15 September 2012

Malta's Feedback on the Concept Paper on the Introduction of fees to be charged by the European Medicines Agency for new pharmacovigilance activities

Malta is concerned that the fees being proposed by the Commission could impact the availability of medicinal products on the Maltese market since many Maltese Marketing Authorisation Holders (manufacturers) (MAH) and Authorisation Holders will be affected by these new fees as their products will need to be included in Periodic Safety Update Report (PSUR) Assessments as well as registered in the new EU database (at a cost).

When their products are included in Periodic Safety Update Report Assessments, there will be an administrative fee of €500 payable to the European Medicines Agency (EMA), while for registration in the EU database, it is proposed that an annual fee of €1,000 per product per company held within the EU database will be paid solely to the EMA.

Malta's general position on consultation document Ares(2012)723154 is the following:

- Administrative fees for Periodic Safety Update Report assessments should be lowered and those for medicinal products authorised in line with Article 126a of Directive 2001/83 as amended should be waived since these products are authorised on public health needs.
- With respect to the Pharmacovigilance service charge fee (for maintenance of medicinal products on the EU database), Malta
    - suggests that the fee is lowered;
    - requests a waiver for Article 126a authorised products authorised on public health grounds;
    - and to obtain 50% of the fee if the EMA asks Malta to check and verify the documentation in the database with respect to authorised products in Malta.

Concerning the questions in the concept paper, Malta's position is the following:

Consultation item n°1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.

The proposed administrative fee of €500 for each additional MAH in the grouping is expected to impact negatively on the availability of medicinal products on small markets. For the Maltese market, the administrative fee of €500 for each MAH (to be kept by the EMA) being involved in a PSUR assessment is financially over burdensome and will affect MAH's decisions to keep marketing the product in Malta. The proposal for grouping in principle could be acceptable to Malta.

It is proposed to waiver the administrative fee for small markets due to public health availability concerns.

Furthermore, medicinal products authorised by Member States under Article 126a of Directive 2001/83/EC should be exempt from paying this administrative fee since the medicinal product is already authorised in another EU Member State.

Consultation item n°2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

Kindly refer to the reply to Consultation item 1.

Consultation item n°3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative.

Kindly refer to the reply to Consultation item 1.

Consultation item n°4: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

Kindly refer to the reply to Consultation item 1.

Consultation item n°5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals? If not, please explain and/or suggest alternative.

The proposed administrative fee of €500 for each additional MAH in the grouping is expected to impact negatively on the availability of medicinal products on small markets. For the Maltese market, the administrative fee of €500 for each MAH (to be kept by the EMA) being involved in a PSUR assessment is financially over burdensome and will affect MAH's decisions to keep marketing the product in Malta. The proposal for grouping in principle could be acceptable to Malta.

It is proposed to waiver the administrative fee for small markets due to public health availability concerns.

Furthermore, medicinal products authorised by Member States under Article 126a of Directive 2001/83/EC should be exempt from paying this administrative fee since the medicinal product is already authorised in another EU Member State.

For Article 31 referral, there is the possibility of a re-examination procedure. The Commission has not proposed a fee for this process and payments that should be made to the PRAC rapporteurs.

Consultation item n°6: Do you agree with the concept of grouping as proposed? If not, please explain and/or suggest alternative.

Kindly refer to the reply to Consultation item 5.

Consultation item n°7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

The pharmacovigilance service fee to be retained by the EMA of €1,000 for active substance per group of products per each MAH is expected to severely and grossly impact in a negative manner the availability of medicinal products on small markets especially on those products authorised via Article 126a of Directive 2001/83/EC. This financially-over burdensome fee will affect MAH's decisions to keep marketing the product in Malta.

Understanding the complexity of the system in EVMPD transmission, there is a possibility that the EMA will request Member States to check the data submitted by MAHs on products on the Member States' markets. This is because the EMA has no means in verifying the data such as what indications are authorised in the Member State since the data is held at a Member State level. Therefore, it is imperative that the provisions relating to pharmacovigilance service fee are legally qualified to include payment to the Member States at a 50% fee for the massive administrative task ahead.

Furthermore, medicinal products authorised by Member States under Article 126a of Directive 2001/83/EC should be exempt from paying this administrative fee since the medicinal product is already authorised in another EU Member State.