FRANCE

Recent and planned developments in pharmaceutical policies 2019

Special topic: patient-based reimbursement decisions

The Social Security Financing Act for 2019

L rate becomes M amount in 2019:
L rate: level of evolution of the turnover of the pharmaceutical industry beyond which it must pay a contribution
In 2018, L rate was split between the Lv (for the outpatient sector) and Lh (for the inpatient sector);
In 2019, L rate merged and became the M amount.
It is set at + 0,5 % every year for the three coming years;
Existing exemptions (orphan drugs and generics) were removed;
M amount is only based on net annual revenue of each manufacturer regardless of its growth.

Reimbursement rate if no substitution:
From January 1st 2020, patients refusing the substitution to a generic will be reimbursed on the basis on the generic price and no longer the originator price.

Hybrids medicines substitution:
In 2020 a registry will be launched allowing the substitution between originators and hybrids medicines.

The next Framework Agreement 2019 - 2021

The current Framework Agreement set between the Pricing Committee (the so-called CEPS) and the pharmaceutical industry representative (LEEM) is valid until December 2018.
The current version has been extended an additional year.
Negotiations on the next version will mid-2019.

New price negotiations procedure:
LEEM and CEPS agreed on the 24th April on a new procedure.
It clarifies negotiation timeline:

- From now on, pharmaceutical industry will have to update its price request based on the HTA report the latest two week its reception;
- CEPS will assess pharma price request within 4 weeks after receiving its update. It will accept it or make the first offer.

Pharma industry as the CEPS have to motivate their pricing proposals based on pricing criteria.
If an agreement is not reach, price request can be suspended.

New ministerial guidelines

Jointly signed on the 4th February 2019 by the ministries of Economy, Health and Public Accounts.

Set global pharmaceutical market increase by 0,5% and by 3% for innovative treatments.

The document points out three elements to consider during price negotiations:

- Medicines with minor medical added value (ASMR IV) cannot lead to spending increase;
- To consider investments and exports in the scope of the current Article 18 of the current Framework Agreement (price stability and not level);
- Ensuring timely access to the market.

New guidelines will be provided after the negotiations of the next Framework Agreement.

SPECIAL TOPIC: Patient-based reimbursement decisions

There are three situations for a medicine to be refund without being included in the reimbursement list:

Import
If a medicine is not available in France but it is approved in another country, a physician can ask the National Regulatory Agency to allow its import from a country where it is available. The medicine is refund at the importing country price.

Nominative early access scheme – *ATU nominative*
If a medicine does not have a marketing authorisation, a prescribing physician can ask the National Regulatory Agency to use it and to get refunded. The price is freely set by the manufacturer.

Cohort early access scheme – *ATU cohort*
If a medicine does not have a marketing authorisation, a manufacturer can ask the National Regulatory Agency to use it for a group of patients and to get refunded. The price is freely set by the manufacturer.