

INSTRUCTIONS TO MARKET AUTHORIZATION HOLDERS

(To be followed in case originally signed documents are not delivered by hand)

The Agreement and Annex 1 (pages 2 - 6) should be printed, duly completed, signed where specified by the Market Authorization Holder (MAH) and returned to the above address, upon transfer of the amount, as specified in the relative table. The payable amount will vary, depending on the time of settlement (Wave1 or Wave 2 or Wave 3). Reduced fees are foreseen for early and timely settlements. Depending on the date you settle the one-off setup/deployment fee (Wave 1 or Wave 2 or Wave 3) you will receive an **original invoice** referring to the amount you have transferred on our account. For your information, a **sample invoice** (page 7) has been included referring to the highest payable fee (Wave 3). Depending on the date you settle the fee (Wave 1 or Wave 2 or Wave 3) you will receive an original invoice for the amount transferred on our account.

Example: If you settle the fee on or before the 15th of February 2018 (Wave 1) you should deposit **€ 2.380,00** on our account:

Fee for Wave 1 (€)	VAT 19%	Total Payable
2.000,00	380,00	2.380,00

VAT should not be included in the fees paid by companies in the EU provided they submit their VAT Registration Number. If the fee is paid by the Local Representative in Cyprus then 19% VAT is applicable.

Upon receipt of the transferred amount the agreement will be signed by the president and vice president of KOEΦ's Management Board and will be returned to you, together with an original Invoice referring to amount transferred, constituting thereby, a formal agreement between you and KOEΦ.

Important Note

The one-time setup/deployment fee should be settled only by MAH's bearing licenses for Prescription Medicines which are sold (they record sales) either on the Private market, or are supplied to the Government through procurement procedures.

Arthur Isseyegh
Director of KOEΦ

AGREEMENT

Between **Cyprus Medicines Verification Organisation** (hereafter KOEΦ) of 2 Sophouli, CHANTECLAIR BUILDING, 9th floor, 1096 Nicosia

And:

.....with registered address

(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 (“Delegated Regulation”), KOEΦ was established in February 2017 as a company limited by guarantee with its Main Members being the **Cyprus Association of Research and Development Pharmaceutical Companies (ΚΕΦΕΑ)** and **Panyprian Association of Manufacturers of Generic Medicines (ΠΑ.ΣΥ.ΠΑ.ΓΕ.Φ.) Ltd** and its Affiliate Members being the Cyprus Pharmaceutical Association (CPA), **Cyprus Association of Pharmaceutical Companies (ΣΦΕΚ)**, the parallel importer Krinera Health Ltd and the pharmaceutical wholesalers MEFAL LTD, KEDIFAP LTD and BLUE PHARMACIES PUBLIC LTD. The Pharmaceutical Services of the Ministry of Health participate in KOEΦ meetings and oversee the implementation of the FMD.

The basic mandate of KOEΦ is to create and effectively implement the Cyprus Medicines Verification System (CyMVS), to support all the entities that have the obligation to implement it and to continuously monitor its operation, so as to bring about the desired results. Furthermore, KOEΦ will manage the link with the European HUB in compliance with the European Medicines Verification System (EMVS) and all Blueprint requirements.

All capitalized terms in this Agreement will have the same meaning as in the FMD and the Delegated Regulation.

As the Delegated Regulation stipulates, the cost for the purposes described above and all related activities to fulfil these purposes must be borne by the marketing authorisation holders.

In view of this, KOEΦ must conclude a services agreement with the marketing authorisation holders defining the scope of the services to be rendered by KOEΦ to the marketing authorisation holders and the costs for such services. In line with the Delegated Regulation, KOEΦ has opted for a yearly flat fee contribution to be paid by the marketing authorisation holders as from February 2019.

However, to cover the one-time Setup/Deployment charges (initial investment) of the IT System during the period 2017-2018, of the National Repository System (the "IT System"), a one-off system Setup/Deployment fee must be paid by all marketing authorisation holders acting within the scope of FMD in Cyprus, at the very latest by 31st January 2019. The main body of this Agreement deals with the arrangements regarding the one-off Setup/Deployment fees. In a subsequent addendum to this Agreement, which needs to be signed by both Parties at a later stage, all other provisions of the services to be rendered by KOEΦ to the MAH will be described in more detail. The Parties therefore agree as follows:

Art.1. - The undersigned MAH agrees to pay to KOEΦ the one-off Setup/Deployment fee as mentioned in the registration form, attached and integrated in this Agreement as Annex 1. The undersigned MAH agrees to pay the one-off Setup/Deployment fee no later than the relevant deadline mentioned in Annex 1. In case the one-off Setup/Deployment 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 payments (i.e., after the relevant deadlines mentioned in Annex 1) will be charged with interest, at the applicable rate of legal interest.

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

Art.4. - In the event that the initial amount of the Setup/Deployment fee would prove to be insufficient to cover all costs of KOEΦ for the development of its activities during the ramp up phase (i.e. until February 2019), KOEΦ reserves the right to charge additional fees to all relevant MAHs on a flat fee basis to cover such costs or activities and the MAH undertakes to pay same.

Art.5. - KOEΦ undertakes to properly manage the development of the IT System, its operations and its activities. An essential focus of KOEΦ will be to minimise its costs where possible, while always ensuring full compliance with the applicable laws and regulations. The minutes of the Annual General Meeting of KOEΦ handling the matter will be used as valid proof of this good management.

Art.6. - Both Parties agree that KOEΦ 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

njuries. 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, an annual flat fee contribution, separate from the one-off deployment charges, will be payable by each MAH to the ΚΟΕΦ. The annual flat fee will be charged to cover, inter alia, the yearly costs of the operation and further development of the ΚΟΕΦ IT System, and costs inherited from the EMVO.

Art.8. - The level of the annual flat fee contribution will be agreed by the Main Members of ΚΟΕΦ, upon consultation with the Affiliate Members, at the Annual General Meeting of ΚΟΕΦ. Both Parties agree that the amount of the annual flat fee for the operation of ΚΟΕΦ will be divided by the number of MAHs and therefore may fluctuate from time to time.

Art.9. - Both Parties agree that if further legislation regarding the implementation of the FMD is enacted, that leads to additional obligations, this Agreement will be amended to take this into account.

Art.10. - All amounts paid by the MAH are definitely acquired by ΚΟΕΦ and are non-reimbursable. Each Party guarantees that all information received from the other Party before, during and after the conclusion of the Agreement, that is marked "CONFIDENTIAL", shall remain confidential.

Art.11. - Since this Agreement covers the execution of compulsory legal provisions, both Parties understand and agree that this Agreement can only be terminated when the MAH no longer has activities in Cyprus or when the applicable legislation (including, but not limited to, the FMD and the Delegated Regulation) ceases to apply to either the undersigned MAH or ΚΟΕΦ. In the event of termination of this Agreement, the undersigned MAH will have no rights whatsoever to be refunded any part of the already paid fees.

Art. 12. - In the event that the roll- out of the FMD project as a whole or the development of the ΚΟΕΦ IT System more specifically is postponed, all development and ramp-up activities may need to be suspended. The Parties understand and agree that, in such an event, any outstanding invoices issued by ΚΟΕΦ to the MAH still need to be settled. ΚΟΕΦ undertakes to bear any potential costs and/or penalties to be paid to the IT Service provider as a result of such postponement. Both Parties understand and agree that any such additional costs may result in additional invoices from ΚΟΕΦ to the MAHs.

Art.13. - The General Meeting of ΚΟΕΦ's Main and Affiliate Members has the sole and exclusive right to decide on how to utilise any remaining funds, as well as to decide on the modalities of a potential refund (including timing and proportion). Such remaining funds will

either be refunded on a pro rata basis of all amounts paid by the MAHs that are still active in Cyprus at the moment of the decision of the afore-mentioned General Meeting, or be carried forward to the following year.

Art.14. - In case the legal obligation to implement the FMD ceases to exist, the same procedure as described in the preceding article will apply, taking into account the provisions in the Memorandum and Articles of Association of KOEΦ with regard to the dissolution of KOEΦ.

Art.15. - This Agreement shall be governed by the laws of Cyprus. Jurisdiction shall lie exclusively with the competent courts of Cyprus. 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.

This Agreement is entered into on by and between the two Parties, in two original counterparts and each Party, agrees to having received one original counterpart.

Signature for MAH

.....

.....

Full name and position

Date:

Signature for KOEΦ

.....

Kyriakos Mikellis

Chairman of KOEΦ's Board of Directors

Date:.....

.....

Andreas Vasiliou

Vice Chairman of KOEΦ's Board of Directors

Date:

ANNEX 1

**PAYMENT OF SETUP/DEPLOYMENT FEES FOR ΚΟΕΦ
(One Form/MAH)**

Identification of MAH		
MAH Full Name		
Company Registration Number		
Address		
MAH Full Address		
Contact Details	Phone	Email
Representative of MAH		
Full Name		
Position		
Address		
Contact Details	Phone	Email
Invoicing Information		
Full Name		
Address		
VAT Number for Invoice		
Purchase order process (if applicable)		

	Payment Deadline	Fee in € (VAT excluded)	Discount in €	Amount to pay in € (VAT excluded)
Check the box of your choice (double click on chosen box then select checked)				
<input type="checkbox"/> Wave 1	15/02/2018	3.000	1000	2000
<input type="checkbox"/> Wave 2	15/07/2018	3.000	500	2500
<input type="checkbox"/> Wave 3	31/01/2019	3.000	-----	3000
Payments to be effected by bank transfer to ΚΟΕΦ's Bank Account as indicated on the attached invoice. Please clearly state your relative identification details on the bank transfer.				

TIC 12365968G
VAT REG. NO. 10365968G

YOUR REF.
OUR REF. R3457/NP
DATE .../01/2018

VAT REG. NO. (IF WITHIN THE EU):

INVOICE NUMBER 2018001

NO.	DESCRIPTION	FEES EUR	DISBURSEMENTS EUR	DISBURSEMENTS EUR
			SUBJECT TO VAT	NOT SUBJECT TO VAT
01.	Subject: Setup/Deployment Fees for Cyprus Medicines Verification Organisation	3,000		
	Setup/Deployment Fees for the Cyprus Medicines Verification Organisation			
TOTAL FEES/DISBURSEMENTS		3,000		
			SUB-TOTAL	3,000
			VAT AMOUNT	570,00
			TOTAL	3,570
			ON ACCOUNT	----
			TOTAL AMOUNT PAYABLE	3,570

VAT analysis			
Code	VAT %	Value EUR	VAT EUR
1	19	3,000	570,00
EU	0		
A	0		
E	0	0,00	0,00
Total		3,000	570,00

Payment may be made by bank transfer to:
PAYMENTS TO: K.O.E.F.LIMITED
ACCOUNT NUMBER: 3570 2736 2465
IBAN NUMBER: CY33 0020 0195 0000 3570 2736 2465
SWIFT CODE: BCYPCY2N
BANK OF CYPRUS PUBLIC COMPANY LIMITED
NICOSIA
CYPRUS

ISSUED BY

Payment terms

- If this invoice is settled by 15/02/18, then the amount of EUR 2,380 (i.e. EUR 2,000 +VAT) is payable only, and a Credit Note will be issued accordingly.
- If this invoice is settled by 15/07/18, then the amount of EUR 2,975 (i.e. EUR 2,500 +VAT) is payable only, and a Credit Note will be issued accordingly.
- If this invoice is settled by 31/01/19, then the **full amount of EUR 3,570** is payable, and no Credit Note will be issued.
- Invoices settled after 31/01/19 will be charged with interest, at the rate of legal interest.