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EU medicine regulation in the new Commission

About-turn on Medicines Agency ensures patients remain the priority

The European Medicines Agency, which is responsible for the evaluation and supervision of medicines in the EU, has been something of a political hot potato over the past weeks. President-elect Juncker tried to shift responsibility for this crucial regulatory agency to the EU Commission's directorate general for enterprise and away from the directorate general for health and consumers. A similar attempt was made in 2009 but this was unsuccessful.

The latest move provoked real concerns, with fears that the regulation of medicines would be approached from a predominantly commercial perspective, instead of with a view to prioritising the interests of patients. The Greens/EFA group wrote to Commission president-elect Juncker to present these concerns.

Thankfully, it has now been announced that this latest move will not take place and that responsibility for the EMA will remain with the directorate general for health and consumers. The Greens/EFA group has welcomed this about-turn as ensuring that patients will remain the priority in the regulation of medicines.

Reacting to the news, Greens/EFA health spokesperson **Michèle Rivasi** said:

"The decision not to shift the responsibility for the EMA is a relief, but I would not say this is good news: it is simply what should have happened anyway. It would be wrong to deal with the regulation of medicines from a mainly commercial perspective at a time when we are seeing an increase in inequality to treatment and access to medical care.

"Medicines and medications are clearly not like other goods and patients must be placed before profit. Ensuring the Commission's directorate general for health and consumers remains responsible for the EMA is the only way to ensure this.

"Important issues in the regulation of medicines - like transparency, access to clinical trial data, improving pharmacovigilance and effective notification of side effects - could have been undermined by this move. However, it is also clear that there are continuing concerns with the EMA, notably as regards conflicts of interest. We will continue to push for these to be redressed.

"The lobbying of the pharmaceutical industry has not been successful thanks to the responsiveness of the European Parliament but also through effective advocacy of patient associations. We hope this momentum continues over the coming legislative term, so we can ensure health is put first."

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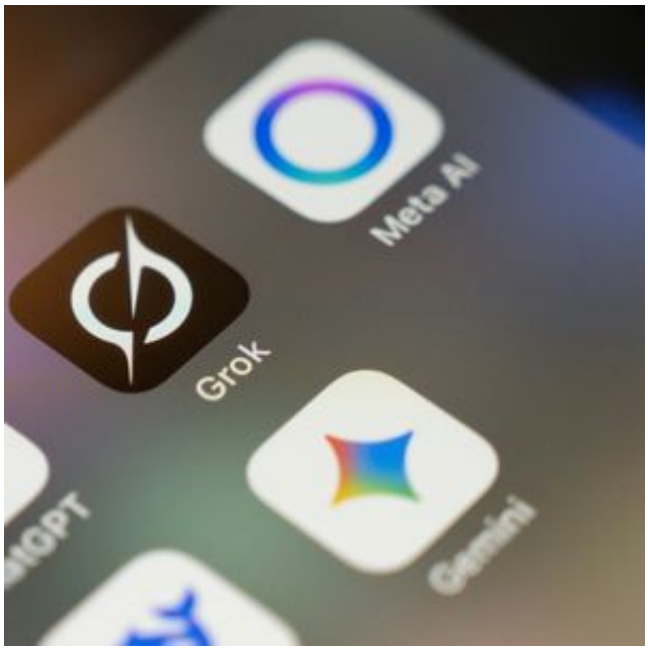


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Michèle Rivasi

Member

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