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A Comparison of Environmental Assessment Requirements of New Human Drugs in the US and the EU

Market authorization of new human drugs in both the US and the EU requires an assessment of potential environmental impacts. In the US, drug approval is overseen by the Food and Drug Administration (FDA), and an environmental assessment (EA) is required pursuant to the National Environmental Policy Act. In the EU, market authorization is overseen by the European Medicines Agency (EMA), and an EA is required under Directive 2001/83/EC. Both agencies have published guidance documents outlining EA requirements. While the EA requirements of veterinary drugs is largely harmonized, the framework for conducting EAs of human drugs is much less harmonized. The objective of our analysis was to compare and contrast the EA framework in the US and EU. We reviewed current guidance and incorporated recent EA experience. We identified some general similarities such as the prioritization of endocrine active drugs, the use of tiered testing frameworks, and the preference for guideline studies conducted in accordance with GLPs. However, we identified many important differences in the FDA and EMA frameworks including the production and use criteria that trigger EAs, the points at which physicochemical properties are considered, and the specific tests needed to satisfy EA requirements. For example, in the US, the predicted annual production volume may qualify a drug for EA exemption; while in the EU, both the indicated dosage and certain physicochemical properties must be considered for potential EA exemption. Our analysis illustrates the need for careful and early planning by pharmaceutical companies to ensure global EA compliance.