FRANCE

Recent and planned developments in pharmaceutical policies 2018

Special topic: national incentives and derogatory procedures for orphan medicines

8th Strategic Council on Health Industry (CSIS)

The CSIS aims to define measures to ensure France maintains his "business friendly" attitude towards the Health Industry.

Measures are set to:

- **Ensure patients get a faster access to innovation**
  - ➔ Reducing the timeframe to access the market to 180 days
  - ➔ Broadening the early access programme not only to new products but also to new indications of products already reimbursed
  - ➔ Clarifying the early access programme to medical devices (the "forfait innovation")
- **Enhance public-private partnerships in research and training**
  - ➔ Launching the "Health Data Hub" aiming at collecting health data available in France
- **Maintain France as a centre of excellence**
  - ➔ Launching the venture capital "Innobio II" – budget of 150 to 250 M€
- **Foster a more stable and predictable pharmaceutical regulation**
  - ➔ Allowing a pharmaceuticals spending increase by at least 0,5% for the global market
  - ➔ Updating the HTA procedure (new criterion?)

Link to access to the report:
http://m.enseignementsup-recherche.gouv.fr/cid132716/8eme-conseil-strategique-des-industries-de-sante-csis.html

The Social Security Financing Act for 2019 *(project)*

Some 8th CSIS measures will be implemented in 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 will merge and and become the M amount.
It will be set at + 0,5 % for the three coming years;
Exemptions (orphan drugs and generics) will be removed;
M amount will be 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:
From 2020, a registry will be launched allowing the substitution between originators and hybrids medicines.

The Financing Act for 2019 will be approved by the Parliament by December 2019

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 will be extended up to an additional year.
Negotiations on the coming version will start in 2019.

SPECIAL TOPIC: National Incentives and Derogatory Procedures for Orphan Medicines

Orphan medicines are considered in France as any other medicine.

The only specific disposition existing is related to their pricing. It corresponds to the Article 14 of the Framework Agreement between the Pricing Committee (the so-called CEPS) and the pharmaceutical industry representative.

Article 14 provides the possibility to agree on an annual fixed amount per patient per year if it exceeds 50 000 €. The CEPS accepts to set a list price in coherence with the prices applied outside of France. The manufacturer commits to provide access to all the eligible patients.