

AGREEMENT

Between:

BeMVO Belgian Medicines Verification Organisation vzw (hereafter “BeMVO”)
Address: Guido Gezellestraat 126, 1654 Huizingen – België;

And:

.....

.....

(correct name, address, KBO number, etc.)

FAGG / AFMPS Registration number : (hereafter “MAH”)

Both hereafter referred to as a “Party”, and together as the “Parties”.

Background

In line with the EU Falsified Medicines Directive 2011/62/EU (“FMD”) and the EU Delegated Regulation 2016/161, the associations representing the market authorisation holders (“MAH’s”) active in Belgium created BeMVO, a non-for profit organisation. All capitalized terms in this Agreement will have the same meaning as in the EU Falsified Medicines Directive and the Delegated Regulation.

BeMVO’s primary non-profit purpose is – on behalf of the MAH companies who bring medicines on the Belgian market – to act as National Medicines Verification Organisation in Belgium and Luxembourg, to establish and manage the National Repository System (“BeMVS”) in the same countries, as well as to establish and manage the link with the European HUB in compliance with the EMVS and all Blueprint requirements.

As the Delegated Regulation stipulates, the cost for the purposes described above and all related activities to fulfil these purposes must be born by the MAH.

In view of this, BeMVO must conclude a services agreement with the MAH defining the scope of the services to be rendered by BeMVO to the MAH and the costs for such services.

In line with the Delegated Regulation, BeMVO has opted for a yearly flat fee contribution to be paid by the MAH as from 2019.

However, to cover the operation costs of BeMVO during the period 2017-2018, and especially the investment in the IT system to run the National Repository System (the “IT System”), a one-off registration fee must be paid by all MAH’s acting within the Belgian scope of FMD as from February 9th 2019.

The main body of this Agreement deals with the arrangements regarding the one –off registration fee. In subsequent addenda to this Agreement, which need to be signed by BeMVO and the MAH at a later stage, all other provisions of the services to be rendered by BeMVO to MAH will be described in more detail.

The Parties therefore agree as follows:

Art.1. - The undersigned MAH agrees to pay to BeMVO the one-off registration fee as mentioned in the registration form, attached to and integrated in this Agreement as Annex 1. The undersigned MAH agrees to pay the one-off registration fee no later than the relevant deadline mentioned in Annex 1.

In case the one-off registration fee mentioned in Annex 1 is paid by a third party, acting in name and on behalf of the undersigning MAH, the undersigning MAH will always remain the sole Party responsible and liable for compliance with this Agreement and the FMD.

Art.2. - Late registrations or late payments (i.e., after the relevant deadlines mentioned in Annex 1) will automatically be regarded as a registration or payment for the subsequent wave. An additional invoice for the surplus amount due for this later wave will be sent to and payable by the MAH.

Art.3. - The MAH must ensure that the invoicing address and other contact information specified in the registration form is correct and up to date. Should the address or other contact information change, it is the responsibility of the MAH to inform the BeMVO immediately.

Art.4. - In the event that the initial amount of the registration fees would prove to be insufficient to cover all costs of BeMVO for the development of its activities during the ramp up phase (i.e. until February 2019), BeMVO will have the right, in line with foreseen procedures in the BeMVO statutes, to charge additional fees to all relevant MAH's on a flat fee basis to cover such costs or activities.

Art.5. - BeMVO commits itself to properly manage the development of the IT System, its operations and its activities. An essential focus of BeMVO will be to minimise its costs where possible, while always ensuring full compliance with the applicable laws and regulations. The yearly minutes of the General Assembly handling the grant discharge of the members of the Board of Directors will be used as valid proof of this good management.

Art.6. - Both Parties agree that BeMVO shall not be liable towards the undersigning MAH or any third party under or in connection with this Agreement or its Termination, in contract, pre-contract, tort or otherwise, for (i) any economic loss (including loss of revenues, profits, contracts, business or anticipated savings); (ii) any loss of goodwill or reputation; (iii) any damage direct or indirect to company, IT, or communications infrastructure; or (iv) physical

injuries. These losses include any special, indirect, incidental, statutory, punitive or consequential losses or damages as well as any losses or damages caused by interruption of operations.

- Art.7. - As from February 2019, a yearly flat fee contribution will be payable by each MAH to the BeMVO. The yearly flat fee will be charged to cover, inter alia, the yearly costs of the operation and further development of the BeMVS and the IT System, costs inherited from the EMVO and all necessary and legally compulsory activities of BeMVO.
- Art.8. - The level of the yearly flat fee contribution will be agreed upon by voting at the General Assembly of BeMVO upon proposal of its Board of Directors. Both Parties agree that the amount of the yearly flat fee (IT-cost and operational cost of BeMVO divided by number of MAH's) may fluctuate from time to time.
- Art.9. - Both Parties agree that when European legislation regarding FMD and guidelines lead to extra responsibilities, an addendum to this Agreement will need to be entered into which will outline in more detail all rights and obligations of both Parties with regard to the subject matter of this Agreement. Such addendum will not jeopardize the rights of BeMVO with regard to the stipulations on the flat fee payment as mentioned in articles 7 and 8 of this Agreement.
- Art.10. - All amounts paid by the MAH are definitely acquired by BeMVO and are non-reimbursable. Each Party guarantees that all information of a confidential nature received from the other Party before, during and after the conclusion of the Agreement shall remain confidential.
- Art.11. - Since this Agreement covers the execution of compulsory legal provisions (mentioned in the FMD, the Delegated Regulation, and possible other legislation), both Parties understand and agree that this Agreement can only be terminated when the MAH no longer has activities in the Belgian Market or when the applicable legislation ceases to apply to either the undersigned MAH or BeMVO. In the event of termination case, the undersigned MAH will have no rights whatsoever to be refunded of the already paid fees (neither as a whole nor pro rata).
- Art.12. - In the event that the roll- out of the FMD project as a whole or the development of the IT-System more specifically would be postponed, all development activities and ramp- up activities may need to be suspended.

The Parties understand that, in such case, the incurred costs and accepted but still outstanding invoices addressed to BeMVO need to be paid. The still outstanding loans given by the MAH associations will be paid back as well as the outstanding loans from third parties. The potential costs and/or penalties to be paid to the ICT Service provider will be provisioned

as well as the cost for the salaries and lay- off costs of the personnel and/or freelancers on the payroll of the BeMVO. Both Parties understand and agree that such additional costs may result in additional invoices by BeMVO to the MAH's.

Art.13. - The Board of Directors of BeMVO has the sole and exclusive right to decide on whether to refund any remaining funds, and to decide on the modalities of a potential refund (including timing and proportion). Such potential refund will be paid on a pro rata basis of all amounts paid by the MAH's that are still active in Belgium at the moment of the decision by the Board of Directors.

Art.14. - In case the FMD project will terminate, the same procedure as described in the preceding article will apply, taking into account the provisions in the statutes of BeMVO with regard to the dissolution of BeMVO.

Art.15. - This Agreement shall be governed by the laws of Belgium. Jurisdiction shall lie exclusively in the competent courts of Brussels. Prior to initiating any legal action arising under or relating to this Agreement, a Party shall provide the other Party written notice of a dispute and the Parties shall actively and in good faith negotiate with a view to speedy resolution of such dispute within ten (10) business days of the receipt of such notice.

Made and entered into in on, in two original counterparts, each Party agrees to having received one original counterpart.

BeMVO

Name: Pieter Boudrez
Function: Chairman of BeMVO
Date: 12 May 2017
Signature:

Name:
Function:
Date:
Signature:



REGISTRATION FORM
(ONE CONTRACT AND ONE FORM PER MAH)

Identification of MAH

Name of the MAH		
FAGG / AFMPS Registration number		
Address		
VAT Number of MAH		
Contact details	Phone	email

Authorized Representative of the MAH

Name		
Function		
Address		
Contact details	Phone	email

Invoicing information

Name			
Address			
VAT number to use on invoice			
Purchase order process	A specific purchase order process is NOT of application	Yes	No
	A Purchase Order number is needed -Please use PO no	Yes	No
	A more specific purchase order process is of application - instructions in annex	Yes	No

	Registration deadline	Payment deadline	FEE (VAT excl)	Discount	Amount to pay (VAT excl)
Check the box of your choice.					
<input type="checkbox"/> Wave 1	31- May - 17	15 - Aug - 17	20 000,00	50%	10 000,00
<input type="checkbox"/> Wave 2	31 – Dec - 17	31-Jan-18	20 000,00	25%	15 000,00
<input type="checkbox"/> Wave 3	31 - May - 18	30-Jun-18	20 000,00	-	20 000,00
Existing MAH's registering later than 31 May 2018 will have to pay an extra admin fine.					