BELGIUM

Recent and planned developments in pharmaceutical policies 2017/2018

Special topic: patient involvement in pricing and reimbursement of medicines

CHANGES IN PRICING

01.01.2018

Ezetimibe: *€ 6.600.000*
price drop because of the transfer chapter IV (prior authorization) -> chapter I (prescription)

01.04.2018

Rosuvastatine: *€18.000.000*
Upon the arrival of the generics, prices are compared to their equivalent doses of atorvastatine. This results in an important price cut, for both generics and the original pharmaceuticals.

Biologicals: *€ 9.000.000*
Price cut of 15% instead of 10% (after 18 years of reimbursement of the molecule or earlier when a biosimilar is available)
When a biosimilar is available: price cut of 15% + remaining price cut(s) after 12 and 15 years of reimbursement of the molecule (simultaneously applied) = "biocliff"

CHANGES IN REIMBURSEMENT

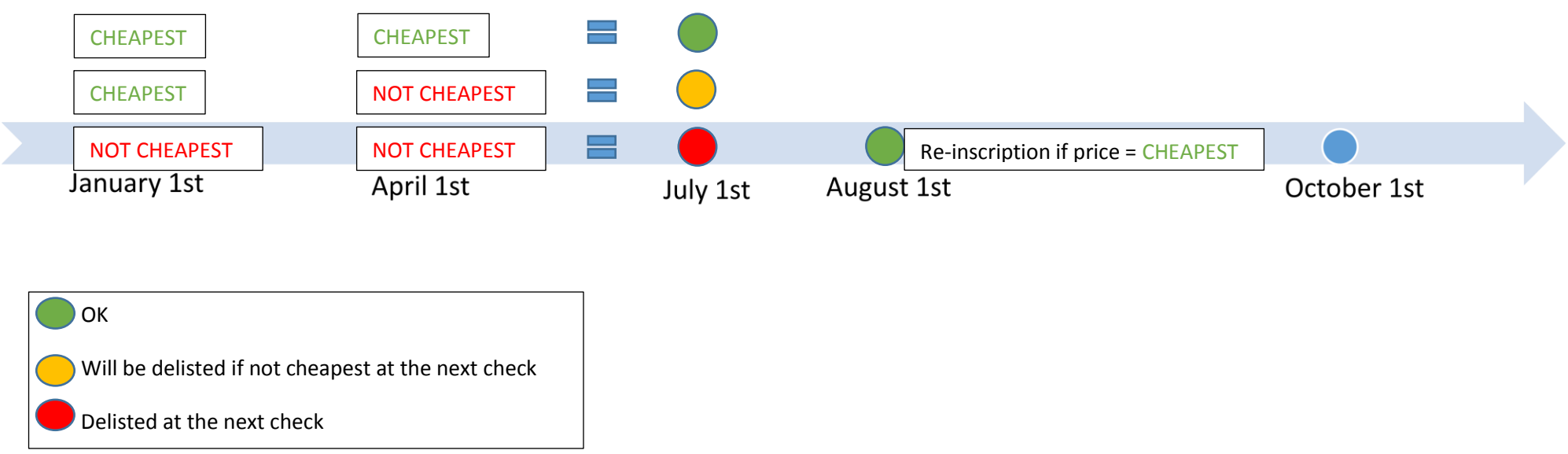
Cheap prescription and cheapest pharmaceuticals

01.01.2018

- Specialists have to make more 'cheap' prescriptions. Percentages of 'cheap' prescriptions are raised. (Average from 41 % to 56 %) **(€ 9.750.000)**

- When determining the "cheapest" products, packages are grouped within clusters of similar sizes: 28-30 units, 31-60 units, 61-90 units, 91-120 units. **(€ 18.600.000)**

01.04.2018: Introduction of the 'ceiling prices' measure
When the reference price system applies for more than two years, only the "cheapest" pharmaceuticals are reimbursed. This status is checked each trimester, and when a product is not 'cheapest' in 2 consecutive checks, it's delisted the next trimester. During the 3 preceding months, no voluntary price cuts are allowed. If the price is lowered to the level of the cheapest pharmaceuticals afterwards, the product will be reimbursed again.
(€ 38.000.000)



First application of the measure on April 1st: 65 pharmaceuticals delisted on 01.07.2018
Visible effects: A lot more price cuts than usual, but increase of the number of originators with aco-payment supplement, so the patient pays more in some cases.

Other:

- 01.01.2018: For products for which the reference price system applies, hospitals are reimbursed for only 90%, similar to the measure already in place for the biologicals with a reimbursed biosimilar and contrast agents. **(€ 22.500.000)**

- The measures 'OLD' and 'BIOLOGICAL' are applied 4 times a year instead of 2 times. They consist of price cuts after a certain number of years in the reimbursement (molecule level).**(€ 4.200.000)**

- 01.05.2018: Quinolones will be reimbursed in chapter IV (restriction regarding the reimbursed indications) instead of chapter I, to prevent inappropriate use.

OTHERS CHANGES

01.10.2017: New pharmaceutical care remuneration possibility: introduction of the concept of the "reference pharmacist", who will accompany and provide a follow-up of the medicinal treatment of chronic patients (convention between the pharmacist and the patient, €31/year/patient)
01.01.2018: The pharmacists fee is raised to 4,27 euros (was 4,20 euros).

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SPECIAL TOPIC: Patient Involvement in Pricing and Reimbursement of Medicines

Pricing and reimbursement procedures of medicines

Patients/citizens do not have the opportunity to raise their voice during medicines pricing and/or reimbursement procedures:

There is no direct representation of patients/citizens in the Reimbursement Committee.

They are only indirectly represented by the insurance bodies.

Related to HTA procedures

Patients/citizens do not have the opportunity to raise their voice during HTA procedures.

But:

- Activities and studies of the King Baudouin Foundation & the Belgian Health Care Knowledge Center (KCE) – in close consultation with the National Institute for Health and Disability Insurance (NIHDI)
  → **Unmet medical Need procedure - early temporary authorization/reimbursement (ETA/ETR)**
  →methodology in which the patient and the public have a place – principles are taken into account by the Reimbursement Committee

- **Commission for human medicines** (Federal Agency for medicines and health products – FAMHP):
  Patient representatives participate in an advisory capacity.

- The **Observatory for chronic diseases** (National Institute for Health and Disability Insurance – NIHDI):

Scientific department	Advisory department
Representatives of: • Universities (specialists) • Professional associations of prescribers, pharmacists, paramedical practitioners and nurses • Insurance bodies • Professional associations for residential care • Ministers of Social Affairs and Health	Representatives of: • Insurance bodies • **Organizations assisting the chronically ill → Patient organizations!** • Ministers of Social Affairs and Health
Role: Definition of the funding	Role: Evaluation of the needs

- **Consensus conference jury** (National Institute for Health and Disability Insurance – NIHDI):
  Patient organizations (2 persons) are involved in the jury who formulates recommendations of good practice for the general physicians.