



Council of the European Union  
General Secretariat

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**Interinstitutional files:  
2022/0417 (COD)**

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**Brussels, 26 April 2023**

**WK 5512/2023 INIT**

**LIMITE**

**PHARM**

**SAN**

**MI**

**COMPET**

**CODEC**

**VETER**

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## **MEETING DOCUMENT**

|          |                                                                                                                                    |
|----------|------------------------------------------------------------------------------------------------------------------------------------|
| From:    | General Secretariat of the Council                                                                                                 |
| To:      | Working Party on Pharmaceuticals and Medical Devices (Attachés)<br>Working Party on Pharmaceuticals and Medical Devices (EMA fees) |
| Subject: | Working Party on Pharmaceuticals and Medical Devices 27 April 2023 - EMA fees<br>- Presentation by the Presidency                  |

Delegations will find in annex presentation prepared by the Presidency for discussion in the Working Party on Pharmaceuticals and Medical Devices on 27 April 2023.

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# Welcome.

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

- Presentation of the adjustments within the Targeted Approach and the General Approach

# Bakground

- The Member States have expressed support for a targeted approach for the procedures listed to the right, as well as a general adjustment for all procedures.
- A request for new fees and remunerations has been sent out to delegates.
- Based on the proposals received, the presidency has calculated new fees and remunerations.

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| Targeted approach for the chosen procedures                       |                                   |
|-------------------------------------------------------------------|-----------------------------------|
| Procedure                                                         | Article                           |
| Scientific Advice                                                 | Annex I, point 1                  |
| Generics                                                          | Annex I, point 3.6 & 3.8          |
| Type II variations                                                | Annex I, point 5                  |
| Referrals                                                         | Annex I, point 6                  |
| Periodic Safety Update Reports (PSURs)                            | Annex I, point 14                 |
| Inspections                                                       | Annex IV, point 1                 |
| Pharmacovigilance Risk Assessment Committee (PRAC) rapporteurship | New fee and remuneration required |

# The proposals for new remunerations that has been considered

- The majority of delegates have sent in the similar suggestions for adjustments.
- The presidency has therefore based the calculations for new fees and remuneration on those suggestions.
- A general increase with a so-called sustainability factor of 20% has been made for the remunerations to NCAs for all procedures outside the Targeted Approach (TA)
- For the procedures within the TA, the remunerations to the left have been considered.
- The part to EMA is adjusted for inflation only.

| Remuneration to NCA:s adjusted for the targeted approach, whilst the part to EMA is adjusted for inflation 2021 & 2022 |         |         |         |
|------------------------------------------------------------------------------------------------------------------------|---------|---------|---------|
| Procedure                                                                                                              | EMA fee | Rapp    | Co-rapp |
| Scientific Advice                                                                                                      | 79 400  | 20 200  | 20 200  |
|                                                                                                                        | 62 900  | 13 400  | 13 400  |
|                                                                                                                        | 49 600  | 9 700   | 9 700   |
| Generics*                                                                                                              | 233 600 | 118 900 | -       |
| Type II variations                                                                                                     | 175 300 | 64 400  | 64 400  |
|                                                                                                                        | 17 100  | 10 100  | -       |
| Referrals                                                                                                              | 210 200 | 27 300  | 27 300  |
| PSURs                                                                                                                  | 32 600  | 16 600  | -       |
| Inspections                                                                                                            | 72 500  | 34 000  | 24 000  |
|                                                                                                                        | 67 100  | 32 000  | 19 000  |
|                                                                                                                        | 56 500  | 20 000  | 20 000  |
|                                                                                                                        | 56 500  | 20 000  | 20 000  |

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- **Additional adjustments:**
  - An increase with 20% has been made for Generics.
  - The Presidency is reflecting on the possibility to clarify that the same approach as the current system for inspections should apply, in which several fees per inspection can be charged.

# Calculations for the general approach

- For any given procedure outside the TA the fees and remunerations is given by:
- $EMA \text{ fee} = \text{Part to EMA} + \text{Remuneration to NCAs}$
- $\text{Part to EMA} = \text{Fee per Commission report} * (1 - 1,2\%)^2 * (1 + 5,3\%) * (1 + 10,4\%)$
- $\text{Remuneration to NCAs} = \text{Fee per Commission report} * (20\%)$

# New fees and remunerations for TA

|                    | Remuneration to NCA:s adjusted for the targeted approach, whilst the part to EMA is adjusted for inflation 2021 & 2022 |         |         |
|--------------------|------------------------------------------------------------------------------------------------------------------------|---------|---------|
| Procedure          | EMA fee                                                                                                                | Rapp    | Co-rapp |
| Scientific Advice  | 79 400                                                                                                                 | 20 200  | 20 200  |
|                    | 62 900                                                                                                                 | 13 400  | 13 400  |
|                    | 49 600                                                                                                                 | 9 700   | 9 700   |
| Generics*          | 233 600                                                                                                                | 118 900 | -       |
| Type II variations | 175 300                                                                                                                | 64 400  | 64 400  |
|                    | 17 100                                                                                                                 | 10 100  | -       |
| Referrals          | 210 200                                                                                                                | 27 300  | 27 300  |
| PSURs              | 32 600                                                                                                                 | 16 600  | -       |
| Inspections        | 72 500                                                                                                                 | 34 000  | 24 000  |
|                    | 67 100                                                                                                                 | 32 000  | 19 000  |
|                    | 56 500                                                                                                                 | 20 000  | 20 000  |
|                    | 56 500                                                                                                                 | 20 000  | 20 000  |

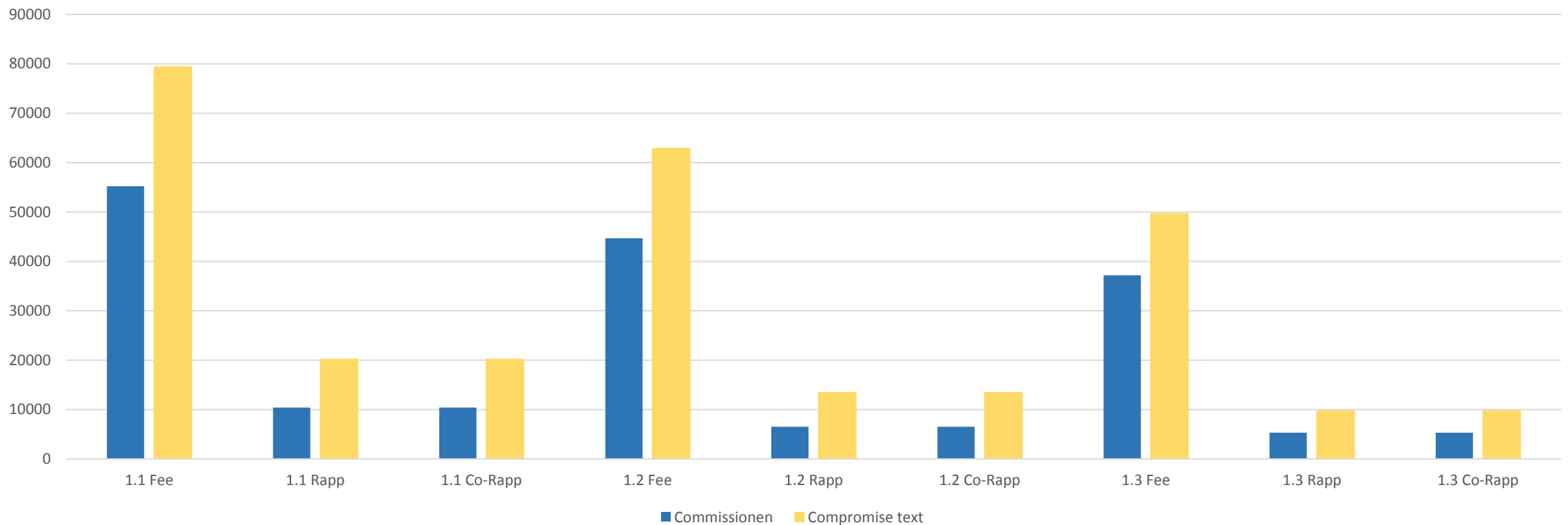
| Percentage increase remuneration from Commission's proposal 13/12/22 |      |         |
|----------------------------------------------------------------------|------|---------|
| EMA fee                                                              | Rapp | Co-rapp |
| 44%                                                                  | 94%  | 94%     |
| 41%                                                                  | 107% | 107%    |
| 33%                                                                  | 83%  | 83%     |
| 65%                                                                  | 196% |         |
| 76%                                                                  | 119% | 119%    |
| 32%                                                                  | 49%  |         |
| 22%                                                                  | 56%  | 56%     |
| 21%                                                                  | 28%  |         |
| 92%                                                                  | 118% | 155%    |
| 52%                                                                  | 63%  | 83%     |
| 56%                                                                  | 49%  | 144%    |
| 56%                                                                  | 49%  | 144%    |

| Percentage increase remuneration from Commission's proposal adjusted for inflation |      |         |
|------------------------------------------------------------------------------------|------|---------|
| EMA fee                                                                            | Rapp | Co-rapp |
| 27%                                                                                | 71%  | 71%     |
| 24%                                                                                | 82%  | 82%     |
| 18%                                                                                | 62%  | 62%     |
| 46%                                                                                | 161% |         |
| 55%                                                                                | 93%  | 93%     |
| 16%                                                                                | 31%  |         |
| 8%                                                                                 | 38%  | 38%     |
| 6%                                                                                 | 13%  |         |
| 69%                                                                                | 92%  | 125%    |
| 34%                                                                                | 44%  | 61%     |
| 38%                                                                                | 32%  | 115%    |
| 38%                                                                                | 32%  | 115%    |

# Difference between COM proposal and compromise text

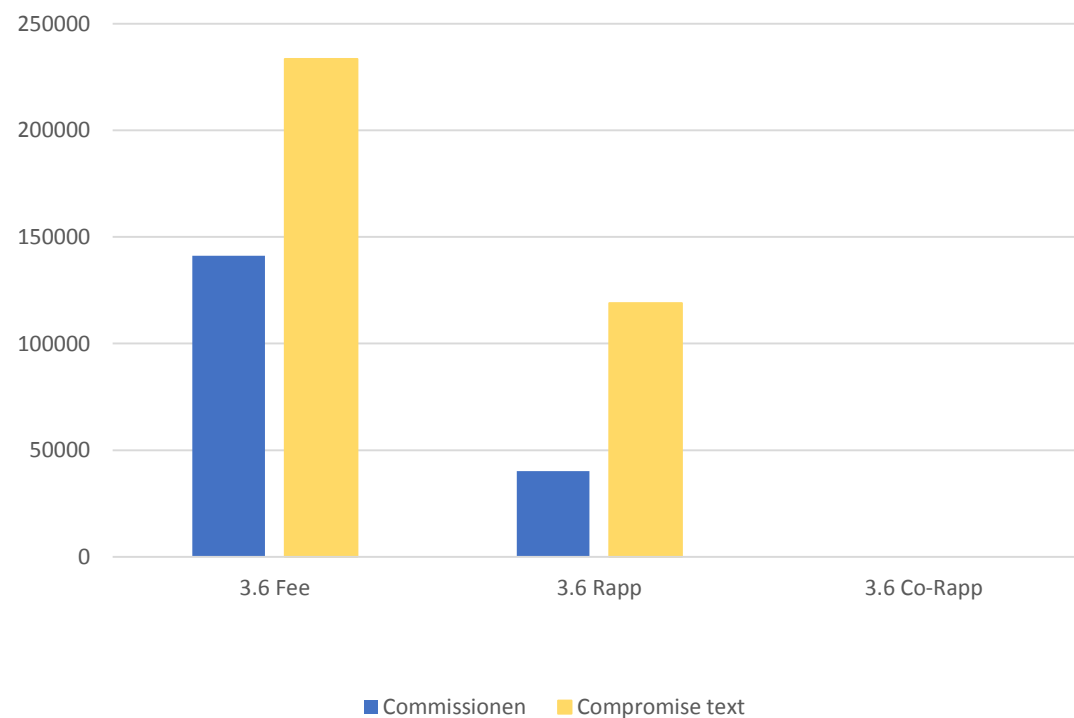
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Scientific Advice

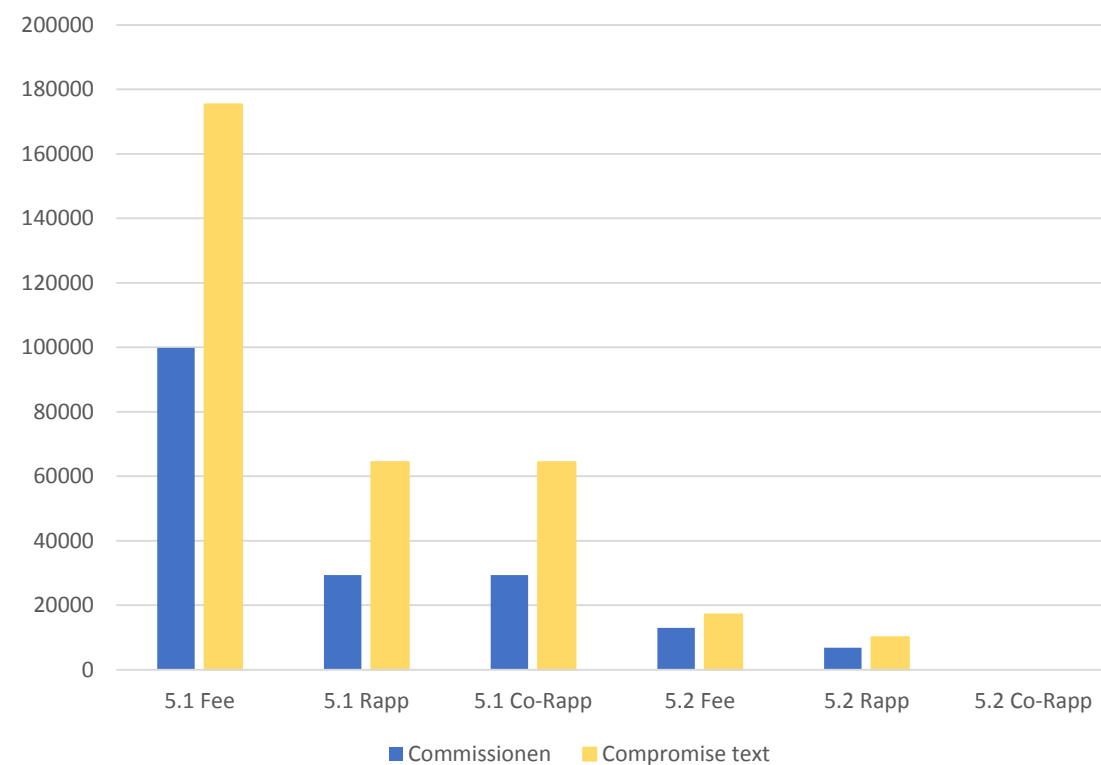




## Generics

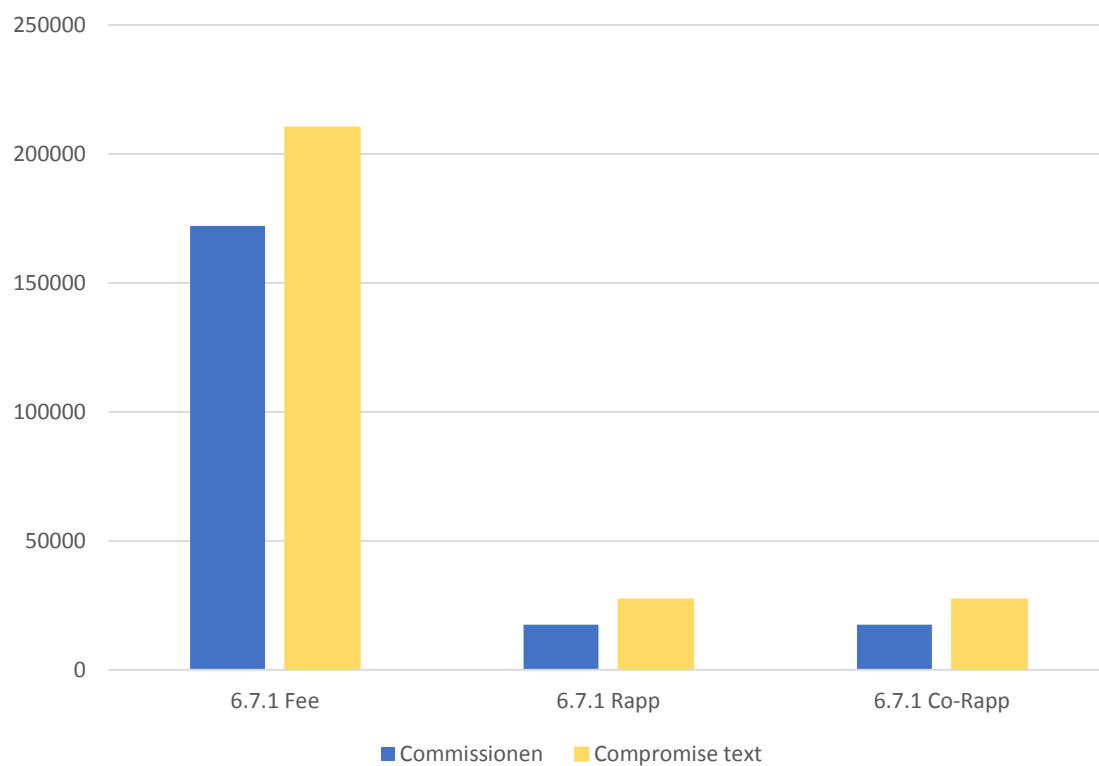


## Type II variations

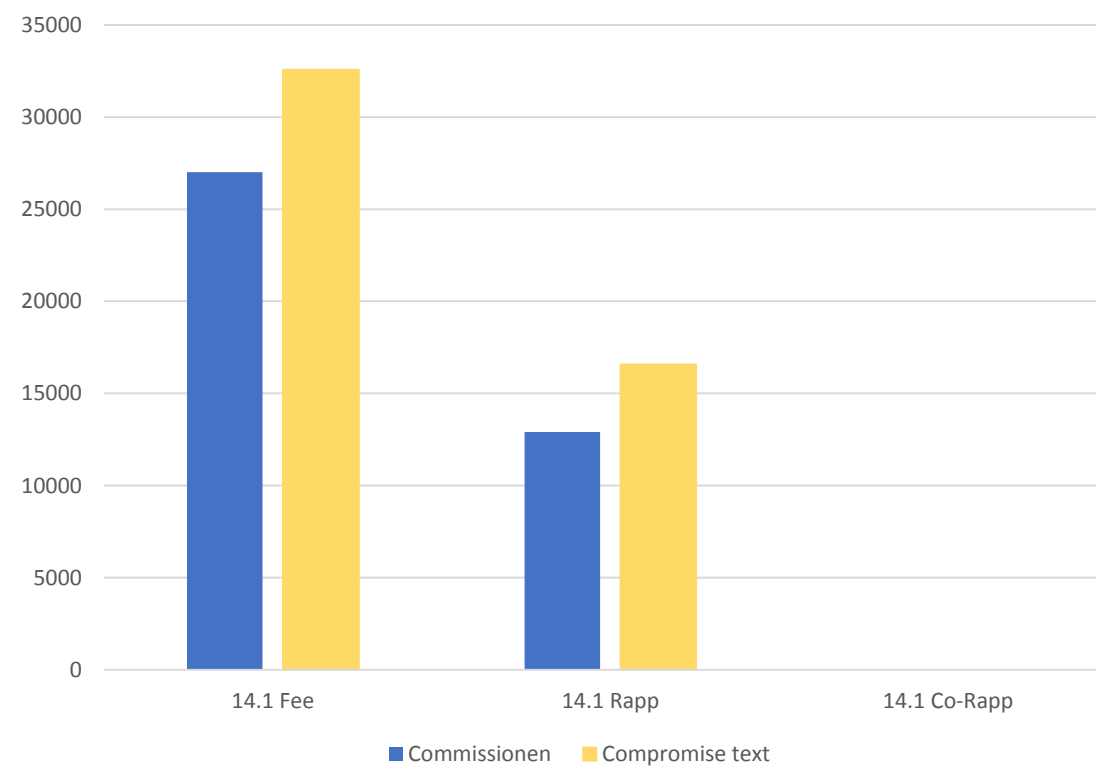




## Referrals

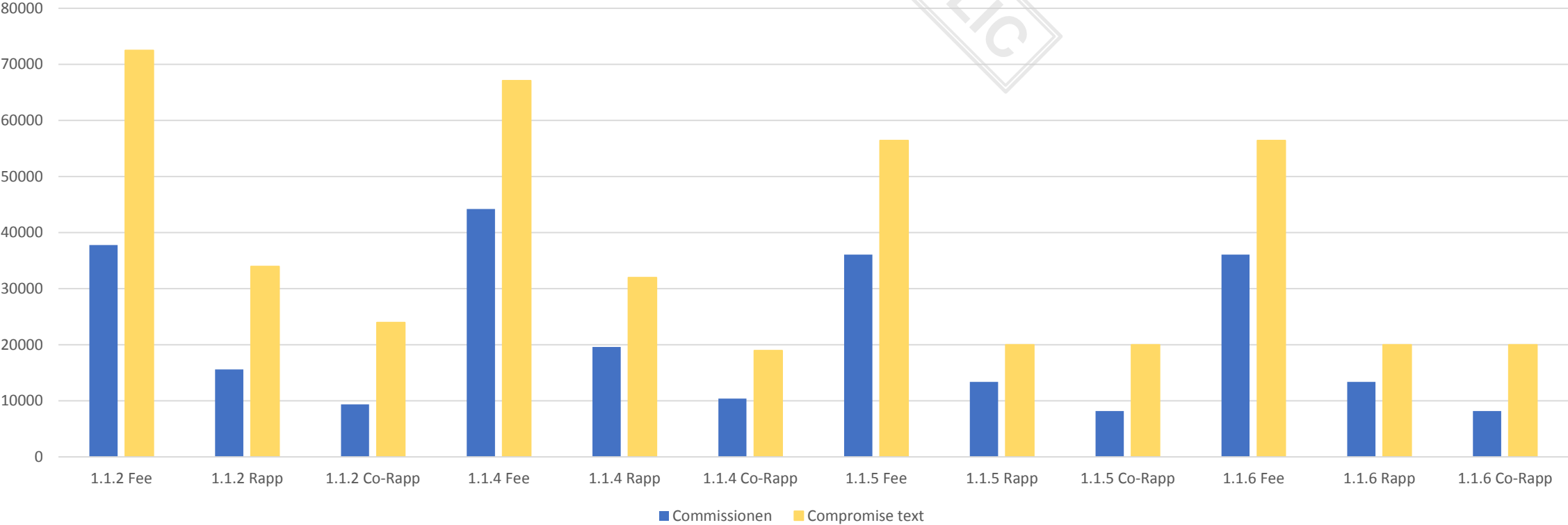


## PSURs





Inspections



The proposals for 1.1.2, 1.1.4, 1.1.5 and 1.1.6 were calculated based on the suggestions by delegations under the assumption of one fee per site. The Presidency is, however, reflecting on the possibility to clarify that the same approach as the current system should apply, in which several fees per inspection can be charged, and how to recalculate the fees.