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FAQ FINANCING LAW – TECHNICAL POINTS

DG PRE authorisation

- With respect to new marketing authorisations it was said that the fee would need to be paid once for each trademark. If a trademark already exists, and an extension of the range is subsequent applied for, will this be considered as a variation or a new application for marketing authorisation?
- Do the fees for reactivation, invalidation and withdrawal also apply to homeopathic medicines?
- The 'orphan' regime will be confirmed at the European level. Why is a national review still necessary?
- How will repayment of for example variable taxes be done?
- As the fees have been revised for the review of variations, will the review deadline also be shorter?
- Does late closing apply to homeopathic medicines?

DG POST authorisation

- In Belgium, medicines for intravenous administration are subject to an authorisation for each packaging volume. In other countries, there is an authorisation per "brand" which groups all different packaging volumes. Does intravenous medicines also require an annual subscription per authorisation number, or does an annual subscription per brand suffice? And will Belgium switch to the principle of one authorisation per brand?
- With respect to medicines for veterinary use, is the current fee for a Periodic Safety Update Report (PSUR) still applicable?
- Will the fee for a PSUR review continue to apply?
- With respect to grouped variations IA, IB and II, is it correct that the fee is determined by the highest variation?
- What if a medicine has different packaging types?
- Is 'output umbrella branding' applicable only to umbrella brands?
- How can we best calculate the transfer of all MAs from business X to business Y, for example under the assumption that there are 100 authorisations? The transfer does not involve a change of distributor, but a change of language role. However, the change of language role is linked to the transfer of the MA.
- Product X, of which 4 strengths and 3 different primary packaging materials:
    1. 3 type IA grouped variations: how to calculate the fee?
    2. 2 type IB and 1 type II Chemistry, Manufacturing and Controls (CMC): how to calculate the fee?
- If we choose to have two clinical variations be closed together, will the late closing principle apply?

- If a recall is followed by a Dear Doctor Letter (DDL), may this be paid from the "comptes courants" or provision?

DG INSPECTION

- Will a distributor who sells packaging types to another distributor in another country be subject to the 'distributor packaging' fee?
- The Certificate of Pharmaceutical Product (CPP) was not mentioned in the presentation. Could this be explained in more detail? Is the CPP subject to the new financing law?
- Will the annual subscriptions for GMP and GDP need to be paid per authorisation number or per place of operation?
- What is meant by 'own medicines' in the detail for the Distribution activity?
- If you have a GDP authorisation issued in 2017, then this will remain valid until 2022. Will the annual fee for GDP then be payable only from 2022 onwards?
- Which annual subscriptions are applicable for distribution? GDP only or GMP as well?
- GDP authorisation and annual subscription: is also not very clear with regard to fees.
- GMP authorisation for sterile and non-sterile: what if the business only does EU Batch certification for sterile and non-sterile products? Which authorisation applies in this case?
- What is the cost of an import authorisation into Belgium?

DG PRE authorisation

Question: With respect to new marketing authorisations (MAs) it was said that the fee would need to be paid once for each trademark. If a trademark already exists, and an extension of the range is subsequently applied for, will this be considered as a variation or as a new application for MA?

Answer: This will be considered a new application for MA, the full fee will be payable.

Question: Do the fees for reactivation, invalidation and withdrawal also apply to homeopathic medicines?

Answer: Yes, they apply to homeopathic medicines.

Question: The 'orphan' regime will be confirmed at European level. Why is a national review still necessary?

Answer: This is necessary since the 'orphan' regime may change over time when the requirements for maintaining an 'orphan' designation are no longer met.

Question: How will repayment of for example variable taxes be done ?

Answer: They will be deducted from the tax for the next year.

Question: As the fees have been revised for the review of variations, will the review deadline also be shorter?

Answer: The FAHMP is continuously working on improving its services.

Question: Does late closing apply to homeopathic medicines?

Answer: Yes, late closing also applies to homeopathic medicines.

DG POST authorisation

Question: In Belgium, medicines for intravenous administration are subject to an authorisation for each packaging volume. In other countries, there is an authorisation per "brand" which groups all different packaging volumes. Does intravenous medicines also require an annual subscription per authorisation number, or does an annual subscription per brand suffice? And will Belgium switch to the principle of one authorisation per brand?

Answer: The current principle will be retained. One annual subscription per authorisation number (volume) is required. We are evaluating the principle of one authorisation per brand, but a change, if any, will not be implemented soon.

Question: With respect to medicines for veterinary use, is the current fee for a Periodic Safety Update Report (PSUR) still applicable?

Answer: Yes, under current legislation.

Question: Will the fee for a PSUR review continue to apply?

Answer: PSURs are subject to current legislation, NOT to the financing law, but the fee will continue to apply.

Question: With respect to grouped variations IA, IB and II, is it correct that the fee is determined by the highest variation?

Answer: Yes, that is correct.

Question: What if a medicine has different packaging types?

Answer: This will be considered as an independent MA, but with respect to the same brand.

Question: Is 'output umbrella branding' applicable only to umbrella brands?

Answer: Yes, that is correct.

Question: How can we best calculate the transfer of all MAs from business X to business Y for example under the assumption that there are 100 authorisations? The transfer does not involve a change of distributor, but a change of language role. However, the change of language role is linked to the transfer of the MA.

Answer: This is an administrative variation. Determine the number of brands involved: you will pay the base amount for the first brand and a fixed surcharge for each additional brand. This is a horizontal grouping.

Question: Product X, of which 4 strengths and 3 different primary packaging materials:

1. 3 type IA grouped variations: how to calculate the fee?
2. 2 type IB and 1 type II Chemistry, Manufacturing and Control (CMC) variations: how to calculate the fee?

Answer 1: This is considered a single brand. Determine the procedure to be followed and the role fulfilled by the FAHMP. This will give you the base fee for the type IA variation that applies to this file. This is a vertical grouping. You will pay the base fee once for the relevant type IA variation.

Answer 2: This is considered a single brand. Determine the procedure to be followed and the role fulfilled by the FAHMP. This will give you the base fee for the various variation types. Then determine the highest-ranked variation for this file. This is a vertical grouping. You will pay the base fee once for the highest variation, in this case the type II variation.

Question: If we choose to have two clinical variations be closed together, will the late closing principle apply?

Answer: This will indeed be considered as late closing.

Question: If a recall is followed by a Dear Doctor Letter (DDL), may this be paid from the 'comptes courants' or the provision?

Answer: Article 29 of the financing law provides that the submission of a file should be accompanied by a proof of payment. This proof of payment may optionally take the form of a request to debit the provision account by the relevant amount. Should the balance on the provision account be insufficient, the same Article 29 of the law provides that the file should be considered inadmissible.

DG INSPECTION

Question: Will a distributor who sells packaging types to another distributor in another country be subject to the 'distributor packaging' fee?

Answer: The 'distributor packaging' fee will not be payable in this case.

Question: The Certificate of Pharmaceutical Product (CPP) was not mentioned in the presentation. Could this be explained in more detail? Is the CPP subject to the new financing law?

Answer: The CPP and the Legalise document industry (not CPP) are not part of the annual subscription. These are Individual Fees for Service (cf. financing law).

D150 - The application for a certificate of pharmaceutical product pursuant to Article 12a (2) of the Medicines Law	Individual Fee for Service	€ 56,00	Annex VII Title 1 Chapter XIV
Commonly known as: D150 - Certificate of Pharmaceutical Product (CPP)			

D151 - The application for legalisation of a document with respect to medicines	Individual Fee for Service	€ 20,00	Annex VII Title 1 Chapter XV
Commonly known as: D151 - Legalise document industry (not CPP)			

Question: Will the annual subscriptions for GMP and GDP need to be paid per authorisation number or per place of operation?

Answer: The annual subscription will be payable based on entities. It is possible for the same place of operation to be considered to be one or more entity/entities.

To the definition of an entity see the information session, BRUSSELS, 02/2018

GDP entity	The number of sites of operation for businesses with authorisation covered by a Wholesale Distributor authorisation (WDA)
GMP entity	Business, production site or part of a production site that, by virtue of: • the process, • the access conditions, • the size of the areas, of the activities, allows an inspection to be conducted within a certain period.

Question: What is meant by 'own medicines' in the detail for the Distribution activity?
Answer: This refers to the medicines for which you are the authorisation holder.

Question: If you have a GDP authorisation issued in 2017, then this will remain valid until 2022. Will the annual fee for GDP then be payable only from 2022 onwards?
Answer: No, the GDP fee is payable every year. At the time of the inspection for GDP authorisation renewal, no additional fee will be payable.

Question: Which annual subscriptions are applicable for distribution? GDP only or GMP as well?
Answer: Distribution of medicines for which you are the authorisation holder is subject to GMP only. If you distribute other medicines as well, both GMP and GDP apply. If you merely distribute and are not yourself an authorisation holder, only GDP authorisation applies. The applicable amounts are listed on slide 28 of the presentation.

Question: GDP authorisation and annual subscription: is also not very clear with regard to fees.
Answer:

Authorisation		Payment	
MIA	WDA	Annual Fee(s) by GMP Entity	Annual Fee(s) by GDP Entity
NO	YES	NO	YES
YES	NO	YES	NO
YES	YES	YES	YES

Question: GMP authorisation for sterile and non-sterile: what if the business only does EU Batch certification for sterile and non-sterile products? Which authorisation applies in this case?
Answer: In this case there are one or more GMP entities for non-sterile.

Question: What is the cost of an import authorisation into Belgium?
Answer:

D340 - The application for an import authorisation for registered substances by or pursuant to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors, Articles 6 and 7, pursuant to Article 1 of the Narcotic Drugs Act	Individual Fee for Services	€ 71,00/authorisation	Annex VII Title 2 Chapter IV
Commonly known as: D340 - import authorisation precursors			

D345 - The application for a Letter of no objection (a certificate confirming that the relevant substances are not subject to an import authorisation), pursuant to Article 1 of the Narcotic Drugs Act	Individual Fee for Services	€ 56,00/letter	Annex VII Title 2 Chapter III
Commonly known as: D345 - HAA Import certificate			

Narcotic drugs	Annex VII Title 2 Chapter 1	For all prices
Commonly known as: Narcotics		