

Annex 3. Fees charged by NMVOs/EMVO for connecting to the repositories system

Member State		One-off fee	Annual fee	Fees charged per product or MAH	Special reductions for SMEs or other smaller players?	Overview
Austria	AT	<p>EUR 2 500 – 25 000</p> <p>Fees for sign on before 31/08/2018. Fee depends on net annual turnover in 2016 for prescription medicines on AT market (T-O):</p> <p>T-O < EUR 100 000 EUR 2 500 (EUR 1 500 before 28/02/2018) + 10% VAT</p> <p>T-O EUR 0.1-1 million EUR 8,500 (5 000 before 28/02/2018) + 10% VAT</p> <p>T-O > EUR 1 million EUR 25 000 (EUR 15 000 before 28/02/2018) + 10% VAT</p>	<p>The annual fee is set to the amount necessary to cover the annual operating expenses of the AMVS. The fees will be staggered based on an agreed key, which will essentially be based on a sales revenue factor (T-O) and a volume factor (V) (annual number of packs in the system) of the individual pharmaceutical company.</p> <p>min T-O < EUR 100 000: EUR 500 max T-O > EUR 250 million: EUR 85 000 and min V < 50 000 packs: EUR 0.009 per serial number max V > 2 million packs : EUR 0.004 per serial number</p>	Fee per MAH	<p>Yes, due to the fact, that the Austrian pharmaceutical market is highly fragmented in small and medium sized companies, the fee structure had been set up accordingly. The goal is to treat all participating companies in a fair and balanced manner.</p> <p>The operational fee structure had been divided: a) a fixed-turnover-fee and b) a volume-turnover-fee, and will take into account the heterogeneous market structure, size of companies and their respective business models. This special consideration was necessary in order to meet the expectations of all participating companies and get the buy-in at an early stage.</p>	<p>One-off fee: EUR 2 500 - 25 000 depending on turnover with possible early bird discounts.</p> <p>Annual fee/ MAH: Depends on turnover and sale volume. Annual fee is EUR 500 - 85 000 plus EUR 0.004 - 0.009 per serial number.</p> <p>Reductions for SMEs: Fees calculated on the basis of turnover and sales volumes, resulting in lower fees for smaller players.</p>
Belgium	BE	<p>EUR 20 000</p> <p>(Early bird discount of 50% when registering before 31/5/2017 and a 25% discount when registering before 31/12/2017.)</p>	<p>The annual flat fee for 2019 has been set to EUR 8 000 per MAH</p>	Flat fee per MAH	<p>There is a special reduction for smaller MAHs based on their annual turnover for products with safety features in Belgium in the year-2 (i.e. 2017 for the flat fee 2019).</p> <p>If their turnover is less than EUR 1 million, the flat fee is EUR 5 000</p> <p>If their turnover is less than EUR 100 000, the flat fee is EUR 2 000.</p>	<p>One-off fee: EUR 20 000 with possible early bird discounts.</p> <p>Annual fee/ MAH: EUR 8 000</p> <p>Reductions for SMEs: flat fee reduction depending on turnover</p>

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Bulgaria	BG	EUR 14 500 An early bird discount of 3% to 5% was applied before 30 June 2018	EUR 12 900 10% discount for payments prior to 30 June 2019 will be applied.	Flat fee per MAH	60% discount for micro and small enterprises (according to EMA definitions) MAH for orphan medicines can apply for a fee waiver. Information is published on the BgMVO website: www.bgmvo.org , Section for MAHs	One-off fee: EUR 14 500 Annual fee/MAH: EUR 12 900 with possible early bird discounts. Reduction: 60% discount for micro and small enterprises (according to SME initiative of EMA)
Croatia	HR	EUR ~6 700 (HRK 50 000)	EUR 7 000 – 10 000 (not yet precisely defined)	Flat fee per MAH	No reduction	One-off fee: ~6 700 Annual fee/ MAH: EUR 7 000 – 10 000 (not yet precisely defined) No special reductions.
Cyprus	CY	From EUR 2 000 to 3 000 (Depends on the date of signing the agreement and payment).	It has not yet been set. (It will be discussed by the Management Board).	Flat fee per MAH	Currently no special reductions (The possibility to introduce a reduction of the annual fee for smaller players will be discussed at a later stage).	One-off fee: EUR 2 000-3 000 Annual fee/ MAH: not decided yet. A reduction of the annual fee for smaller players may be discussed at a later stage.
Czech Republic	CZ	From EUR 3 237 to 4 856 Depends on registration date: EUR 4 047 until 3/6/2019 EUR 4 653 until 31/12/2019 EUR 4 856 after 1/1/2020	For 2019, expected fee EUR 7 361 per MAH For subsequent years, the fee should be lower based on increasing number of MAHs using the system.	Flat fee per MAH	Reduction based on turnover: MAH with turnover less than EUR 500 000 EUR in the past year or new MAH will have EUR 2 000 reduction from the fee.	One-off fee: EUR 4 047-4 856 Annual fee/MAH: EUR 7 361 Reductions based on turnover.
Denmark	DK	EUR 20 000 (Early discounts: 50% if contract signing from 01/12/2017 to 31/03/2018 and 25% from 01/04/18 to 30/09/2018).	EUR 8 500 (The annual fee is based on the number of active MAHs. It will probably be different from year to year, as the number of active MAHs may vary from year to year).	Flat fee per MAH	No special reductions	One-off fee: EUR 20 000 with possible early discounts. Annual fee/ MAH: EUR 8 500 No special reductions

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Estonia	EE	No one-off fee	EUR 8 000 per year (2019) Reductions for SMEs based on turnover (T-O): EUR 6 000 (T-O 50 000- 99 999) EUR 3 000 (T-O 8 000- 49 999) EUR 1 000 (T-O 1 000- 7 999) EUR 100 (T-O 0- 999)	Fee per MAH	Reductions based on turnover	No one-off fee Annual fee/ MAH: EUR 8 000 standard fee Reductions for SMEs
Finland	FI	No one-off fee	EUR 6 800/MAH in 2019 (The yearly fee depends on the amount of MAHs on the Finnish market as FimVO applies a full flat-fee per MAH).	Flat fee per MAH	No special reductions	No one-off fee Annual fee/ MAH: EUR 6 800 (2019) No special reductions
France	FR	No one-off fee	It depends on the annual turnover (T-O) of the MAH. T-O > EUR 1 million EUR 20 000 T-O < EUR 1 million 3% of T-O (min EUR 1 500, max EUR 20 000)	Fee per MAH	Yes, fee is based on MAH annual turnover.	No one-off fee Annual fee/MAH: EUR 1 500 – 20 000 depending on the annual turnover of the MAH. Reductions: yes. For MAH with a turn-over < EUR 1 million
Germany	DE	EUR 30 000 per MAH In addition, all pharmacies/hospitals connecting to the pharmacy-server will have to pay a one-time on-boarding fee of a few hundred euros.	Monthly fee of EUR 350 (EUR 4 200 per year)	In addition to the fee charged per MAH, there is also a fee for each unique identifier (UI) uploaded into the national system per year. The fee per UI is decreasing with the amount of UI uploads per company per year and currently ranges from EUR 0.009 - 0.0009 UI. This pricing model may be amended when all costs of the system are known. (According to: http://www.securpharm.de/en/mah/participating-and-costs.html , this amount varies from EUR 450 for 50 thousands packs to EUR 17 300 for 20 million packs).	Yes. MAH with a lower number of packs with the safety features on the market will pay less.	One-off fee: EUR 30 000 Annual fee /MAH: EUR 4 650 for 50 000 packs to EUR 21 500 for 20 million packs *Please note there is an additional fee for each UI. Total annual fee/MAH + one-off fee: EUR 34 650 - 51 500 Reductions: MAH with a lower number of packs with the safety features on the market will pay less.
Greece	EL					

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Hungary	HU	EUR 1 600	EUR 13 000	Flat fee per MAH	No special reductions	<p>One-off fee: EUR 1 600</p> <p>Annual fee/MAH: EUR 13 000</p> <p>No special reductions.</p>
Iceland	IS					
Ireland	IE	<p>EUR 16 000</p> <p>Reduced to EUR 6 400 for MAHs with a turnover of less than EUR 100 000.</p> <p>(Early bird discounts: 50% discount if paid by 31st Jan 2018, 25% if paid between 1st Feb and 31st Dec 2018).</p>	<p>EUR 12 000 in 2019</p> <p>Reduced to EUR 4 800 for MAHs with a turnover of less than EUR 100 000.</p>	Flat fee per MAH	<p>Yes. MAHs with a turnover of less than EUR 100 000 receive a 60% reduction</p>	<p>One-off fee: EUR 6 400 or 16 000 depending on turnover with possible early discounts.</p> <p>Annual fee/MAH (2019): EUR 4 800 or 12 000 depending on turnover.</p> <p>Total annual fee/MAH + one-off fee: EUR 11 200 or 28 000</p> <p>Reductions: MAHs with a turnover of less than EUR 100 000 receive a rebate of 60%.</p>
Italy	IT					
Latvia	LV	<p>EUR 8 000</p> <p>Early bird discount of 50% when registering before 30.06.2018; and 25% discount when registering before 30.09.2018.</p> <p>Late comers or new MAH as of 09.02.2019 pay on-off fee of EUR 14 000 /MAH.</p>	EUR 6 000/ MAH in 2019.	Flat fee per MAH	No special reductions	<p>One-off fee: EUR 8 000 / MAH with possible early bird discounts.</p> <p>Late comers or new MAH as of 09.02.2019 pay on-off fee of EUR 14 000 /MAH.</p> <p>Annual fee/ MAH (2019): EUR 6 000</p> <p>No special reductions</p>

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Liechtenstein	LI	EUR ~8 850 – 26 500 depending on turnover	Fixed fee EUR ~1 325 and turnover based fee EUR 0 – 61 900	Decreasing fee from EUR 0.008 - 0.0026 per pack	No	<p>One-off fee: EUR 8 850 to 26 500 depending on turnover</p> <p>Annual fee/MAH (2019): EUR 1 325 and turnover based fee EUR 0 – 61 900</p> <p>No special reductions</p>
Lithuania	LT	EUR 3 000	EUR 5 000 – 7 000 per year. (The fee is directly dependent on the number of MAH's connected to the National system).	Flat fee per MAH	No special reductions	<p>One-off fee: EUR 3 000</p> <p>Annual fee/MAH (2019): EUR 5 200</p> <p>Total annual fee/MAH + one-off fee : EUR 8 200</p> <p>No special reductions</p>
Luxembourg	LU	EUR 4 000 EUR 4 200 for late payers (if on list of MAH in Luxembourg before 1 August 2018 but only signed agreement after 31 July 2018)	In 2019, there are four fees (calculated according to turnover of serialised products in LU in 2017): Turnover of EUR 0: EUR 0 Turnover equal to or below EUR 20 000: EUR 500 Turnover above EUR 20 000 and below or equal to 200 000: EUR 1 200 Turnover above EUR 200 000: EUR 2 500 EUR Future fees will depend on costs and the number of MAHs.	Flat fee per MAH	Annual fee depends on turnover	<p>One-off fee: EUR 4 000</p> <p>Annual fee per MAH according to turnover: EUR 0 – 2 500.</p> <p>Reductions: MAHs with lower turnover pay less</p>
Malta	MT	No one-off fee	Annual fee depends on the number of marketing authorisations (MAs) per marketing authorisation holder (MAH). 1-5 MAs: EUR 650 6-25 MAs: EUR 1 650 26-50 MAs: EUR 4 200 51-300 MAs: EUR 12 500 300+ MAs: EUR 35 500	Fee per MAH/MA	Yes. Companies with fewer marketing authorisations pay less.	<p>No one-off fee</p> <p>Annual fee: EUR 650 – EUR 35 500 depending on number of Mas</p> <p>Reductions for those with fewer MAs</p>

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Netherlands	NL	EUR 25 000	EUR 10 000	Flat fee per MAH	SMEs can pay the one-off fee in five annual instalments (five years).	<p>One-off fee: EUR 25 000</p> <p>Annual fee: EUR 10 000</p> <p>SME reduction: it is possible to pay the one-off fee in five annual instalments</p>
Norway	NO	No one-off fee	EUR 5 500 (MAH who sign up in 2017 pay 156 000 NOK (EUR 16,500) for 2017-2019, while those who sign up in 2019 have to pay 312 000 NOK (EUR 33,000) to cover 2017-2019).	Flat fee per MAH	No special reductions	<p>No one-off fee</p> <p>Annual fee/ MAH: EUR 5 500 if sign up in 2017 and EUR 11 000 if sign up in 2019.</p> <p>No special reductions</p>
Poland	PL	EUR 14 000 Discounts for joining early: EUR 7 000 (by 30 Sep 2018) EUR 10 000 (by 31 Dec 2018)	EUR 8 500 in 2019	Flat fee per MAH	No special reductions	<p>One-off fee: EUR 14 000 with early discounts (EUR 7 000 or 10 000).</p> <p>Annual fee/MAH (2019): EUR 8 500.</p> <p>No special reductions</p>
Portugal	PT	No one-off fee	EUR 1 000 – 10 000 (plus tax) Companies with more than 10 MA/PA or turnover over EUR 1 million pay EUR 10 000 plus tax. Companies with turnover under EUR 1 million and up to 10 marketing (MA) or parallel import authorisations (PIA) and pay EUR 1 000 per MA/PIA plus tax.	Fee per MAH	Yes. Companies with up to 10 authorisations and annual turnover under EUR 1 million pay less.	<p>No one-off fee</p> <p>Annual fee/ MAH: EUR 1 000 - 10 000 (plus tax)</p> <p>Reductions for SMEs</p>
Romania	RO	EUR 9000 Up until 30 June 2018: EUR 6000	EUR 9500 for 2019	Flat fee per MAH	No	<p>One-off fee: EUR 9000 (EUR 6000 before June 2018)</p> <p>Annual fee/MAH: EUR 9500 (2019)</p> <p>No special reductions</p>

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Slovakia	SK	No one-off fee	EUR 8 000	Flat fee per MAH	No special reductions	<p>No one-off fee</p> <p>Annual fee/ MAH: EUR 8 000</p> <p>No special reductions</p>
Slovenia	SI	No one-off fee	EUR 10 000 (on-boarding until 30 June 2018) (Increase of annual fee for later signatures is planned. If MAH signs the Agreement after 30 June 2018, the fee increases by 10%. If MAH signs the agreement after 31 December 2018, the fee increases by 20%).	Flat fee per MAH	No special reductions currently planned	<p>No one-off fee</p> <p>Annual fee/ MAH: EUR 10 000 for payments until 30 June 2018. If MAH signs the agreement after 30 June 2018, an increase of 10 % is applied. If MAH signs after 31 December 2018, the fee increases by 20%.</p> <p>No special reductions</p>
Spain	ES	SEVeM will not invoice Marketing Authorisation Holders (MAHs) until 2019. The proposed fee is: EUR 40 000 for all those MAHs that annually bill EUR 40 million or more. For contracts signed in 2018 and 2019, the fee is divided into four payments of EUR 10 000 parts in years 2019, 2020, 2021 and 2022.	In 2019, the annual fee is EUR 40 000 for all MAHs that annually bill EUR 40 million or more.	Fee per MAH	The following special reductions are foreseen for smaller players for both the one-off and annual fees: A minimum fee of EUR 2 000 for all those MAHs whose annual billing is less than EUR 2 million. For MAHs whose annual turnover is between EUR 2-40 million, the standard fees are limited to 0.1% of the annual turnover of sales of serialized products.	<p>Standard one-off fee: EUR 40 000</p> <p>Annual fee/ MAH: EUR 40 000</p> <p>Special reduction foreseen for smaller players based on turnover</p>

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Sweden	SE	No one-off fee	EUR 10 000 (The fees will be charged from 2019, when the system becomes mandatory).	Flat fee per MAH (A company may have several MAHs (x). In such cases the company will pay x times the annual fee. Marketing Authorisation Holders include MAHs, but also others – we usually say that whoever is responsible for placing the product on the Swedish market will pay Sweden’s organisation, e-VIS (e-Verifikation i Sverige); e-VIS will sign agreements with all payers in 2018.)	No special reduction	No one-off fee Annual fee/ MAH: roughly EUR 10 000 No special reductions
UK	UK	EUR 19 500 – 40 000 (it depends on the date of registration with the UK NMVO – the earlier the registration, the cheaper the one-off fee)	N/A	The one-off fee is charged per MAH	N/A	One-off fee EUR 19 500 – 40 000 Annual fee not yet decided No special reductions
EMVO	EU	EUR 3 000 - 45 000 (This fee depends on the number of Marketing Authorisation Holders represented by an OPB and on the date of on-boarding the system – the earlier, the cheaper: OBP for 1 MAH EUR 3 000 - 6 750 OBP for 2 MAH EUR 6 000 - 13 500 OBP for 3-5 MAH EUR 8 000 – 18 000 OBP for 6-12 MAH EUR 10 000 - 22 500 OBP for > 12 MAH EUR 20 000 - 45 000	Paid by NMVOs - not MAHs – based on their market size (calculated on a volume/value basis). Value not yet defined.	On-boarding fee paid by each OBP depending on the number of MAH it represents. Annual fee paid by NMVOs based on their market size (calculated on a volume/value basis).	Fees are lower for OBPs representing fewer MAHs. Contribution of the NMVOs depends on market size	One off fee: EUR 3 000 - 45 000 (paid by OBP depending on number of MAH represented and the date of on-boarding) Annual fee (paid by NMVOs): not yet decided Reductions for smaller players