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General Secretariat

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MEETING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés)
Subject:	Working Party on Pharmaceuticals and Medical Devices 2 February - Presentation from the Commission

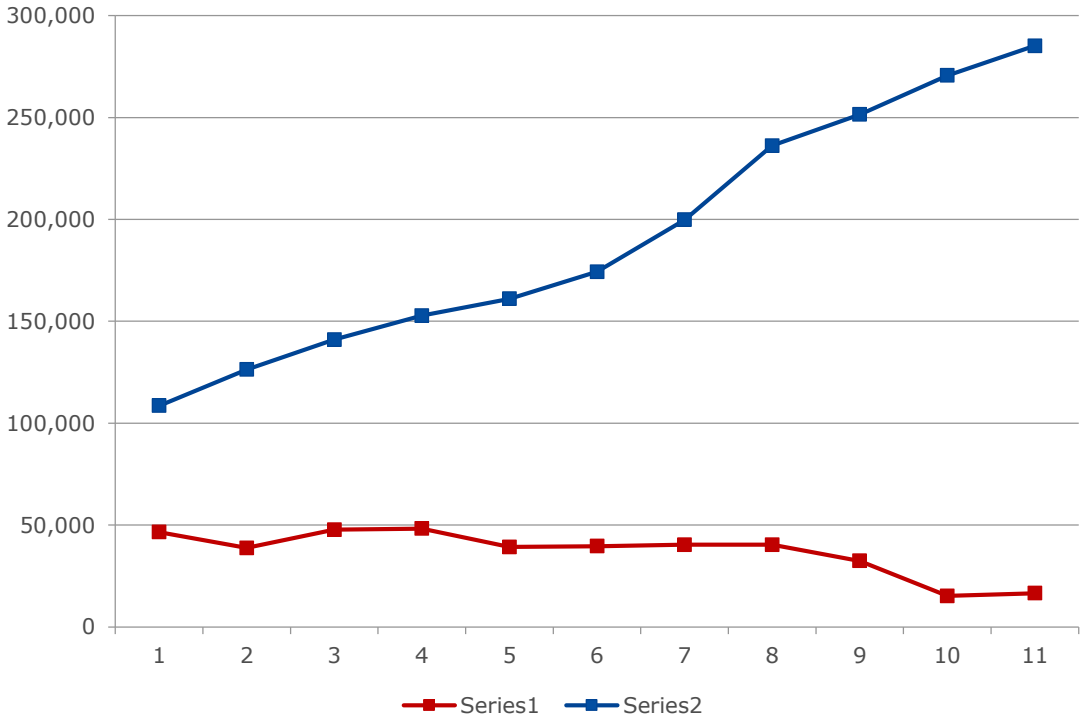
Delegations will find in annex presentation from the Commission services on methodology on EMA fees proposal.

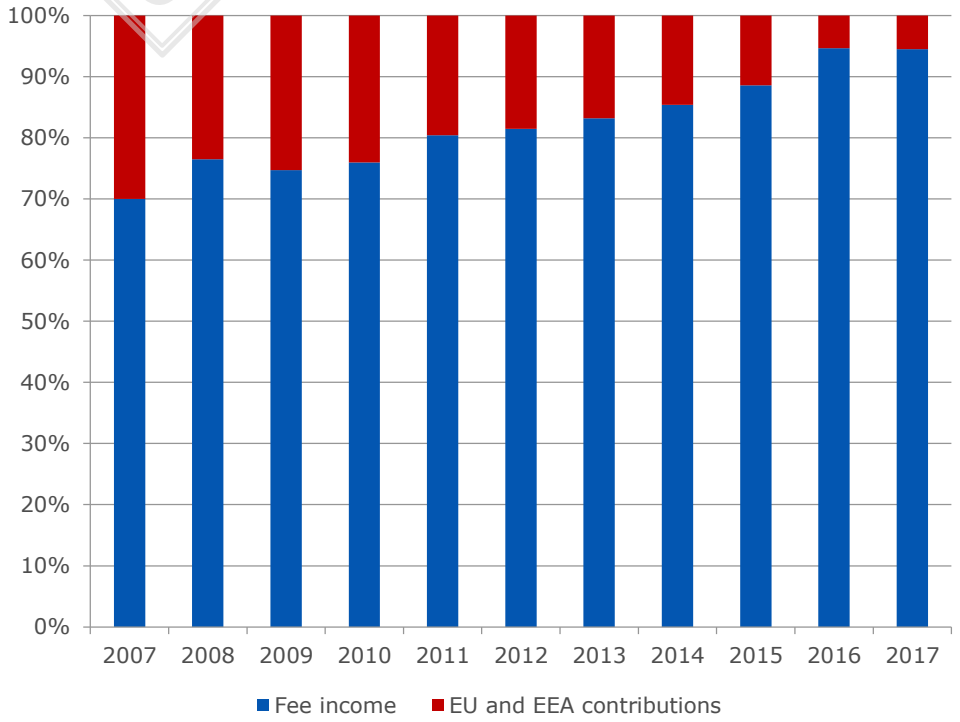
Methodological aspects of the study supporting the impact assessment

Proposal for a Regulation of the European Parliament and of the Council on Fees and Charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council

DG SANTE, 02.02.2023

Introduction: Evolution of EMA financing





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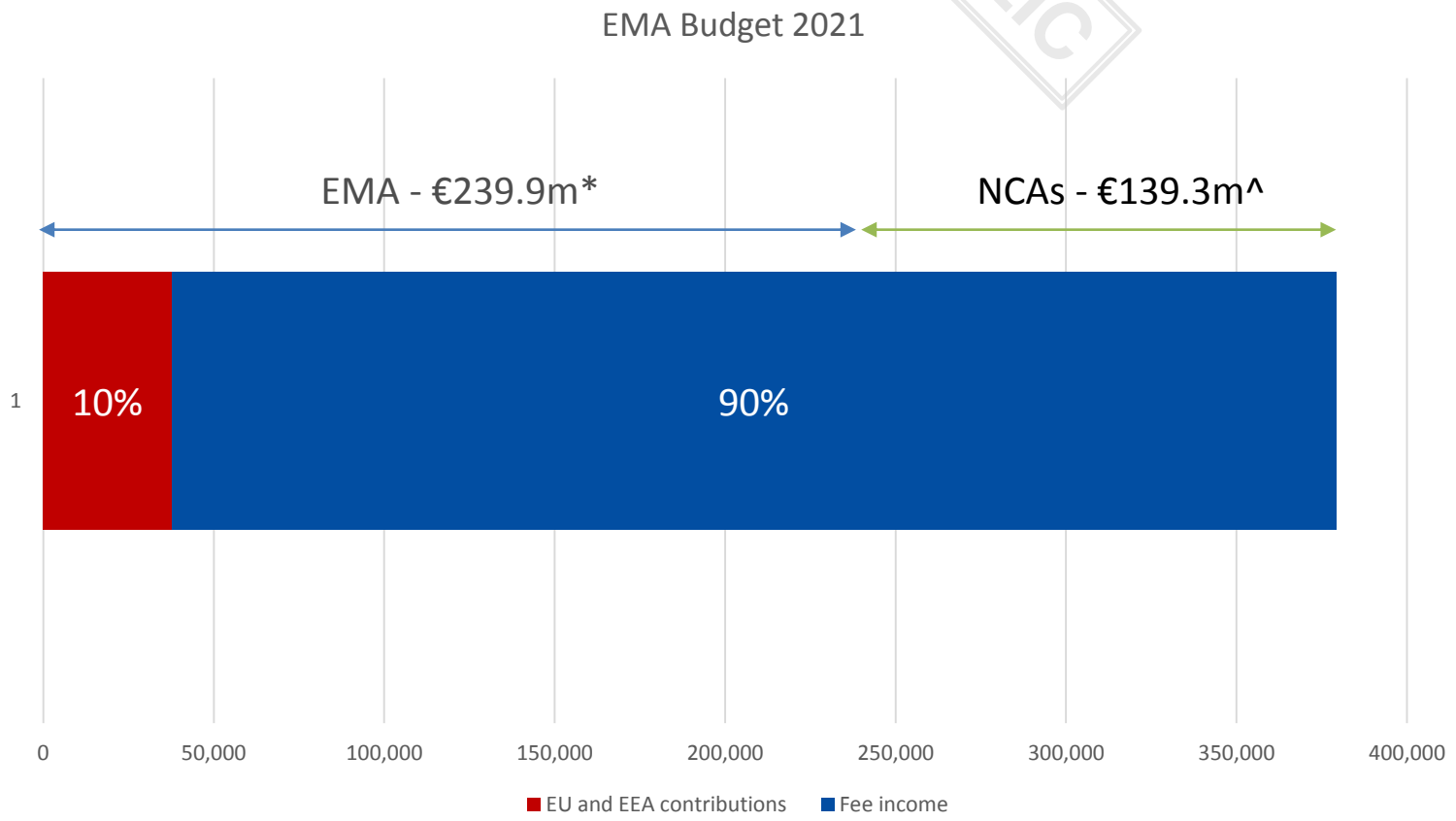
Introduction: EMA budget 2021

*EMA costs include meeting costs, reimbursements for delegates, cost of incentives, salaries, building, etc.



^NCAs amount stated in the figure represents only remuneration from fees. Reimbursement for meeting participation (travel, daily allowances, etc.) are not included here, but appear in the EMA costs

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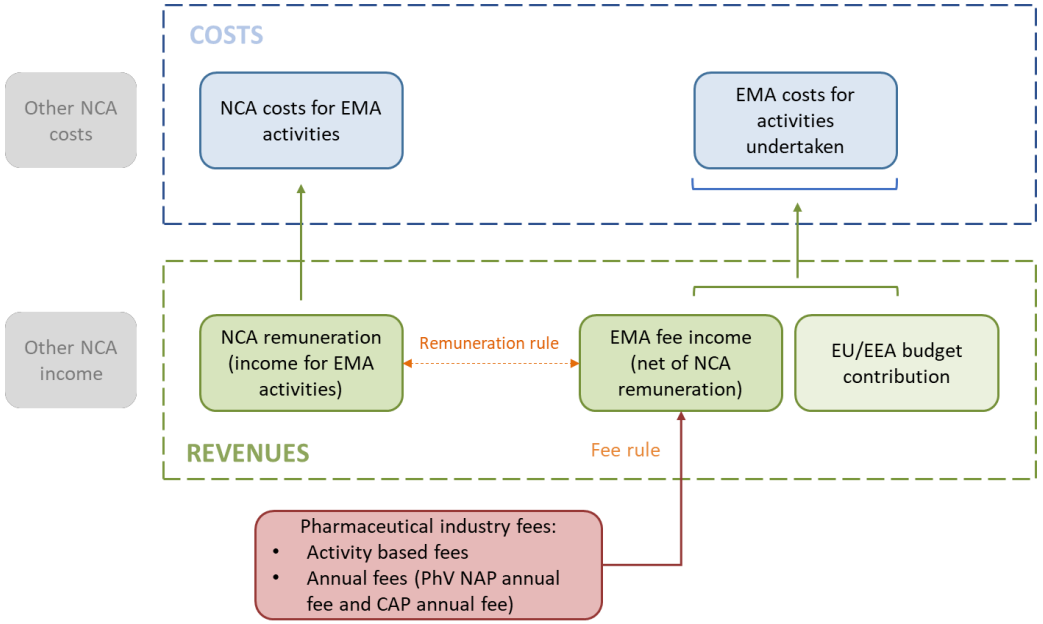
Overview

- Financial model that calculates fees based on estimated costs, revenues to EMA and remuneration to NCAs, and quantifies the overall financial impact of different options for the revision of the fee system.
  - Does **not** replicate financial accounting systems of stakeholders
    - NCAs individual costs are an input based on declarations and estimated frequencies
  - Does **not** take into account the impact of timing of payments on stakeholders
    - One model year is not one calendar year or one financial year, but one ‘synthetic’ year where there is no time lag between procedures and payments

Cost and revenue model



The model has two parts:

1) **Cost**:

- Costs for NCAs to undertake EMA activities
- EMA costs

2) **Revenue**:

- NCAs: remuneration income received by NCAs
- EMA: total EMA fee revenue (less NCA remuneration) + EU budget contribution

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Model Outputs

- The model generated the following annual outputs (for all options):
  - **Total yearly fees** paid to EMA by fee payers
    =
  - **EMA yearly fee income**: Yearly fees paid to EMA net of remuneration paid to NCAs.
  - **Total NCA annual remuneration from EMA fees** : for NCAs undertaking human medicine activities and/or veterinary medicine activities
- Model also generates:
  - **EMA unitary fees**: fees before any incentives are applied
  - **Unitary remuneration received by NCAs** : remuneration for centralised procedural activities and annual fee remuneration (for additional eligible activities + minor post-authorisation procedures in selected option).

EMA Costs

- Determination of costs for EMA's procedural activities (i.e. scientific and administrative work) using an **activity-based costing methodology**:
  - Cost-based fees include distributed overhead costs and (scientific and administrative) staff costs.
  - Costing methodology: total cost = $(\text{cost/hour}_{\text{activity,staff}})$ x total time
    - Hourly cost data is derived from EMA budget data (2020) and EMA's forecast budget data (2022-2026) and assumed to be independent of the type of activity undertaken within staff groups.
    - Time data is derived from the MBDG exercise (2015-2017) of the EMA Management board (tab 'time data')

Projected cost increase by 5% per annum for labor costs and 2% per annum for non-labor costs

EMA – Horizontal activity - Costs

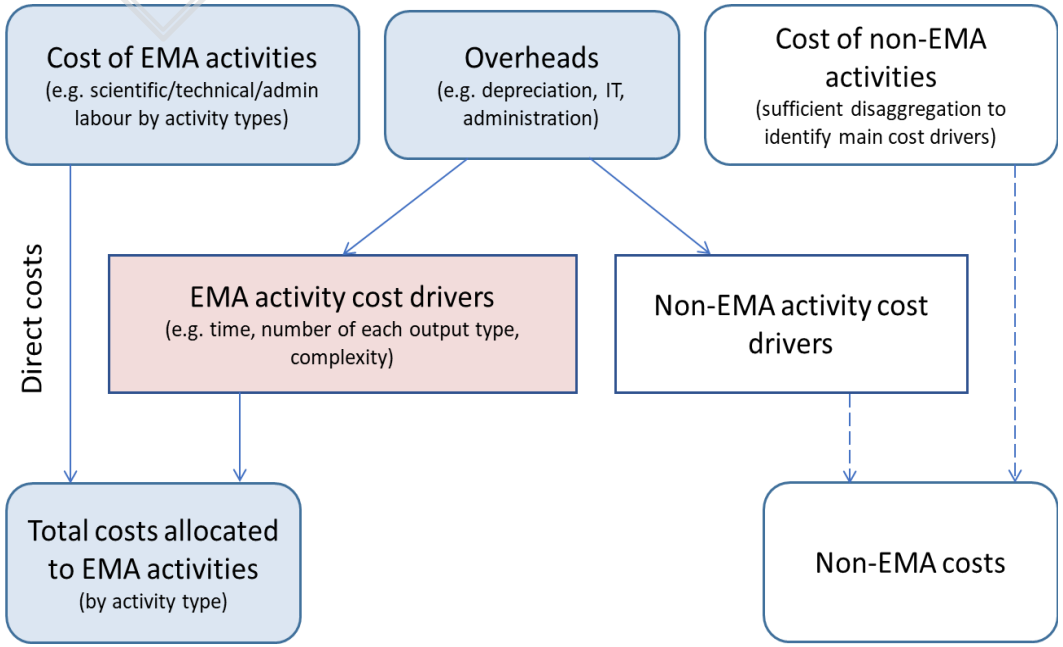
- Horizontal activities include:
  - Product maintenance activities and pharmacovigilance (**CAPs**) costs
  - General Pharmacovigilance (data management and databases) (**NAPs**) costs (human only) that annual CAP and Pharmacovigilance fees, respectively, are intended to cover under the existing system.
- From 2024, EHDS/DARWIN EU maintenance costs covered by human Pharmacovigilance annual fee and human CAP annual fee in proportion to the number of NAPs (75%) and CAPs (25%).

NCA costs

NCA costs: costs for **EMA-level activities performed by NCAs** and the proportion of **NCA overheads that can be attributed to NCA work for these EMA activities.**

Activity-based costing methodology was applied for each NCA's:

- **Scientific** and **administrative** staff hourly costs
  - Was multiplied during the costing exercise by a factor of 1.2, to allow for NCAs on average allocating more senior, and hence more costly, staff to EMA activities
  - Time data based on the 2016 MBDG exercise
- Annual cost of EMA-related activities by activity type.



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NCA costs

	Annual hours	
Scientific / technical staff members for NCAs are defined as the scientifically qualified staff acting as rapporteur, co-rapporteur, co-ordinator, quality, safety or efficacy assessor, inspector, peer reviewer, quality assurance, and/or external expert **Admin staff members for NCAs are defined as all staff other than scientific/technical staff** **Organisational costs**	Costs of undertaking all **EMA-requested activities** - excluding overhead costs	**Scientific staff** costs
		Administrative staff costs
		Non-staff costs
	Costs of **all other activities in your NCA** - excluding overhead costs	**Scientific staff** costs
		Administrative staff costs
		Non-staff costs
	Overhead costs - i.e. costs that cannot be directly attributed to specific activities	**Scientific staff** costs
		Administrative staff costs
		Non-staff costs
	Number of **FTE scientific staff**	
	Number of **FTE administrative staff**	

Structure of NCAs cost declaration for the evaluation exercise in 2016

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NCA costs

- The following steps were applied to each NCA separately (evaluation):
  - Determine hourly costs of NCA scientific and administrative staff conducting EMA activities.
  - Determine the annual cost of EMA activities by activity type. This includes not only staff costs but also an allocation of overhead costs
  - Hourly cost data for each NCA have been **derived directly in the coding from aggregate organisational cost data collected for the 2016 model** (incl. salary, overhead and non-staff costs, **FTEs and annual hours worked for the two 'scientific' and 'administrative' staff types that match the MBDG data set**)

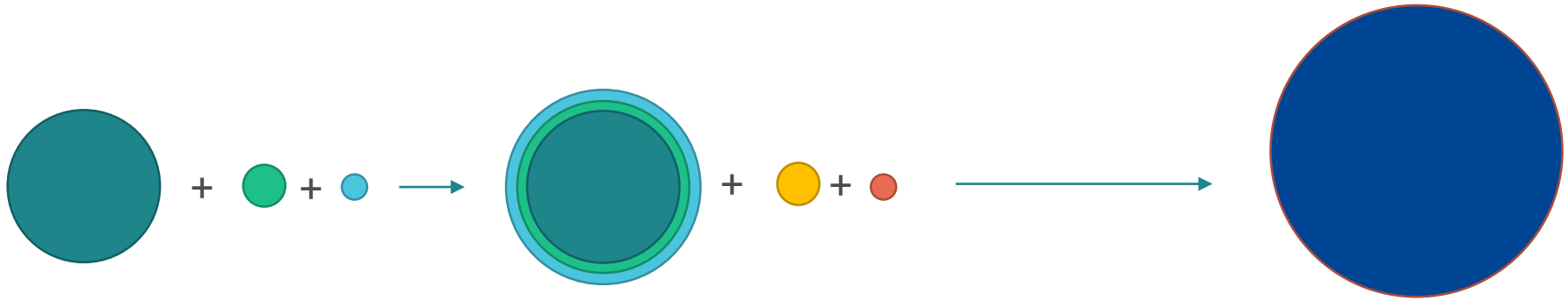
NCA costs

- The hourly costs of UK NCA staff have been removed from the dataset, and the UK procedures have been allocated to the NCAs that have taken over that work – based on projection of how EMA activities would be distributed across other NCAs

- The UK bodies' time inputs contribute to the estimates of average time taken, due to limited sample sizes in the MBDG exercise. But **the estimates of average NCA costs per activity in the financial model no longer take into account the UK organisations' staff costs per hour but only the staff costs per hour of the NCAs that conduct the work.**

NCA costs

- The 2016 aggregate cost data (used to determine hourly costs per NCA for the period 2022 to 2026) of all NCAs have been increased: by an **assumed 5% per annum for labour costs and 2% per annum for non-labour costs since 2016**. These are the same rates of cost increase that were applied to EMA costs. They have been used also for NCAs for consistency as no new cost data was collected from NCAs in this study.
  - For NCAs that did not provide data to the 2016 model, the average cost/hour of NCAs that did provide data has been applied. This average cost/hour was also used to calculate cost-based fees for infrequent activities. However, this cost was not used elsewhere in the model.



NCA 1: **2016 aggregate** + 5%/2% => **2017 aggregate** +5%/2% => … +5%/2% => **2026 aggregate** => NCA 1 C/H
NCA 2: **2016 aggregate** + 5%/2% => **2017 aggregate** +5%/2% => … +5%/2% => **2026 aggregate** => NCA 2 C/H

NCA costs

- For a given type of procedural activity :

Total cost (per NCA)/ year = Average time taken of the procedural activity x no. of procedures/ year

These costs are summed across the different roles (rapporteur, co-rapporteur) and activities to provide the total yearly procedural activity cost of a given NCA.

- A **weighted yearly average** cost *per procedure* for each type of procedural activity is calculated from the total yearly cost divided by the number of procedures.
- The **distribution of rapporteur and co-rapporteur roles** is derived from ‘purchase order’ data and scaled to **forecast the total number of procedures** for each activity provided by EMA according to available information.
- *As with EMA, projected cost increase by 5% per annum for labor costs and 2% per annum for non-labor costs

Remuneration calculation

Procedure type 1

NCA 1 hours
NCA 1 hours
NCA 2 hours
NCA 3 hours

Average NCA hours

NCA 1 hourly cost x 2/4
NCA 2 hourly cost x 1/4
NCA 3 hourly cost x 1/4

4

Weighted average NCA *remuneration for this specific procedure, with this specific mix of NCAs*

Procedure type 2

NCA 1 hours
NCA 2 hours
NCA 3 hours

Average NCA hours

NCA 1 hourly cost x1/3
NCA 2 hourly cost x 1/3
NCA 3 hourly cost x 1/3

3

Weighted average NCA remuneration *for this specific procedure, with this specific mix of NCAs*

Procedure type 3

NCA 1 hours
NCA 2 hours
NCA 3 hours
NCA 4 hours
NCA 5 hours

Average NCA hours

NCA 1 hourly cost x 1/5
NCA 2 hourly cost x 1/5
NCA 3 hourly cost x 1/5
NCA 4 hourly cost x 1/5
NCA 5 hourly cost x 1/5

5

Weighted average NCA remuneration *for this specific procedure, with this specific mix of NCAs*

Data sets

MBDG hours

Activities	Avg EMA (hrs)		Average NCA (hrs)			
	EMA AD	EMA AST	Rap AD	Rap AST	Co-Rap AD	Co-Rap AST
Procedure 1	28,96	30,92	26,20	2,50	21,93	2,78
Procedure 2	42,86	31,21	38,34	2,39	38,34	2,39
Procedure 3	47,23	32,40	61,80	0,00	55,40	1,60
Etc.	30,30	31,60	49,20	3,90	27,30	2,60

distribution of NCAs across procedures

Activities involving	NCA X	NCA Y	NCA Z
Procedure 1	7	3	4
Procedure 2	2	0	19
Procedure 3	1	1	13
Etc.	0	0	0

distribution of reductions

Activities involving	ATMP	MICRO	OMP
Procedure 1	2		7
Procedure 2	5		24
Procedure 3	8		36
Etc.	0		4

NCA remuneration

- For the cost-based options, NCA remuneration for a given activity is determined from a weighted average of NCAs' costs that typically undertake the activity, and the (average MBDG) time taken to undertake it (both factors influence the amount).

- The assumed inflation rate is 1.2% per annum up to 2024 and 1.4% per annum after.

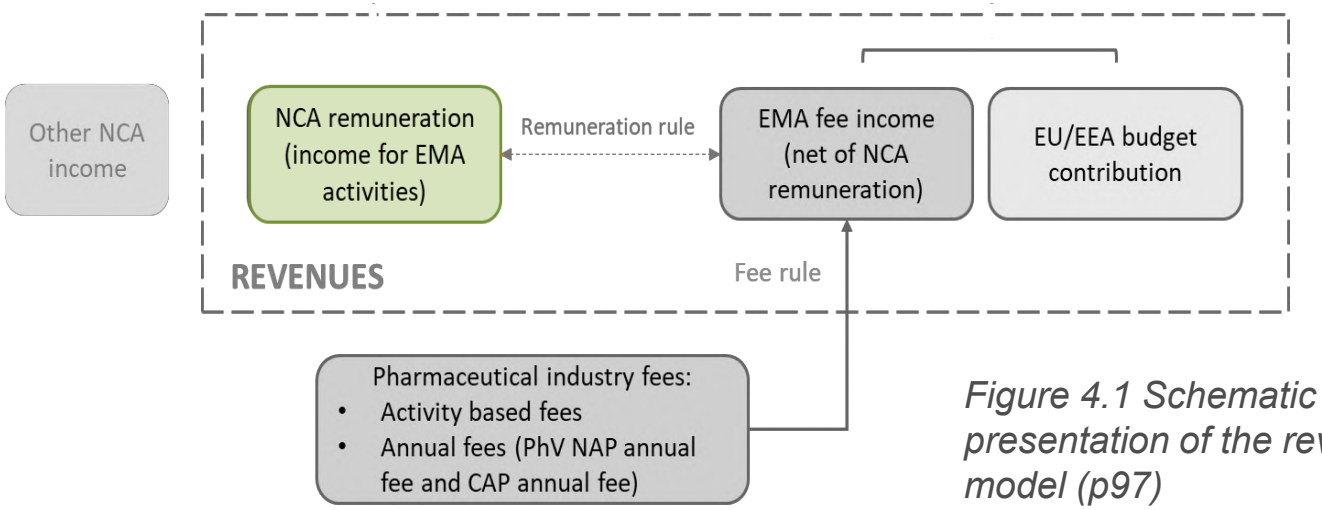


Figure 4.1 Schematic presentation of the revenue model (p97)

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NCA remuneration

Procedural fees included in the annual fee under option 3 and option 3 ‘light;

Activity	Op. 3	Op. 3 light
Renewals	Y	Y
Type II variations (incl. Line Extensions)	Y	N
Type II Worksharing Administrative Fee	Y	N
Type IB variations	Y	Y
Type IB Worksharing Administrative Fee	Y	Y
Type IA variations	Y	Y
Type IA Worksharing Administrative Fee	Y	Y

- All NCAs continue to receive the same level of payment as one another for all rapporteurs and co-rapporteurs (no country coefficients). Remuneration is calculated based on the distribution of purchase orders or self-reported survey data used in cost.
- In Options 3 and 3 ’ *light’*, the annual remuneration also covers the costs of some procedural activities that are no longer remunerated per procedure in those options

NCA remuneration – horizontal measures

Table 4.5: Country-specific scaling coefficients

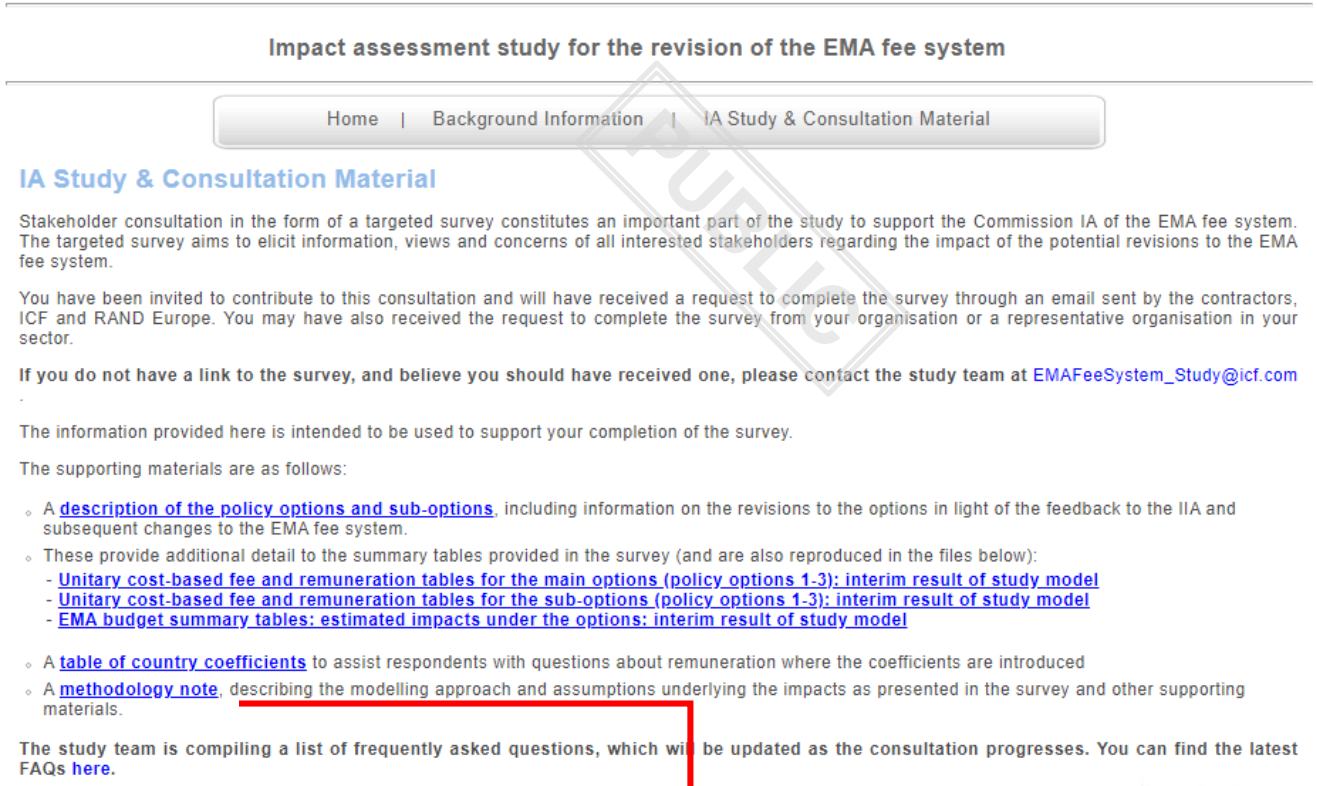
Country	Coefficient
Austria	105
Belgium	100
Bulgaria	51
Croatia	74
Cyprus	74
Czech Republic	73
Denmark	133
Estonia	78
Finland	119
France	114
Germany	96
Greece	79
Hungary	70
Ireland	118
Italy	98
Latvia	73
Lithuania	70
Luxembourg	100
Malta	86
Netherlands	108
Poland	67
Portugal	81
Romania	64
Slovakia	76
Slovenia	81
Spain	88
Sweden	127
Norway	136
Iceland	134

- Two possible adjustments to NCA remuneration were considered, and **ultimately rejected**, as part of the horizontal measures:
  - NCAs share the cost of incentives applied to fee income with EMA, so that NCA remuneration is reduced accordingly.
  - Each NCA's remuneration is scaled by a country-specific coefficient so that different NCAs receive a different level of remuneration for the same activity

NCA costs for additional activities eligible for EMA remuneration

- In addition to procedural activities, the evaluation study estimated overall costs (for all NCAs together) for a range of 'additional activities' but did not analyse their relevance for EMA remuneration
    - NCA were consulted to provide further explanations and attribute relative weights
    - Analysis of eligibility
    - Consultation
    - Post-consultation

Consultation



Impact assessment study for the revision of the EMA fee system

Home | Background Information | IA Study & Consultation Material

IA Study & Consultation Material

Stakeholder consultation in the form of a targeted survey constitutes an important part of the study to support the Commission IA of the EMA fee system. The targeted survey aims to elicit information, views and concerns of all interested stakeholders regarding the impact of the potential revisions to the EMA fee system.

You have been invited to contribute to this consultation and will have received a request to complete the survey through an email sent by the contractors, ICF and RAND Europe. You may have also received the request to complete the survey from your organisation or a representative organisation in your sector.

If you do not have a link to the survey, and believe you should have received one, please contact the study team at EMAFeeSystem_Study@icf.com

The information provided here is intended to be used to support your completion of the survey.

The supporting materials are as follows:

- A description of the policy options and sub-options, including information on the revisions to the options in light of the feedback to the IIA and subsequent changes to the EMA fee system.
- These provide additional detail to the summary tables provided in the survey (and are also reproduced in the files below):
  - Unitary cost-based fee and remuneration tables for the main options (policy options 1-3): interim result of study model
  - Unitary cost-based fee and remuneration tables for the sub-options (policy options 1-3): interim result of study model
  - EMA budget summary tables: estimated impacts under the options: interim result of study model
- A table of country coefficients to assist respondents with questions about remuneration where the coefficients are introduced
- A methodology note, describing the modelling approach and assumptions underlying the impacts as presented in the survey and other supporting materials.

The study team is compiling a list of frequently asked questions, which will be updated as the consultation progresses. You can find the latest FAQs here.

Type of organisation	Number of organisations
National Competent Authority and Ministries	86
Other national institutions	45
Patient and Consumer Association	6
Research Associations	13
EU level Healthcare Professional's Associations	28
Industry organisations and the associations representing them	31
Other (EMA and HMA)	2
TOTAL	211

Study supporting the Impact Assessment of the Revision of the EMA Fee System

SANTE/2019/B5/043

Methodology note to support the targeted consultation

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Revised cost-based approach to annual fee remuneration, to take into account the NCA feedback

- Stability proxy: stable annual fee remuneration as a proportion of total fee remuneration received by NCAs.
- Cost for annual fee remuneration was adjusted so to maintain the current approximate ratio at aggregate system level => upward adjustment of unitary annual remuneration (=> unitary annual fees), as compared to the amounts presented for consultations.
- **Cost-based check**: the resulting higher annual fee remuneration of NCAs per year, as estimated by the study model, falls within the overall maximum envelope covering all non-procedural activities declared, including both 'eligible' (cost of contribution to EMA) and 'non-eligible' (cost of implementation of EU legislation) activities.
- **One-off approach**: this choice meant that some costs were accepted as 'eligible', whereas, had complete quantification been possible, they might not have been. However, in view of the difficulty to perform a full analysis of all non-procedural activities declared by NCAs, combined with the arguments raised in the consultation feedback, this was accepted for the purpose of the impact assessment. The monitoring mechanism will take over.
    - Reflecting the cost of eligible non-procedural activities in the annual fee remuneration paid to rapporteurs is supported by the observation made during the evaluation study that, for a given NCA, the level of engagement in non-procedural activities in support of EMA is likely to be proportionate to the level of engagement in procedural activities.

Stakeholder Consultations

2024	Do minimum *(baseline)*	Option1	Option 2	Option 3	Option 3 *'light'*
EMA income ***(€'000)***					
Total industry procedural fees	225,236	230,466	183,513	144,976	164,037
Total industry annual fees	137,174	171,634	195,683	234,220	215,159
Tot industry fees	*362,410*	*402,100*	*379,196*	*379,196*	*379,196*
Total EU budget contribution	34,000	34,000	34,000	34,000	34,000
Tot EMA income	**396,410**	**436,100**	**413,196**	**413,196**	**413,196**
EMA expenditure ***(€'000)***					
Total expenditure on human and veterinary procedures	114,269	114,527	116,080	116,080	116,080
Total expenditure on other activities	162,141	162,141	162,141	162,141	162,141
Tot activities expenditure	*276,410*	*276,668*	*278,221*	*278,221*	*278,221*
NCAs remuneration from procedural activities	120,620	123,032	117,808	102,657	114,008
NCAs remuneration from annual fees	39,394	39,615	17,167	32,318	20,968
Total remuneration to NCAs	*160,014*	*162,647*	*134,975*	*134,975*	*134,975*
Tot EMA expenditure	**436,424**	**439,315**	**413,196**	**413,196**	**413,196**

Post-Consultation - final calculations

2024	Do minimum *(baseline)*	Option 1	Option 2	Option 3	Option 3 '*light*'
EMA income ***(€'000)***					
Total industry procedural fees	235,918	238,246	185,276	148,912	165,927
Total industry annual fees	141,690	173,683	223,751	260,116	243,101
Total industry fees	*377,608*	*411,929*	*409,027*	*409,027*	*409,027*
Total EU budget contribution	34,000	34,000	34,000	34,000	34,000
Total EMA income	**411,608**	**445,929**	**443,027**	**443,027**	**443,027**
EMA expenditure ***(€'000)***					
Total expenditure on human and veterinary procedures	113,436	113,436	113,218	113,218	113,218
Total expenditure on other activities	162,141	162,141	162,141	162,141	162,141
Total activities expenditure	*275,577*	*275,577*	*275,359*	*275,359*	*275,359*
NCAs remuneration from procedural activities	126,562	128,271	108,394	92,864	104,215
NCAs remuneration from annual fees	41,107	39,398	59,274	74,805	63,454
Total remuneration to NCAs	*167,669*	*167,669*	*167,669*	*167,669*	*167,669*
Tot EMA expenditure	**443,246**	**443,246**	**443,027**	**443,027**	**443,027**

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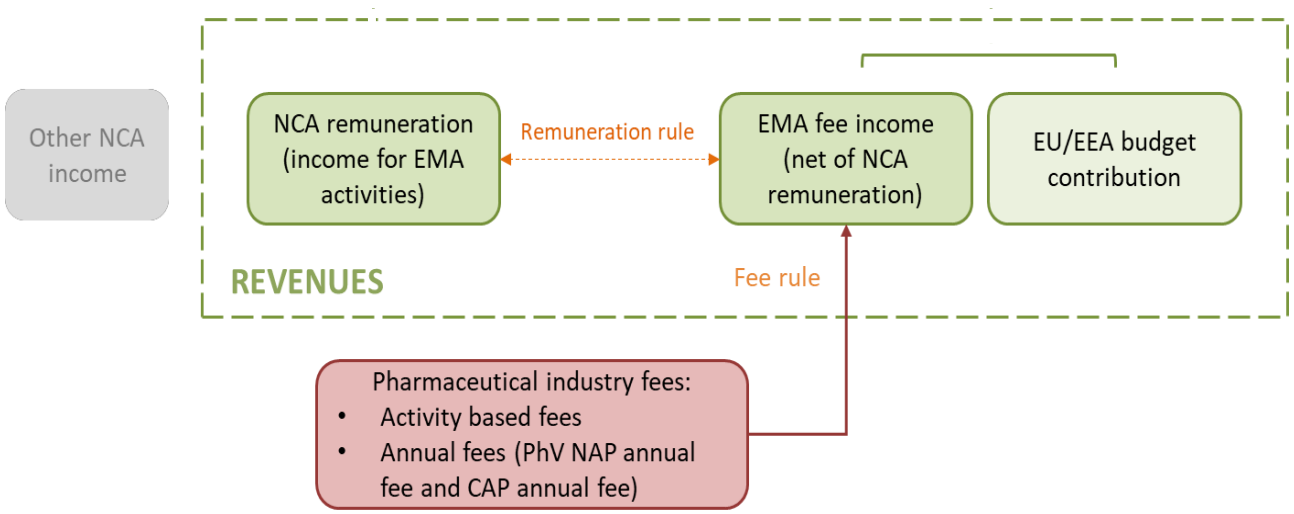
Revenue model

- The revenue model includes:
  - **EMA fee income:** depends on unit fee, the number of procedures and the incentive rate
  - **EU/EEA budget contributions**



EU/EEA budget contributions

- The EU budget contributions include a specific component for DARWIN EU in 2022 and 2023 to offset the costs incurred by EMA for that purpose (project phase). This is replaced by fee income as of 2024

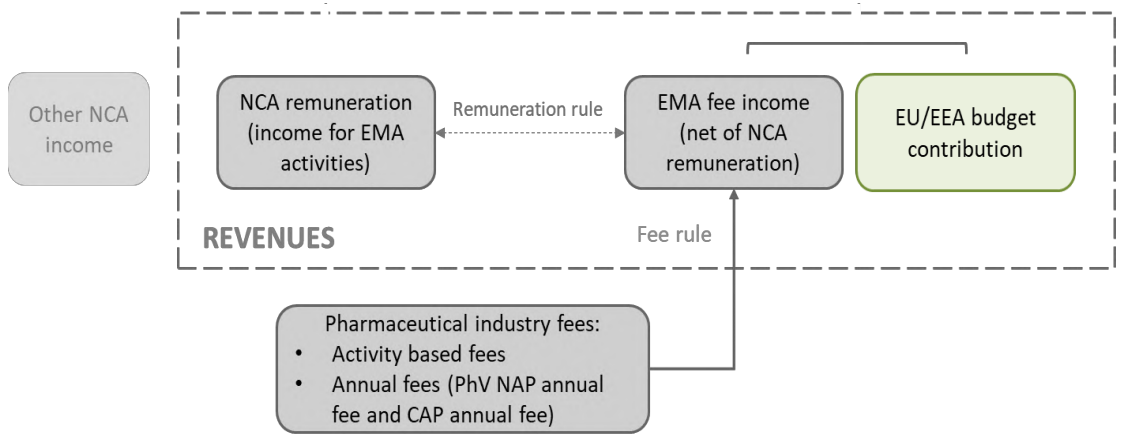


Figure 4.1 Schematic presentation of the revenue model (p97)

Table 4.3: EU/EEA yearly budget contributions (€) to EMAc

EU/EEA budget contributions	2022	2023	2024	2025	2026
Initial MFF proposal non-orphan	22,500	22,500	18,700	18,700	18,700
Initial MFF proposal - orphan medicines	14,000	14,000	14,000	14,000	14,000
EMA Reinforced Role proposal (objectives 1&2)	22,090	22,700	15,300	15,300	15,300
EMA Reinforced Role proposal	8,000	8,000	0	0	0
TOTAL	44,590	45,200	34,000	34,000	34,000

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EMA annual fees

Annual CAP fees are **calculated to balance the EMA budget** after taking into account cost-based procedural and pharmacovigilance fees, reductions and EU budget contributions.

The revenue model was used to balance the EMA budget for the central year of the forecast period (2024)

Table 4.4: Allocation of horizontal costs to CAP and Pharmacovigilance annual fees

	CAP	Pharmaco vigilance
Product maintenance activities and Pharmacovigilance (CAPs) - human	100%	
Signal detection (CAPs)	100%	
Genral Pharmacovigilance (data management and databases) (NAPs) - (PHARMACOVIGILANCE) - human		100%
Literature monitoring (Pharmacovigilance)		100%
DARWIN EU (as of 2024)	25%	75%
Product maintenance activities and Pharmacovigilance (CAPs) - Vet	100%	
Vet public health -product availability / MUMS (CAPs)	100%	
Signal management (vet) (CAPs)	100%	
Vet public health - AMR - Total expenditure	75%	25%
Vet databases (Pharmacovigilance)		100%

Fee reductions

- Reduction rates from the current fee system are applied to:
  - Human medicine: all options
  - Veterinary medicines: all options, in connection to VMP regulation
    - Model was constrained by both not reducing NCA remuneration V and implementing the reduced V fees as per the selected option
- For fee reductions under cost-based options, two approaches were tested:
  - Cost of incentives shared with NCA: burden of fee reduction shared proportionally between EMA and NCA (the model of the current PhV regulation).
  - **Cost of incentives borne by EMA budget alone -> Selected option: no reduction of NCA remuneration**
    - **The EMA budget = fee income (net of NCA remuneration) + EU budget contribution**

Thank you

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