

## FRANCE

<p style="text-align: center;"><b>High-cost medicines</b></p> <ul style="list-style-type: none"> <li>- No specific funding and reimbursement schemes for high-cost / innovative medicines for <u>out-patient</u>. Still price-volume agreements are common.</li> <li>- Regarding <u>in-patient</u>, there exists a supplementary list outside the DRGs system for high-cost / innovative medicines. Their official price is negotiated by the French price committee (CEPS, same committee as for out-patient) and are published in the Official Journal. This price represents the maximum amount of reimbursement. In case the purchasing price is below the maximum level of reimbursement, the difference is equally shared between the hospital and the National Health Fund.</li> </ul>	<p style="text-align: center;"><b>Generic policies</b></p> <ul style="list-style-type: none"> <li>- Generic substitution in place since 1999 on voluntary basis. Both doctor and patient may oppose generic substitution. However in that case, the patient will have to pay the price difference out-of-pocket. Generic substitution is promoted through: <ul style="list-style-type: none"> <li>- a financial incentive to pharmacists (higher margin);</li> <li>- an agreement between the UNCAM and the union of pharmacists to increase the rate of substitution;</li> <li>- the non-exemption of initial payment of the patient to the pharmacist (the system of direct payment by the health insurance fund to the pharmacist known as "tiers-payant" and applied in most situations)</li> </ul> </li> <li>- INN prescribing mandatory according to new law<sup>1</sup></li> <li>- No tendering-like practices in the out-patient sector</li> <li>- A generic group is defined for all molecules of the same Anatomic Therapeutic Chemical (ATC) classification level 5, with the same dosage and the same packaging.</li> <li>- The reference price system in France (known as TFR) was implemented in 2003. In 2010, 194 generic groups with about 95 molecules were under TFR among the 548 generic groups. The TFR market accounted for 17% of the generics market in value. Medicines included in a TFR group have the same level of reimbursement. The reimbursement limit called "tariff level" is often equal to the generic price and the reimbursement rate is often based on this tariff. If a product under this scheme is more expensive than the "tariff" (reference price), the patient must make up the difference.</li> <li>- As of January, 1<sup>st</sup> 2012, change in price decrease at patent expiry: <ul style="list-style-type: none"> <li>- brand : -20% instead of -15%</li> <li>- generic : -60% of brand ex-factory price instead of -55%</li> </ul> <p>Moreover, the -60% decrease of brand ex-factory price also applies to current generics on the market for statins, RASs and PPI</p> </li> <li>- Generics share in out-patient reimbursement market, 2010: <ul style="list-style-type: none"> <li>- volume = 25%</li> <li>- value = 14%</li> </ul> </li> </ul>
<p style="text-align: center;"><b>Changes in the pharmaceutical system – end 2011/2012</b></p> <ul style="list-style-type: none"> <li>- Price <ul style="list-style-type: none"> <li>- March 2012 : price cut statins, Proton Pump Inhibitor (PPI) and renin-angiotensin system (RAS) ...</li> <li>- Planned : clopidogrel, pharmaceuticals for alzheimer disease</li> </ul> </li> <li>- Reimbursement <ul style="list-style-type: none"> <li>- rate of 35% change to 30% applicable as of 2 may 2011</li> <li>- de-listing : VASODILATORS and insufficient SMRs (SMRi) including Multaq, Vastarel</li> </ul> </li> <li>- Change in wholesale margin, applicable 1 January 2012 : if ex-factory price lower than 450€ = maximum of (6,68% and 0,3€), 0€ over 450€</li> <li>- Change in the VAT rate from 5.5 to 7% for non-reimbursable medicines enter into force on 1 January 2012</li> <li>- Reference price systems <ul style="list-style-type: none"> <li>- New TFR : march 2012 (eg : RSAs)</li> <li>- Change in substitution thresholds for TFR decision</li> </ul> </li> <li>- Generics : as of January, 1<sup>st</sup> 2012, change in price decrease at patent expiry: <ul style="list-style-type: none"> <li>- brand : -20% instead of -15%</li> <li>- generic : -60% of brand ex-factory price instead of -55%</li> </ul> <p>Moreover, the -60% decrease of brand ex-factory price also applies to current generics on the market for statins, RASs and PPI</p> </li> </ul>	<p style="text-align: center;"><b>Evaluations and studies on pharmaceutical policies</b></p> <p><b>Expenditures of reimbursable pharmaceuticals in 2010 and cost of generics</b></p> <ul style="list-style-type: none"> <li>- CNAMTS press release 29 september 2011</li> </ul> <p><b>Comparisons of consumption of pharmaceuticals for 8 classes in Europe : 2010 update</b></p> <ul style="list-style-type: none"> <li>- CNAMTS press release 10 mars 2011</li> </ul> <p><b>Comparisons of consumption of pharmaceuticals for 8 classes in Europe</b></p> <ul style="list-style-type: none"> <li>- " Points de repères" number 12 december 2007, CNAMTS</li> <li>- Aim: Comparison of prices and volumes in Europe for 8 therapeutic classes. Consumption in volumes (packs, standard unit) and expenditures (excluding distribution margin and VAT) for 8 main out-patient therapeutic classes including antibiotics, diabetics, proton pump inhibitors, statins</li> </ul> <p><b>Expenditures of reimbursable pharmaceuticals dispensed by community pharmacists : 2009 update</b></p> <ul style="list-style-type: none"> <li>- Published in " Points de repères" number 34 december 2010</li> <li>- Aim : Expenditures of reimbursed medicines dispensed by community pharmacies in 2009</li> </ul> <p><b>Reimbursed health expenditure of people treated for diabetes: 2001 and 2007 Entred studies</b></p> <ul style="list-style-type: none"> <li>- Pratiques et Organisation des Soins volume 41 n° 1 / jan.- march 2010</li> </ul>

<sup>1</sup> LOI n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé