SCIENTIFIC ADVICE COMPENSATION

Compensation for the national scientific advice activity is proportionate to its complexity and to the combination of the questions the Company puts forward (quality and/or safety and/or clinical). In addition, the compensation is subject to the consideration that the SA is a first request or a follow-up advice.

Compensations for the national scientific advice activity are fixed in the amount of 50% (fifty) compared to those applied by the EMA. Starting on June 24th 2014 the compensations are the following:

Starting request

Level III compensation

€ 41.200 for multidisciplinary questionings on**:**

- Quality, and clinical and safety development, or
- Quality and clinical development, or
- Safety and clinical development.

Level II compensation

€ 30.900 for questionings about:

- Clinical development, or
- Quality and safety development, or
- Quality and bioequivalence studies for generic medicinal products

Level I compensation

€ 20.550 for questionings about**:**

- Quality development, or
- Safety development, or
- Bioequivalence studies for generic medicinal products.

Follow – up Scientific Advice

Level III compensation

€ 20.550 for the follow up about**:**

- Quality, safety and clinical development, or
- Quality and clinical, or
- Safety and clinical development.

Level II compensation

€ 15.450 for the follow – up about:

- Clinical development, or
- Quality and safety development, or
- Quality and bioequivalence studies for generic medicinal products.

Level I compensation

€ 10.300 for the follow – up about:

- Quality development, or
- Safety development, or
- Bioequivalence studies for generic medicinal products.

HTA Scientific Advice

- EMA/HTA parallel Scientific Advice: € 10.300
- Purely national HTA Scientific Advice: € 15.450

GMP Scientific Advice

- GMP Scientific Advice, starting request: € 20.550
- GMP Scientific Advice, follow-up: € 10.300

REDUCTIONS

In case the Company shows proof of its status of small and medium-sized enterprises (SMEs) according to the Decree no. 53 of 29 March 2012, art 4, paragraph 6, a 25% reduction of compensations is applied. The same reduction is applied in case of requests from public institutions.

A 50% reduction of compensation is applied for:

- Orphan medicinal products
- Advanced-therapy medicinal products