Reducing gene-damaging impurities in medicines

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Drug manufacturers have been adjusting to strict new government standards that limit the amount of potentially harmful impurities in medicine, according to the cover story of the current issue of Chemical & Engineering News (C&EN), ACS' weekly newsmagazine. The impurities are "genotoxic," capable of damaging the DNA in genes.

C&EN Senior Correspondent Ann Thayer notes that internationally accepted regulations long have limited the levels of impurities permitted in prescription drugs. But guidelines have not covered so-called genotoxic impurities (GTIs), substances that can potentially increase the risk of cancer. That changed in 2007, after European regulators put guidelines in place and the U.S. Food and Drug Administration soon after followed suit. The challenging new limits for GTIs are about 1,000 times lower than the levels allowed for most other impurities.

Although drug companies are complying with the guidelines, some regard the limits as too strict, the article notes. Some industry scientists also question the approaches proposed to categorize and test for GTIs. Nevertheless, drug companies are working to change or control their manufacturing methods so that GTIs either do not form in the first place or form at much lower levels.

More information: "Genotoxic Impurities", This story is available at pubs.acs.org/cen/coverstory/88/8839cover.html