Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency and Summary of the Assessment of Impacts

DG SANTE, 26 01 2023

"The views expressed may not in any circumstances be regarded as stating an official position of the European Commission"

What does this proposal cover?

(1) EMA fees and charges

- both pharmacovigilance and non-pharmacovigilance fees, in one single legal instrument

- charges: introduced to align with EMA founding regulation (e.g. for administrative services provided by EMA)

(2) Remuneration for the services provided by national competent authorities (NCAs)

(4) Fee reductions and waivers

- e.g. SMEs, some veterinary fees;

- reductions in 'sector-specific' legislation continue to apply (e.g. orphan, paediatric, ATMPs, SME)

(5) Cost monitoring provisions

(6) Flexibility

- amendment of annexes through delegated acts, based on objective criteria

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General objectives 1/2

- Contribute to a **sound financial basis supporting EMA's operations**, including **remuneration for services** rendered by NCAs to the EMA for the completion of its mandate.
    - Concerns expressed by NCAs during consultations phase addressed: balanced approach for the proposal, including update of costs and analysis of non-procedural activities eligible for EMA remuneration.
- **Cost-based fee and remuneration amounts,** following a thorough evaluation of the costs of the EMA and its various statutory tasks and the cost of the NCA contributions to EMA's work.

General objectives 2/2

- **Simplify the fee structure** and minimise the unnecessary complexity of the corresponding legal framework.
  - The approach followed in the proposal can be seen as a compromise between the objectives '*simplification*' (less detailed fee grid) and '*cost-based*' (more detailed fee grid).

Specific objectives

- Address problems identified by the evaluation:
  - complexity of the fee system;
  - misalignment of some fees / NCA remuneration with underlying costs
  - lack of fees or NCA remuneration for some procedural activities
  - discrepancies between the main EMA Fee Regulation (Council Regulation (EC) No 297/95) and the Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014).
- Align to:
  - recent changes to the EMA Founding Regulation 726/2004
  - Regulation (EU) 2019/6 (VMP Regulation)

Current EMA Fee Framework ➡ Proposal

Sector-specific legislation - incentives

- Main EMA Fee Regulation (Council Regulation (EC) No 297/95)
  - Implementing rules: remuneration to NCAs
  - Adjustment of amounts: co-decision; 'automatic' adjustment to inflation only (Commission act)
- Pharmacovigilance Fee Regulation (Regulation (EU) No 658/2014).
  - No implementing rules (remuneration to NCAs in set in legislation)
  - Adjustment of amounts: co-decision; Commission delegated acts based on monitoring of inflation only

- Proposal: A **single legal instrument** bringing together all fees and respective remuneration.
  - Working arrangements (NB: remuneration to NCAs set in the legislation)
  - Adjustment of amounts: delegated acts based on monitoring of inflation and costs & EMA budget reporting

The Commission Proposal

Regulation structure

17 Articles

1. Subject matter
2. Definitions
3. Types of fees and charges
4. Additional fees and charges
5. Payment of remuneration to competent authorities of the Member States for the provision of services to the Agency
6. Reductions
7. Payment of fees and charges
8. Working arrangements
9. Due date and measures in case of non-payment
10. Transparency and monitoring
11. Revision
12. Estimate of the Agency's budget
13. Exercise of the delegation
14. Amendment to Regulation (EU) No 2017/745
15. Repeal
16. Transitional provisions
17. Entry into force and application

7 Annexes

- 1. Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use
- 2. Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products
- 3. Annual fees and remuneration (medicinal products for human use and veterinary medicinal products)
- 4. Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices
- 5. Fee reductions
- 6. Performance information
- 7. Correlation table

Main text of the draft regulation : zoom-in 1/7

- **Article 1** *Subject matter*
  - Fees, charges, remuneration, established on cost-based evaluation
  - Monitoring of costs, including cost for remuneration
- **Article 2** *Definitions*
  - 'Chargeable unit', defined now also for veterinary medicinal products
- **Article 3** *Types of fees and charges*
  - Mapping of annexes: Human ***(Annex 1+5)*** / Veterinary ***(Annex 2+5)*** / Annual ***(Annex 3+5)*** / Other ***(Annex 4+5,*** **includes consultations for medical devices and fees in common Human/Veterinary sectors)**
- **Article 4** *Additional fees and charges* ***(Annex 4+5)***
  - Flexibility in case a new scientific service is not covered by a fee or an administrative service needs to be covered by a charge. Must be within a range provided for in the annexes. Set by the EMA Management Board, following a favourable opinion by the Commission. Must be taken into account by Commission in a subsequent review.

Main text of the draft regulation : zoom-in 2/7

- **Article 5** *Payment of remuneration to NCAs for services to EMA* ***(Annex 1-4)***
  - Fee-related remuneration amounts: set in the annexes
  - Principle followed: NCA remuneration (provided for in annexes) not reduced when fee reductions apply (currently this varies)
    - => Support to products/applicants benefiting from reductions is financed by the overall EMA budget

- **Article 6** *Reductions of fees and charges* ***(Annex 5)***
  - Reduction rates, set out in annex, apply in addition to reductions laid down in sector-specific legislation: the most favourable apply (same as currently)
  - Fees waived in case the assessment is requested by a MS or an EU institution
    - Remuneration paid nevertheless (in accordance with Article 5)

Main text of the draft regulation : zoom-in 3/7

- **Article 6** *Reductions of fees and charges (continued)*
  - Flexibility: beyond reductions provided for in the annexes ***(Annex 5)***, two possibilities for additional reductions:
    - Granted by EMA MB, on a duly justified proposal by the EMA Executive Director, following a favourable opinion of the Commission
    - Granted ad-hoc by the EMA Executive Director, in exceptional circumstances and for imperative reasons related to public or animal health
      - Except for PhV referrals, PSUR, PASS and post-marketing surveillance studies (Vet) and PhV annual fees. For all these fees the chargeable unit will be used for the calculation of the amount payable per marketing authorisation holder.
- **Article 7** *Payment of fees and charges* and **Article 9** *Due date and measures in case of non-payment*
  - Technical provisions e.g. due date for payment of fee/charge; deadline considered as complied with only if payment made in full; possibility of suspension of services in case of unpaid fees.

Main text of the draft regulation : zoom-in 4/7

- **Article 8** *Working arrangements*
  - Technical document adopted by the EMA Management Board, following a favourable opinion by the Commission, facilitating the application of the regulation. Examples:
    - Greater level of technical detail, such as due dates, technical details for implementation of rules in provisions
    - Amounts of additional fees/charges as per Art. 4, within the range provided for in the respective annex of the Regulation
    - Additional reductions granted by the Board pursuant to Art. 6
    - Detailed technical rules for payment of NCAs remuneration pursuant to Art. 5 (amounts in annexes of the Regulation)

Main text of the draft regulation : zoom-in 5/7

- **Article 10** *Transparency and monitoring*
  - EMA to provide detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation (in the annual activity report)
  - NCAs may provide every year, or les frequently, evidence of significant changes in the costs of services provided to EMA
    - excluding inflation and excluding activities that do not constitute a service to EMA,
    - in a common format to be provided by EMA + possible supporting information,
    - the information to be used for the special report below.
  - Every three years, EMA Executive Director may provide the Commission with a special report with recommendations to amend the annexes. Those recommendations need to be duly justified and supported by verifiable information and quantification.
    - Frequency may be shortened in case of a public health emergency, a change of the legal mandate of EMA or in case there is clear and compelling evidence of significant changes in the costs or the cost-revenue balance of the Agency, including costs for cost-based remuneration to competent authorities of the Member States.

Main text of the draft regulation : zoom-in 6/7

- **Article 11** *Revision*
  - Flexibility: amendment of the annexes through delegated acts, when justified in view of:
    - the special report referred to in Article 10,
    - the findings from the monitoring of the inflation rate,
    - a change in the statutory tasks of EMA leading to a significant change in its costs,
    - the budgetary reporting of EMA,
    - other relevant information, in particular on practical aspects for the execution of activities for which EMA collects fees or charges.
  - First occasion most likely the upcoming review of the basic pharmaceutical legislation
- **Article 12** *Estimate of EMA budget*
  - EMA to provide detailed information on income from each type of fees and charges and respective remuneration.
- **Article 13** *Exercise of the delegation (under Art. 11)*
  - Standard clause, 5-yearly report

Main text of the draft regulation : zoom-in 7/7

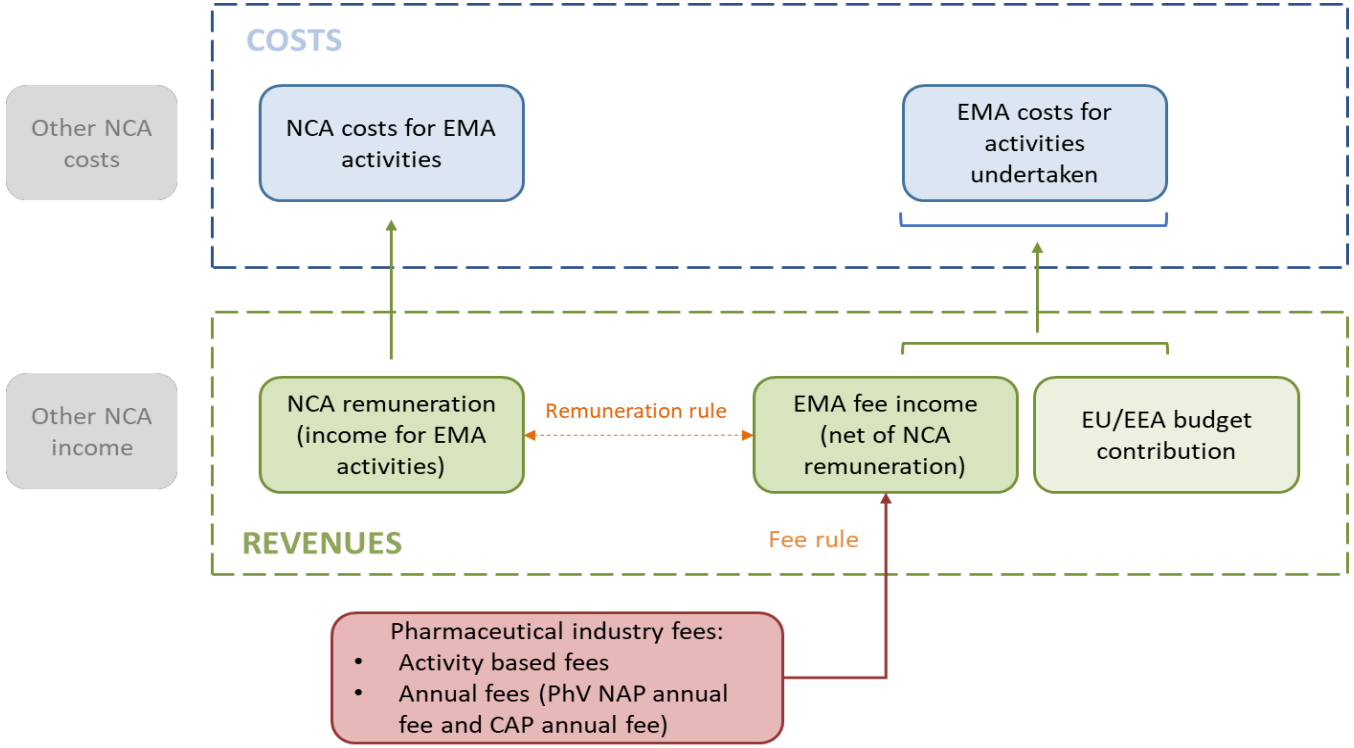
- **Article 14** *Amendment to Regulation (EU) No 2017/745 (MDR)*
  - Provides that fees for expert panels activities are payable to EMA (instead of to the Commission-consistency)
    - No other changes to that article of the MDR.
  - Such fees are not introduced by this proposal. Will be calculated and introduced at a later stage, in line with Art 106(13) of the MDR.
    - The fees in Annex IV of this proposal are for consultation on medical devices as part of a marketing authorisation, i.e. not for expert panels activities.
- **Articles 15,16,17** *Repeal, Transitional provisions, Entry into force and application*
  - Two current EMA fee regulations repealed.
  - References in sector-specific regulation to the current main fee regulation (Regulation (EC) No 297/95) continue to apply: correlation table
  - Cut-off dates (avoid double payment under the current/new rules)
  - 20 days + 6 months for applicability (EMA, industry and NCAs to prepare for changes)

IA : Policy Options

Do-minimum scenario	Policy Option 1 – no change other than for VMP	Policy Option 2 : cost-based system without simplification	Policy Option 3 – cost-based system with simplification
The structure of the fee system is unchanged. The **procedural fees** follow the classification of procedures of the new veterinary rules (to the extent possible without a legal change) and the amounts, where necessary, are **benchmarked** to the current fee system. **The approach to NCA remuneration**, as well as fees for human and veterinary medicine procedures remains **unchanged** Relevant incentives are applied as existing + DARWIN	• **Cost-based fees for veterinary medicines only,** aligning the system to the VMP Regulation • Human fees are not impacted • Remunerations: approach unchanged • + DARWIN	• **Cost-based fees and remunerations amounts for all EMA activities (H & V)** • No changes to the structure of the fee system • Remunerations: set in legislation • + DARWIN	• **Cost-based fees ad remuneration amounts for all EMA activities (H & V)** • **Simpler system structure** • Remunerations: cost-based • DARWIN
	• ***Sub-option (a)*** same as Option 1, but a **50% general reduction for veterinary medicines** is applied to all veterinary fees. No additional incentives are applied. • ***Sub-option (b)*** same as Sub-option 1a, but it also includes **specific incentives that are applied for limited markets.** • ***Sub-option (c)*** same as Option 1, but **specific incentives are also applied for limited markets**. No general reduction is applied to veterinary medicines cost-based fees	• **Applying a country coefficient to NCA remuneration** Adjustment to remuneration that is linked to national costs in each Member State. • **Sharing the cost of incentives between EMA and NCAs** Incentives to cost-based fees applied before remuneration to NCAs • **A 'light' version of option 3** This sub-option was added following the feedback to the Inception impact assessment includes only a partial simplification of the fee system structure	

Assessment of impacts

- Based on a financial model: calculated cost-based fees, revenues to EMA and remuneration to NCAs => quantified the impact of different options
  - Did not replicate financial accounting systems of stakeholders
  - Did not take into account the impact of timing of payments on stakeholders.
  - Took into account full MFF EU budget contribution to EMA



IA: Outputs generated

- Yearly outputs generated (for all options, projections 2022-2026):
  - **Total yearly fees** paid to EMA by fee payers
    - CAP annual fees are calculated to balance the EMA budget after taking into account procedural fee net income, reductions (100% on EMA budget) and MFF EU budget contributions.
  - **EMA yearly fee income**: Yearly fees paid to EMA net of fee remuneration paid to NCAs.
  - **Total NCA yearly fee remuneration** by EMA
- Model also generated:
  - **EMA unitary fees**: fees before any incentives are applied
  - **NCA unitary remuneration** from EMA: remuneration for EMA procedural activities and annual fee remuneration for additional eligible activities (includes also minor post-authorisation procedures in selected option) .

NCA remuneration

- For the cost-based options, NCA remuneration for a given activity is *de facto* determined from a weighted average of costs (evaluation) of NCAs undertaking the activity, and the average time taken to undertake it (MBDG-evaluation).
  - The assumed inflation rate is 1.2% per annum up to 2024 and 1.4% per annum thereafter.
  - Projected cost increase for both EMA and NCA 5%/year labor and 2%/year non-labor
- The cost of ‘additional activities’ determine the annual fee remuneration

Analysis of Impacts

		Do-minimum (baseline)	Option 1	Option 2	Option 3	Option 3L
Nr	**Indicator**	**Performance**	**Performance**	**Performance**	**Performance**	**Performance**
1	**Fee system covers relevant aggregate costs**	***Low***	***Low***	***High***	***High***	***High***
2	Alignment of fees with costs of individual activities	*Low*	*Low*	*High*	*Medium*	*High*
3	Alignment of NCA remuneration with NCA costs for EMA activities	*Low*	*Low*	*High*	*Medium*	*High*
4	Capacity of fee system to adjust to cost changes	*High*	*High*	*High*	*Low*	*Medium*
5	Balance between simplicity (less fee levels) and granular cost-based approach (more fee levels)	*Low*	*Low*	*Low*	*Medium*	*High*
6	Capacity of fee system to adjust to ensure financing if incentives	*Medium*	*Medium*	*Medium*	*Medium*	*Medium*
7	Adaptability to exceptional circumstances	*Medium*	*Medium*	*Medium*	*Medium*	*Medium*
8a, 8b, 8c	Predictability for EMA, NCAs, fee payers	*Low*	*Low*	*Low*	*High*	*Medium*
9a, 9b	Reducing administrative burden - EMA, NCAs, all fee payers	*Low*	*Low*	*Low*	*High*	*Medium*
9c	Reducing administrative burden on SMEs relative to other fee payers	*Medium*	*Medium*	*Medium*	*Medium*	*Medium*
10	Position of SMEs	*Medium*	*Medium*	*Medium*	*Medium*	*Medium*
11	Impact on research and innovation	*Medium*	*Medium*	*Medium*	*Medium*	*Medium*
12a	Functioning of internal market and competition: generic medicines	*Low*	*Low*	*Low*	*High*	*Medium*
12b	Functioning of internal market and competition: innovative medicines	*Low*	*Low*	*Low*	*Medium*	*High*

Preferred Option: 3 “light”

Medicines for Human Use	Veterinary Medicines
• Fees and remuneration amounts calibrated on underlying costs (cost-based fees and remunerations expressed as amounts) • Simplified structure : T.I and renewals included in annual fees; no add-on amounts for IA fees; => less fee levels p/type of procedure • Introduction of NCAs remuneration for non remunerated procedures (e.g. OD/PD procedures)	• Fees and remuneration amounts calibrated on underlying costs (i.e. direct amounts) • Simplified structure : T.I and renewals included in annual fees; no add-on amounts in IA fees; => less fee levels p/type of procedure • Alignment with VMP • Targeted support to veterinary sector: 50% reduction for LM & IMM + 25% reduction annual fees for all other products

Cross-cutting Sub-options:

- Application of country coefficients : discarded in view of the feedback
- Cost of all fee incentives : not reflected in NCA remuneration, borne in full by EMA budget

Annexes – 1/3

- The final option implemented in the proposal can be seen as a compromise between the objectives '*simplification*' (less detailed fee grid) and '*cost-based*' (more detailed fee grid).

  For example:

  - *Simplification*: A single authorisation fee covers all strengths / forms / presentations (V – all target species) included in the same application
  - *Simplification*: Annual fee and respective remuneration includes costs for minor post-authorisation procedures
    - Type I Variations (H) / Renewals (H) / Variation not requiring assessment (V)
  - *Cost-based*: rapporteur remuneration may be different than co-rapporteur remuneration (based on significant difference in data)

Annexes – 2/3

- All amounts based on impact assessment – generated data
  - Workload and cost estimations (EMA MBDG => evaluation => impact assessment)
  - Updated and developed further since the evaluation (including based on inflation, more detail)
  - Ensuring a balanced EMA budget, taking into account estimated costs, frequencies, fee reductions and EU budget contribution
- Stages
  - **Draft** detailed amounts presented in detail during consultations
  - Cost-based approach **updated** post-consultation to take into account NCA feedback to consultations:
    - stabilising role of annual fee in **overall remuneration** not sufficiently taken into account
    - no reduction in overall NCA revenue
    - no specific input on procedural amounts provided by NCAs

revised approach to cost estimation for annual fee remuneration

Annexes – 3/3

- 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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Conclusion

- Fee *legislation* becomes more detailed
- Simplification of the *system* itself
  - One legal instrument, minor procedures under annual fee, grouping of some fee levels
- Flexibility for agile adjustment based on objective data (sustainability)
  - Including possibility to implement changes related to review of basic legislation
- Currently non-remunerated assessments now remunerated (orphan, paediatric, re-examination, etc.)
- Non-procedural services to EMA covered by the annual fee remuneration

Thank you

European Commission

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0417 (COD)

Brussels, 30 January 2023

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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 26-27 January 2023 - EMA fees - Commission presentation

Delegations will find in annex the presentation given by the Commission services in the Working Party on Pharmaceuticals and Medical Devices 26-27 January 2023.