EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/IFAH Europe Info Day
Procedural Update - Post-authorisation procedures

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An agency of the European Union

Improvements - reducing regulatory burden

Two particular areas to mention –

- Practical – handling editorial changes (to come) ✓
- Financial – fee incentives (reductions) for epizootic diseases and certain Pharmacovigilance variations (April and July 2015) ✓

Handling editorial changes

- Frequently questions are received on minor changes/corrections which are not variations

- Existing post-authorisation procedural guidance on variations will be updated with a new Q&A on how to notify the Agency of editorial changes within the dossier

Handling editorial changes within variations

- Editorial changes should be included within a variation affecting *same* part of dossier
- Aim is to ensure that changes are traceable within system for future reference and amended documents are stored in the correct repository (rather than within email attachments)
- Q&A will elaborate on what constitutes an editorial change within Part 1.B (product information) and Part 2 (quality)

Fee incentives - April 2015

A total exemption from the payment of the fees laid down in the fee regulation is granted for certain post-authorisation activities in relation to vaccines against bluetongue, pandemic avian influenza, foot and mouth disease and classical swine fever for which

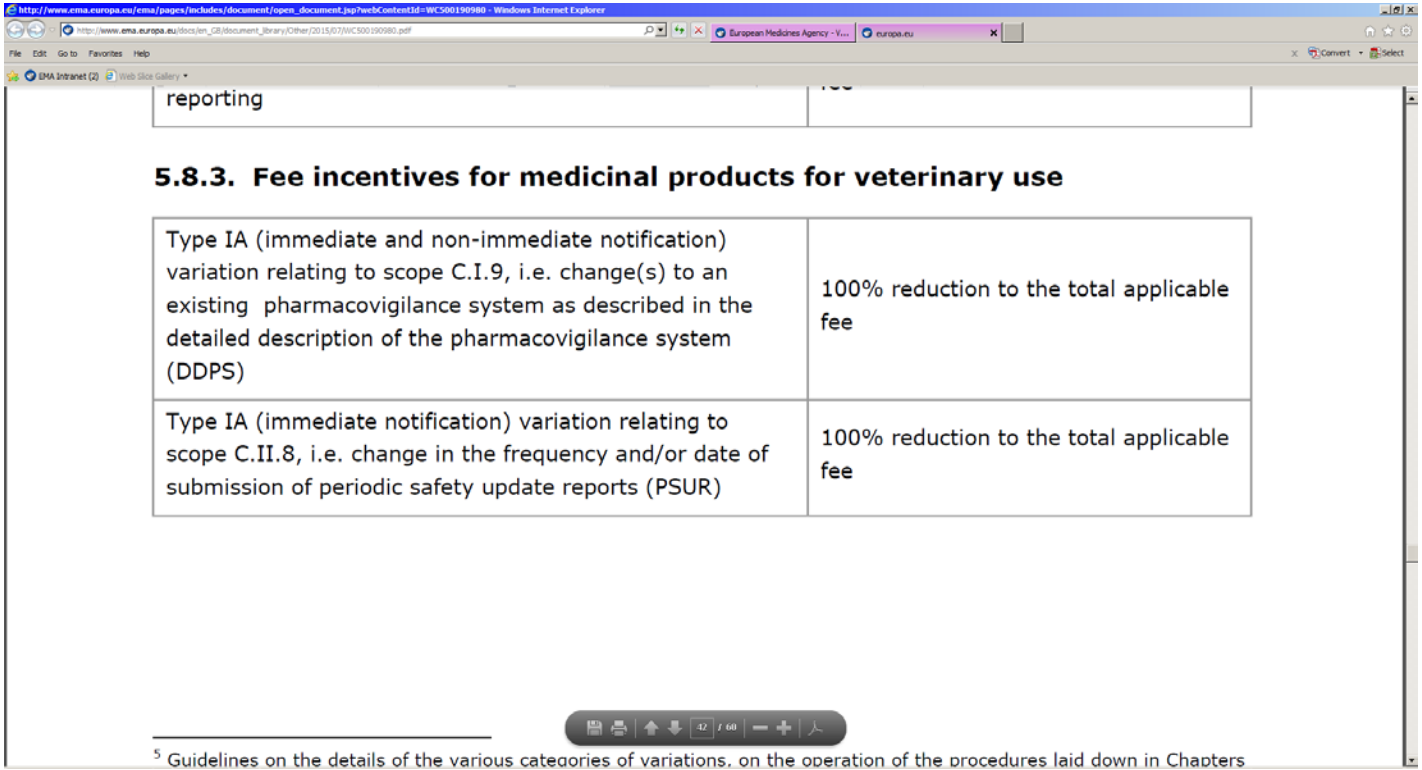
- the vaccine is authorised under normal circumstances &
- the product has not been marketed within the EU/EEA at any time during the totality of the period covered by the fee

*If you wish to apply for this incentive, please send a justified request and a declaration of lack of sales via email to vet.applications CC product-shared mailbox at least two weeks before the fee is due, in order for EMA to be able to process your request in time.

5.9.2. Fee incentives

- Renewal of marketing authorisation 100% reduction to the total applicable fee
- Annual fee 100% reduction to the total applicable fee

Fee incentives – July 2015



reporting

5.8.3. Fee incentives for medicinal products for veterinary use

Type IA (immediate and non-immediate notification) variation relating to scope C.I.9, i.e. change(s) to an existing pharmacovigilance system as described in the detailed description of the pharmacovigilance system (DDPS)	100% reduction to the total applicable fee
Type IA (immediate notification) variation relating to scope C.II.8, i.e. change in the frequency and/or date of submission of periodic safety update reports (PSUR)	100% reduction to the total applicable fee

[5] Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters

Thank you for your attention!