

## **BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION**

### **DISTILBENE** (diethylstilbestrol), hormones

**No clinical benefit demonstrated by comparison with comparators in the treatment of prostate cancer.**

#### **Main points**

- ▶ DISTILBENE has a Marketing Authorisation in the treatment of prostate cancer.
- ▶ No new clinical study has been conducted by the company.
- ▶ The ANSM has identified a risk of severe cardiovascular and thromboembolic effects, even taking preventive anticoagulant treatment. There are no evidences between DISTILBENE and hepatobiliary adverse effects.
- ▶ There is a potential benefit in a limited number of very weak or very old patients (without cardiovascular contraindication) who can no longer be treated by chemotherapy and who still develop the prostate cancer despite of complete adrenergic blockade. The absence of clinical efficacy data and a poor safety profile show that this clinical benefit is low in the prostate cancer treatment.

#### **Therapeutic use**

- In metastatic stages of the disease, LHRH agonist or antagonist hormone therapy is the standard 1<sup>st</sup> line treatment. Its early or secondary establishment must be discussed, as well as its continuing or intermittent nature. The benefit of a local treatment (radiotherapy or surgery) must be considered case-by-case, based on tumour volume, lymph node involvement, the patient age and associated multiple diseases.
- In the context of 1<sup>st</sup> line systemic treatment of metastatic castration-resistant prostate cancer, the following treatments are recommended: enzalutamide; abiraterone acetate; docetaxel; radium-223 (for symptomatic bone metastases without known visceral metastasis).
- **Role of the medicinal product in the therapeutic strategy**  
DISTILBENE can be used in very weak or very old patients without cardiovascular contraindications, who can no longer be treated by chemotherapy and who still develop the prostate cancer despite of complete adrenergic blockade and after taking anti-androgens for hormone-resistant cancers (abiraterone and enzalutamide).

#### **Benefit of the medicinal product**

- The actual benefit\* of DISTILBENE remains low.
- DISTILBENE does not provides any clinical added value\*\* (CAV V) in the management of prostate cancer.
- The Committee recommends the inclusion of this product on the list of reimbursable products for supply by pharmacists and for hospital use.



HAUTE AUTORITÉ DE SANTÉ

This document was created on the basis of the Transparency Committee Opinion of 20 April 2016 (CT-14921) available at [www.has-sante.fr](http://www.has-sante.fr)

\* The actual clinical benefit (ACB) of a medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. HAS Transparency Committee assesses the ACB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

\*\* The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV (equivalent of "no CAV") means "no clinical added value".