

How France pay for expensive drugs

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Diane Paillet-Testart,

- **Context : How France pay hospitals**
- Focus on drugs
 - Common payment = DRG
 - Expensive drug list
 - Financing before marketing authorisation
- For more information ...

Context

In France, around 3 300 hospitals have different activities :

- Medicine, surgery and obstetric (MCO)
- Home care (HAD)
- Rehabilitation (SSR)
- Psychiatry

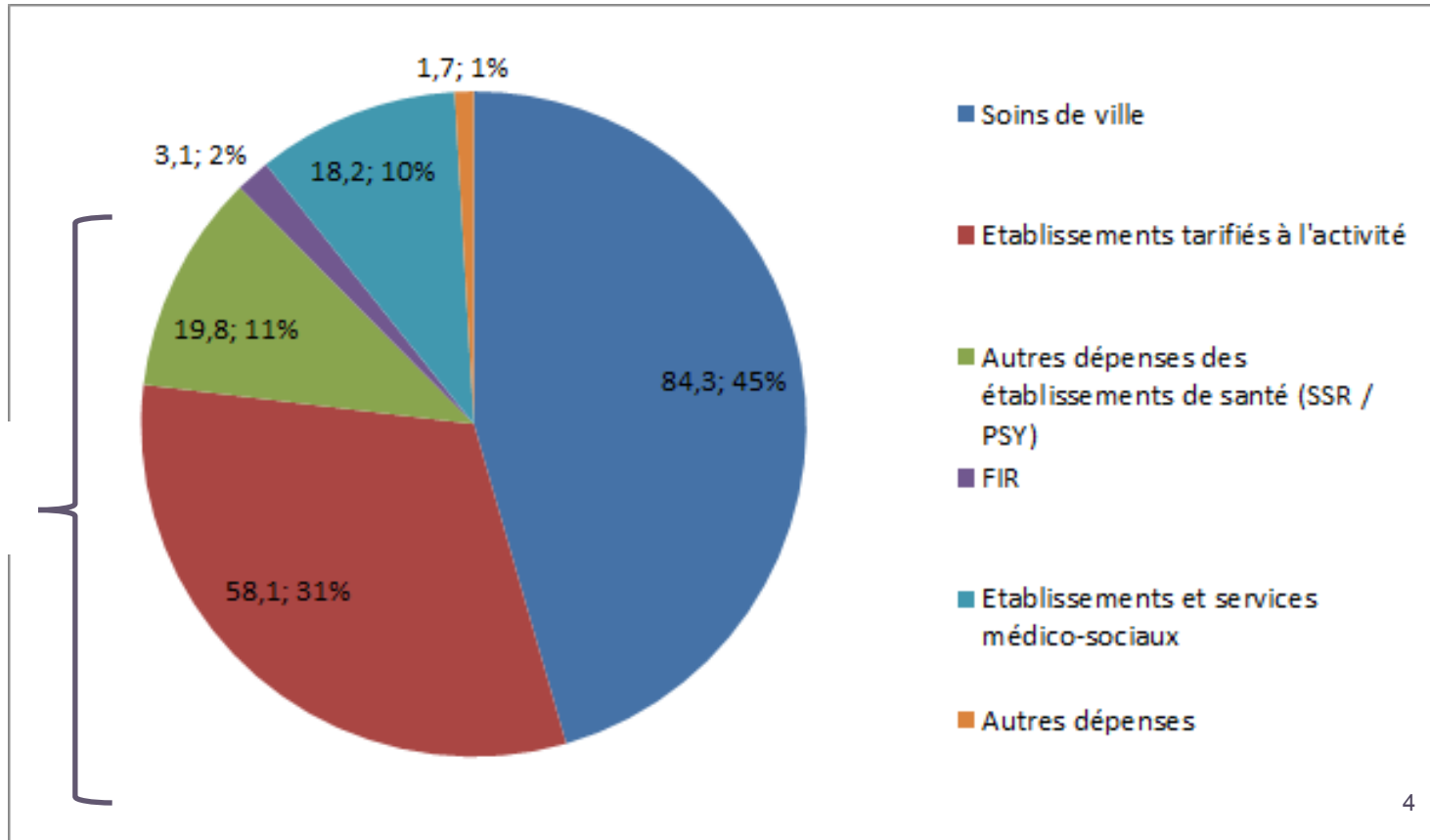
Each hospital could be under different legal status : public, non-profit private or private.

Hospitals are mainly paid by the national health insurance.
However, mutual fund or patient may also pay for some part.

Ondam 2016

ONDAM, Voted by the parliament 185 Billion € +1,75%

ONDAM for hospitals
78 Billion €
(42%)



Financial amounts

- MCO activity represents 75% of the total budget
- Many ways to pay for MCO activities
 - Grant not link to the activity : general interest mission : 11%
 - Price based on previous activity for some activities : 2%
 - Payment in real-time based on the activity : 87% nearly 50 Billion €

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Drugs in French system

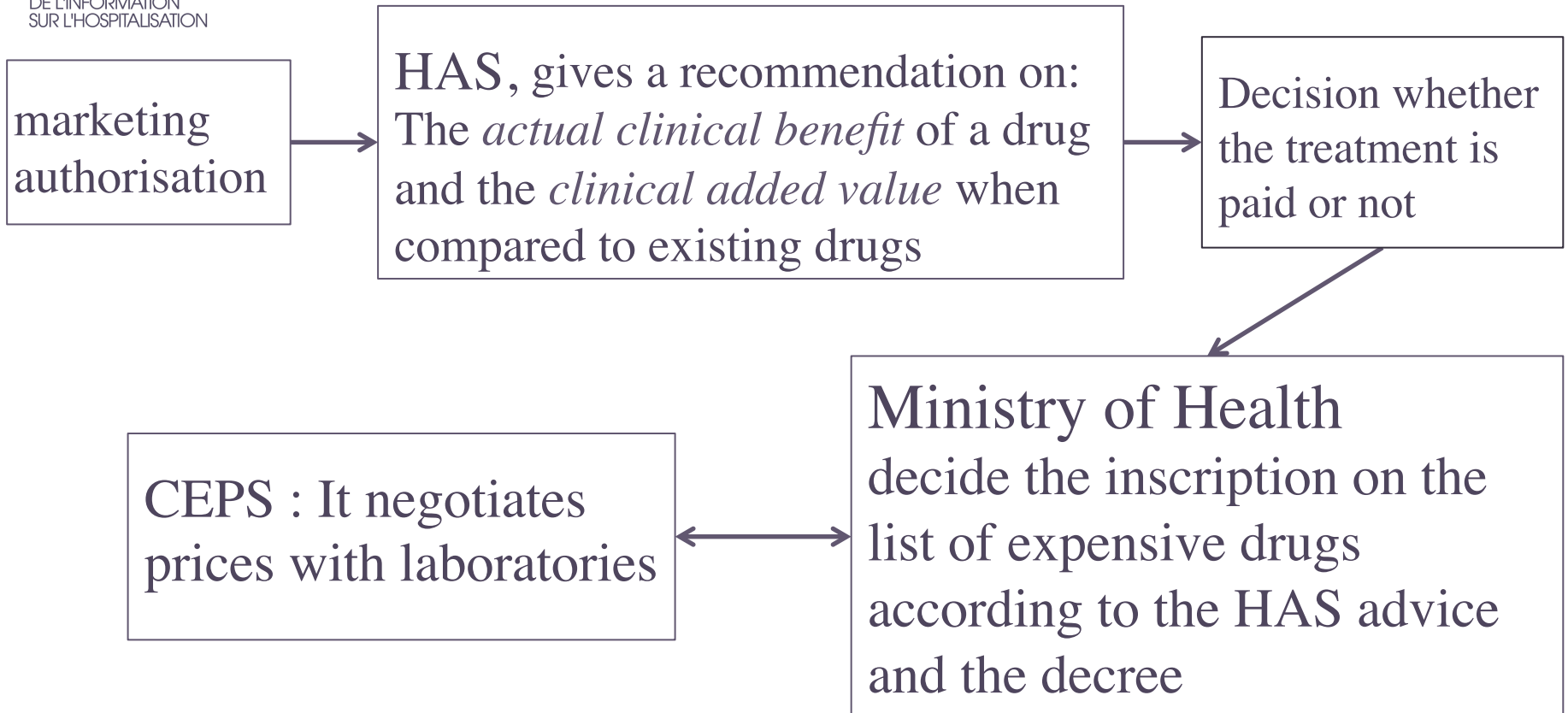
- Drugs are mainly paid by diagnosis related group - DRG
 - Methotrexate
 - Docetaxel ...

- For some innovative drugs, the DRG group price is not sufficient
 - Expensive drug list

- ATU

Expensive drugs

After marketing authorisation



HAS : French National Authority for Health
CEPS : Economic comity on drugs and devices

Expensive drugs

After marketing authorisation

- Prices are negotiated between CEPS and laboratories
- The price is published in the official journal
- Price are regularly reviewed

Expensive drugs

After marketing authorisation

- Rules to regulate the list of expensive drugs are available on a decree 25 march 2016
 - Expected use : Hospital / In town
 - Actual clinical benefit (ACB) Major or important
 - Clinical added value (CAV)
 - I major, II important, III moderate
 - Frequency in DRG group
 - > 80 % should be paid by the DRG
 - In many different DRG → List of expensive drugs

Expensive drugs

After marketing authorisation

- More rules :
 - Mean treatment cost per stay
 - < 30 % du DRG, paid by the DRG
 - > 30 % du DRG → List of expensive drugs
 - Equality between laboratories

Expensive drugs

After marketing authorisation

- This list aims to allow access to innovative expensive drug, therefore :
 - Actual clinical benefit must be sufficient
 - Older drugs must be removed of the list
- Registration on the list should be of short-term
- After removal, drugs are paid through DRG

Expensive drugs

After marketing authorisation

- Lately a new paradigm :
 - Payment related to the indication of a product and its benefits
 - A drug with many indications can be paid through
 - The DRG if the benefit is low
 - The list of expensive drugs if the benefit is high

Expensive drugs list

- Expensive Drugs + Expensive Medical Device = 5 Billion €
 - Expensive Drugs = 3 Billion € almost 6% of payment based on the activity
- 351 Codes are on the list in September 2016
 - 57 start with L01 : Antineoplastic agents

Expensive drugs

After marketing authorisation

	Amount M6 2016 in M€	Evolution M6 2015/2016	Contribution to the increase M6 2015/2016	Relative proportion (M6 2016)
L01 : ANTINEOPLASTIC AGENTS	623.5	+3.8%	37.9%	50.1%
L04 : IMMUNOSUPPRESSANTS	288.3	+5.7%	26.1%	23.2%
J06 : IMMUNE SERA AND IMMUNOGLOBULINS	134.8	+7.9%	16.4%	10.8%
A16 : OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS	79.8	+17.7%	20.1%	6.4%
Other ATC class	118.0	+117.5	-0.4%	-0.8%
TOTAL	1 244.1	+5.1%	100.0%	100.0%

Expensive drug **Before marketing authorisation**

- Drugs can be used before marketing authorisation, temporary use authorisation (ATU)
- Should be asked to ANSM, French Drug and Medical Device agency
- Drug price is estimated by laboratories
- Drugs are paid according to a defined amount

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Links to French documents

○ HAS recommendations are available in English

http://www.has-sante.fr/portail/jcms/c_2035649/en/assessment-of-medicinal-products

○ National decree for the regulation of expensive drug list :

<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000032291186&categorieLien=id>

○ List of expensive drugs available on ATIH website :

<http://www.atih.sante.fr/unites-communes-de-dispensation-prises-en-charge-en-sus>

○ Annual statistics are available on ATIH website :

http://www.scansante.fr/applications/synthese-dmi-mo-sus/submit?rapport=/mco/mahos/dgf/mo_public.html

Thank you for your attention

**Agence technique de l'information
sur l'hospitalisation**

117, bd Marius Vivier Merle 69329 Lyon cedex 03

Téléphone : 04 37 91 33 10

Fax : 04 37 91 33 67

www.atih.sante.fr

diane.paillet@atih.sante.fr