# Flash statement on permanent withdrawals from the market

Disclaimer: biased, personal view from a small EU member state

- Withdrawn medicinal products cannot be directly replaced by new entrants (existing pool of successfully treated patients, long-term prescribing experience)
- Most common root causes: discontinuation of API production, lack of commercial interest
- When the competent authority is notified, the MAH has already reached the decision internally
- Public health risk criteria assessment, but competent authorities have no means at hand to prevent a withdrawal if the MAH insists on it
- Ways forward: prolongation of notice period, »stick & carrot« approach, a more harmonised EU-wide approach
- Let‘s learn from past experience and be more proactive together

API: active pharmaceutical ingredient
MAH: marketing authorisation holder