Sehr geehrte Damen und Herren,

zu folgenden Thema möchten wir Sie gern informieren:

Sollten Sie rund um dieses Thema Unterstützung benötigen oder weitere Fragen haben, stehen wir gern zur Verfügung.

1. PHARMAKOVIGILANZ-GEBÜHREN DURCH DIE EMA

Ab 01.07.2015 werden seitens der EMA Pharmakovigilanz-Gebühren erhoben. Basis für die Kalkulation der Jahresgebühr für jeden pharmazeutischen Unternehmer sind die in XEVMPD eingepflegten Daten, d.h. wenn die Mitteilung über die Gebühren (elektronisch in Form einer ‚Advice Note') eintrifft, sollte dieser zunächst sorgfältig geprüft werden. Von der QPPV wird erwartet, die Inhalte der Mitteilung zu prüfen, und ggf. bei fehlerhaften Angaben entsprechende Änderungen in der XEVMPD-Datenbank vorzunehmen.

Zusammenfassend heißt das, dass pro Arzneimittel eine Jahresgebühr von etwa 67 € erhoben wird. Je nachdem, ob der jeweilige Zulassungsinhaber SME-Status hat oder aufgrund der Einordnung der einzelnen Arzneimittel in „generic", „well-established" o.ä. gibt es eine entsprechende Reduktion der zu zahlenden Jahresgebühr.

Die Zustellung der Rechnung wird elektronisch über ein Webportal erfolgen, welches momentan entwickelt wird (über das Portal soll es dann ebenfalls möglich sein, mit der EMA mögliche Fragen zu klären, und schließlich die Rechnung zu begleichen). Die EMA wird entsprechende Trainings anbieten und zudem ein Youtube-Video zum Umgang mit dem Portal publiziert.

Wir haben Ihnen hier die Informationen der EMA zusammengestellt und verweisen insbesondere auf die „explanatory note" der EMA, die unter folgendem Link abrufbar ist:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/03/WC500183456.pdf

Pharmacovigilance fees – Information for companies on fees for safety monitoring of medicines

EMA document explains how fees are calculated and collected

The European Medicines Agency (EMA) has published an explanatory note on the fees payable to the Agency for its monitoring of the safety of medicines authorised in the European Union (EU). The document describes types of fees, fee exemptions and explains how the Agency charges and collects fees from marketing-authorisation holders of medicinal products for human use.

In August 2014, EMA started charging fees for pharmacovigilance procedures, including the assessment of periodic safety update reports, and the assessment of post-authorisation-safety-

study (PASS) protocols and study results, and for pharmacovigilance-related referrals. These fees are charged to companies whose medicines, whether centrally or nationally authorised, are included in these procedures.

From 1 July 2015 and annually thereafter, the Agency will charge and collect annual fees for nationally authorised medicines. Annual fees related to centrally authorised products are covered by the Regulation No 297/95 for centrally authorised products.

In addition to the explanatory note published today, the Agency will provide companies with the opportunity to review the information on their medicines held by EMA on which annual fees are calculated. **The qualified person for pharmacovigilance will be supplied with an 'advice note' which will contain the line listing of their chargeable units in April 2015.**

The European Medicines Agency (EMA) charges and collects fees from pharmaceutical companies for carrying out pharmacovigilance activities.

The adoption of Regulation (EU) No 658/2014 enables the EMA to collect fees to cover the costs for the conduct of pharmacovigilance activities as assigned to it by the 2010 Pharmacovigilance Legislation that became applicable in July 2012. Consequently, marketing authorisation holders of medicinal products for human use will be levied a fee for the conduct of pharmacovigilance activities by the Agency. These activities include the scientific assessment performed by rapporteurs in the framework of Union-wide pharmacovigilance procedures; the monitoring of literature cases and the improved use of information technology tools.

The Agency charges two types of fees for pharmacovigilance activities:

1. **Procedure-based fees**: The Agency charges procedure-based fees for the single assessment of periodic safety update reports (PSURs), for assessment of post-authorisation-safety-study (PASS) protocols and study results, and for pharmacovigilance-related referrals. The Agency started charging for these procedures from the 26th August 2014.
2. **Annual fee**: An annual fee will be charged on nationally authorised medicines only, with respect to the monitoring of literature cases and the improved use of information technology tools. An annual fee will be due on 1st of July of every year in respect of that calendar year as from 2015.

The **income from procedure-based fees** will be used to remunerate the national competent authorities (NCAs) of the EU for the scientific assessment carried out by the rapporteurs of the Pharmacovigilance Risk Assessment Committee (PRAC).

The **income from annual fees** will support the implementation and maintenance of measures from the 2010 pharmacovigilance legislation, including:

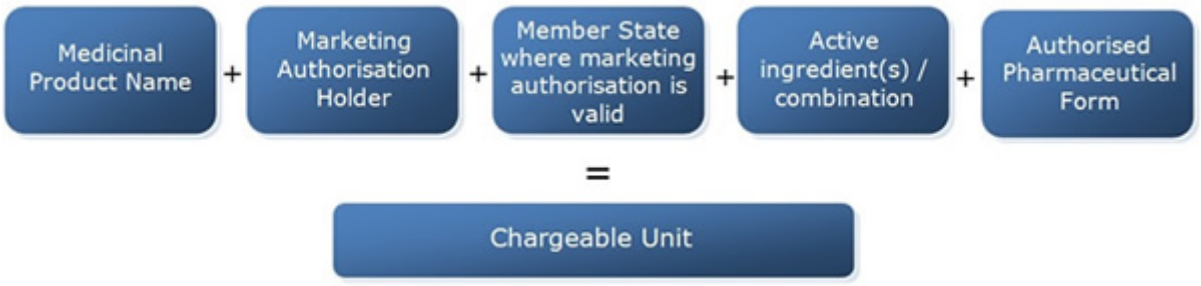
- literature monitoring;
- the European medicines web portal;
- enhanced functionalities for EudraVigilance;
- a repository of PSURs.

These activities will directly benefit marketing authorisation holders by reducing administrative burden, simplifying reporting and streamlining processes.

Calculating the fee

The basis of calculation of pharmacovigilance fees for PSURs, pharmacovigilance referrals and the annual fee is the **Chargeable Unit** (CU), which is defined in Article 2 of Regulation (EC) 658/2014 as a unique combination of the following dataset derived from information on all medicinal products authorised in the Union held by the Agency, and consistent with the obligation of marketing authorisation holders referred to in points (b) and (c) of Article 57(2) of Regulation (EC) No 726/2004 to submit such information to the database referred to in point (l) of the second subparagraph of Article 57(1) of that Regulation:

- Name of the medicinal product, as defined in point 20 of Article 1 of Directive 2001/83/EC;
- Marketing authorisation holder;
- The Member State in which the marketing authorisation is valid;
- Active substance or a combination of active substances; and
- Pharmaceutical form.



Please note that, for PASS procedures, a flat amount to be paid in two instalments is applied.

Fee amounts to be levied on marketing authorisation holders

Pharmacovigilance Fee	Fee Amount	Fee Split
Periodic Safety Update Report	**€19,500** due at date of start of procedure.	Fee will be **divided among marketing authorisation holders** involved in the procedure by **charging them proportionately to the respective number of chargeable units held** by each marketing authorisation holder.
Post-Authorisation Safety Study	**€43,000** paid in two instalments: • €17,200 due at start of the procedure for assessment of draft protocol • €25,800 due at start of the procedure for assessment of final study report	Fee will be **divided among all marketing authorisation holders** having the obligation to produce the study by **charging equal amounts** to each marketing authorisation holder.
Pharmacovigilance-related Referral	**€179,000*** if it only concerns 1 or 2 active substances. + €38,800 will be charged for every additional active substance or combination. **€295,400** Maximum fee. Due at the start date of the procedure.	Fee will be **divided among marketing authorisation holders** involved in the procedure by **charging them proportionately to the respective number of chargeable units held** by each marketing authorisation holder.
Annual fee for information technology systems and literature monitoring	**€67 per chargeable unit** due on 1st July every year.	N/A

* If the procedure involves one substance or one combination of substances *and* one marketing authorisation holder, the Agency shall levy a reduced amount of the fee on that marketing authorisation holder (two thirds of the basic fee).

Fee reductions and exemptions

Fee reductions and exemptions are in place for Micro-, small- and medium-sized-enterprises (SMEs) and for certain categories of medicines such as generics, well-established use, homeopathic and herbal products.

The below table details the various fee reductions and exemptions applicable per pharmacovigilance fee type:

Pharmacovigilance Fee	**Micro Enterprises**	**Small and medium-sized enterprises**	**Generics, well-established use, authorised homeopathic and herbal medicinal products**
Periodic Safety Update Report	Exempt	60% of the applicable fee or share of fee	Full fee*
Post-Authorisation Safety Study	Exempt	60% of the applicable fee or share of fee	Full fee
Pharmacovigilance-related Referral	Exempt	60% of the applicable fee or share of fee	Full fee
Annual fee for information technology systems and literature monitoring	Exempt	60% of the applicable fee	80% of the amount applicable to the chargeable units corresponding to those products.

* A full fee applies to generics, well-established use, homeopathic and herbal products when they are within the scope of the procedure, as specified in the EURD list.

Advice Notes

Prior to issuing an invoice, the Agency provides marketing authorisation holders with an opportunity to review the information recorded in the Article 57 database by supplying the qualified person for pharmacovigilance with an advice note. The advice note contains the line listing of the chargeable units and a reference to the related products (as recorded in the Article 57 database) as well as regulatory background and electronic submission guidance.

Mit freundlichen Grüßen

Ihr DiaMed-Team