

## **Concept Paper submitted for public Consultation**

Opinions of the National Organisation for Medicines(EOF), Greece

Consultation item 1.

- *We are in agreement*

Consultation item 2.

- *We are in agreement*

Consultation item 3.

- *We are in agreement*

Consultation item 4.

- *In our opinion the catalogue is complete*

Consultation item 5.

- *We agree to only include the aspects under a) in the scope of the CAP.*

Consultation item 6.

- *The matter could be referred to the Commissions or the Agency for a decisions at EU level.*

Consultation item 7.

- *CAP is mandatory for all multinational clinical trials.*

Consultation item 8.

- *We believe that a pre-assessment is workable in practice, however it will have to be done in a harmonised manner.*

Consultation item 9.

- *We are in agreement*

Consultation item 10.

- *We are in agreement*

Consultation item 11.

- *We are in agreement*

Consultation item 12.

- *We find the key aspects are already covered*

Consultation item 13.

- *We are in agreement*

Consultation item 14.

- *Insurance requirement should not be removed*
- *There should be no burden on national budgets(all costs should be covered by the sponsor)*

Consultation item 15.

- *There should only be a single sponsor*

Consultation items 16 and 17. *We are in agreement*