

FRANCE

Recent and planned developments in pharmaceutical policies 2017/2018

Special topic: patient involvement in pricing and reimbursement of medicines

CHANGES IN PRICING

The Social Security Financing Act for 2018:

Selling price limit (PVL):

For inpatient medicines, selling prices cannot be higher than the price negotiated by the CEPS.

Temporary recommendation for use (RTU):

RTU: Recommending a medicine use outside its label. Medicines prices can now be update in case of RTU.

OTHERS CHANGES

The Social Security Financing Act for 2018:

L rates for 2018:

L rate: level of evolution of the turnover of the pharmaceutical industry beyond which it must pay a contribution

Lv: rate for the outpatient sector at 0%

Lh: rate for the inpatient sector at 3%

Pharmacists' margin changed from the 1st January 2018:

For the MSP between :	Margin rate
0 et 1,91 €	10 %
1,92 et 22,90 €	21,4%
22,91 et 150,00 €	8,5 %
150,01 et 1515,00 €	6 %
Supérieur à 1515,00 €	0 %

CHANGES IN REIMBURSEMENT

The Social Security Financing Act for 2018:

Single refund price:

The CEPS can set a single refund price for inpatient medicines with equivalent efficacy (e.g. generics, biosimilars or any other comparable medicine in terms of indication or therapeutic use).

This mechanism already exists for outpatient medicines. It is called: fixed accountability tariff (TFR).

Request for prior agreement (DAP):

The DAP mechanism allows to condition a reimbursement by obtaining a prior agreement from a medical service of the statutory health insurance.

REGULATION EVOLUTION in 2018/2019

A series of events will lead to substantial changes in the regulation of the drug in 2018/2019:

- Fusion of the SMR and ASMR into a single score
- Single reimbursement rate?
- New inpatient medicines purchasing rules?

SPECIAL TOPIC: Patient Involvement in Pricing and Reimbursement of Medicines

Patients' involvement in HTA

To date, 2 patients associations sit at the HTA commissions and have a deliberative voice; as such, they receive all the files and documents sent to the members of the HTA commissions.

The HTA commissions can also solicit one or more selected associations, at their initiative on some files. In this case, the HTA commissions may receive written contributions, or audition them in a session.

Finally, a solicitation system has been set up on a voluntary basis via the publication of a list of the reimbursement files submitted. Associations wishing to contribute can then send a written contribution that is sent to HTA commissions members and is presented at the session at which the product is reviewed.

Patients' involvement in Pricing

Article L.162-17-4-2 of the Social Security Code enables patients to voice their perspective during medicines prices negotiations by giving patients' associations the possible to be invited for hearing by the French Pricing Committee. The patients' contribution is formalised by a Patient Framework Agreement.

Patients' associations receive the Pricing Committee agenda. They can ask to be heard by the Committee in the context of a specific medicine negotiation. However, they won't be informed about the pricing