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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - comments from the Polish delegation

Delegations will find attached comments from the Polish delegation on EMA fees proposal.

COMMENTS FROM POLAND

ANNEX I
Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

1. Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004

1.1. A fee of EUR 55 200 shall apply to any of the ~~following~~ initial requests referring to:

(a) a request on quality, non-clinical and clinical development;

(b) a request on quality and clinical development;

(c) a request on non-clinical and clinical development;

(d) a request on qualification of novel methodologies

The remuneration for assessment of each of initial request shall be EUR 10 400 for each of the two scientific advice co-ordinators.

A fee of EUR […] shall apply to any of the ~~following~~ follow-up requests referring to:

(a) a request on quality, non-clinical and clinical development;

(b) a request on quality and clinical development;

(c) a request on non-clinical and clinical development;

(d) a request on qualification of novel methodologies

The remuneration for assessment of each of follow-up request shall be EUR […] for each of the two scientific advice co-ordinators.

1.2. A fee of EUR 44 700 shall apply to any of the ~~following~~ initial requests referring to:

(a) a request on clinical development;

(b) a request on quality and non-clinical development;

(c) a request on quality and bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b) of Directive 2001/83/EC.

The remuneration for assessment of each of initial request shall be EUR 6 500 for each of the two scientific advice co-ordinators.

A fee of EUR […] shall apply to any of the ~~following~~ follow-up requests referring to:

(a) a request on clinical development;

(b) a request on quality and non-clinical development;

(c) a request on quality and bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b) of Directive 2001/83/EC.

The remuneration for assessment of each of follow-up request shall be EUR […] for each of the two scientific advice co-ordinators.

1.3. A fee of EUR 37 200 shall apply to any of ~~following~~ initial requests referring to:

(a) a request on quality development;

(b) a request on non-clinical development;

(c) a request on bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b), of Directive 2001/83/EC.

The remuneration for assessment of each of initial request shall be EUR 5 300 for each of the two scientific advice co-ordinators.

A fee of EUR […] shall apply to any of ~~following~~ follow-up requests referring to:

(a) a request on quality development;

(b) a request on non-clinical development;

(c) a request on bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b), of Directive 2001/83/EC.

The remuneration for assessment of each of follow-up request shall be EUR […] for each of the two scientific advice co-ordinators.

<u>Rationale:</u> Following the Commission explanations presented during the working party meetings we believe it should be clarified in the text that both initial and follow-up requests concerning the scientific advice procedures mentioned in point 1 Scientific advice provided by the Agency in accordance with Article 57(1)(n) of Regulation (EC) No 726/2004 are covered by the designated fee.

The change in the writing method is to reflect that remuneration for each of the two scientific advice co-ordinators shall be for each of the initial and each of the follow-up request

We do not agree with the remuneration of scientific advice co-ordinators proposed in the proposal. We believe that the remuneration should be differentiated depending if it concerns:

a) a request on quality, non-clinical and clinical development;
b) a request on quality and clinical development;
c) a request on qualification of novel methodologies
d) a request on non-clinical and clinical development;
e) a request on clinical development;
f) a request on quality and non-clinical development;
g) a request on quality and bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b) of Directive 2001/83/EC.
h) a request on quality development;
i) a request on non-clinical development;
j) a request on bioequivalence studies for generic medicinal products as defined in Article 10(2), point (b), of Directive 2001/83/EC

In our opinion the amount of remuneration should be adapted to the current level of transfers to the national competent authorities acting for the benefit of European Medicines Agency for assessment of scientific advice carried out by national European experts

In our opinion the amount of fee for the follow-up requests should be adapted to the current percentage level of fee for the follow-up requests