Manx Healthcare Ltd. (UK)

From: Jane Moore <Jane.Moore@manxhealthcare.com>
Sent: 14 September 2012 14:37
To: SANCO FEES PHARMACOVIGILANCE
Subject: PC/12/05 - Public Consultation on pharmacovigilance fees

Importance: High

Please find below our responses to the consultation points raise in the 'Introduction of fees to be charged by the EMA for pharmacovigilance' (Ref Ares(2012)723154-18/06/2012):

Consultation item no 1: Do you agree with the proposed fee for single assessment of PSURs? If not, please explain and/or suggest alternative.

No, we do not agree with the proposed fee for single (API) assessment of PSURs.

The consultation document states that '… In line with the benching marking approach, it is proposed to charge (a basic) fee of maximum 80,300 Euros for each assessment of a PSUR. This maximum amount is equal to the current fee for a Type II variation, ……..'

The current UK (MHRA) fee for a national type II variation is £794.00
The current UK (MHRA) fee for a RMS/or Reference Authority for work sharing type II variation is £962.00

For companies with only national MAs, the maximum fee of 80,300 Euros (equivalent to approx £64,000.00) for a single PSUR for a product authorised over 2 years, will be a rate limiting factor and business prohibitive. In the UK, an MAH is already required to pay an annual fee for each granted MA dependent upon sales.
Effectively companies will be required to pay a fee twice over, once to their CA and a much larger fee to the EMA.

The EMA may be performing literature searches, however this does not allow the MAH to stop their own weekly literature searches including evaluation and reporting as currently required, as such there is no cost saving to the MAH.

Consultation item no 2: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

The concept of grouping with regards to a single PSUR with different MAHs will be extremely difficult, if not impossible in practice.
MAHs (companies) which would normally have no correspondence would be required to exchange specific product and commercial information as required in a PSUR, additionally this would all have to take place in a relatively short timeframe to ensure the PSUR was submitted within the specified timeframe and would also require review and approval/sign off by all the QPPVs for the MAHs.
This is practice would be impossible to arrange and manage.

Consultation item no 3: Do you agree with the proposed fee for the assessment of PASSes? If not, please explain and/or suggest alternative.

No we do not agree with the proposed fee of 80,300 Euros for the assessment of a post-authorisation safety study.

The consultation document again states that the proposed fee is equal to the current fee for a type II variation.
Please see comment for item no 1.

This is disproportionate, a small company that owns a licence that attracts this fee and it is only one of a few licences held then they will be paying a disproportionate amount compared to a larger company with many licences, of which others may not attract such fee.

Consultation item no 4: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

The concept of grouping to perform a joint PASS by more than one MAH in practice is not a valid option. The likelihood of two or more MAHs wanting to perform a PASS for the same product at the same time is highly unlikely, therefore the proposed fee would be for each PASS.

Generic products and its market place are highly competitive and therefore the sharing of any information is unlikely.

Consultation item no 5: Do you agree with the proposed fee for the assessment of pharmacovigilance referrals? If not, please explain and/or suggest alternative.

We do not agree with the proposed fee range of 80,300 Euros to a maximum of 267,400 Euros depending upon the workload involved for assessment of pharmacovigilance referrals.
We understand that the maximum fee is equal to the current fee for an initial MA application in the centralised procedure; however for companies with only national MAs, the introduction of even the minimum fee of 80,300 Euros is considerably more than would be paid now.

Consultation item no 6: Do you consider relevant the concept of grouping as proposed? If not, please explain and/or suggest alternative.

The option of grouping could work for a product which has different MAHs in different MSs, which are linked by the parent MA; and as such may offer a saving to individual MAHs with regards to the fee, assuming however that sufficient MAHs are involved to also cover the extra 500 Euro fee per MAH.

For different MAHs with MAs for a single active substance or combination of substances, which are not linked by a parent MA, then grouping is not a realistic option. The sharing of information will be difficult in the current climate, when the generics market is highly competitive; also the providing of common answers/clarifications, which must be agreed between a number of QPPvs whom have not previously worked together.

Consultation item no 7: Do you agree with the proposed pharmacovigilance service fee? If not, please explain and/or suggest alternative.

No, as a company which only hold national MAs, we do not agree with the proposed pharmacovigilance service fee of 1,000 Euros/year/product (same API).

Essentially this fee is acting as a retainer for each MA granted in the EU payable to the EMA, irrespective of whether the MA is granted by the national, MR, DCP or centralised route and whether the product is commercialised. In the UK, for example, the MHRA already charge an annual service fee per UK granted MA dependent upon sales; as such a UK MAH with national MAs, would be required to pay two sets of annual fees; one set to the MHRA – the CA for the MAs and one set of fees to the EMA essentially for nothing.

The consultation document declares that 30% of the proposed fee is foreseen for EMA pharmacovigilance and inspection staff costs.
The rationale behind the remaining 70% of the proposed fee is for the EV database and general activities.

For a company holding only national MAs, the pharmacovigilance service fee offers no benefit to the MAH.
The EMA may perform literature searches; however we are still required to perform our own weekly literature searches, including evaluation and reporting where necessary. As such the EMA literature searches will not decreased our workload or costs.
As a national MAH only, we would also not receive any potential AE reports, as a national MAH only.

An alternative option, would be to charge companies based upon the proportion of usage of the EMA pharmacovigilance system.
So companies with national only MAs would be charged either no fee or a token fee compared to MAHs with licences obtained via MRP, DCP and/or centralised routes.

Consultation item no 8: Do you agree with the proposed approach for fee reductions for SMEs as regards the pharmacovigilance procedures at EU level (point 3.5.1)? If not, please explain why and provide suggestions how this could be improved.

This will depend on if the calculation for qualification for an SME is on a company or a group basis. If on a group basis, human medicines
may only be a minority of the group turnover. The calculation for SME reductions should only be based on turnover and/or balance sheet value for that part of the business involved in human medicine sales and marketing. In short the fee structure should be calculated using turnover of human medicinal products for which they have an MA and not overall size of company.

The approach of a 50% reduction in fees for SMEs relating to PSUR assessment, PASS assessment and the Pharmacovigilance service fee is a step in the right direction; however 50% of the maximum PSUR assessment fee represents a substantial increase on current costs.

Consultation item no 9: Do you agree with the proposed approach with regard to the pharmacovigilance service fee for SMEs (point 3.5.2)?

The approach of a reduction in fees for SMEs relating to the Pharmacovigilance service fee is a step in the right direction; however the proportion of the reduction is not stated and any fee represents a substantial increase on current costs.

The EMA may be performing literature searches, however this does not allow the MAH to stop their own weekly literature searches including evaluation and reporting as currently required, as such there is no cost saving to the MAH.

Consultation item no 10: What other aspects would you like to raise? Do you have additional comments?

MAs are applied for in a climate of known, on going cost. Throughout the lifecycle of a MA work is undertaken, at a cost to the company, again with the company making a long term valuation of the potential benefit of the MA to the company. Often a 10 year view will be taken as to maintain/apply for a licence. We have been given relatively short notice of this fundamental change together with the overall impression that the overall cost and obligations for companies for pharmacovigilance would reduce.
Actually the opposite has happened. We would further question if it would be possible for companies to secure reimbursement for cost and fees as licences it now wishes to cancel due to the substantial increase in costs, that is has incurred over the last 5 years.
It is unclear how these fees have actually been calculated – please can this information be provided. Whilst maximum fee figures have been given at no stage has the expected average figure been suggested, therefore making the consultation difficult to accurately respond to.

On behalf of
Manx Healthcare Ltd