



European Medicines
Verification Organisation



NMVO FEE MODELS STATUS 26TH APRIL 2018

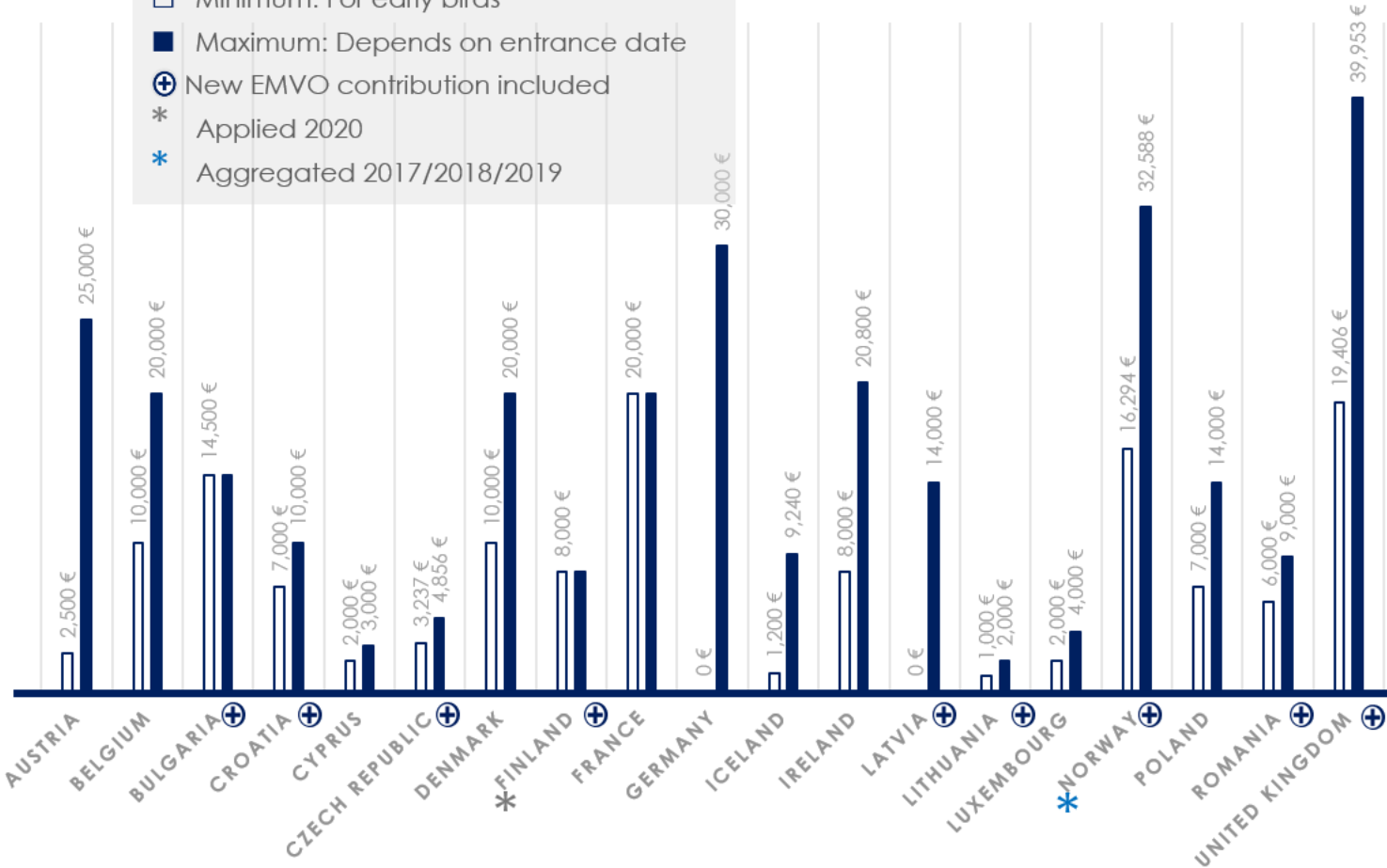
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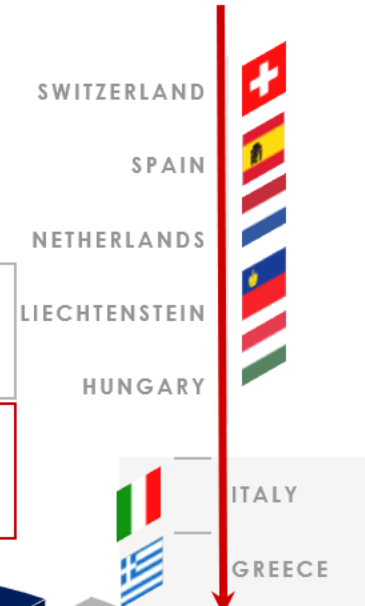
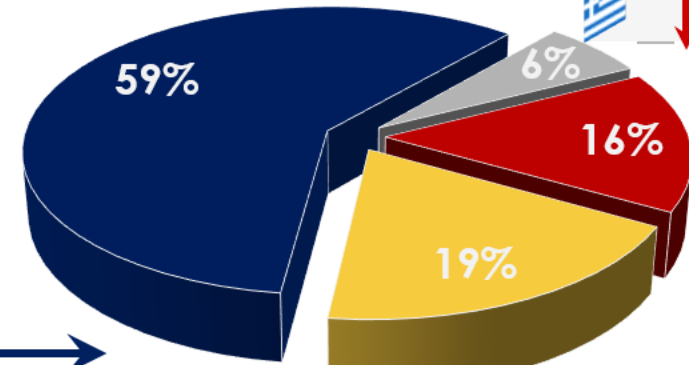
NMVO'S ENTRANCE FEES * Not legal binding



- Minimum: For early birds
- Maximum: Depends on entrance date
- ⊕ New EMVO contribution included
- * Applied 2020
- * Aggregated 2017/2018/2019

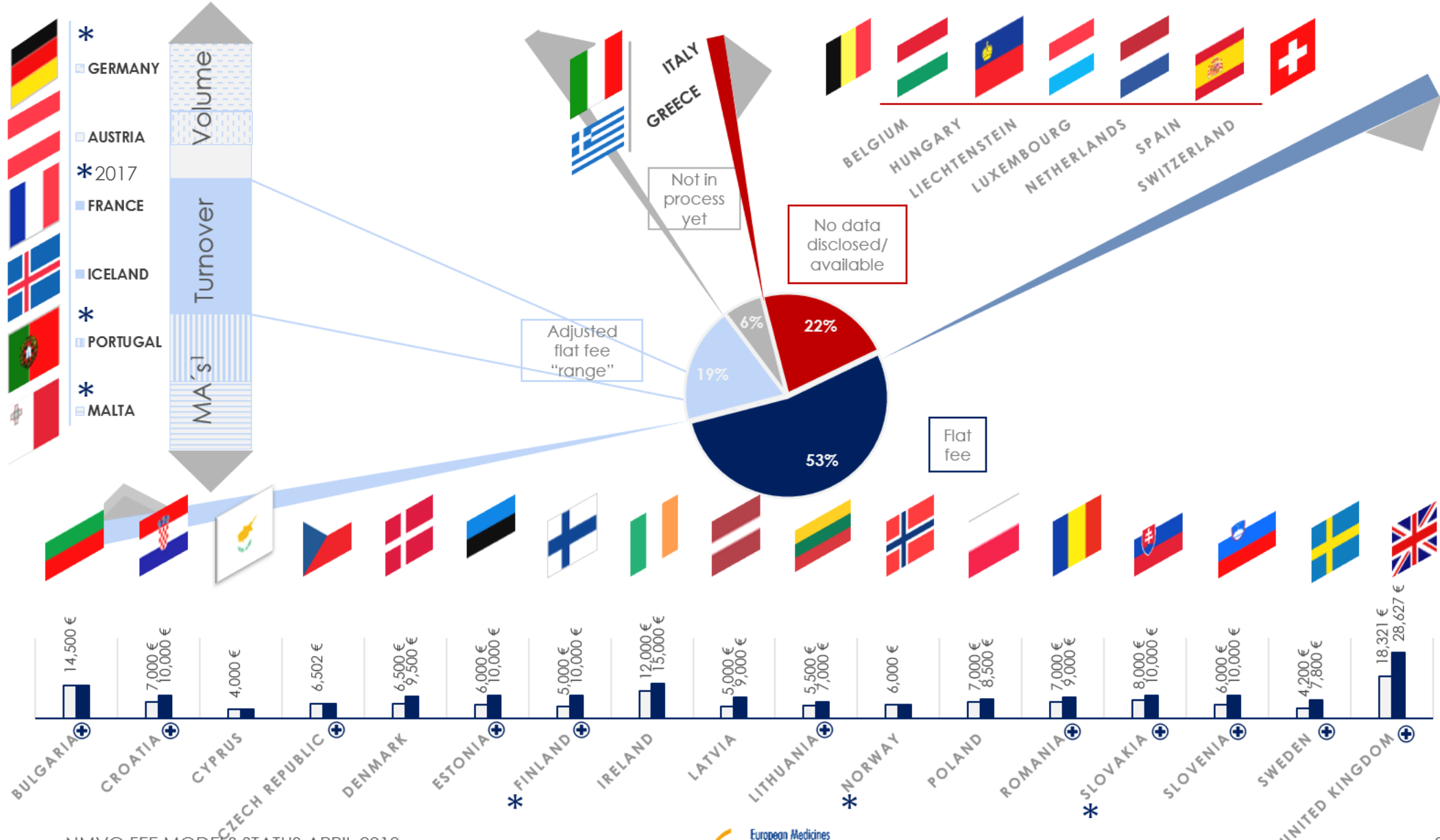


Entrance fees	Not in process yet
No Entrance fees	No data disclosed/available



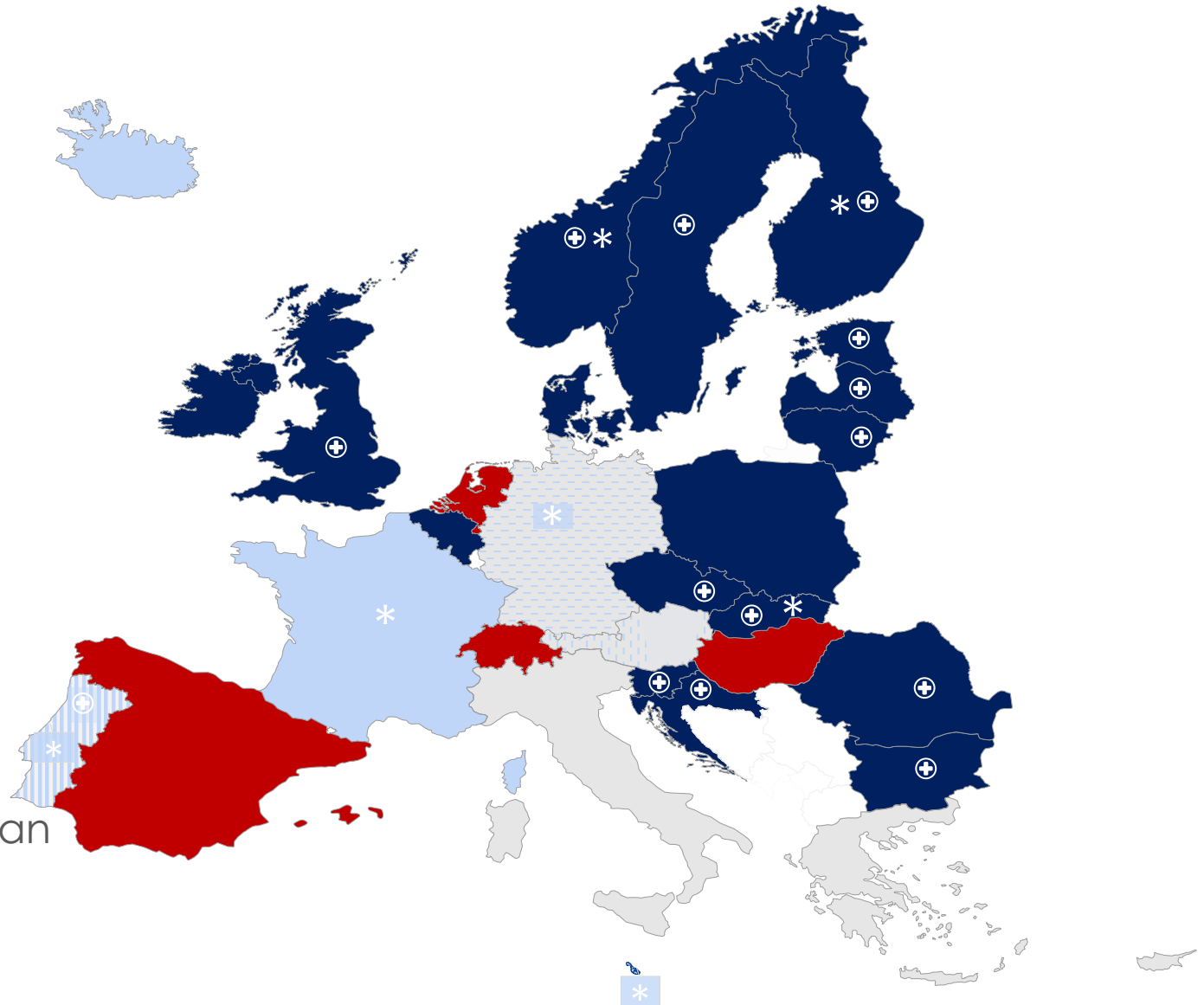
YEARLY OPERATIONAL FEE ESTIMATION * Not legal binding

Marketing authorization



FEE MODEL TYPES * Not legal binding



- Flat fee model
- Adjusted flat fee model
 - Volume based
 - Volume & turnover based
 - Turnover based
 - Turnover & MA based
 - MA based
- No data disclosed/available
- Not in process yet
- ⊕ New EMVO contribution included
- * Application of annual fees earlier than 2019



VOLUME BASED MODEL GERMANY *

Usage costs – Case studies

The case studies below show the costs for four different companies in the year 2016 depending on the number of packs provided into the database system of the pharmaceutical industry by the marketing authorization holder in question.

Fee model	Company I	Company II	Company III	Company IV
				
Component A	25,000 € as from 1 July 2017			
One-time initial set-up fee	30,000 € as from 1 January 2018			
Component B	350 €			
monthly operating fee				
Component C	50 thousand packs	500 thousand packs	5 million packs	20 million packs
Fee per data set / pack volume (degressively scaled)	450 €	2,000 €	6,150 €	17,300 €
Total costs per year (without initial set-up fee)	<u>4,650</u>	<u>6,200</u>	<u>10,350</u>	<u>21,500</u>

The above information represents general information about the fee model of ACS PharmaProtect GmbH; it is no substitute for a specific quotation. Only the user agreement in its current version will be binding. Please contact us anytime for additional information or a specific model calculation for your company.



Source: pharmaprotect.de
* = Application earlier than 2019

Adjusted
flat fee

VOLUME & TURNOVER BASED MODEL AUSTRIA (1)



Fixed Turnover based Part		Variable Volume based Part	
Turnover € / User p.a.	Operational Fee € / User p.a.	Price-Quantity Scale p.a.	€/serial number
<100k	500	< 50.000	0,009
100k-3,0 Mio	3 000	50.000 - 500.000	0,008
3Mio-10 Mio	5 000	500.000 - 2.000.000	0,007
10-30 Mio.	15 000	> 2.000.000	0,004
30-50 Mio.	25 000		
50-70 Mio.	35 000		
70-100 Mio.	45 000		
100-150 Mio.	55 000		
150-200 Mio.	65 000		
200-250 Mio.	75 000		
>250 Mio.	85 000		

Turnover based fee is calculated by the turnover of the past year (due at the beginning of the following year)*.
Degressiv calculation of the volume based part by uploaded serial numbers (model for MMPs in discussion) in the current year

Basis for both parts are medicinal products obligated to serialisation in Austria.
*Amount Netto in Euro

Source: Daniel Dangl

Adjusted
flat fee

VOLUME & TURNOVER BASED MODEL AUSTRIA (2)



MODEL FOR ACCESSION FEE AUSTRIA

Turn over groups	until 02/2018	until 08/2018	after 08/2018
< 0,1 mio €	1,500	2,500	4,000
0,1 – 1,0 mio €	5,000	8,500	15,000
> 1,0 mio €	15,000	25,000	40,000

Netto in Euro, turn over based on medicinal products obligated to serialisation in Austria

Source: Daniel Dangl

Adjusted
flat fee

TURNOVER BASED MODEL FRANCE *

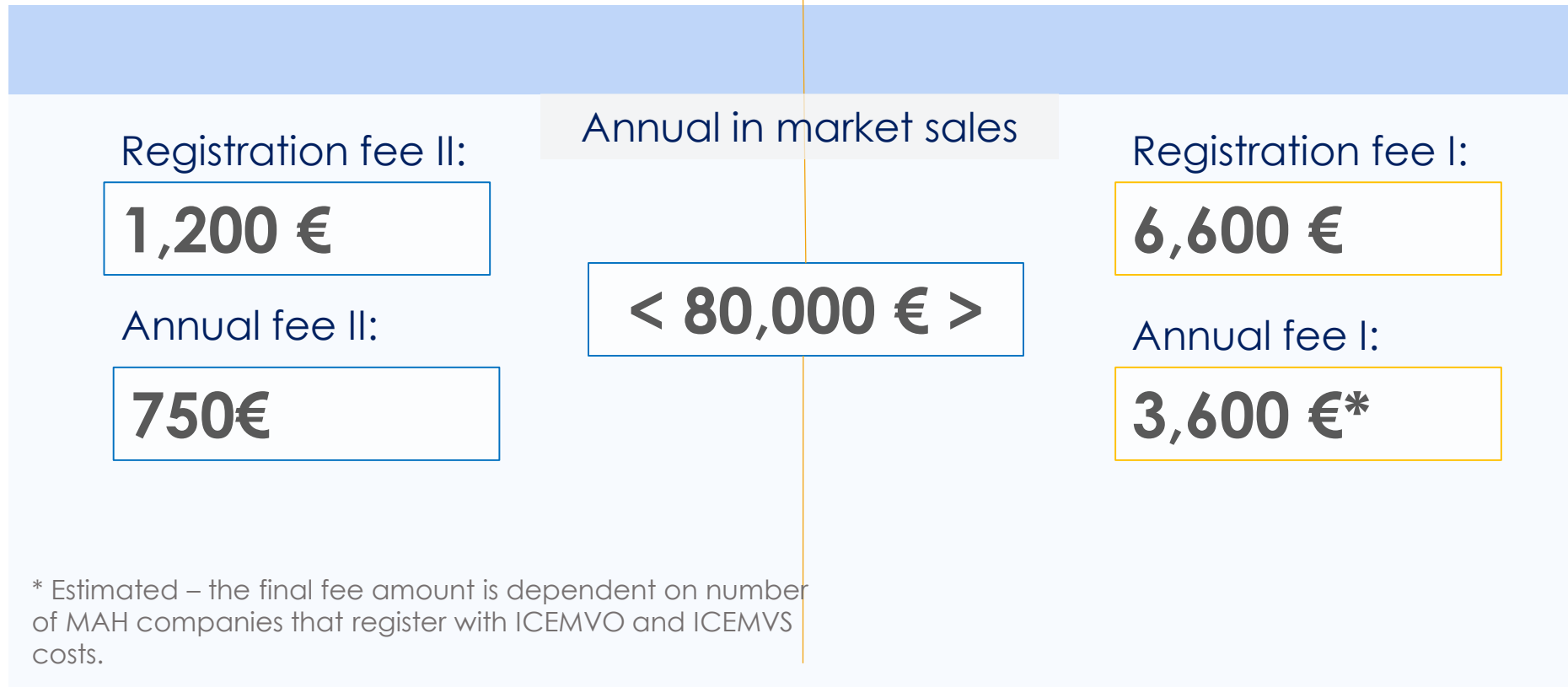


Turnover	3% of Turnover = Fee
< 50,000 €	Min. 1,500 €
> 50,000 – 666,666 €	“Exploitant” example: Turnover: 280,000€ Fee: 8,400 €
> 666,666 €	Max. 20,000

* = Application since 2017

Adjusted
flat fee

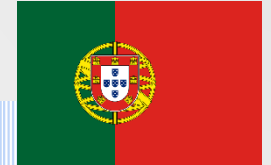
TURNOVER BASED MODEL ICELAND



* Estimated – the final fee amount is dependent on number of MAH companies that register with ICEMVO and ICEMVS costs.

Adjusted
flat fee

MA & TURNOVER BAES MODEL PORTUGAL



1,000 €

Turnover a year
< 1,000,000€ >

10,000 €

Number of MAs

< 10 >

- * = Application earlier than 2019
- ⊕ = New EMVO contribution included

Adjusted
flat fee

MA BASED MODEL MALTA *



MAAs per MAH	Contribution per MAH/ €
1-5	650
6 - 25	1,650
26 - 50	4,200
51 - 300	12,500
300+	35,500

* = Application earlier than 2019