EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance Fees

3rd industry stakeholder platform - operation of EU pharmacovigilance legislation

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Pharmacovigilance fees regulatory background

- In June 2014, Regulation (EU) No 658/2014 of the European Parliament and of the Council on fees payable to the EMA for the conduct of pharmacovigilance activities in respect of medicinal products for human use was published

- Two types of fees (in view of the diversity of the pharmacovigilance activities)
  - The **annual fee** to cover mainly EMA's information technology-related activities for pharmacovigilance (applicable to NAPs only)
  - The **procedure-based fees** to cover the cost of the EU-wide assessments including financial compensation of the national competent authorities for the services provided

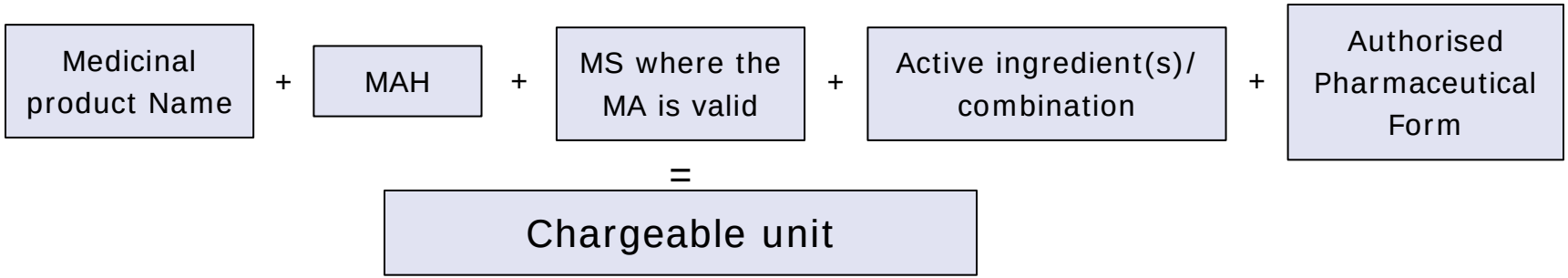
➢ Fees apply to pharmacovigilance referrals, PSURs and PASS procedures for which the assessment starts on or after 26 August 2014

➢ The annual fee will be invoiced in July each year, starting in July 2015

Type of service	Standard Fee	Micro enterprises	Small and medium-sized enterprises	Generics, well-established use, homeopathic and herbal products
Assessments of PSURs	19 500 €/ procedure, levied to one or more MAH (if two or more, according to chargeable units*), due at the date of start of procedure.	Exempted	60% of the applicable share	Full fee
Assessment of PASS (conducted in more than one member state)	43 000 €/PASS, levied to one MAH or more MAH (joint PASS, even division of the fee), 17 200 due at the date of start of protocol assessment and 25 800 due at the date of start of final report assessment.	Exempted	60% of the applicable share	Full fee
Assessment of Pharmacovigilance Referrals (107i to 107k, 31(1) and 31(2) of Directive 2001/83/CE or 20(8) of Regulation nº726/2004)	179 000€ if 1 or 2 AS/combination included. For every additional AS/combination, additional 38 800 €, up to maximum fee of 295 400€. If levied to one MAH, the fee is reduced to two thirds; if levied to two or more MAH, fee is shared according to chargeable units; due at the date of start of procedure.	Exempted	60% of the applicable share	Full fee
Annual Service (information technology and monitoring of selected medical literature)	67€/Year per chargeable unit, due on 1st July every year.	Exempted	60% of the applicable fee	80% of the applicable fee

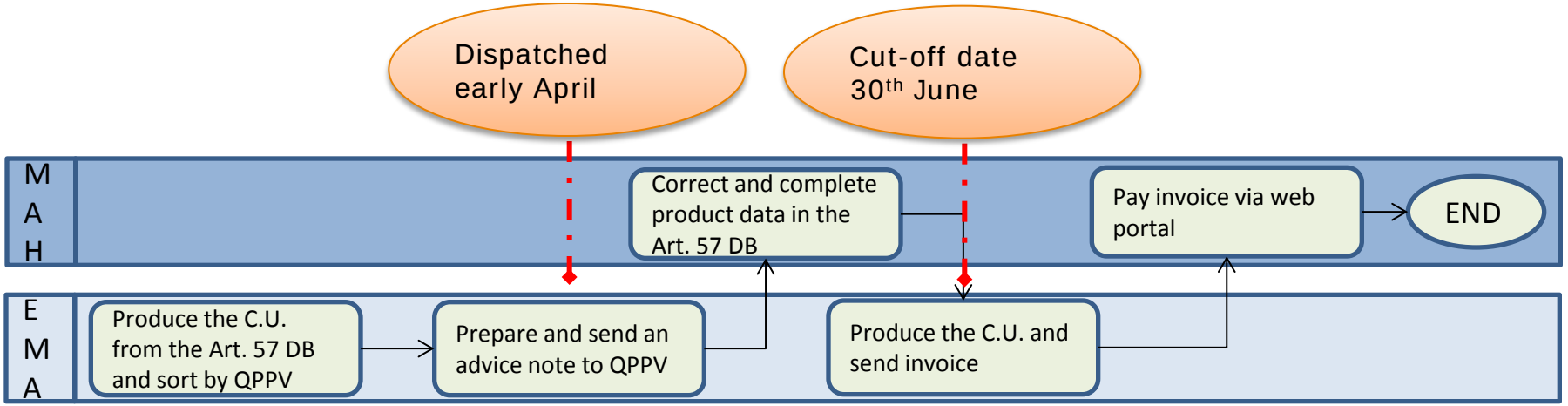
'Chargeable unit' (C.U.) Definition

'Chargeable unit' (C.U.) means a unit defined by a unique combination of the following dataset derived from information on all medicinal products for human use authorised in the Union held by the Agency and consistent with the obligation of marketing authorisation holders referred to in Article 57(2)(b) and (c) of Regulation (EC) No 726/2004 (thereafter referred as to the Article 57 database)



Pharmacovigilance annual fees implementation

- According to the PhV fee Regulation, Article 57 Database is the official source of information to calculate chargeable unit (CU) and to support the Pharmacovigilance fee calculation
- As a service to industry, before sending out final invoices, EMA will provide QPPVs with a detailed 'advice note' to provide a preview of the CU listing
- QPPVs will have a chance to review and, if necessary, correct the product data in the Article 57 database
- Invoices will be sent electronically, through a web portal currently being developed, and companies will have the opportunity to raise queries and to pay the invoices through the portal



Advice Note – Scope and Objectives

- As a service to industry, before sending out final invoices, EMA will provide QPPVs with a detailed ‘advice note’ (AN) to provide a preview of the CU listing
- It is applicable for Annual Fee, PSURs and Referrals, not applicable for PASS procedures
- It is not a pre-invoice, it does not give a calculated amount
- QPPVs will have a chance to review and, if necessary, correct the product data in the Article 57 database (timelines will differ according to procedure type)
- QPPVs will be the contact point for submission of Advice Note
- AN allows MAHs via QPPV to rectify quality for data in Art 57 DB in case of inconsistences
- Content of Advice Note and Invoice may vary due to regulatory amendment
- Invoice will be calculated based on the data at the time of Invoicing; it will be sent electronically, through a web portal currently being developed, and companies will have the opportunity to raise queries and to pay the invoices through the portal

Pharmacovigilance fees: project plan

- **Current Status**: invoices for procedure based fees (PSURs) are already being issued using an interim solution that will be replaced by a more efficient automated solution when Article 57 database will be fully functional
  - **Key dates**:
    - Annual Fee advice notes despatched: April 2015
    - Query Management solution: available from annual fee advice notes despatch date
    - Annual Fee invoices sent: July 2015
    - Payment portal: available for annual fees invoice payment
  - **Communication and support:**
    - Pharmacovigilance Programme Newsletter (QUARTERLY)
    - Explanatory note on pharmacovigilance fees on EMA web-site (March 2015)
    - FAQs on PV Fees on EMA Landing Page (March 2015)
    - Introducing the payment portal to accounts payable teams (April 2015)
    - Training pack for payment portal provided to accounts payable teams (April 2015)
    - YouTube video – Introduction to Pharmacovigilance Fees (April 2015)

Thank you for your attention

Further information

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