objectively and that it is not misleading."
Article R. 4235-70 – Replacement
"The chief pharmaceutical officer must verify that all of the provisions are made for his replacement in the event of absence. He must make sure that his replacement satisfies the required conditions."
C.2 Discipline

Article L. 4234-6 – List of the disciplinary penalties
“The chamber of discipline imposes, if necessary, one of the following penalties:
1° Warning;
2° Note of the infraction in the personal pharmacist file;
3° Temporary or permanent ban on serving one or all of the supplies made, in whatever way, to public or public service establishments, municipalities, departments or the Government;
4° Being banned, for a maximum period of five years, with or without a suspended sentence, from practicing pharmacy;
5° Permanent ban on practicing pharmacy.
The last two penalties include a permanent ban on belonging to a council of the National Council of Pharmacists of Pharmacists.

C.3 Pharmaceutical establishments that manufacture, import and supply human and veterinary medications

Article L. 5124-1 – Manufacturing and wholesale distribution of medications for human use
“The manufacturing, importing, exporting and wholesaling of the medications, products and objects mentioned in article L. 4211-1, the manufacturing, importing and sale of experimental medications, with the exception of gene therapy preparations, xenogeneic cell therapy preparations, and the use of pharmaceutical specialties or other medications, generators, kits or precursors defined in paragraphs 8°, 9° and 10° of article L. 5121-1 can only be done in pharmaceutical establishments governed by this chapter.”

Article L. 5142-1 (vet.) – Industrial preparation and wholesaling of veterinary medications
“The manufacturing, importing, exporting and wholesaling of veterinary medications, the manufacturing, importing and sale of medications subject to clinical trials, and the use of veterinary medications, can only be done in establishments governed by this chapter.”
The establishments

The Public Health Code distinguishes, among the authorized activities, 15 types of pharmaceutical establishments for medications for human use (Art. R. 5124-2) and 14 types of establishments for veterinary medications (see details in article R. 5142-1 of the CSP, the first 4 types are identical).

Art. R. 5124-2 (Hum.)

1. manufacturer,
2. importer,
3. operator ("exploitant"),
4. depositary,
5. wholesaler distributor "medication",
6. wholesaler of "products, objects, articles, generators, kits or precursors (Art. L. 4211-1), medicinal plants or divided pharmaceutical products (Art. L. 5121-1),
7. export wholesaler,
8. humanitarian aid wholesaler,
9. wholesaler of medications derived from blood,
10. distributor of experimental medications,
11. wholesaler of medicinal plants,
12. wholesaler of gas for medical uses
13. wholesaler of armed forces health services,
14. pharmaceutical establishment involved in operations for the purchase, manufacturing, importing, and exporting of products necessary for the protection of the population in the face of several health threats, for their distribution,
15. pharmaceutical buying group

Art. R. 5142-1 (vet.)

1. manufacturer,
2. importer,
3. operator,
4. depositary,
5. wholesaler of veterinary medications,
6. wholesaler specializing in exporting,
7. wholesaler of veterinary anti-parasite medications intended for external treatment of pets,
8. wholesaler of veterinary medications subject to clinical trials,
9. wholesaler of medication premixes,
10. wholesaler specializing in the exporting of medication premixes,
11. manufacturer of medicated food products,
12. importer of medicated food products,
13. distributor of medicated food products,
14. export distributor of medicated food products
C. 4 Pharmacists in industry
(human and veterinary medications)

NB: for veterinary medications, the pharmaceutical activities can be carried out under the responsibility of a chief veterinarian (Cf. CSP, art. L. 5142-1).

Article L. 5124-4, L. 5142-1 (vet.) – Personal exercising by chief and delegated pharmacists
“The chief pharmaceutical officer and the delegated pharmacists must do their work personally…”, “They are personally responsible…”

Article R.5124-19 – Effective control of pharmaceutical acts
Articles R. 5142-20 and R. 5142-31 (vet., see details in CSP)
“All pharmaceutical acts must be carried out under the effective control of a pharmacist who fulfills the conditions for working as a pharmacist in France”.
“The chief pharmaceutical officer… or the delegated pharmacist… Exercises his functions permanently and continuously.”

Article R. 5124-20 – Registration with the National Council of Pharmacists and registration of the diplomas of the chief and delegated pharmacists
Article R. 5142-21, R. 5142-22 and R. 5142-23 (vet., see details in CSP)
“All chief or delegated pharmacists, with the exception of the chemical pharmacists of the armed forces, after their registration with the National Council of Pharmacists register their diplomas in the conditions provided for in article L. 4221-16.”.

Article R. 5125-36 - Registration with the National Council of Pharmacists and registration of the diplomas of the assistants
Article R. 5142-37 (vet., see details in CSP and read “section B” instead of “section D”)
“… an assistant pharmacist can only carry out this function if he is listed in the table of the appropriate section of the National Council of Pharmacists…”

4.1 Chief Pharmaceutical Officer

Article L. 5124-2 – Place of the chief pharmaceutical officer in the company
Article L. 5142-1 (vet., see details in CSP, read “or a veterinarian”)
“Any company which includes at least one pharmaceutical establishment must be owned by a pharmacist or a company in which a pharmacist is involved in the Board of management.”
“The pharmacists mentioned in the preceding paragraph are called chief pharmaceutical officers…”

Article R. 5124-20 – One single company per diploma for the chief pharmaceutical officer
Articles R. 5142-22 and R. 5142-31 (vet., see details in CSP)
“… The diploma of the chief pharmaceutical officer can only be registered for one single company or one organization…”
“The functions of chief or delegated pharmacist … are incompatible with the functions of chief or delegated pharmacist of a company or an establishment … except for two establishments of the same company located at the same site.”

Article R. 5124-36 – Missions of the chief pharmaceutical officer
Article R. 5142-35 (vet., see details in CSP)
“…the chief pharmaceutical officer…takes on the following missions:
1 He organizes and monitors all of the pharmaceutical operations: …manufacturing, advertising, information, pharmacovigilance, batch monitoring and recalls, sales, and the importing and exporting of medications,…storage…
2 He monitors… transport… so that the transport conditions ensure good conservation, the integrity and the safety of these medications, …
3 He signs…, the market release authorization applications… and any other application linked to the activities that he organizes and monitors …
4 He takes part in the elaboration of the research and study program…
5 He has authority over the delegated and assistant pharmacists…
6 He appoints the deputy delegated pharmacists;
7 He reports…all obstacles to or limitations on the exercising of these attributions… the chief pharmaceutical officer takes part in the deliberations of the administration National Council of Pharmacists, management or supervision bodies or National Council of Pharmacists of the company …”
8. He implements all of the means necessary for the respecting of the obligations provided for in articles R.5124-48 and R.5124-48-1 (appropriate and continuous procurement, guaranteeing the integrity,...)
9. He makes sure,... that the safety systems mentioned in article R. 5121-138-1 are used in the packaging
10. He reports to the Agency... any release on the domestic market of medications that he considers have been falsified ... In the event of a disagreement ... between a management body,... and the chief pharmacist, the chief pharmacist will inform the General Director of the Agency of this... The chief pharmacist takes part in the deliberations of the management bodies,...

4.2 Deputy chief pharmaceutical officer
Article R. 5124-23 – Replacement of the chief pharmaceutical officer
Article R. 5142-26 (vet., see details in CSP)
“...the appropriate social organization...appoints at the same time as the chief pharmaceutical officer one or several deputy chief pharmaceutical officers”
“The deputy chief pharmaceutical officer must be given for the replacement periods the same powers and attributions as those given to the chief pharmaceutical officer and he effectively exercises them throughout the duration of the replacement...”
“The identity of the pharmacists handling these replacements, the dates and durations of these replacements are kept in the establishment for a period of five years.”
“If the deputy chief pharmaceutical officer... is a delegated pharmacist...of the company, a deputy delegated pharmacist... is appointed at the same time by the chief pharmaceutical officer.”

4.3 Delegated pharmacist
Article L. 5124-2 – One diploma per site
Article L. 5142-1 (vet., see details in CSP)
“...In each pharmaceutical establishment of the company, a delegated pharmacist monitors the observance of the provisions of this document under the authority of the chief pharmaceutical officer of the company...”
Article R. 5124-20
Article R. 5142-22 (vet., see details in CSP)
“The diploma of the delegated pharmacist can only be recorded for one pharmaceutical establishment... except in the case where the same pharmacist works as the delegated pharmacist of two pharmaceutical establishments located at the same site.”

4.4 Assistant pharmacist
Articles R. 5124-38 to 40 – Pharmacist who assists and/or replaces
Articles R. 5142-37 to 40 (vet., see details in CSP)
“For each “manufacturer, importer, operator establishment, the number of assistant pharmacists...is fixed as a function of the staff level...”

C.5 Request of a Practical experience

Articles R. 5124-16 and R. 5124-17 – Practical experience of chief and delegated pharmacists
Articles L. 5142-1, R. 5142-16 to R. 5142-18 (vet., see details in CSP)
“The chief [and deputy] pharmacist officers and the delegated pharmacist(s) of the companies or organizations... have documented practical experience...
• In activities involving the qualitative analysis of medications, quantitative analysis of active ingredients and tests and verifications necessary to guarantee the quality of the medications... [at the premises of a manufacturer and/or importer, for a manufacturing and/or importing company]
• ...in a operator (“exploitant”) pharmaceutical establishment, as long as this experience involved at least one of the activities for the batch monitoring associated with pharmacovigilance activities... [at the premises of an operator, for an operations company]
• the duration of the practical experience is reduced to 6 months within the framework of a study program of at least 6 years...”

NB: A Pharmacist with “Manufacturing” experience is applicable for an operator (“exploitant”) establishment, but not the inverse.
C.6 Replacement chief pharmacist officer or delegate pharmacist

Articles R. 5124-21, R. 5124-27 and R. 5124-30 – Registration with the National Council of Pharmacists

Articles R. 5142-23, R. 5142-24 and R. 5142-27 (vet., see details in CSP)

"...a pharmacist handling a replacement requests, in National Council of Pharmacists to do this, his registration in the table of the appropriate section of the national National Council of Pharmacists of pharmacists...

The deputy chief pharmaceutical officers and deputy delegated pharmacists... the managers after death ... carry out the same formalities, at the time of their appointment."

"When the company is owned by a pharmacist, he can be replaced by:
1 A delegated or assistant pharmacist of the same company;
2 A pharmacist having no other professional activity throughout the duration of his replacement and registering to do this with the appropriate section of the national National Council of Pharmacists of pharmacists."


"... a delegated pharmacist is replaced ...:
3 By the deputy delegated pharmacist ...
4 or, failing that, by an assistant pharmacist of the same company or the same organization or by a pharmacist who has no other professional activity during the replacement...
5 or, failing that, by a pharmacist who requested his registration in the appropriate section of National Council of Pharmacists... while awaiting a ruling on his request and who has no other professional activity..."


Articles R. 5142-26, R. 5142-29 and R. 5142-30 (vet., See details in CSP)

"... the appropriate social organization... appoints, at the same time as the chief pharmaceutical officer, one or several deputy chief pharmaceutical officers.
If the deputy chief pharmaceutical officer is a delegated pharmacist of the company or organization, a deputy delegated pharmacist is appointed at the same time by the chief pharmaceutical officer."

"... director after a death... is chosen from among the pharmacists mentioned in article R. 5124-27..."

"The pharmacists who handle the replacement or management after the death have the necessary practical experience ...".

Article R. 5124-23 – Scope of the assignment

Article R. 5142-26 (vet., see details in CSP)

"... The deputy chief pharmaceutical officer receives, for the replacement periods, the same powers and attributions as those granted to the chief pharmaceutical officer and effectively exercises them throughout the duration of the replacement."

Articles R. 5124-31, R. 5124-32 and R. 5124-33 – Exclusive activity

Articles R. 5142-31 and R. 5142-32 (vet., see details in CSP)

"Pharmacists who replace chief or delegated pharmacists devote themselves exclusively to this activity during the period when they hold this position."

"The exercising of the functions of chief or delegated pharmacist of a company, an establishment or an organization mentioned in article R. 5124-2 is incompatible with the operation of a pharmacy or the management of a mutual pharmacy or a mining rescue company pharmacy."

"As an exception...a manufacturing pharmaceutical establishment adjoining their pharmacy... can operate the aforesaid establishment at the same time as their pharmacy as long as they remain the owner of the latter...

Articles R. 5124-22 and R. 5124-23 – Duration and traceability of absences

Articles R. 5142-24 and R. 5142-25 (vet., see details in CSP)

"If chief or delegate pharmacists are absent or unable to fulfill their responsibilities, their replacement may not exceed one year..."

"If the chief pharmaceutical officer permanently ceases to exercise his functions ... without delays ... the designation of a new chief pharmaceutical officer."

"... The identity of the pharmacists providing the replacements, and the dates and durations of these replacements are kept within the establishment for a period of five years."

"When the replacement exceeds thirty consecutive days, the party involved announces to the director [of the ANSES] the name, address and position of his replacement." [for veterinarians only]
C.7 Certification Reference for representative’s calls (HAS) – Medical Rep’s Charter

In accordance with articles L. 162-17-4 and L. 162-17-8 of the Social Security code, the elaboration of a certification of the rep's calls falls within the framework of the law of August 13, 2004. It is set of references, the Superior Authority for Health (Haut Autorité de Santé - HAS) specifies: “the company director and the chief pharmaceutical officer organize the quality approach linked to the quality of the resp's calls…” (Chapter 1 section 1.1.2, paragraph 2)

C.8 The Main Criminal and Financial Penalties

Criminal penalties that can target the chief pharmaceutical officer and financial ones targeting the chief pharmaceutical officer and/or the company (Ordonnance of December 19, 2013)

8.1 Human medicine

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<td>Clinical trials</td>
<td>L. 1126-1: Absence of obtaining of consent</td>
<td>3 years imprisonment Fine of 45,000 €</td>
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<td>L. 1126-3: Have a search for infractions of the provisions carried out</td>
<td>3 years imprisonment Fine of 45,000 € Banned from practicing (5 years)</td>
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<td>1 year imprisonment Fine of 15,000 €</td>
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<td>L. 4212-7: Management of distribution of Unused Medications (MNU)</td>
<td>2 years imprisonment Fine of 30,000 €</td>
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<td>General Public Advertising</td>
<td>L. 5122-8-1 and L. 5122-16: Non-obtaining of General Public Advertising approval</td>
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<tr>
<td>Marketing Authorization</td>
<td>L. 5421-2 and L. 5421-3: Distribution of medication without AMM (Marketing Authorization)</td>
<td>5 years imprisonment Fine of 375,000 €</td>
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<td>Information about the product</td>
<td>L. 5421-4: Non communication of information acting on the risk/benefit ratio, or delay in transmitting data L. 5421-5: Lack of immediate information concerning all actions in whatever countries (blocking of batch, suspension, recall, withdrawal, etc.)</td>
<td>2 years imprisonment Fine of 150,000 €</td>
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<td>advertising for Deputy Authorized Use product</td>
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<td>Advertising to the public: For a prescription, or reimbursable medication, or non-observance of the restrictions involving wording for indications that are forbidden or that did not obtain approval (or for which the authorization was withdrawn or suspended)</td>
<td>1 year imprisonment  Fine of 150,000 €</td>
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<td>L. 5422-8:</td>
<td>Non-observance of the rules for the Giving of Free Samples</td>
<td>1 year imprisonment Fine of 75,000 €</td>
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<td>Absence of nomination of Chief and Delegated Pharmacist</td>
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<td>Absence of ANSM decision for not exporting</td>
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<td>If organized group conspiracy: 7 years imprisonment Fine of 750,000 €</td>
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### 8.2 Veterinary medicine

(to supplement the above articles applicable on a case-by-case basis)

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<th>Possible Penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical trials</strong></td>
<td>L. 5441-2: Absence of communication of regulatory information to experimenters.</td>
<td>2 years imprisonment Fine of 30,000 €</td>
</tr>
<tr>
<td></td>
<td>L. 5441-3: Absence of transmission to the Agency of information and non-observance of the decisions of the Agency</td>
<td>Idem</td>
</tr>
<tr>
<td><strong>Marketing authorization</strong></td>
<td>L. 5441-8: Sale of medication without marketing authorization</td>
<td>Idem</td>
</tr>
<tr>
<td></td>
<td>L. 5441-9: Preparation of autovaccines without authorization</td>
<td>Idem</td>
</tr>
<tr>
<td></td>
<td>L. 5441-10: Possible withdrawal of an authorization</td>
<td>Idem</td>
</tr>
<tr>
<td><strong>Information about the product</strong></td>
<td>L. 5441-7: Non declaration of stocks, upon the request from the administration, in the event of the fight against an epizooty</td>
<td>Fine of 30,000 €</td>
</tr>
<tr>
<td></td>
<td>L. 5441-14: Non declaration, without delay, of an incident or accident …that could create a risk for public health, including batch withdrawal</td>
<td>2 years imprisonment Fine of 30,000 €</td>
</tr>
<tr>
<td><strong>Pharmacovigilance</strong></td>
<td>L. 5441-15: Absence of declaration of severe undesirable effects, or undesirable effects on people</td>
<td>Idem</td>
</tr>
<tr>
<td><strong>Pharmaceutical establishment</strong></td>
<td>L. 5441-4: Absence of appointment of Pharmacist or Chief veterinarian and GM or absence of Pharmacist or Delegated Veterinarian in each establishment</td>
<td>Idem</td>
</tr>
<tr>
<td></td>
<td>L. 5441-5: Absence of pharmaceutical authorization site</td>
<td>Idem</td>
</tr>
<tr>
<td></td>
<td>L. 5441-6: Issuing of veterinary medications to the public</td>
<td>Idem</td>
</tr>
<tr>
<td></td>
<td>L. 5441-10: In the event of a court action</td>
<td>Possibility of closing of the establishment</td>
</tr>
</tbody>
</table>

Criminal penalties targeting an individual (including a chief pharmaceutical officer or chief veterinarian) may not be insured nor reimbursed by the company.
## C.9  Calendar of pharmaceutical declarations

### 9.1 Main declarations and taxes

<table>
<thead>
<tr>
<th>Month</th>
<th>Subject</th>
<th>Authority</th>
<th>Regulatory source*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15: Annual statement of stocks held as of December 31 of the preceding year</td>
<td>ANSM</td>
<td>R. 5132-83</td>
</tr>
<tr>
<td></td>
<td>15: Updated list of people authorized by the holders for operations on MOTs (Micro-Organisms and highly pathogenic Toxins)</td>
<td>ANSM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>15: Declaration of direct sales</td>
<td>URSSAF</td>
<td>L. 138-1 and following of the Social Security Code. Veto: NA</td>
</tr>
<tr>
<td>FEBRUARY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual declaration of sales of veterinary antibiotics – upon receipt of the letter from the ANMV</td>
<td>ANMV</td>
<td>Based on the OIE guidelines “surveillance of the quantities of antibiotics used in animal rearing”</td>
</tr>
<tr>
<td>MARCH</td>
<td>March 1: Annual adjustment of the contribution to the promotion expenses of medication preparation companies</td>
<td>URSSAF (ACOSS) Adelphe</td>
<td>Social Security Code L. 245-5-1A</td>
</tr>
<tr>
<td></td>
<td>10: Declaration of the LPP codes</td>
<td>CNIL ANSM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual declaration of clinical trial files (human medicine)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>31: Annual statement of establishments (includes the annual declaration of pharmaceutical staff) (human and veterinary medicine)</td>
<td>ANSM AND/OR ANMV</td>
<td>R. 5124-46 R. 5142-42 (vet.)</td>
</tr>
<tr>
<td></td>
<td>31: Quarterly declaration of sales / income tax (human medicine for members of the Leem)</td>
<td>LEEM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>31: Declaration concerning sales benefitting from a market release authorization</td>
<td>ANSM</td>
<td>L. 5121-17 L. 5121-18 D. 5121-67</td>
</tr>
</tbody>
</table>

* Public Health Code, unless there is specific wording.
<table>
<thead>
<tr>
<th>Month</th>
<th>Subject</th>
<th>Authority</th>
<th>Regulatory source*</th>
</tr>
</thead>
<tbody>
<tr>
<td>APRIL</td>
<td>15: Declaration of the advertising expenses of the past year and recovery of the actual amount of the tax (human)</td>
<td>National Council of Pharmacists</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30: Payment of the contributions of the pharmacists registered with the National Council of Pharmacists – upon receipt of the letter from the National Council of Pharmacists</td>
<td>National Council of Pharmacists</td>
<td></td>
</tr>
<tr>
<td>MAY</td>
<td>31: Declaration concerning the annual tax on veterinary sales, referred to as the “market release authorization tax” (after receipt of a letter from the ANMV)</td>
<td>ANMV</td>
<td>L. 5141-8 (vet.) / R. 5141-60 (vet.) References - Articles L. 5141-8, D. 5141-55 to D. 5141-59 of the Public Health Code NB since Jan. 1, 2011, new payment procedures: the tax is to be paid upon receipt of the monthly notice (Art. D. 5141-60, D. 5142-64 and D. 5142-65)</td>
</tr>
<tr>
<td>JUNE</td>
<td>01: Payment of the contribution to promotion expenses corresponding to 75 % of the contribution for the preceding year</td>
<td>URSSAF (ACOSS)</td>
<td>Social Security Code Art. L. 245-1, L. 245-2, L. 245-5 2 L. 245-5-5, L. 245-5-1A</td>
</tr>
<tr>
<td></td>
<td>=15: Declaration of forecasted imports of psychotrophic and narcotic substances</td>
<td>ANSM</td>
<td>Response to a letter from the ANSM</td>
</tr>
<tr>
<td></td>
<td>30: Quarterly sales declaration (human medicine, Leem members)</td>
<td>LEEM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>30: Annual declaration of support and aid given to associations of patients and health care users; (human medicine) – guide and procedure on the HAS site</td>
<td>HAS</td>
<td>L.1114-1</td>
</tr>
<tr>
<td></td>
<td>Annual “opening authorization” tax on veterinary pharmaceutical establishments</td>
<td>ANMV</td>
<td>D. 5142-65 (vet.) L. 5141-8</td>
</tr>
<tr>
<td>JULY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUGUST</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SEPT</td>
<td>30: Quarterly sales declaration</td>
<td>LEEM</td>
<td></td>
</tr>
<tr>
<td>OCT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NOV</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEC</td>
<td>1/12: Declaration of the promotion expenses of the preceding year (human medicine)</td>
<td>URSSAF</td>
<td></td>
</tr>
<tr>
<td></td>
<td>31: Quarterly sales declaration</td>
<td>LEEM</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Annual declaration of doctor files (human medicine)</td>
<td>CNIL</td>
<td></td>
</tr>
</tbody>
</table>

* Public Health Code, unless there is specific wording.
9.2 Initial and/or periodic declarations (deadlines in line with of the activity of the company)

<table>
<thead>
<tr>
<th>Subject</th>
<th>Authority</th>
<th>Source*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declaration of appointment / change of the chief pharmaceutical officer</td>
<td>ANSM or ANMV</td>
<td>R. 5124-35 and R. 5142-34 (vet.)</td>
</tr>
<tr>
<td>and deputy chief pharmaceutical officer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Declaration of change of pharmacovigilance responsible</td>
<td>ANSM or ANMV</td>
<td>R. 5121-164 and R. 5141-108 (vet.)</td>
</tr>
<tr>
<td>Declaration of the undesirable effects on Eudravigilance for the severe and serious effects (15 days) and non-severe undesirable effects (90 days)</td>
<td>EMA, ANSM or ANMV</td>
<td>R. 5121-166 and R. 5141-103 (vet.) and R. 5121-152 (vet.)</td>
</tr>
<tr>
<td>Declaration of an incident or accident for a batch that could lead to a risk for public health, and recall of batch</td>
<td>ANSM or ANMV</td>
<td>L. 5124-6 and R. 5124-55 and R. 5142-49 (vet.)</td>
</tr>
<tr>
<td>Declaration for clinical trial</td>
<td>ANSM or ANMV</td>
<td>L. 1123-8 and R. 1123-30 and R. 5141-8 (vet.)</td>
</tr>
<tr>
<td>Declaration of end of biomedical research</td>
<td>ANSM/ANMV</td>
<td>R. 1123-59 and L. 5142-3-1 (vet.)</td>
</tr>
<tr>
<td>Application for advertising approval (see R. 5122-1 and following)</td>
<td>ANSM/ANMV</td>
<td>L. 5122-8 General public L. 5122-9 Health care professional R. 5141-86 (vet.)</td>
</tr>
<tr>
<td>Declaration of risk of stock outage</td>
<td>ANSM or ANMV</td>
<td>L. 5124-6 and R. 5124-49-1 and L. 5142-3-1 (vet.)</td>
</tr>
<tr>
<td>Quarterly review of the handling of stock outages</td>
<td>ARS/ANSM</td>
<td>R. 5124-49-1</td>
</tr>
<tr>
<td>Declaration of commercialisation (each presentation)</td>
<td>ANSM or ANMV</td>
<td>L. 5124-5 and L. 5142-3-1 (vet.)</td>
</tr>
<tr>
<td>Declaration of end of commercialisation (last presentation)</td>
<td>ANSM or ANMV</td>
<td>L. 5124-6</td>
</tr>
<tr>
<td>Declaration of the stopping of commercialisation, ban or restriction on all products in whatever countries</td>
<td>ANSM</td>
<td>L. 5121-9-2 and L. 5121-9-4</td>
</tr>
<tr>
<td>Declaration of the totality of the productions, imports and stock in the event of the fight against an epizooty (upon request)</td>
<td>ANSM</td>
<td>L.5142-5 (vet.)</td>
</tr>
</tbody>
</table>

* Public Health Code, unless there is specific wording.
### 9.3 Other applications linked to the activity of the laboratory

<table>
<thead>
<tr>
<th>Subject</th>
<th>Authority</th>
<th>Regulatory Source*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for the opening of a pharmaceutical establishment</td>
<td>ANSM or ANMV</td>
<td>L. 5124-3, R. 5124-5 to R. 5124-15 L. 5142-2 (vet.) R. 5142-5 (vet.) and R. 5142-7(vet.)</td>
</tr>
<tr>
<td>Application for (or declaration of) modification of a pharmaceutical establishment</td>
<td>ANSM or ANMV</td>
<td>L. 5124-3, R. 5124-10, R. 5124-10-1, R. 5124-10-2 L. 5142-2 (vet.), R. 5142-9 (vet.)</td>
</tr>
<tr>
<td>GMP certificate request</td>
<td>ANSM or ANMV</td>
<td></td>
</tr>
<tr>
<td>Closing of a pharmaceutical establishment</td>
<td>ANSM</td>
<td>R. 5124-12</td>
</tr>
<tr>
<td>Opening authorization transfer application</td>
<td>ANSM or ANMV</td>
<td>R. 5124-13 and 14 R. 5142-13 and 14 (vet.)</td>
</tr>
<tr>
<td>Marketing authorization renewal application</td>
<td>EMA, ANSM Or ANMV</td>
<td>R. 5121-45 Taxes: D. 5121-63 and following R. 5141-39 (vet.)</td>
</tr>
</tbody>
</table>

* Public Health Code, unless there is specific wording.
<table>
<thead>
<tr>
<th>Subject</th>
<th>Authority</th>
<th>Regulatory Source*</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATU (deputy authorization for use) application</td>
<td>EMA, ANSM or ANMV</td>
<td>L. 5121-12, R. 5121-68, L. 5141-10 and L. 5141-10-1 (vet.)</td>
</tr>
<tr>
<td>ATU renewal application</td>
<td>EMA, ANSM</td>
<td>R. 5121-74</td>
</tr>
<tr>
<td>Marketing authorization modification application</td>
<td>EMA, ANSM or ANMV</td>
<td>R. 5121-41 to R. 5121-41-5-2, D. 5121-65, R. 5141-35 and following (vet.), Taxes: D. 5141-55 and following (vet.)</td>
</tr>
<tr>
<td>Change of Marketing authorization holder</td>
<td>ANSM</td>
<td>R. 5121-46</td>
</tr>
<tr>
<td>Change of Marketing authorization operator (“exploitant”)</td>
<td>ANSM</td>
<td>R. 5121-41</td>
</tr>
<tr>
<td>Change of importing authorization and CPP</td>
<td>ANSM and/or ANMV</td>
<td>L. 5124-13, R. 5121-108 to R.5121-113, L. 5142-7 (vet.), R. 5141-123, and following (vet.)</td>
</tr>
</tbody>
</table>

* Public Health Code, unless there is specific wording.
**ANSM** Agence Nationale de Sécurité du médicament et des produits de santé (National Agency for the Safety of Medications and Health Care Products)

1. Surveillance Department
   Director
   **Falip Evelyne** 01 55 87 35 23
   Deputy Director
   **Bruneaux Francois** 01 55 87 40 06
   Deputy Director
   **Maison Patrick** 01 55 87 37 96
   Health Care Product Epidemiology Unit
   **Zureik Mahmoud** 01 55 87 33 27
   Market Control Unit
   **Debourges Dominique** 01 55 87 39 88
   Platform for reception and orientation of reports Unit
   **Debourges Dominique** 01 55 87 39 88
   Reception Platform Unit
   **Debourges Dominique** 01 55 87 39 88
   Materiovigilance: materiovigilance@ansm.sante.fr
   Reactovigilance: reactovigilance@ansm.sante.fr
   Pharmacovigilance: pharmacovigilance@ansm.sante.fr
   Quality complaints: dvs.defauts-qualite@ansm.sante.fr
   Medication error: erreur.medicamenteuse@ansm.sante.fr
   Stock outages: rupture-stock@ansm.sante.fr

Main texts

Article R. 5121-150 – “The purpose of pharmacovigilance is the surveillance of the risk of undesirable effects ...

Article R. 5121-151 “Pharmacovigilance includes:
   • The reporting of undesirable effects ...
   • The recording, evaluation or use of this information ...
   • The carrying out of all studies ...

Article R. 5121-153: definition of the terms “undesirable effect”, .... “misuse”....

The actors of the pharmacovigilance system as mentioned in article L. 5121-23 are:
1 The National Agency for the Safety of Medications and Health Care Products;
2 The regional pharmacovigilance centers mentioned in article R. 5121-158;
3 The health care professionals mentioned in article R. 5121-161, the pharmacies for internal use mentioned in article L. 5126-1 and the holders of the authorization provided for in article L. 4211-6;
4 Companies or organizations that use a medication or product mentioned in article R. 5121-150 and any third party carrying out all of part of the operations that constitute the pharmacovigilance mentioned in the fourth paragraph of article R. 5124-47 on behalf of the companies and organizations mentioned above;
5 Pharmaceutical establishments, including those managed by the pharmaceutical establishments of the public health care establishments mentioned in articles R. 5124-68 to R. 5124-73 for their activity of making hospital preparations and dispenser’s preparations.

The patients and approved patients’ associations mentioned in article R. 5121-161 contribute to this system.

Article R. 5121-170 to 173
   “...all companies or organizations that use authorized or registered medications or products, .... must send periodic updated safety reports...

Article R. 5121-178
   “Any organization that uses a medication must at all times have a doctor or pharmacist responsible for pharmacovigilance, who has documented pharmacovigilance experience. The ANSM must be informed of the identity and the job title of this person as of his appointment...
2. Inspection Department

Director
Rudant Gaetan 01 55 87 39 11
Fax 01 55 87 39 12

Deputy Director
Morenas Jacques 01 55 87 39 11
Fax 01 55 87 39 12

Unit for Methodology and Means of Inspection
Awaiting appointment 01 55 87 39 31
Fax 01 55 87 39 12

Unit for Inspection of biological products
Ribes Olivier 01 55 87 40 31
Fax 01 55 87 40 32

Unit for Inspection of pharmaceutical products and fraud prevention 1
Viormery Lionel 01 55 87 39 71
Fax 01 55 87 39 72

Unit for Inspection of pharmaceutical products and fraud prevention 2
Ribeiro Virginie 01 55 87 39 71
Fax 01 55 87 39 72

Raw Material Inspection Unit
Renaud Guillaume 01 55 87 40 71
Fax 01 55 87 40 72

Unit for Inspection of Tests and Vigilance
Awaiting appointment 01 55 87 40 11
Fax 01 55 87 40 12

Market Surveillance Inspection Unit
Born Jean-Christophe 01 55 87 40 51
Fax 01 55 87 40 52

Registration and inspection of establishments for the manufacturing, distribution and importing of raw materials for pharmaceutical use: insmp@ansm.sante.fr
Directory of pharmaceutical establishments: etapharm@ansm.sante.fr
Clinical trials – Good clinical and inspection practices: bpc_bpf@ansm.sante.fr

Main texts

Article L. 5124-6:
“A pharmaceutical company that uses a medication or product subject to the provisions of chapter I of this volume which decides to suspend or cease marketing or which is aware of facts that could lead to the suspension or stopping of this marketing must inform, at least one year before the planned or foreseeable date, the National Agency for the Safety of Medications and Health Care Products if this medication is used in one or several severe pathologies in which it has no alternatives available on the French market. The stopping of the marketing may not take place before the end of the period necessary to implement alternative solutions to cover this need. If the medication is not used in one or several severe pathologies for which it has no alternatives available on the French market, the notification must take place two months before the suspension or stopping of the marketing at the latest. In the event of an emergency requiring that the suspension or the stopping occur before the end of the period set above, the company will immediately inform the agency of this, justifying the urgency. It must also inform the National Agency for the Safety of Medications and Health Care Products of any risk of a stock outage or any outage of a medication or products with no available therapeutic alternative, for which it handles the operations, linked to a sudden and unexpected increase in demand. When the medication is used in one or several severe pathologies for which there are no alternatives available on the French market, the company will collaborate with the agency for the implementation of alternative solutions to cover this need and the necessary accompanying measures. A pharmaceutical company that uses a medication or product subject to the provisions of chapter one of this volume must immediately inform the agency of any action taken to withdraw a determined batch.”

“BPF” in effect, chapter 8.

Article R. 5124-55:
“When the chief pharmaceutical officer of a manufacturer, importer or user of medications … becomes aware, after the marketing of a batch of medications or products, of an incident or accident that occurred during the manufacturing or the distribution of this batch and which could lead to a risk for public health, he must declare this without delay to the general director of the French Agency for the Safety of Health Care Products.”
ANSES  Agence Nationale chargé de la Sécurité Sanitaire de l’alimentation, de l’Environnement et du travail (National Agency in charge of the Health Safety of Food Products, the Environment and Labor)

ANMV  Agence nationale des médicaments veterinaires (National Agency for Veterinary Medications)

New common address
Ansens-Agence nationale du medicament veterinaire
8 rue Claude Bourgelat – Parc d’Activités de la Grande Marche – Javené
BP 90203 – 35302 FOUGERES Cedex
For all questions concerning market release authorizations and the evaluation of chemical and immunological medications:
Telephone: 02 99 94 78 60 – Fax: 02 99 94 78 64

Registration unit: enreg@anses.fr
New market release authorization application, type I and II modifications, renewal of market release authorizations, abandoning of market release authorization, suspensions/withdrawals of marketing authorizations, clinical trials, ATU (deputy authorizations for use), importing, mutual recognition, CMDv, homeopathy, CNMV, list of veterinary medications, RCP (summary of product characteristics).
Unit for the evaluation of chemical medications:
evalchimie@anses.fr
marketing authorization procedures, clinical/efficacy, LMR/residues, quality, toxicology.
Unit for the evaluation of immunological medications:
evalbio@anses.fr
All information relating to vaccination files.
For all questions concerning establishments, inspections, quality control for medications and advertising:
Telephone: 02 99 94 66 65 – Fax: 02 99 94 66 71

Establishments unit: etab@anses.fr:
pharmaceutical establishment file (including the establishments of the medicated food products sector), exporting, OCABR (official release of batches), annual statements, autovaccines, APSA, monitoring of BPF, BPD, BPFDAM and BPL inspections.
Inspection unit: insp@anses.fr: BPF, BPD, BPL inspections, advertising/labeling, handling of quality complaints and batch recalls (defaultsqualiteMV@anses.fr).
Medication quality control unit: analyses or controls of medications, network of OMCLs.
Advertising: publicite-anmv@anses.fr

For all questions concerning pharmacovigilance:
Telephone: 02 99 94 78 43 – Fax: 02 99 94 66 71
Pharmacovigilance department: secSPv@anses.fr:
declaration, undesirable effects, PSUR
Clinical trials – Good clinical practices and inspection:
bpcl_bpf@ansm.sante.fr
Main texts

**Article R. 5141-89 (vet.):**
“The purpose of veterinary pharmacovigilance is to monitor the effects of veterinary medications, mainly their undesirable effects on animals and human beings, and the scientific evaluation of the information collected for this purpose ...”.

**Article R. 5141-90 (vet.) – “Pharmacovigilance includes:**
- The reporting of undesirable effects ...
- The collecting, recording, evaluation and use of this information ...
- The carrying out of all studies...

**Article R. 5141-94 (vet.)**
“The National Agency for the Health Safety of Food Products, the Environment and Labor implements the national veterinary pharmacovigilance system”

**Articles R. 5141-104 and 105 (vet.)**
“...any company or any organization that uses an authorized or registered medication or product, ..., must send a periodic updated safety report ...

**Article R. 5141-108 (vet.) - “Any organization that uses a medication has at all times a doctor or pharmacist in charge of pharmacovigilance who has documented experience in pharmacovigilance. The identity and the job title of this person are announced to the ANSM as of his appointment...”

For all other questions,
call 02 99 94 78 78
<table>
<thead>
<tr>
<th>Organization</th>
<th>Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Council of Pharmacists</td>
<td>4, avenue Ruysdael – 75379 PARIS cedex 08</td>
</tr>
<tr>
<td>Agence nationale de securite du medicament et des produits de sante (ANSM)</td>
<td>143-145, boulevard Anatole France – 93285 Saint-Denis cedex</td>
</tr>
<tr>
<td>European Medicines Agency (EMA)</td>
<td>7, Westferry Circus Canary Wharf – London E 14 4HB – Great Britain</td>
</tr>
<tr>
<td>Direction Generale de La Sante (DGS)</td>
<td>Ministère de la santé – 14, avenue Duquesne – 75350 PARIS 07 SP</td>
</tr>
<tr>
<td>Direction de la Securite Sociale (DSS)</td>
<td>Ministère de la santé – 14, avenue Duquesne – 75350 PARIS 07 SP</td>
</tr>
<tr>
<td>Comite Economique des Produits de Sante (CEPS)</td>
<td>8, avenue de Sécur – 75007 Paris</td>
</tr>
<tr>
<td>Haute Autorite de la Sante (HAS)</td>
<td>2, avenue du Stade de France – 93218 Saint-Denis cedex</td>
</tr>
<tr>
<td>Agence Nationale chargee de la Securite Sanitaire d'alimentation, de l'Environnement et du travail (ANSES)</td>
<td>8, rue Claude Bourgelat Parc d'Activités de la Grande Marche-Javené BP 90203 35302 Fougères cedex</td>
</tr>
<tr>
<td>Agence nationale des veterinary medications (ANMV)</td>
<td></td>
</tr>
<tr>
<td>LEEM (Les Entreprises du Medicament)</td>
<td>88, rue de la Faisanderie – 75016 PARIS</td>
</tr>
<tr>
<td>CODEM (Comite de deontovigilance du Leem)</td>
<td>25, rue de Montevideo – 75116 PARIS</td>
</tr>
<tr>
<td>Ordre National des Medecins</td>
<td>180, boulevard Haussmann – 75008 PARIS</td>
</tr>
<tr>
<td>Tulipe, (Transfert d’Urgence et Solidarite Internationale des Entreprises de sante)</td>
<td>15, rue Rieux – 92100 Boulogne</td>
</tr>
<tr>
<td>Pharmaciens Sans Frontieres (PSF)</td>
<td>9, rue André Darbon – 33300 Bordeaux</td>
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<tr>
<td>Association Francaise de l’Industrie Pharmaceutique pour une Automedication responsable (AFIPA)</td>
<td>8 rue Saint-Saëns – 75015 PARIS</td>
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<tr>
<td>Commission Nationale de l’Informatique et des Libertes (CNIL)</td>
<td>8, rue Vivienne – CS 30223 – 75083 PARIS cedex 02</td>
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<tr>
<td>Centre Anti-poison et de Toxicologivigilance de Paris</td>
<td>Hôpital Fernand Widal – 200, rue du Faubourg Saint-Denis – 75475 Paris cedex</td>
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<td>Direction Generale de la Concurrence, de la Consommation et de la Repression des Fraudes (DGCCRF)</td>
<td>Ministère de l’économie et des Finances – Télédoc 51 139, rue de Bercy – 75572 Paris cedex 12</td>
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<tr>
<td>Brigade nationale d’enquetes veterinares et phytosanitaires(DGAP)</td>
<td>Brigade de Toulouse – BP57 – 31326 Costanet Tolosan cedex</td>
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<td>Telephone</td>
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<td>00 44 (0) 20 74188400</td>
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