Question for written answer E-003404/2023
to the Commission
Rule 138
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Subject: The EMA bans Pneumorel, a drug from the French laboratory Servier, owing to two deaths in 50 years, but fails to react to the 12 000 deaths reported following COVID vaccination

Fenspiride (Pneumorel) had been used to treat symptoms of respiratory diseases (notably as a cough medicine).

In the 50 years since it was first placed on the market in 1973, there have been two cases of sudden death[1] and five cases of heart rhythm problems[2] globally[3]. In those five cases, other medicines or risk factors were present[4].

In May 2019, the EMA's safety committee (PRAC) recommended that marketing authorisations for fenspiride-based medicinal products be revoked. The review was carried out following a request from France in February 2019[5].

1. Why does the Commission consider that the risks outweigh the benefits of Pneumorel – even though it is used to treat symptoms of a mild disease and the only serious effects linked to its safety have been the five cases of heart problems reported in 50 years globally – and yet for the COVID vaccines, the 12 000 deaths reported in the space of one or two years[6] and the confirmed risk of fatal myocardial do not influence the benefit-risk ratio for certain populations (healthy young people / soldiers), even after the end of the pandemic was announced by the WHO on 5 May 2023?

2. What objective criteria does the Commission use to assess EMA recommendations?

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1 The cause of death has not been confirmed in either of the two cases.
2 QT prolongation.
3 https://tinyurl.com/ym2zscuv
4 The five cases include one attempted suicide by overdose, and in another case the medicine was not deemed to have been responsible https://www.ema.europa.eu/en/documents/referral/fenspiride-containing-medicinal-products-article-107i-referral-rationale-triggering_en.pdf. A study on ten guinea pig hearts was used.
5 https://www.ema.europa.eu/en/documents/referral/fenspiride-containing-medicinal-products-article-107i-referral-withdrawal-marketing-authorisations_en.pdf
6 EMA: fatal outcomes reported for 11 977 persons; ‘There is an increased risk of myocarditis and pericarditis following vaccination with the Pfizer vaccine, and more often in younger males; fatal cases have been observed’ (SPC, p. 4; 15.10.2023. https://ec.europa.eu/health/documents/community-register/2023/20231019160809/anx_160809_en.pdf