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T.R.A.D.E. Hot Topics

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Distribution of pharmaceutical products: a changing environment?

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CARPMAELS & RANSFORD

Code of Ethics and Compliance

- codified law? soft law?
- mandatory?
- sanctions?
- growing in importance?
- effect on distribution of pharmaceuticals?

Code of Ethics and Compliance

French perspective - Overview

- Anti-gifts law
- Transparency regulations
- Chart on promotion of drugs
- Disparagement of competitors

Code of Ethics and Compliance

French perspective - Anti-gifts law

- It is forbidden for healthcare professionals to directly or indirectly receive benefits in kind or in cash from companies that manufacture or market reimbursed pharmaceutical products (article L4113-6 § 1 of the French Public Health Code).
- The law was amended by a decree of 19 January 2017 (fully in force by July 2018):
  - **Scope:** now covers health products whether or not reimbursed by the French national insurance.
  - **Not benefits:** Wages/fees of salaried employees and self-employed contractors, IP rights assignments, commercial benefits from commercial cooperation between businesses, negligible benefits in cash or in kind.
  - **Clear exceptions for:** Donations for exclusive R&D financing, financing of professional training or continuous professional development, accommodation during professional, scientific, or product promotion meetings (within reason).
- Penalty: Violations are **criminal offences**:
  - Receiving a benefit: 1 year's imprisonment and a maximum 75,000 EUR fine
  - Offering a benefit: 2 years' imprisonment and a maximum 150,000 EUR fine.

Code of Ethics and Compliance

French perspective - Transparency regulations

- Web site: "*base transparence santé*" (transparence.sante.gouv.fr).
- Companies manufacturing or marketing pharmaceuticals products must **declare on this web site all agreements / advantages entered into with / granted to** other healthcare professionals (mainly doctors, associations, foundations, professional associations, etc.) and state their purpose, date, and direct and end-beneficiaries.
- Since 26 January 2016: new obligation to declare the **amount of the convention** (vs. advantage).
- The information, **publicly available** since the first semester of 2012, covers all corporate bodies operating in France and individuals (healthcare professionals) registered in France.
- The deliberate refusal to publicly disclose an interest is a criminal offence:
  - Maximum 45,000 EUR criminal fine
  - Publication of the judgment
  - Possible ban on the manufacturing, importing, or marketing of pharmaceutical products.

Code of Ethics and Compliance

French perspective - Chart on promotion of drugs

• Negotiated between the French federation of pharmaceutical companies (LEEM) and the *Comité économique des produits de santé* (CEPS), the French committee in charge of fixing the price of reimbursed drugs (new charter in force since October 2014).

•**Broad scope:** Applies to any type of **promotional** action for pharmaceutical products (to the exclusion of the sale itself). Basically covers the **canvassing of doctors**. Does not apply to the activities of medical representatives (sales forces) selling to pharmacists.

•Charter includes **best practice guidelines**: Improved information quality, continuous professional learning for promotional teams, no sampling, compliance with the internal procedures of public hospitals, lunch/dinner invitation limited to normal work conditions.

•**Penalties:**

- No criminal penalties
- Unfair competition actions by competing pharmaceutical companies
- Cancellation of the canvassing authorization issued by the Haute Autorité de santé (HAS)
- Financial penalties imposed by the CEPS

Code of Ethics and Compliance

French perspective - Disparagement of competitors

- Sanofi-Aventis markets both a princeps brand-name drug (Plavix) and its generic (Clopidogerl Wintrop).
- A decision by the *Autorité de la concurrence* (ADLC) on 14 May 2013 found that Sanofi-Aventis had violated French and EU laws (abuse of dominant position) through a policy of disparagement of the Plavix generics. Financial penalties: 40 million EUR.
- Sanofi-Aventis had devised and implemented a global, systematic strategy of disparagement:
  - Same speech delivered by promotional teams to all doctors
  - Substitution of generics for brand-name drug prohibited according to promotional teams
  - Alleged risk due to a difference in composition (salts) between Plavix and generics
  - Alleged case of thrombosis after use of other generics
- Misleading effect of such a practice: "*Given how medical practitioners are averse to change and how healthcare professionals are averse to risk, just circulating negative information about or instilling doubt on the intrinsic properties of a drug can be enough for the latter to be immediately discredited in the eyes of medical practitioners and healthcare professionals*".

Code of Ethics and Compliance
UK perspective (I)

- Rooted in EU law
  - Directive 2001/84/EC, Directive 2004/27/EC (as amended) and implemented.
- Self-regulation
  - Ethics Code (known as the ABPI Code) is enforced by PCMPA – set up by ABPI - UK branch of EFPIA
  - Sanctions: Audit, public reprimand, expulsion from ABPI
  - Astellas' suspension from ABPI *(Case AUTH/2747/1/15)*

Code of Ethics and Compliance

UK perspective (II)

- Hot Topics
- Contractual restrictions on third parties

Anonymous v BMS AUTH/2879/10/16

- *Homecare representatives attended patient without an appointment.*
- *Possible breaches of Clauses 2, 9.1, 18.1 and 18.4 of the 2014 Code.*

Anonymous v AstraZeneca AUTH/2866/8/16

- *Training and consultancy delivered by a third party.*
- *Possible breaches of Clauses 2, 9.1, 18.1, 18.6, 21 and 23.1 of the 2016 Code.*

Code of Ethics and Compliance

Slovak perspective

- Mandatory reporting of marketing costs, financial and in-kind considerations to HCPs and HCOs by MAHs, wholesalers and “pharmaceutical companies“
- 19% withholding tax from financial and in-kind considerations from MAHs, wholesalers , manufacturers, pharmacies and “pharmaceutical companies“ to HCPs, HCOs and their employees
- Code of Ethics of the local industry association – disclosure of transfers of value mirroring EFPIA Disclosure Code

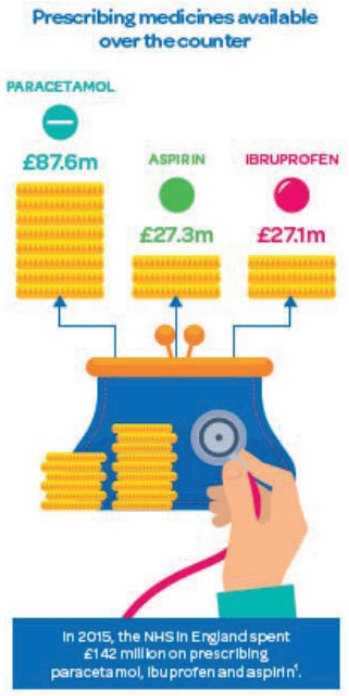
Costs and Reimbursement Cuts

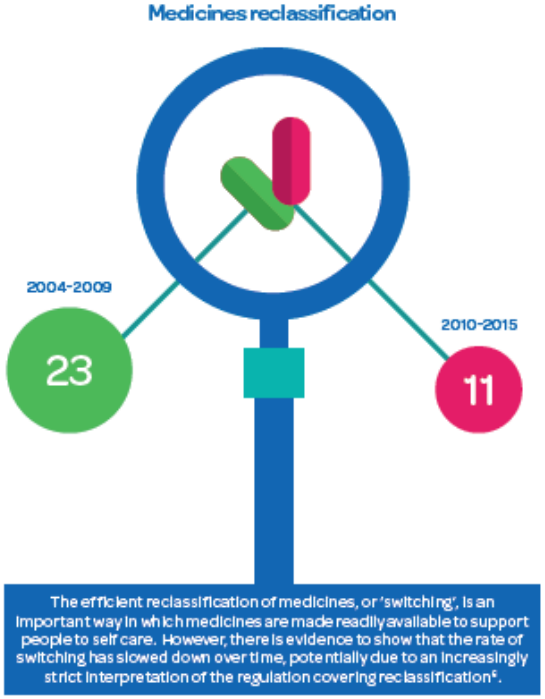
- trend to cut costs and/or reimbursement of healthcare costs?
- means to do so?
- influence on how pharmaceuticals are distributed?

Costs and Reimbursement Cuts

UK perspective (I)

Two areas for potential cost cuts in the NHS:





Illustrations taken from,

"Five examples of waste in the NHS",

publication created by PAGB and available from

https://www.pagb.co.uk/content/uploads/2016/06/Five-examples-of-waste-one-pager-.pdf

Costs and Reimbursement Cuts

UK perspective (II)

- Branded is always more expensive than generic, right?

*Flynn Pharma Ltd and Flynn Pharma (Holdings) Ltd v Competition and Markets Authority (*Case CE/9742-13*)*

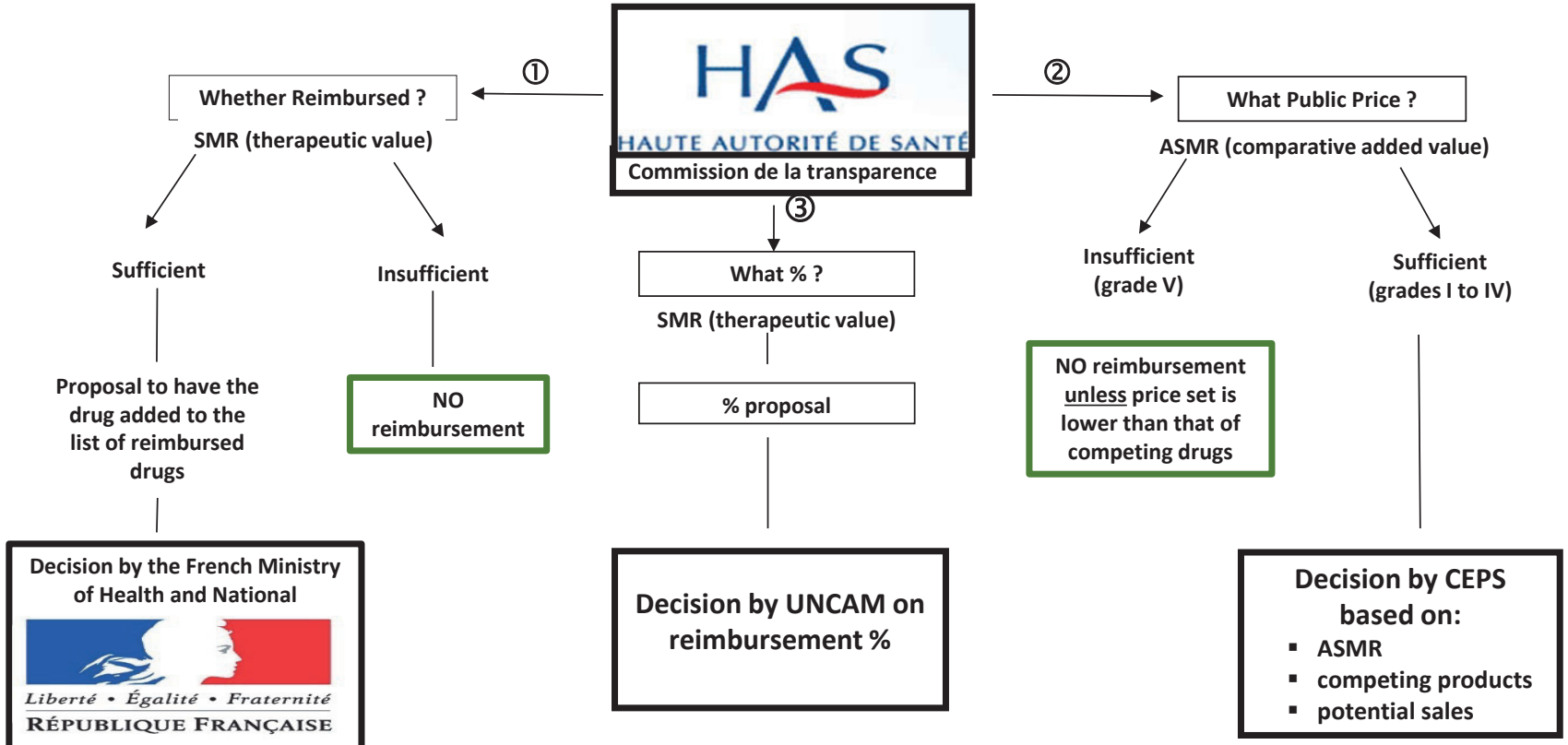
- 2012 - MA for phenytoin sodium transferred from Pfizer to Flynn
- Off-patent: majority of prescriptions were “open” (could be for any manufacturers’ product)
- Practical monopoly outside pricing regulation - tariff price based on manufacturer’s list price: pricing hike from £2m per year in 2012 to £50m in 2013
- Found to have abused their dominant position - £84.2m fine.

Costs and Reimbursement Cuts

Slovak perspective

- Amendment now in discussion, in force from 1 January 2018
- Products with overall reimbursement over EUR 1.5 M: maximum amount of reimbursement determined for 12 months
- New system of calculation of costs thresholds
- Cost / risk sharing agreements between MAHs and HICs
- Lower maximum prices for reimbursement of generics and biosimilars
- Exceptional reimbursement only below EU reference price; 5 % participation of HCPs from 1 January 2019

Costs and Reimbursement Cuts
French perspective



Availability, Distribution Channels and Generics

- problems with availability of pharmaceuticals?
- control of exports?
- parallel imports?
- new distribution channels, e.g. online sales?
- favourable legislation towards generics or rather the opposite?

Availability, Distribution Channels and Generics

Slovak perspective

- From 1 January 2017: reimbursed products may be exported only by the manufacturer, MAH, or a wholesaler based on a power of attorney from the MAH
- Restrictions on distribution channel:
  - MAHs to wholesaler only for the final supply to a pharmacy
  - Wholesaler to wholesaler only for the final supply to a pharmacy
  - Pharmacy to pharmacy only for the final dispensing to a patient
  - Back sales
- Mandatory emergency channels established by MAHs

Availability, Distribution Channels and Generics

French perspective – Online sales

- Freedom of trade (CJEU 11.12.2003 Doc. Morris) *v*. pharmaceutical activities monopoly.
- Transposition of the EU Directive of 08 June 2011 in France difficult. Last update by an Act (26 January 2016) and two decrees (28 November 2016).
- "**Click-and-mortar**" model: Web sites must be linked to a pharmacy with pharmacists.
- Online sales cover all **OTC drugs** but not prescription drugs.
- The **management of an e-commerce business is highly regulated**: Ex : Subcontracting and the purchase of Google key words are prohibited, the structure and functionalities of the web site are also heavily regulated.
- Compliance with EU rules of the technical constraints regarding the management of an e-commerce drugs web site subject to discussion.

Availability, Distribution Channels and Generics

French perspective – Discount policy princeps vs. generics

- **Discounts, rebates and other benefits** granted by suppliers to pharmacists shall not exceed:
  - for brand-name princeps drugs : up to 2.5 % of manufacturing price,
  - for generics : up to 40 % of manufacturing price.

  → Violations incur criminal penalties.

- **Duty to declare** to CEPS such discounts, rebates and other benefits:
  - ➢ Lack of declaration : financial fines by CEPS (up to 5 % of turnover).

Availability, Distribution Channels and Generics

UK perspective (I)

- Pricing controls on unbranded generics
  - Health Service Medical Supplies (Costs) Act 2017
- Equivalents
  - *Actavis UK Limited and others (Appellants) v Eli Lilly and Company (Respondent)* [2017] UKSC 48
  - Patent for a dosage regimen pemetrexed (marketed as Alimta) with vitamin B12
  - "*pemetrexed disodium*" vs Actavis' proposed generic - free acid or different salts
  - UK courts have historically not adopted a "doctrine of equivalents":
    - New test of infringement by "immaterial variation"
    - Actavis' proposed products satisfy new test ➔ infringe
  - UK more closely into line with other European courts (e.g. DE, IT & NL)
  - Expected to make it harder for generics to launch in the UK.

Availability, Distribution Channels and Generics

UK perspective (II)

Hot Topics – Brexit

- Industry recommendations:
  - Continued membership of customs union (or same access)
  - UK alignment to GMP and GDP
  - UK decisions and inspections recognised between EU and UK

Personalized Medicine

Open discussion

£6.8m genetic medicine plan for targeted treatment

By Owain Clarke
BBC Wales health correspondent

6 July 2017 | Wales | Share

"It's the ultimate personalised medicine, a model of your body for testing drugs."

Teresa Woodruff

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Health

'New era' of personalised cancer drugs, say doctors

By James Gallagher
Health editor, Chicago

4 June 2016 | Health Share

Thank you !

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