



European Medicines
Verification Organisation



European Federation of Pharmaceutical
Industries and Associations



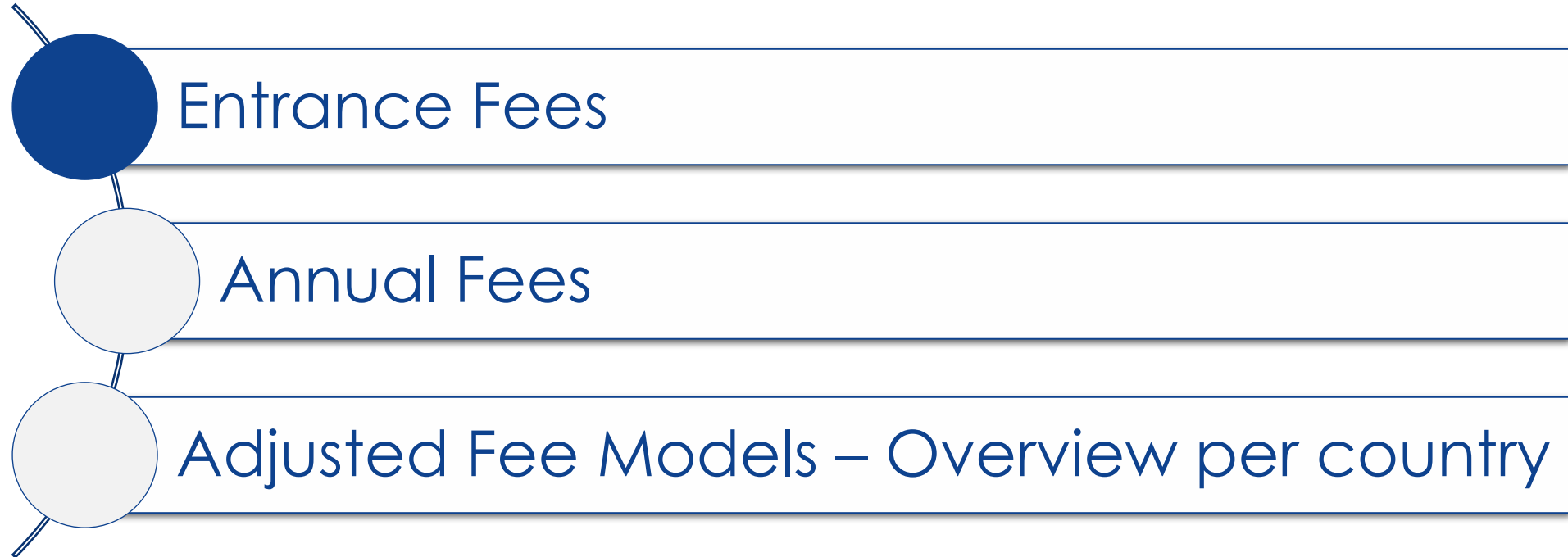
PGEU GPUE



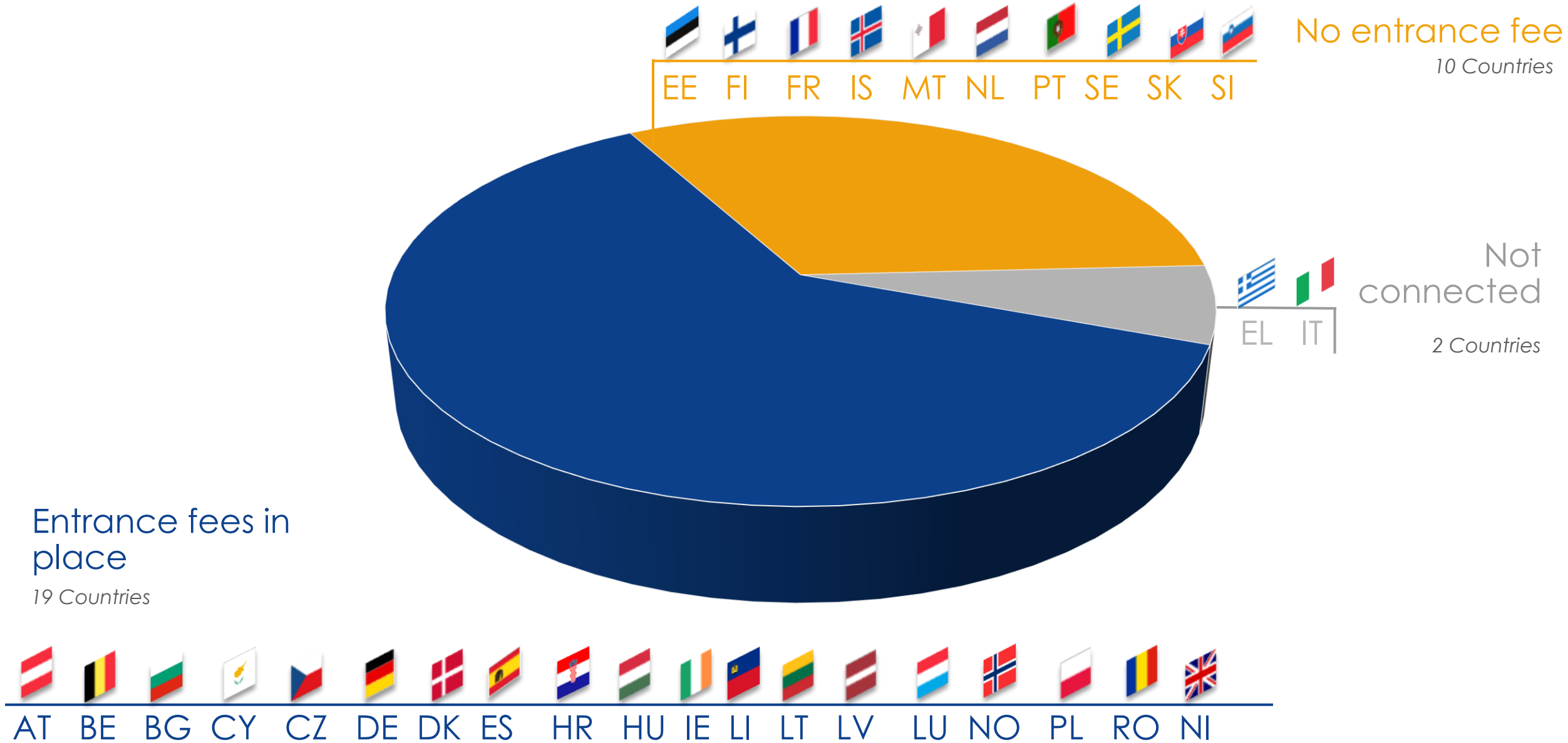
NMVOs FEE MODEL 2022

January 2022

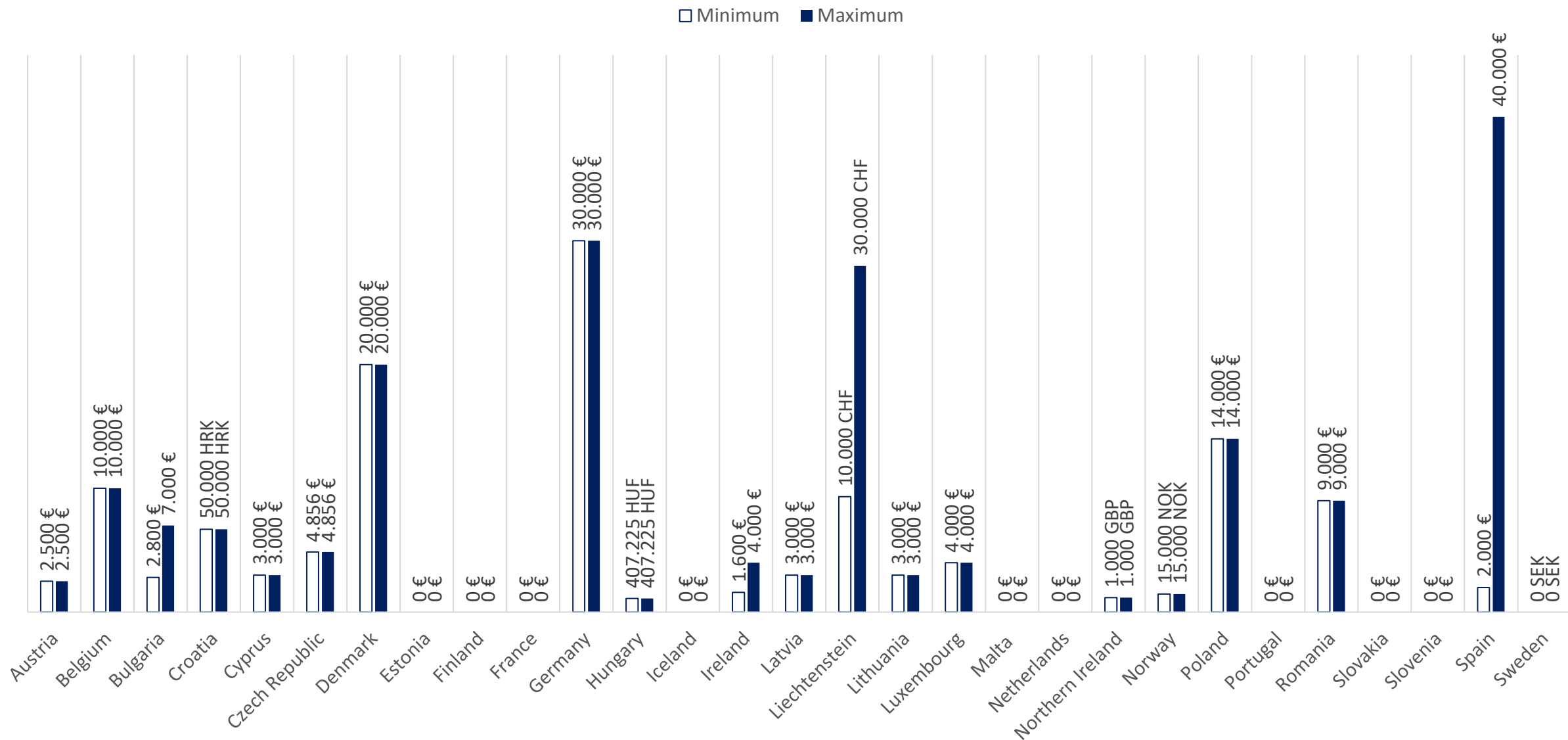
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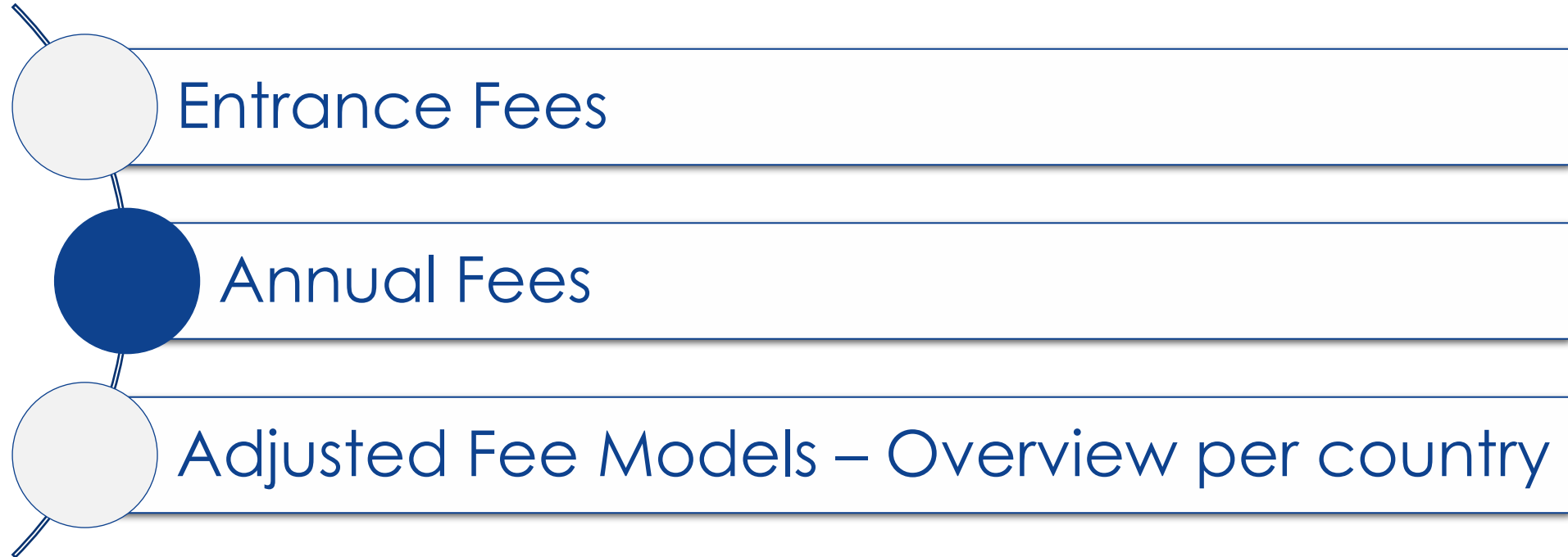
ENTRANCE FEES OVERVIEW



ENTRANCE FEES RANGE



CONTENT



ANNUAL FEES OVERVIEW

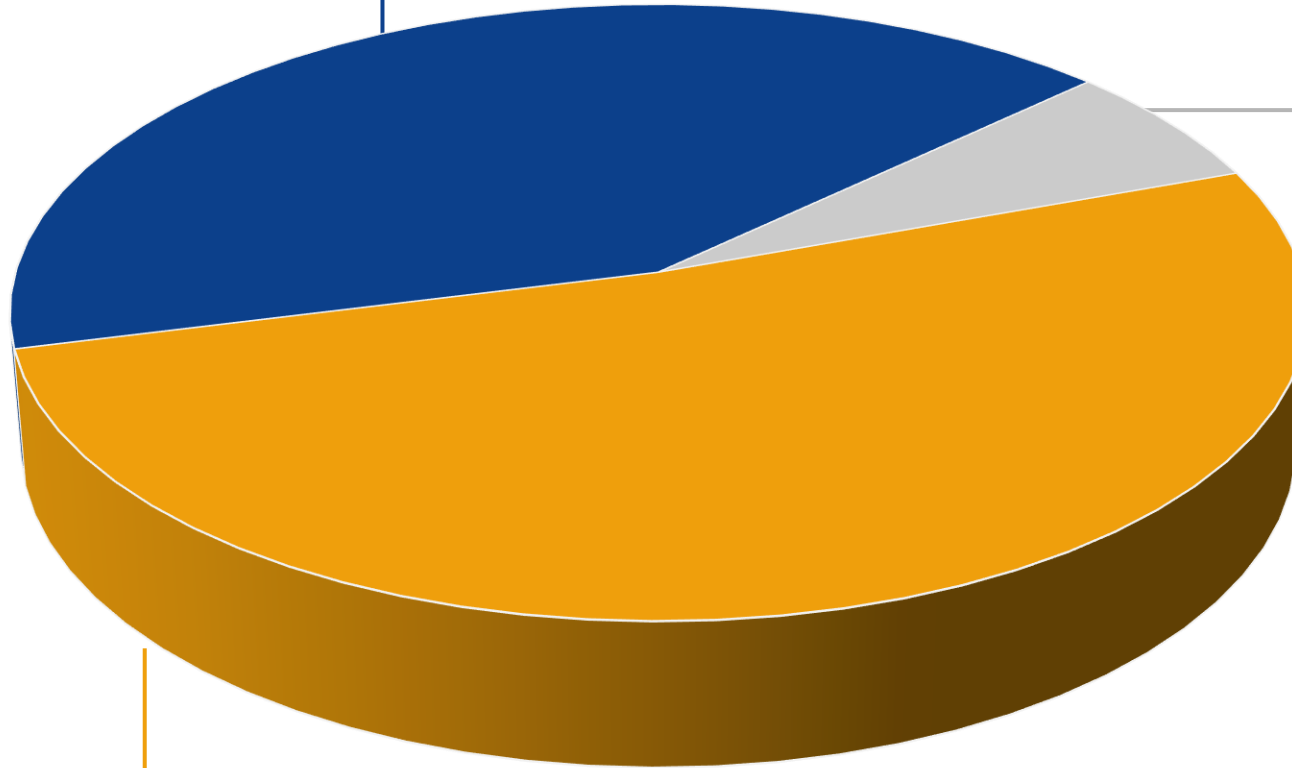
Flat fee

13 Countries

CY DK FI HR HU LV LT NI NL PL RO SI SK

EL IT

Not connected
2 Countries

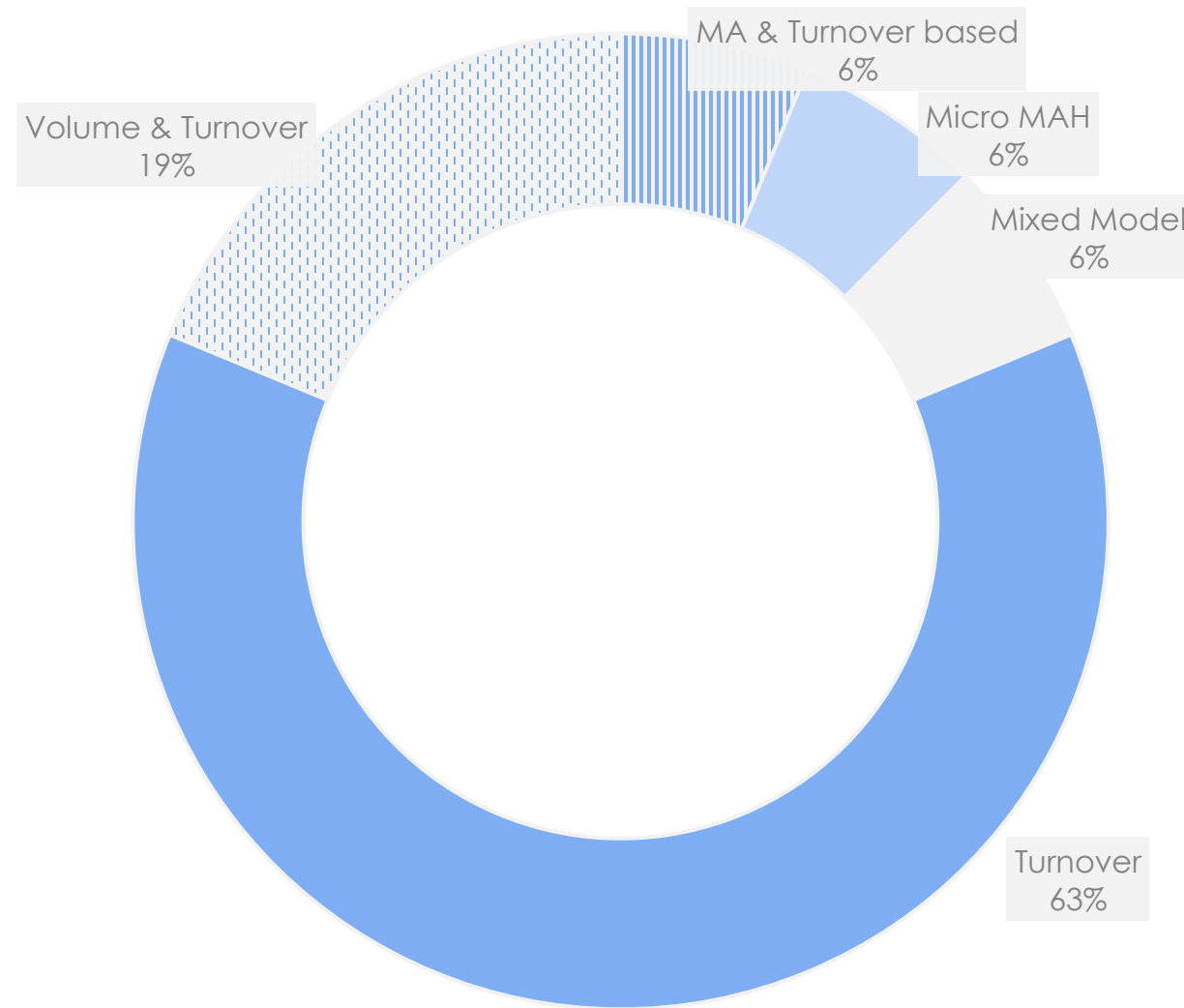


AT BE BG CZ DE EE ES FR IE IS LI LU MT NO PT SE

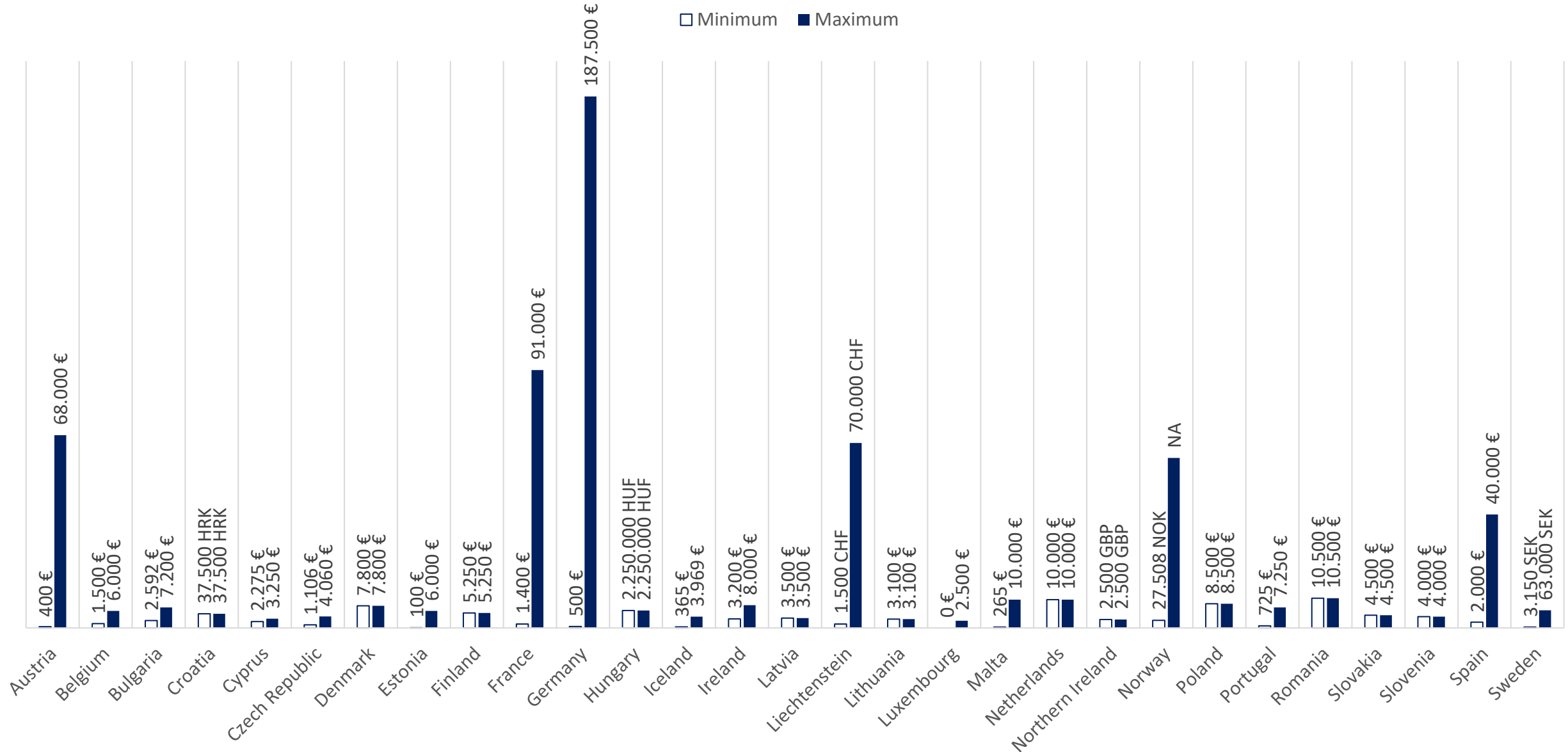
Adjusted Flat Fee

16 Countries

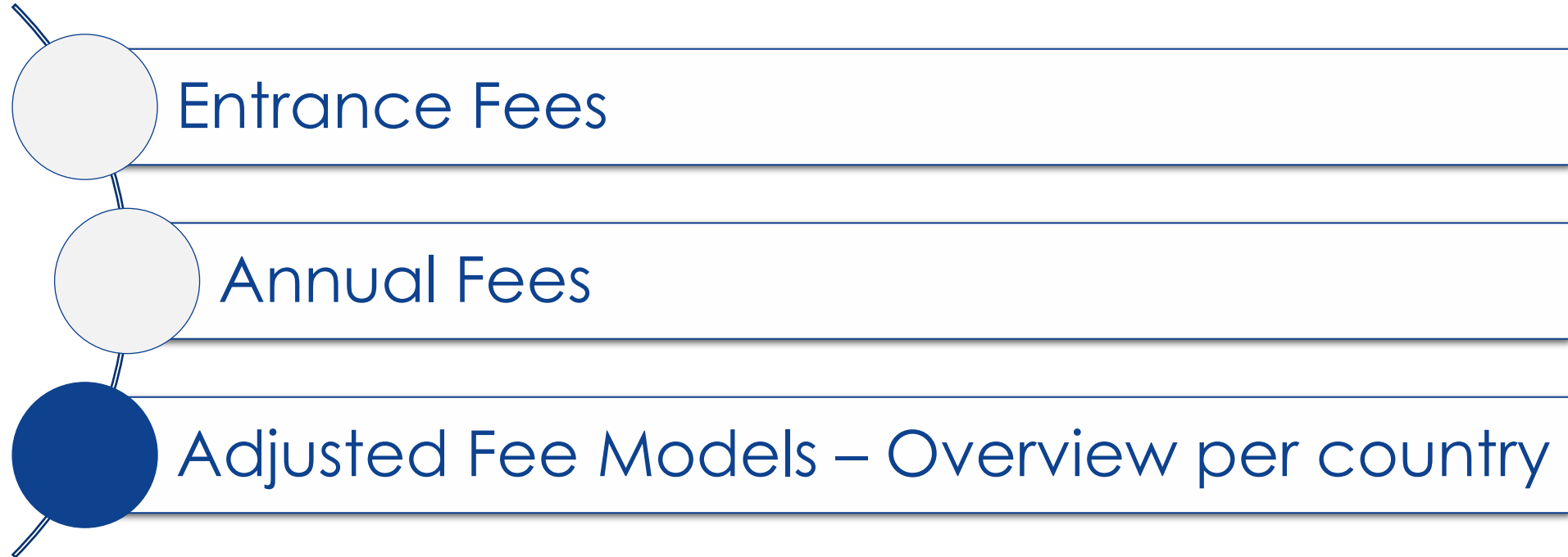
ANNUAL FEES – ADJUSTED FLAT FEE MODELS



ANNUAL FEES RANGE 2022



CONTENT





VOLUME & TURNOVER BASED MODEL - AUSTRIA



AUSTRIA

Reduction 20% on Fixed Fee
Simplified & reduced Variable Volume Fee

Part of fixed Turnover based

Turnover € / User p.a.	Fee NEW from 2022 € / User p.a.
< 100k	400
100k-1.5 Mio	1 200
1.5-3 Mio	2 400
3-10 Mio	4 000
10-20 Mio	6 000
20-30 Mio	12 000
30-50 Mio	20 000
50-70 Mio	28 000
70-100 Mio	36 000
100-150 Mio	44 000
150-200 Mio	52 000
200-250 Mio	60 000
< 250 Mio	68 000

Part of Variable Volume based

Price-Quantity Scale p.a.	€ / serial number
≤ 2.000.000	0,007
≥ 2.000.001	0,004

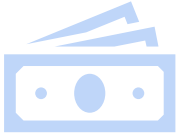
Turnover based fee is calculated by the turnover of the past year (due at the beginning of the following year).

Degressiv calculation of the volume based part by uploaded serial numbers in the current year

amvs
Austrian Medicines
Verification System

TURNOVER BASED MODEL BELGIUM

Adjusted
Flat Fee



If the turnover for the products in scope is below a certain amount, it is possible to apply for a reduced fee.

Turnover for products in scope	Fee
< 100.000€	1.500€
< 1.000.000€	3.750€
> 1.000.000€	6.000€

The procedure to apply for a reduced Flat Fee is:

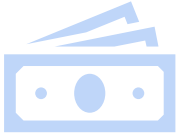
- The reduced fee is not allocated automatically. The Marketing Authorisation Holder needs to request the reduced fee level.
- This request must be supported by documents providing proof of the turnover, such as market research data, audit data, ...

More information can be consulted on BeMVO's [website](#).

“MICRO MAH” MODEL BULGARIA



BULGARIA

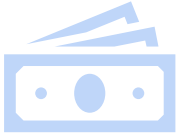


- If a MAH qualifies as a micro or small enterprise according to the criteria of the SME initiative of EMA, and is listed in the EMA registry, the MAH is entitled to a 60% reduction of the annual fee.

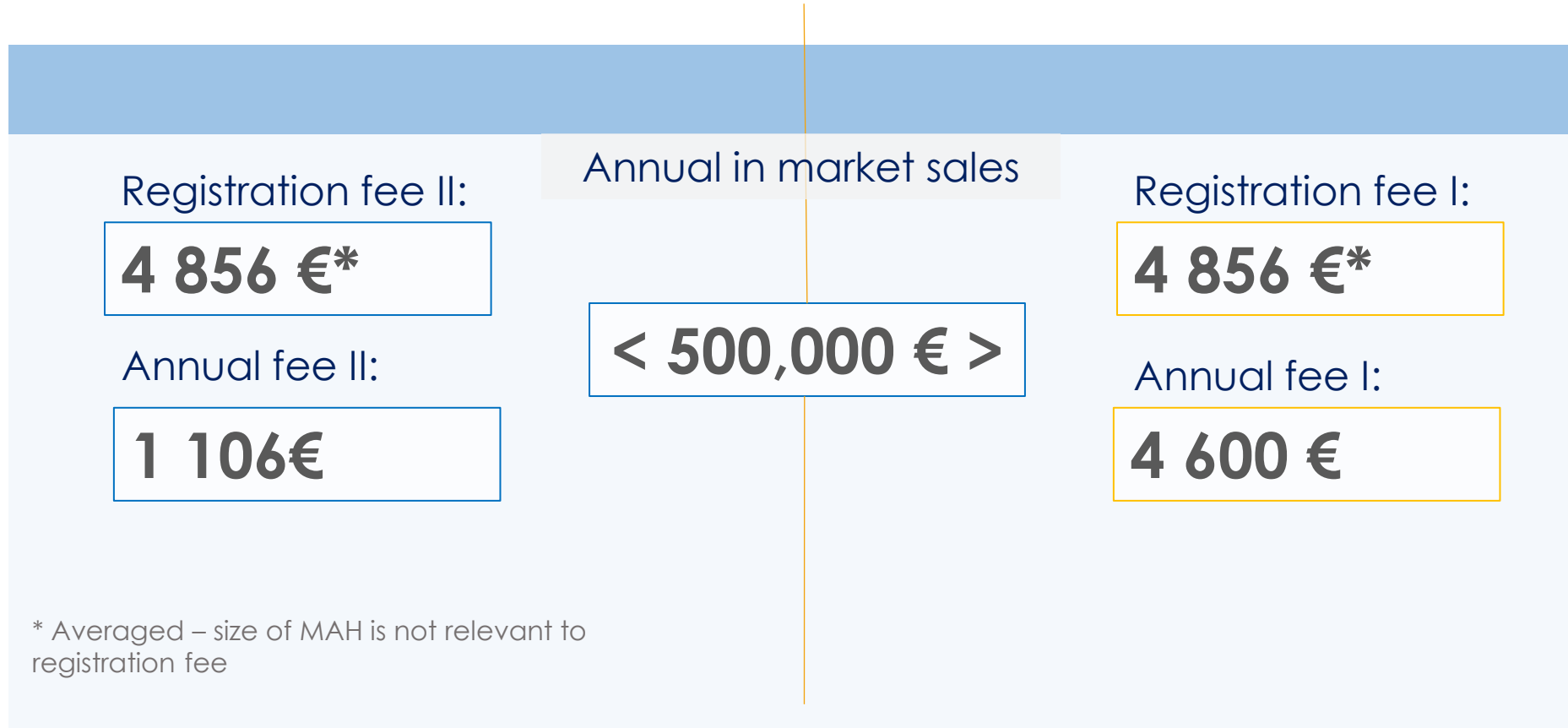
Full Fee	Micro MAH Fee
7.200€	2.880€

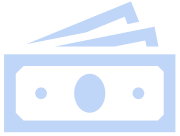
- 10% discount for early payment is applicable if the fee is paid before 30 September 2022

Early Payment Fee	Early Payment Micro MAH Fee
6.480€	2.592€



TURNOVER BASED MODEL - CZECH REPUBLIC





TURNOVER BASED MODEL - ESTONIA



ESTONIA

MAH annual turnover

> 100 000 €

50 000 – 99 999 €

8 000 – 49 999 €

3 000 – 7 999 €

< 3 000 €

Flat fee

Exception 1

Exception 2

Exception 3

Exception 4

Flat Fee and exceptions for 2022*

6 000 €

3 000 €

1 500 €

5000 €

100 €

*Applications to 2022 exceptions must be sent to info@reks.ee



TURNOVER BASED MODEL – FRANCE*

PROVISIONAL FEE



FRANCE

For members of

GEMME

Turnover	Fee
(+) 25M€	35 000€
15-25 M€	25 000€
5- 15 M€	6 000€
(-) 5 M€	1 400€

For members of



& not members of
pharmaceutical
unions

Turnover	Fee
(+) 50 M€	91000€
25-50 M€	35 500€
15-25 M€	25 000€
5- 15 M€	6 000€
(-) 5 M€	1 400€

*Application in 2022
Ex factory prices, free of taxes

VOLUME & TURNOVER BASED MODEL - GERMANY



GERMANY

Adjusted
Flat Fee



A. Part of fixed Turnover based

Turnover € (net.) p.a. Range	Fee € (net.) p.a.
> 1,778,000,000 ∞	140,000
> 1,000,000,000 1,778,000,000	115,000
> 562,300,000 1,000,000,000	98,500
> 316,200,000 562,300,000	87,500
> 177,800,000 316,200,000	74,500
> 100,000,000 177,800,000	60,000
> 56,230,000 100,000,000	46,500
> 31,620,000 56,230,000	34,500
> 17,780,000 31,620,000	25,000
> 10,000,000 17,780,000	17,500
> 5,623,000 10,000,000	12,000
> 3,162,000 5,623,000	8,000
> 1,778,000 3,162,000	5,500
> 1,000,000 1,778,000	3,500
> 562,300 1,000,000	2,300
> 316,200 562,300	1,500
> 177,800 316,200	950
> 100,000 177,800	600
> 0 100,000	500

B. Part of fixed Volume based

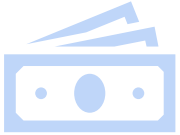
Volume Turnover Packages p.a. * Range	Fee € (net.) p.a.
> 31,623,000 ∞	47,500
> 10,000,000 31,623,000	38,000
> 3,162,300 10,000,000	30,000
> 1,000,000 3,162,300	25,000
> 316,230 1,000,000	16,000
> 100,000 316,230	11,000
> 31,623 100,000	6,500
> 10,000 31,623	3,000
> 0 10,000	1,300

*No Volume based part
if Turnover (net. p.a.) < 100,000 €

Registration fee = 30,000 € (net.)
Annual fee = Fee (Part A) + Fee (Part B)

Remark : the above annual operational fee remains unchanged from one year to the other.

Adjusted
Flat Fee



TURNOVER BASED MODEL - ICELAND



IDM 2021 Sales Turnover	Annual Fee
> 80.000€	3.969€
16.000€ - 80.000€	1.215€
< 16.000€	365€



ENTRANCE FEE - LIECHTENSTEIN

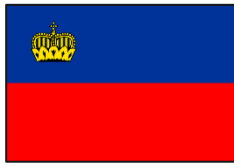


LIECHTENSTEIN

Turnover Rx/Mio. CHF	Registration Fee in CHF
0 to 30	10.000
30 to 200	20.000
From 200	30.000

Remark : the above entrance fee remains unchanged from one year to the other.

ANNUAL OPERATIONAL FEE - LIECHTENSTEIN



LIECHTENSTEIN

Adjusted
Flat Fee



FIX BASE FEE CHF 1'500 (10-15% OF TOTAL FEE)

Turnover Based (60-70% of total fee)

Rx Ex-Factory Turnover TCHF	Fee CHF
0 – 100	0.-
100 – 3'000	2'000.-
3'000 – 10'000	5'000.-
10'000 – 30'000	15'000.-
30'000 – 50'000	20'000.-
50'000 – 70'000	25'000.-
70'000 – 100'000	30'000.-
100'000 – 150'000	40'000.-
150'000 – 200'000	50'000.-
200'000 – 300'000	60'000.-
ab 300'000	70'000.-

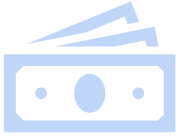
Volume Based/Cumulative (20-25% of total fee)

Sold Rx-Packs	CHF/Pack
0 – to 50'000	0.009
from 50'000 – to 1'000'000	0.007
from 1'000'000 – to 2'000'000	0.005
from 2'000'000	0.003



= Corporation based (not MAH)

Remark : the above annual operational fee remains unchanged from one year to the other.



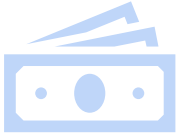
TURNOVER BASED MODEL - IRELAND



IRELAND

Turnover	Entrance Fee	2022 Annual Fee
> 100.000€	4.000€	8.000€
< 100.000€	1.600€	3.200€

MAHs who wish to be considered for the lower fees must complete a rebate application form (available from mah@imvo.ie). The turnover figure (which is based on sales in Ireland in the previous year) will be self-certified, but IMVO reserves the right to request supporting evidence and/or audit the declared turnover. Fee rebate decisions will be valid for one financial year only. Separate application must be made in subsequent year(s) if a MAH considers that it continues to be eligible for a rebate and such application(s) will be considered by IMVO independently of previous decision(s).



TURNOVER BASED MODEL - LUXEMBOURG



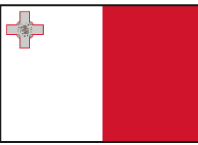
LUXEMBOURG

2021 Sales Turnover	2022 Annual Fee
> 200.000€	2.250€ = 2.500€ -10% discount in 2022
20.000€ - 200.000€	1.080€ = 1.200€ - 10% discount in 2022
< 20.000€	450€ = 500€ -10% discount in 2022
0€	0€

Please note that the MAH must provide a proof of the turnover for the affected products, and LMVO can request further information at any time.

Moreover, the request for reduced fee should be submitted before December 15th.

MIXED MODEL - MALTA



MALTA



Group A:

Authorisation Holders Uploading Products into the MaMVS

Fee	Fee Model
8.000 € ⁽¹⁾	Flat rate fee per authorisation holder

- (1) Cumulative 15% discounts apply to:
- Regular Contributors,
 - Data Uploaded for Only 1-5 Authorisations,
 - Orphan or Rare Disease Medicinal Products,
 - SMEs.

Group B:

Authorisation Holders placing medicinal products on the Maltese market but uploading data to another national repository

No. of Licences	Fee	Fee Model
1-33	265 €	Per licence
34-300	9 000 €	Flat fee
> 300	10 000 € ⁽²⁾	Per 100 licences or part thereof

- (2) 10% discount will be applied to entities holding more than 500 licences.

More information on the two groups can be found on [MaMVO Website](#).

“MICRO MAH” MODEL – NORTHERN IRELAND



NORTHERN IRELAND



✓ If an MAH fulfils
2/3 of criteria...

➤It is considered
as a “micro MAH”
and may postpone
the entrance and
the yearly fees by
one year.

I
≤ Turnover (UK) GBP £632,000 >

II
≤ Balance sheet: GBP £316,000 >

III
≤ Employees: 10 >

⊗ If an MAH does
not fulfil **2/3** the
criteria...

ENTRANCE FEE

FIXED

1.000 GBP

YEARLY FEE

FIXED

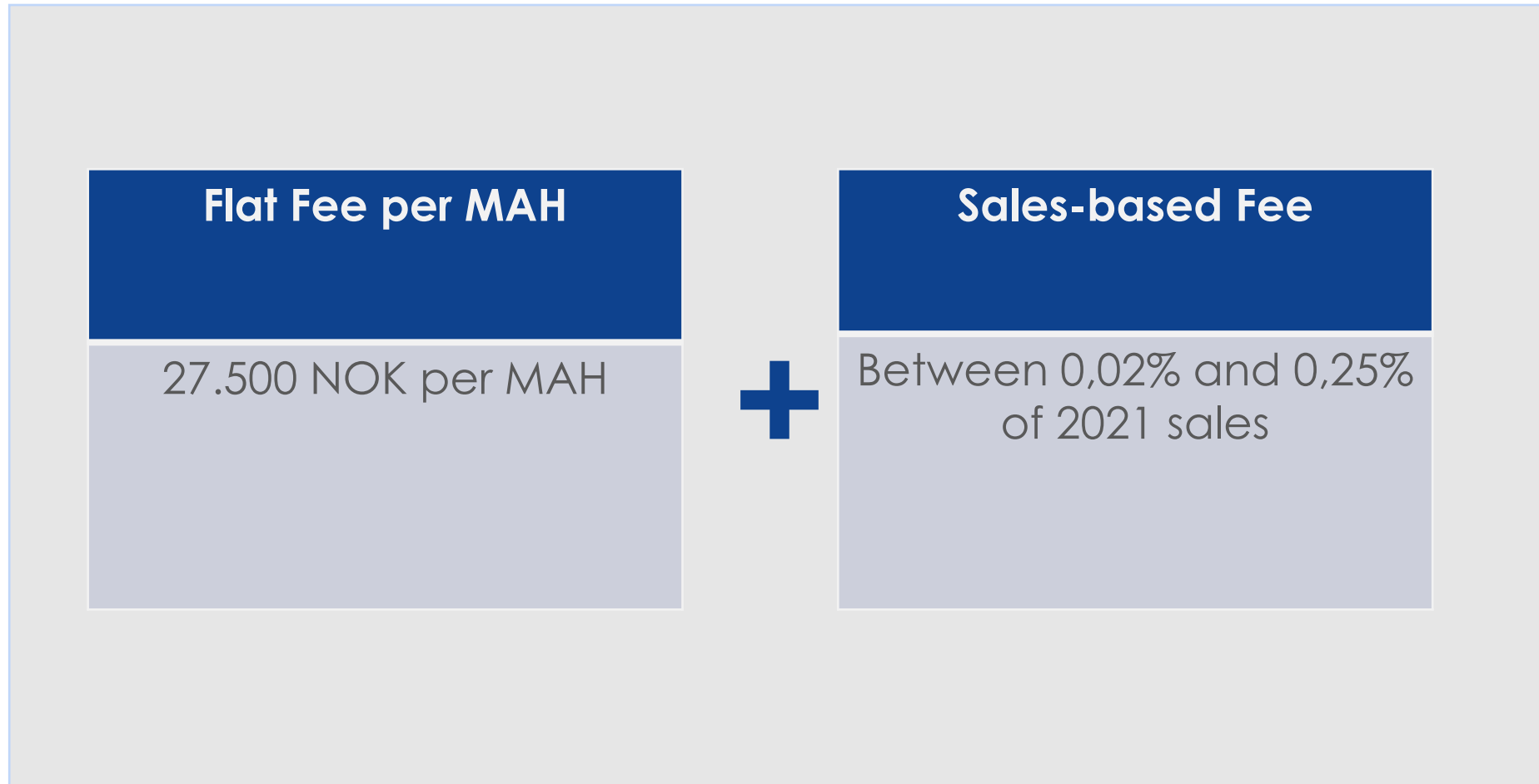
2.500 GBP



ANNUAL FEES - NORWAY



NORWAY



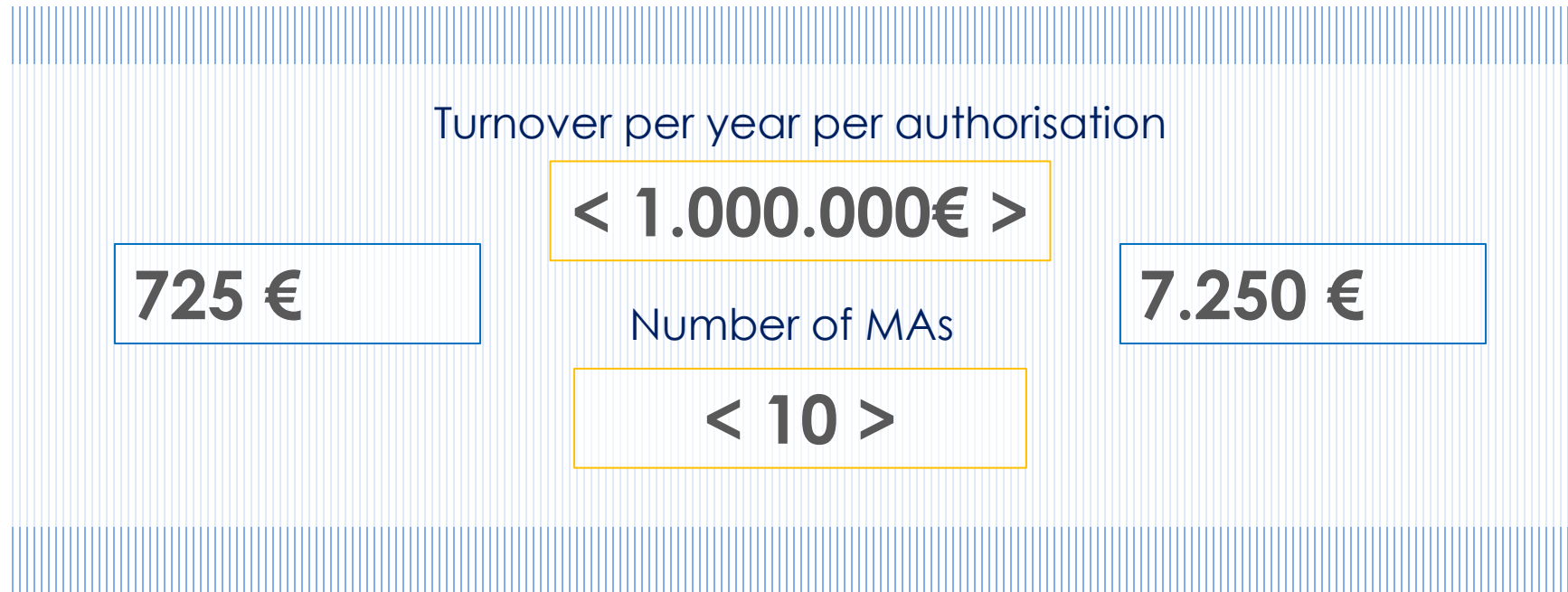
More information can be found on [Nomvec's website](#).



MA & TURNOVER BASED MODEL - PORTUGAL



PORTUGAL



More information can be found on [MVO Portugal's website](#)



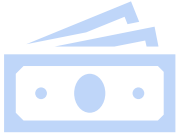
TURNOVER BASED MODEL - SPAIN



SPAIN

Turnover	Fee
$\leq 2,000,000 \text{ €}$	Min. 2,000 € *
$> 2,000,000 \text{ €} - 40,000,000 \text{ €} <$	Fee limited to the 0,1% of the turnover *
$\geq 40,000,000 \text{ €}$	Flat 40,000 €

* = Declaration of Responsibility Required



TURNOVER BASED MODEL - SWEDEN



SWEDEN

Sales	Discount offered	Annual Fee
> 1.000.000 SEK	0%	63.000 SEK
500.000 SEK – 999.999 SEK	25%	47.250 SEK
100.000 SEK - 499.999 SEK	75%	15.750 SEK
0 SEK - 99.999 SEK	95%	3.150 SEK

To apply for a reduced fee notify e-VIS at administration@e-vis.se. e-VIS will then send an application form to be completed. It is the responsibility of the company to give notice if they meet the criteria for a reduced fee at the latest **November 19, 2021**.