

The new tax and fee system applicable to health-care products

The reform of the taxes and fees before paid to the Afssaps

Within the scope of the general system concerning the reform of medicinal products and to increase the independence of the Afssaps, as from 1 January 2012, the Afssaps will cease to be paid the taxes and fees paid by the pharmaceutical laboratories and the medical devices industry.

The Social Security Finance Act in 2012 transfer the payment of taxes and fees to the State and to allocate the income to the CNAAMTS.

The implementation of this reform will result in the financial link between the Afssaps and the industries concerned being broken, thereby guaranteeing the independence of the agency the missions and organisation of which are moreover changed within the scope of the bill on increasing the health safety of medicinal and other health-care products.

What is changing?

- ▶ Taxes and fees will no longer be paid to the Afssaps. They will be paid to the State.
- ▶ The Afssaps will be financed by a state subsidy to replace the taxes and fees paid to it up to now.
- ▶ The amounts shall be changed.
- ▶ The liabilities for certain annual taxes will be changed.
- ▶ The Afssaps will change its name.

What will continue?

- ▶ The Agency will still be a national public establishment under the supervision of the ministry responsible for health.
- ▶ The Agency will have missions entrusted to it by the law and the prerogatives relating to the exercise of public authority.
- ▶ The operations relating to health safety which today are carried out by the Agency will still be carried out by the Agency.

Taxes and fees concerned by the change in payment

Annual taxes

- Annual tax on proprietary products (medicines for which a Marketing Authorisation or a Parallel Import Authorisation was granted);
- Annual tax on Medical Devices and *In Vitro* Diagnostic Medical Devices;
- Annual tax to carry out the National Quality Control.

Administrative taxes

- Application for a marketing authorisation, their modifications and their renewal;
- Application for recognition of a marketing authorisation;
- Registration of homeopathic products, their modifications and their renewal;
- Registration of traditional herbal medicines, their modifications and their renewal;
- Application for a parallel import authorisation, their modifications and their renewal;
- Filing of advertising;
- Approval of advertising.

Fees

- Application to release batches of immunological medicinal products;
- Application to release batches of medicinal products derived from blood, plasma and substances;
- Certificate of quality issued to the exporters of medicinal products;
- Delivery of reference substances in the pharmacopoeia;
- Application for a "good practices – raw materials" inspection.

New taxes

- Analysis of the protocol for batch release outside Europe (royalty system);
- Tax on cosmetic products (annual taxes system).

When does this change take place?

- On 1 January 2012.

Who pays the taxes?

Those liable for the taxes are the same as those liable before with the exception of three taxes:

- the annual tax on proprietary products;
- the annual tax on Medical Devices and *In Vitro* Diagnostic Medical Devices;
- the annual tax on cosmetic products (new tax paid to the State for the CNAMTS set up by Article 26 of the Social Security Finance Act).



...those liable are "the persons subject to VAT in application of the provisions of Article 256 A who make the first sale in France".

What is the legal basis for these changes?

- The new taxes are created by the Social Security Finance Act in 2012 (Article 26);
- A decree will set the amount of the taxes within the scope of the law;
- The new amounts, scales and rates will be available on the Public Finance website (impots.gouv.fr).

The practical details on functioning for 2012

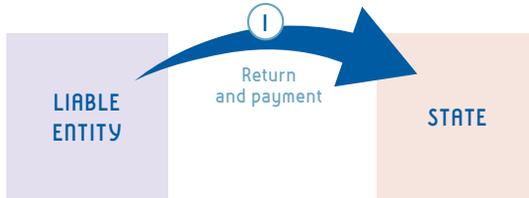
The annual taxes

How to declare the annual taxes?

- Those liable will declare the tax on the appendix to the return mentioned in article 287 and filed on the basis of the operations for the month of March or the first quarter of the calendar year.

When should the annual taxes be paid?

- The annual taxes will be paid when filing the return.



The return on sales

- This mandatory return is maintained for medicinal products, Medical Devices and In Vitro Diagnostic Medical Devices and should be sent to the Agency and the CEPS at the latest by 31 March of the year.
- A return has been introduced for cosmetic products by Article 26 of the Social Security Finance Act in 2012. It should be sent to the Agency at the latest by 31 March of the year.

Fees

When should the corresponding fees be paid?

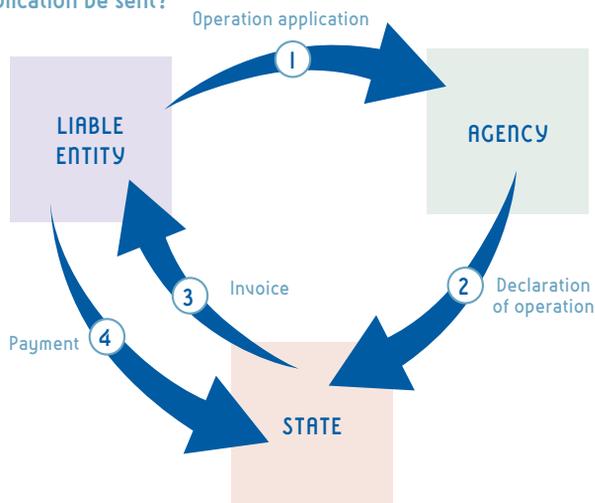
- After the operation has been carried out.

To whom should the corresponding fees be paid?

- To the State services.
- The State will issue an invoice for those liable for the fees.

Where should the application be sent?

- To the Agency.



Administrative taxes

When should be corresponding fees be paid?

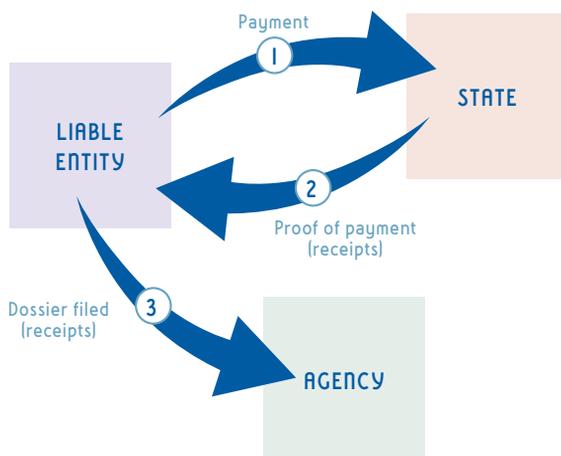
- Before sending the application (e.g. filing an MA application dossier) with the Agency.

To whom should the corresponding fees be paid?

- To the special debt department at the Châtelleraut Tax Office.

Where should the application be sent?

- To the Agency.
- It is mandatory that the application (e.g. filing an MA application dossier) should be accompanied by proof (receipt) that payment has been made to the special debt department at the Châtelleraut Tax Office.



Attention

- ▶ Any dossier filed with the Agency as from 1 January 2012 should be accompanied by a receipt issued by the special debts department of the Châtelleraut Tax Office.
- ▶ Transfers should not be made to the Agency in payment of dossiers filed as from 1 January 2012.