EU Agency Endorses Suspension of Oral Methadone Products

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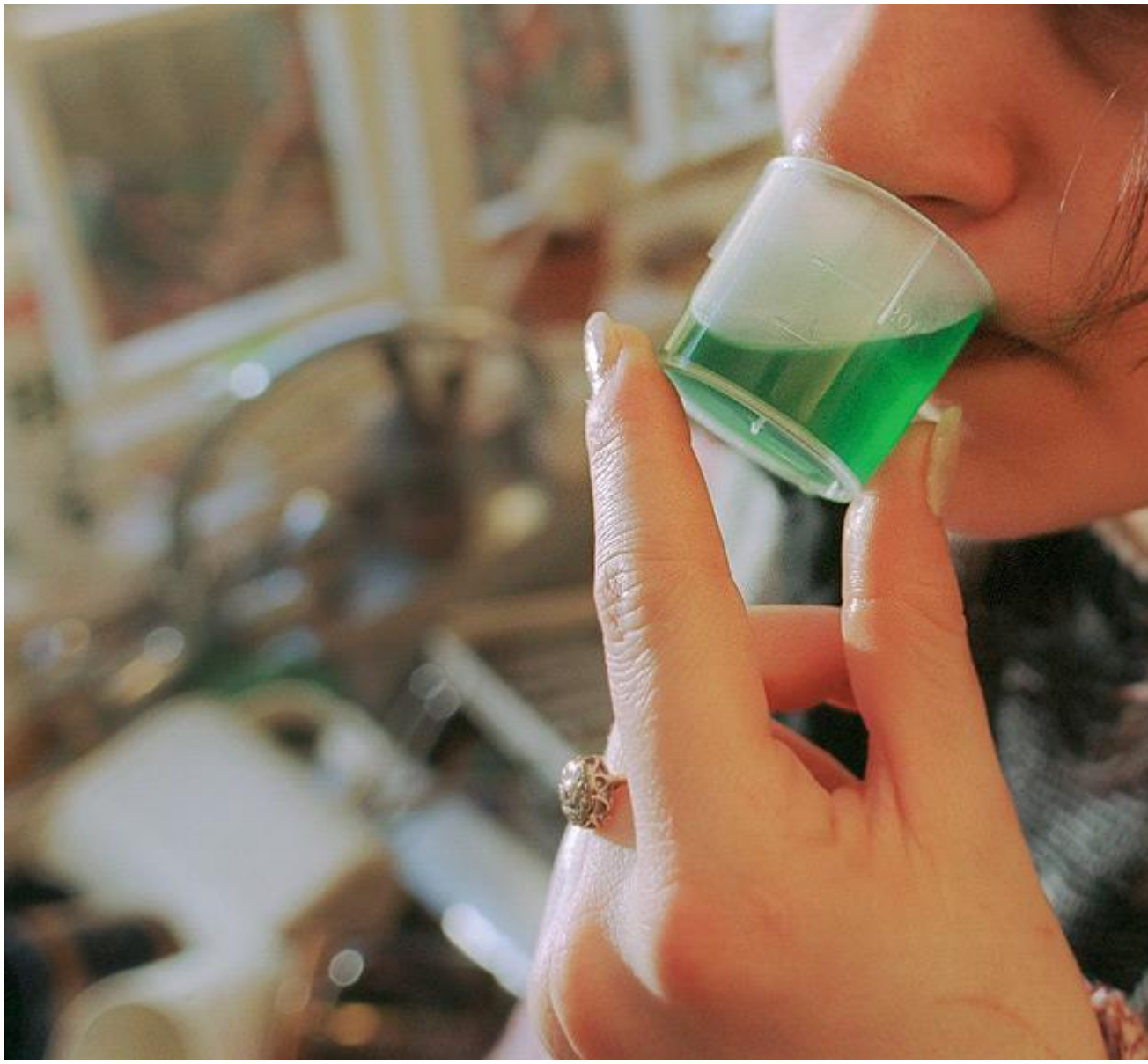

EU Panel Reviewing Safety of Methadone Containing Povidone

Methadone Accounts for One Third of Pain Med Overdose Deaths

The Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), a regulatory body representing the European Union (EU), has added its endorsement to recommendations calling for suspension of marketing authorization of methadone oral solutions that contain high molecular weights of the additive povidone until the product can be reformulated.

The oral version of methadone, which is prescribed to treat symptoms of withdrawal in patients who are dependent on opioids, is sometimes misused by injecting into a vein. Products containing high-molecular-weight povidone (K90) accumulate inside the cells of vital organs instead of being excreted. This accumulation can lead to serious harm, including tissue damage and even death.

After reports surfaced in Norway of serious adverse events occurring in former and current drug abusers, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) conducted a safety review in April and subsequently suspended methadone oral solutions containing K90 from the Norwegian market.

"The PRAC concluded that risk minimization measures would be insufficient to mitigate the risks with oral solutions containing high molecular weight povidone," according to a release from the EMA.

"They will need to be appropriately reformulated before being reintroduced on the European Market," added the organization.

Because the recommendation has now been "endorsed by consensus" by the CMDh, it will be implemented in all EU member states. The oral solutions had been authorized in Denmark, Finland, Malta, Sweden, the United Kingdom, and Norway.

Patients in these locations who are currently taking the high-molecular-weight products as part of their treatment program should be switched immediately to alternative, lower-risk methadone medications.

Interestingly, the CMDh agreed with the consensus that this suspension should not include methadone tablets with low-molecular-weight povidone (K25 or K30) — as long as they are marketed with revised product information, including information in the package leaflets.

Povidone of this lower molecular weight does not accumulate inside vital cells and can be excreted from the body. Still, the new product information will need to highlight that the tablets should only be used orally.

These tablets are currently authorized in Denmark, Finland, Sweden, Norway, Hungary, Iceland, Romania, and Spain.