Medicinal products susceptible to 'dose dumping' should be fully tested

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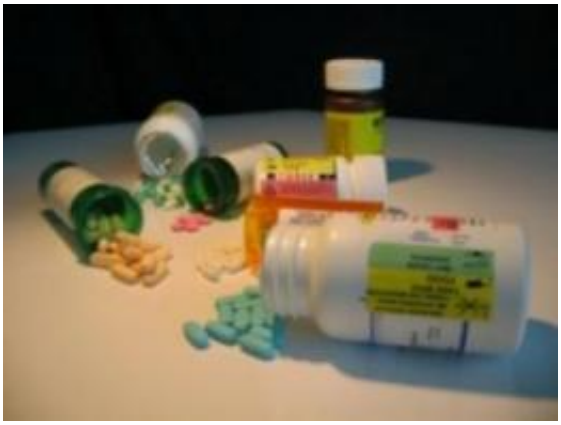

Pills and capsules that show a tendency toward a dangerous interaction called "dose dumping" should be withheld from the market until proven safe, a research review concludes. Credit: California Department of Toxic Substances Control

Controlled release pills and capsules that show a tendency in the standard laboratory test toward "dose dumping" — releasing their medicine in a faster and potentially unsafe manner in patients who have consumed alcohol — should be withheld from the market until proven safe with testing in people. That's the conclusion of a review of existing studies in the September-October issue of ACS' *Molecular Pharmaceutics*.

In the article, Hans Lennernäs analyzed the gastrointestinal factors that may contribute to dose dumping when a vulnerable formulation interacts

with alcohol present in the stomach. However, these factors are highly variable and depend on individual drinking behavior, whether food is present in the stomach, and other circumstances. That makes it "almost impossible" to predict whether a patient will experience an overdose as a result of dose dumping.

Lennernäs thus concludes that when laboratory testing of a product indicates that the drug will be released more quickly than intended, the product also should be tested in humans, or it should be re-formulated. Indeed, Lennernäs believes that lab testing over a two hour period in a range of alcohol strengths is an "absolute minimum standard" in screening for dose dumping because products with a problem in the lab may also be dangerous to patients.

Lennernäs cites as an example a formulation of the pain medication hydromorphone, which was removed from the U.S. market when testing revealed that alcohol intake caused the risk of overdose. He noted, however, that there is currently a generic oxycodone product on the market in the European Union which will "most likely" lead to dose dumping in patients.

More information: "Ethanol-Drug Absorption Interaction: Potential for a Significant Effect on the Plasma Pharmacokinetics of Ethanol Vulnerable Formulations", Molecular Pharmaceutics, DOI: 10.1021/mp9000876

Source: American Chemical Society (news : web)