



2021/2132(DEC)

8.12.2021

AMENDMENTS

1 - 20

Draft opinion

Pascal Canfin

(PE699.211v01-00)

2020 discharge : European Medicines Agency
(2021/2132(DEC))

AM_Com_NonLegOpinion

Amendment 1
Michèle Rivasi

Draft opinion
Paragraph 1

Draft opinion

1. Emphasises the important role of the European Medicines Agency ('the EMA') in protecting and promoting **public** and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

Amendment

1. Emphasises the important role of the European Medicines Agency ('the EMA') in protecting and promoting **human** and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and **regulatory** incentives to stimulate the development and improve the availability of innovative new medicines;

Or. en

Amendment 2
Monika Beňová

Draft opinion
Paragraph 1

Draft opinion

1. Emphasises the important role of the European Medicines Agency ('the EMA') in protecting and promoting public and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

Amendment

1. Emphasises the important role of the European Medicines Agency ('the EMA') in protecting and promoting public **human** and animal health by making independent, science-based recommendations on the quality, safety and efficacy of medicines, and providing scientific advice and incentives to stimulate the development and improve the availability of innovative new medicines;

Or. en

Amendment 3
Alexandr Vondra

Draft opinion
Paragraph 2

Draft opinion

2. Notes that, ***owing to the global*** COVID-19 pandemic, 2020 was an extremely challenging year for the EMA, requiring ***a shift in its priorities and*** extreme agility and resilience to maintain the EMA's activities while supporting global efforts to combat the pandemic in a new and challenging environment;

Amendment

2. Notes that ***following its relocation in 2019, the EMA had planned to resume full-scale activities in 2020; however, the COVID-19 outbreak forced a re-prioritisation of its operations to tackle the*** pandemic; ***stresses that*** 2020 was ***consequently*** an extremely challenging year for the EMA, requiring extreme agility and resilience to maintain the EMA's activities while supporting global efforts to combat the pandemic in a new and challenging environment;

Or. en

Amendment 4
Michèle Rivasi

Draft opinion
Paragraph 2

Draft opinion

2. Notes that, owing to the global COVID-19 pandemic, 2020 was an extremely challenging year for the EMA, requiring a shift in its priorities and extreme agility and resilience to maintain the EMA's activities while supporting global efforts to combat the pandemic in a new and challenging environment;

Amendment

2. Notes that, owing to the global COVID-19 pandemic, 2020 was an extremely challenging year for the EMA, requiring a shift in its priorities and extreme agility and resilience to maintain the EMA's activities while supporting ***enhanced collaboration between Member States to manage the supply of medicines and*** global efforts to combat the pandemic in a new and challenging environment;

Or. en

Amendment 5
Michèle Rivasi

Draft opinion
Paragraph 5 a (new)

Draft opinion

Amendment

5a. Stresses that despite the majority of funding coming from private sources, the EMA is a public authority; underlines that the perception of the EMA's independence and integrity is crucial and therefore a high degree of transparency needs to be ensured through all its activities to avoid regulatory capture and ensure citizens maintain their faith in the marketing authorisation system in the Union;

Or. en

Amendment 6
Monika Beňová

Draft opinion
Paragraph 6

Draft opinion

Amendment

6. **Welcomes** the EMA's decision to waive all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines as of 13 March 2020, and **to waive** all fees for provision of scientific advice to academic researchers developing orphan medicines from 19 June 2020;

6. **Notes** the EMA's decision to waive all fees for scientific advice applications from developers of potential COVID-19 therapeutics or vaccines as of 13 March 2020, and **welcomes the waiving of** all fees for provision of scientific advice to academic researchers developing orphan medicines from 19 June 2020; **highlights that other instances of waiving fees subject to specific criteria set out by the EMA notably regarding SMEs should follow;**

Or. en

Amendment 7
Monika Beňová

Draft opinion
Paragraph 8

Draft opinion

8. Is pleased that the EMA successfully maintained the quality and continuity of its operations whilst relocating its seat to its final premises in Amsterdam following the United Kingdom's withdrawal from the Union; notes that potential liabilities arising from the lease on the EMA's former office premises in London remain a matter of concern;

Amendment

8. Is pleased that the EMA successfully maintained the quality and continuity of its operations whilst relocating its seat to its final premises in Amsterdam following the United Kingdom's withdrawal from the Union; notes that potential liabilities arising from the lease on the EMA's former office premises in London remain a matter of concern; ***recognises that the EMA was able to respond effectively to the workload associated with the COVID-19 pandemic and welcomes the work on facilitating access to new vaccines and therapeutics to treat and prevent the spread of COVID-19;***

Or. en

Amendment 8
Michèle Rivasi

Draft opinion
Paragraph 10

Draft opinion

10. Welcomes the proposal to extend the EMA's mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by corresponding increases in the EMA's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure;

Amendment

10. Welcomes the proposal to extend the EMA's mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by ***sufficient*** corresponding increases in the EMA's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure ***and threatens the quality of the EMA's work;***

Or. en

Amendment 9
Alexandr Vondra

Draft opinion
Paragraph 10

Draft opinion

10. Welcomes the proposal to extend the EMA's mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by corresponding increases in the EMA's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure;

Amendment

10. Welcomes the proposal to extend the EMA's mandate but expresses concern that the addition of significant new tasks and its increasing workload over the years has not been accompanied by corresponding increases in the EMA's staff and resources, and that such a shortage of staff puts the continuity of its operations under significant pressure ***at an already critical time***;

Or. en

Amendment 10
Nathalie Colin-Oesterlé

Draft opinion
Paragraph 10 a (new)

Draft opinion

10a. Recommends, in particular, that sufficient additional resources be allocated to the EMA to improve its competence in the fight against medicine shortages. Invites the European Commission to evaluate in detail the feasibility of granting the EMA additional capacity to manage shortages, incorporating the desirable future transformation of the European Shortages Monitoring Platform into a proper and effective common European database;

Or. fr

Amendment 11
Michèle Rivasi

Draft opinion
Paragraph 11

Draft opinion

11. ***Acknowledges*** the revised policy on the handling of competing interests of the Management Board, which took effect from 1 July 2020 and the practice of systematic ex-ante controls on all declarations of interest submitted by Management Board members together with the requirement that those members undertake training before their declaration of interest can be submitted;

Amendment

11. ***Welcomes*** the revised policy on the handling of competing interests of the Management Board, which took effect from 1 July 2020 and the practice of systematic ex-ante controls on all declarations of interest submitted by Management Board members together with the requirement that those members undertake training before their declaration of interest can be submitted;

Or. en

Amendment 12
Michèle Rivasi

Draft opinion
Paragraph 11 a (new)

Draft opinion

Amendment

11a. Notes with satisfaction the exceptional transparency measures the EMA implemented with regard to medicines for COVID-19, including accelerated publication timelines for clinical data and providing more information to the general public such as publication of the product information with details of the conditions of use at the time of the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) on the marketing authorisation application; publication of the full European public assessment report (EPAR), within three days of authorisation by the Commission; publication of clinical data submitted to the EMA in support of the applications

for COVID-19 medicines after the authorisation of a medicine and once personal data have been anonymised; and the publication of the full risk management plan for authorised COVID-19 medicines; invites the EMA to apply the same transparency measures to all products regulated by the EMA;

Or. en

Amendment 13
Monika Beňová

Draft opinion
Paragraph 14

Draft opinion

14. Notes, ***in addition***, that the Court identified irregularities in a catering and restaurant services framework contract, including a failure to verify that the amounts invoiced were correct;

Amendment

14. Notes, that the Court identified ***public procurement weaknesses and also*** irregularities in a catering and restaurant services framework contract, including a failure to verify that the amounts invoiced were correct;

Or. en

Amendment 14
Alexandr Vondra

Draft opinion
Paragraph 14

Draft opinion

14. Notes, ***in addition***, that the Court identified irregularities in a catering and restaurant services framework contract, including a failure to verify that the amounts invoiced were correct;

Amendment

14. Notes, ***with concern***, that the Court identified irregularities in a catering and restaurant services framework contract, including a failure to verify that the amounts invoiced were correct;

Or. en

Amendment 15
Alexandr Vondra

Draft opinion
Paragraph 15

Draft opinion

15. Notes with satisfaction that the EMA cooperates with other agencies, in particular with the European Centre for Disease Prevention and Control and with the European Food Safety Authority, including on the European Vaccination Information Portal *and* on antimicrobial resistance;

Amendment

15. Notes with satisfaction that the EMA cooperates with other agencies, in particular with the European Centre for Disease Prevention and Control and with the European Food Safety Authority, including on the European Vaccination Information Portal, *for monitoring vaccine safety and reporting side effects, as well as on antimicrobial consumption and* resistance;

Or. en

Amendment 16
Stanislav Polčák

Draft opinion
Paragraph 15 a (new)

Draft opinion

15a. Highlights the importance of involving the relevant stakeholders, such as representatives of health professionals, of patients and of other parties, in the light of the alarming prevalence of disinformation regarding the COVID-19 pandemic in the conversation on protection of public health and calls on the EMA to continue the development of this conversation as actively as possible, based on the latest scientific knowledge;

Or. cs

Amendment 17
Stanislav Polčák

Draft opinion
Paragraph 15 b (new)

Draft opinion

Amendment

15b. Welcomes the fact that tackling increasing antimicrobial resistance (in particular through supporting the development of new medicines, collecting data on veterinary antimicrobial consumption and promoting responsible use of such medicines) remains one of the EMA's priorities, even in the light of the current situation;

Or. cs

Amendment 18
Stanislav Polčák

Draft opinion
Paragraph 15 c (new)

Draft opinion

Amendment

15c. Emphasises that the COVID-19 pandemic is impacting all aspects of health care, including the availability of medicines due to supply chain disruptions; considers that the situation has only served to highlight the need, of which we were already aware, to ensure the highest possible level of self-sufficiency in the development and production of medicines within the European Union; welcomes the EMA's commitment to continue contributing to the development and strengthening of the European Union's response system in the event of reduced availability of medicines;

Or. cs

Amendment 19

Stanislav Polčák

**Draft opinion
Paragraph 15 d (new)**

Draft opinion

Amendment

15d. Welcomes the level of assistance that the EMA has provided to companies developing vaccines and medicines against COVID-19; lauds its consistently scientific approach, which places the health of EU citizens above all else;

Or. cs

**Amendment 20
Stanislav Polčák**

**Draft opinion
Paragraph 15 e (new)**

Draft opinion

Amendment

15e. Welcomes the EMA's efforts to increase the level of transparency of its decision-making, as evidenced, for example, by the publication of data from clinical trials submitted in the marketing authorisation process for COVID-19 medicines or the increased level of communication with the media and the public; feels that this transparent approach is crucial in the current situation;

Or. cs