BACKGROUND
• Conflicts of interest, defined as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest”, have been at the heart of the debates on Mediator saga. Indeed, the slow reaction of French authorities to the Mediator saga in 2009 led to accusations of conflicts of interest among healthcare experts and politicians, and questioned the way conflicts of interest were reported.
• As a consequence a new law related to the “Strengthening of Health Protection for Medicinal and Health Products”, Law no. 2011-2012 also known as the Bertrand Law (Loi Bertrand) or French Sunshine Act, was established in order to set new transparency procedures for companies producing or marketing health and cosmetic products intended for human usage or providing services associated with such products.
• Despite the fact that specific requirements on conflicts of interest already existed within the French National Health Agency (Agence Nationale de Sécurité du Médicament et des Produits de Santé; ANSM), including 17 categories of products, such as pharmaceuticals, medical devices, diagnostics, cosmetics, contact lenses or tattoos.

OBJECTIVES
• Review and get a better understanding of the Bertrand Law
• Report and analyse case law from the French COS related to conflicts of interest in French Health Technology Assessment (HTA) recommendations.

METHODS
• Literature review and analysis of recent laws and decrees were conducted to understand French policy in the field of conflict of interest.
• A review of COS’ decisions related to conflicts of interest among members of HAS was performed.

RESULTS
Review the Bertrand Law
• The Law no. 2011-2012 or Bertrand Law was adopted in December 2011 but entered into force only in May 2013 following intense debates among health professionals.
• The Decree no. 2013-414 implementing the Bertrand Law specifies the scope of disclosure obligations, encompassing all agreements concluded between health care professionals and companies, as well as all financial benefits in kind or in cash representing or exceeding €10.

Table 1. Cases ruled by the French COS against HAS

<table>
<thead>
<tr>
<th>Request date</th>
<th>ruling date</th>
<th>Claimant</th>
<th>Subject</th>
<th>Arguments</th>
<th>Decision</th>
<th>Follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>15/02/2006</td>
<td>12/02/2007</td>
<td>Pharmaceutical companies (Top Pharm, Levjac, Medisulm, Feria)</td>
<td>Removal of Aliskiren and Mergazolise from the reimbursed list</td>
<td>Negative conflict of interest for one member of TC* (financial interests within a competitor)</td>
<td>Insulation of the decree and fine of €1,000 payable to the State to each company</td>
<td>✓</td>
</tr>
<tr>
<td>08/11/2011</td>
<td>01/12/2011</td>
<td>Pharmaceutical company (Jelly Jell)</td>
<td>Removal of Alphosporin from the reimbursed list</td>
<td>• Indirect conflict of interest: some members of TC* had interests in competing. • Requirement of urgency: risk of substitution by therapeutic classes leading to public health risks and higher costs and financial risk for the company as the drug represents 50% of its annual turnover</td>
<td>Suspension of the decree</td>
<td>✓</td>
</tr>
<tr>
<td>07/12/2009</td>
<td>27/04/2011</td>
<td>Association of physicians (Fondation)</td>
<td>Publication of guidelines on type 2 Diabetes</td>
<td>4 conflict of interest declarations were not available</td>
<td>Abrogation of the guidelines and fine of €8,000</td>
<td>✓</td>
</tr>
<tr>
<td>07/12/2009</td>
<td>22/02/2012</td>
<td>Manufacturers of hypoglycemic drugs</td>
<td>Decision to forbid use of liposynthesis techniques for aesthetic purposes</td>
<td>• Some declarations of interest of TC* members were not available. • Conflict of interest of one member of the TC*</td>
<td>Request rejected as the HAS provided these documents when required by legal authorities and as there was no proven conflict of interest</td>
<td>✓</td>
</tr>
<tr>
<td>19/05/2011</td>
<td>05/09/2012</td>
<td>Pharmaceutical company (Therabe Lucien)</td>
<td>Removal of Darinax from the reimbursed list</td>
<td>• Conflict of interest of one member of TC* • Requirement of urgency: financial risk for the company as this drug represents a significant proportion of its annual turnover in the company is in deficit</td>
<td>Suspension of the decree and fine of €6,000</td>
<td>✓</td>
</tr>
<tr>
<td>16/08/2012</td>
<td>13/11/2013</td>
<td>Pharmaceutical company (Novartis)</td>
<td>Refusal to add Ezetab Hydrochlorothiazide on the reimbursed list</td>
<td>• Conflict of interest of one member of TC* • Two declarations of interest of TC* members were not available</td>
<td>Request rejected as the HAS provided these documents when required by legal authorities and as there was no proven conflict of interest</td>
<td>✓</td>
</tr>
</tbody>
</table>

* TC: Transparency Committee, a commission of the HAS
1 SMR: Service Medical Rentals/Actual Benefit, set by the TC and is a critical criterion for the decision of Health Ministry on level on reimbursement
✓ Suspension or insulation of decisions based on HAS recommendations due to conflicts of interest
✓ Request rejected

REFERENCES

CONCLUSIONS
It is surprising that ex-post filling of declaration of interest is considered by the Council of State as fair. The strengthening of the regulation on declarations of interest might lead to more transparency, although already criticized (Formindip already filled two requests with the COS), but also more cases ruled by the COS.