

Spanish Presidency Flash

Meeting of the Working Party on Pharmaceuticals and Medical Devices

Friday, 15th of September 2023
10:00-13:00

Dear colleagues,

The Spanish Presidency is glad to invite you to the second Working Party on Pharmaceuticals and Medical Devices of this semester. Please, find attached the Presidency flash for the meeting.

Friday, 15th of September 2023, morning (10:00-13:00) session

Point I - Update by the Presidency on the on-going negotiations and preparation for the trilogue (Proposal for a Regulation 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 - 2022/0417(COD))

WK 11431/23

The Presidency will debrief you on the state of interinstitutional negotiations of the EMA fees file, and will present the possibilities for a package on the most salient issues discussed. We will seek guidance from delegations and propose a way forward.

The ES Presidency had the first trilogue on the 5 September, which gave a broad mandate for negotiations at technical level. Four intense technical meetings followed, on 6, 8, 12 and 14 September. An additional one has been scheduled for Monday 18 September, to hopefully green all text. It became clear during these meetings that there was a common interest in finding a swift provisional agreement. However, several parts of the text appeared to be stumbling blocks. In particular, they were:

- EP transparency amendments: Rows 78 and 79 (Articles 6.4 and 6.5), Row 93 (Article 10.2), Row 93a (Article 10.2a (new)), Row 97 (Article 10.6), Row 99c (Article 10. (6.1) (new)), Row 99d and 99e (Article 10.6.a and paragraph 6b(new)), Row 103 (Article 10.8), Row 464 (Annex VI)
- Veterinary sector: Annex II figures
- Reduction of annual fee on pharmacovigilance (Annex V)
- Sustainability factor of 7%
- 50% reduction in remuneration for total waivers
- Inclusion of academia in the scope of the Regulation, with full waiver of fees and remunerations
- Generics: Annex I.3.6 figures
- Variations type II (Annex I, point 5.1 and 5.2) figures
- PRAC rapporteurship
- EMA Management Board role
- Fees for inspection outside the EU

Additionally, you saw in the WK 11431/23, there were advances in many other parts of the text. We would like to highlight in particular that the EP accepted to include “adapt [specification of activities](#)” as a new possible recommendation of the special report (Row 99a – Article 10.6.c). Moreover, for the [scientific advice](#) we agreed at technical level on the EP numbers (higher than ours) for all but Annex I.3 (row 161), where their number was lower. For that, the General Approach figure was kept.

Transparency: we were flexible on several of their demands except for Row 93a on “list a detailed breakdown of all remunerated amounts paid to the national authorities for their work”. This row remains to be discussed in package. We would like to get your feedback on possible compromises.

To be noted that the EP dropped their amendments that were problematic for us as it would create duplications and unnecessary burden: Row 96 (Article 10.5) ([no Commission report on inflation](#)), Row 99c (Article 10. (6.1) (new)) ([report is no longer submitted to the colegislators](#)), Row 99d

and 99e (Article 10.6.a and paragraph 6b(new)) (no stakeholders consultations), and Row 103 (Article 10.8) (no clarification request for legislators).

Management board-special report:

- The EP is flexible with the General approach text on [the adoption of the special report by the Management Board](#) (Row 97 - Article 10.6). However, in case of change in the statutory task of the Agency, EP would like to introduce a deadline for adoption of 3 months after the proposal entered into force. (Row 99b – Article 10.6.d).
- The EP signalled as a hard red line our proposal that allowed the Management board to shorten the time interval to the special report (Row 107b – Article 10.9.e).
We should consider if this is acceptable, in view of the overall package.

Veterinary sector

[The EP accepts the Council proposal on an update for inflation \(50%\)](#), but asked to change Row 97 (Article 10.6): the 1st Special report should not be earlier than 12 months (instead of 9 months). We believe this is acceptable.

Horizontal adjustments and remunerations on waivers

The EP agreed on all the [adjustments for inflation for 2021 and 2022](#) and on the [concept of a sustainability factor](#) (and the adjustment on inflation 2021-2022), but requested to lower the number. This appeared to be another hard red line for the EP.

We proposed to maintain 7% of sustainability factor but we could think about their request to cut in half remunerations in case of waivers.

Their proposal would be to lower it to 3 % and take their text on the reduction of remunerations in case of waivers.

The Presidency believes that this is an unacceptable deal, and would like to discuss possible ways ahead with delegations.

Academia

Pending the result on the overall package, we could see with sympathy the possibility of fee waivers for academia, even if [redrafted to avoid legal issues explained in our previous working party](#). Good language has been found between the three institutions (with an addition in Article 8 for the Management Board to better define eligibility in the working arrangements).

No deal on the linked remunerations: we signalled that we would like to keep the full remuneration. We believe that this discussion should be connected to the negotiations on the sustainability factor, and the EP agrees.

Generics – Annex I 3.6 – see Annex

This was clearly highlighted by both the EP and the Commission as a problematic change in the General Approach. A substantial reduction was requested for both Annex I 3.6 and Annex I 5.2.

The EP asked to adjust both procedures with the horizontal approach.

The Presidency considered this proposal as unacceptable. We checked if a recalculation of fee and remunerations, multiplying the Commission proposal by 20% for inflation and sustainability, 20% for multinational teams, and 20% for the recalculation of working hours, could be acceptable. It seemed not enough.

We would like to sound with you the possibility of offering a lower fee without lowering the remunerations any further (as per the previous offer). See Annex.

Additionally, hearing the concerns of the two institutions, the Presidency proposes to agree on the 30% reduction of pharmacovigilance annual fee.

Variations type II (Annex I, point 5.1 and 5.2) – see Annex

For Annex I.5.1, a small reduction to our figures was requested. We proposed a 10% reduction in the remunerations, but preserving the part of the EMA of the proposal + inflation. The EP asked to apply a 20% reduction, but we suggest to maintain the explained position if delegations agree with us.

As regards Annex I.5.2, a more substantial effort was requested by EP, supported by Commission. We proposed to keep the fee applicable at present (23 700 €), preserving the part of the EMA of the proposal + inflation. The remainder was the remuneration, that added up to 16 700 €. This was challenged, and as explained above the EP would like a horizontal adjustment.

A possible compromise could be to reduce the fee as shown in the Annex. We would like to know the position of the delegations.

PRAC rapporteur

The EP could provisional agree on the new fees for the [PRAC rapporteur](#).

Inspections – see Annex

The EP agreed on the changes in the operative part of the text on [distinct inspections](#). However, considered our figures too high, and would like to have a horizontal adjustment only.

We consider this offer as unacceptable. Alternatively, we wanted to test with you the figures in the Annex.

Other targeted approaches

The EP could preliminarily agree on our general approach text as regards [Rolling reviews](#), [PSURs](#), and [Referrals](#).

Way ahead:

Due to agenda problems of the rapporteur, the second trilogue is delayed to 3 of October. Consequently, the COREPER meeting preparing the discussion would be the 27 of September.

Next ITM is on 18 of September.

ANNEX

VARIATIONS AND GENERICS

Fee		Current figures	Commission/ EP	General Approach	New proposal	Rationale
GENERIC 3.6	Fee	121.500	141.200	239.500	185.000	Commission proposal was revised and corrected by inflation, working hours not included and multinational teams (3 x 20%) (fee 190.100). EP asked in ITM for a further reduction of the fee to 185.000, at the expenses of EMA part of the fee, maintaining the revised remuneration.
	EMA part	60.750	101.000	114.700	109.600	
	Rapp	30.375	40.200	118.900	69.500	
	CoRapp	30.375	NA	NA	NA	
	PRAC	NA	NA	5.900	5.900	
5.1 Type II variations, new therapeutic indication or modification of an approved indication	Fee	94.000	99.800	175.300	162.420	Reduced %10 in the amounts introduced by the GA, while preserving EMA increase corrected by inflation.
	EMA	47.000	41.000	46.500	46.500	
	Rapp	23.500	29.400	64.400	57.960	
	CoRapp	23.500	29.400	64.400	57.960	
5.2 Type II variations, clinical & non-clinical	Fee	23.700	13.000	28.500	20.000	Proposal in ITM to maintain current fee, while preserving EMA increase corrected by inflation: • Fee 23.700 • Remuneration to Rapp: 16.700 EP asked to set the fee to a maximum of 20.000€, reducing EMA part of the fee and the remuneration proportionately (16% approx.).
	EMA	11.850	6.200	7.000	5.900	
	Rapp	5.925	6.800	21.500	14.100	
	CoRapp	5.925	na	na	na	

GMP INSPECTIONS.

Adjustment of all amounts **to the lowest increase** (in percentage) in the GA proposal (28%).

Fee		Current figures	Commission/ EP	General Approach	% Increase	New proposal(1)
Annex IV, 1.1.2	Fee	23.700	37.800	56.000	48	46.500
	EMA	11.850	12.800	14.500		14.500
	Lead	7.900	15.600	24.800		20.000
	Support	3.950	9.400	16.700		12.000
Annex IV, 1.1.4	Fee	23.700	44.200	56.600	28	54.500
	EMA	11.850	14.200	16.100		16.100
	Lead	7.900	19.600	25.800		25.100
	Support	3.950	10.400	14.700		13.300
Annex IV, 1.1.5	Fee	23.700	36.100	47.300	31	44.100
	EMA	11.850	14.500	16.500		16.500
	Lead	7.900	13.400	16.700		17.100
	Support	3.950	8.200	14.100		10.500

(1) New amount result: EMA share as per GA (plus 13% inflation) + Remuneration increased based on the lowest increase of percentage (28%)



Council of the European Union
General Secretariat

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

Brussels, 15 September 2023

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	Working Party on Pharmaceuticals and Medical Devices of 15 September - Flash from the Presidency

Delegations will find attached the Presidency flash for the meeting of the Working Party on Pharmaceuticals and Medical Devices of 15 September 2023. The draft agenda is set out in CM 4275/23.