PROTECTING PATIENT SAFETY IN BIOPHARMACEUTICALS

GLOBAL REGULATORY ALIGNMENT FOR NITROSAMINES IS ESSENTIAL TO PATIENT SAFETY

WHAT ARE NITROSAMINES?

Nitrosamines are a group of chemical compounds that have been categorized as probable or possible human carcinogens by the World Health Organization's International Agency for Research on Cancer (IARC). There are many types of nitrosamines and they vary in their chemical properties and potential carcinogenicity.

According to the U.S. Food and Drug Administration[i] (FDA), "small amounts of exposure [to nitrosamines] are not considered to be harmful." Most everyone is exposed to some level of nitrosamines, as they are commonly found in everyday items, including in water and foods such as cured and grilled meats, dairy products and vegetables. Nitrosamines can be formed naturally outside of the body, formed during product manufacture or processing, and can even be formed in stomach acid from precursor molecules consumed in the diet. In most instances, when it comes to the presence of nitrosamines in medicines, the benefits of receiving the treatment far outweigh any potential risks from exposure.

The FDA also notes,[ii] "a person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer. Patients taking prescription medications with potential nitrosamine impurities should not stop taking their medications. Patients should talk to their health care professionals about concerns and other treatment options."

THE INNOVATIVE BIOPHARMACEUTICAL INDUSTRY IS COMMITTED TO PATIENT SAFETY

The biopharmaceutical industry is committed to ensuring the medicines we make are safe and effective. This includes regularly testing and evaluating medicines to make sure they do not contain unacceptable levels of nitrosamines.

In instances where nitrosamine impurities may be found above acceptable limits in some pharmaceuticals, manufacturers can take immediate action to protect patient health, including voluntarily recalling products, suspending distribution of supplies and working with global regulators to address acceptable levels of nitrosamine impurities.

Ensuring safety standards for all medicines around the globe is vital. Our industry is committed to working closely with the FDA and other global biopharmaceutical regulators to help prevent potential risks associated with nitrosamine impurities as well as working with regulators to ensure that regulatory guidance is based on available science. That is why the industry supports broader global adoption of uniform standards across all regions to ensure that the latest science about nitrosamines will guide decisions about the risk and management of potential impurities.

HOW ARE NITROSAMINES CURRENTLY REGULATED?

For medicines, health regulatory authorities around the globe have issued requirements for the control of nitrosamine impurities. Biopharmaceutical companies monitor nitrosamine impurities that can occur in certain medicines in line with global health regulators' requirements and guidance. Biopharmaceutical companies work with regulators should impurities like nitrosamines be detected at unacceptable levels. However, medicine regulatory authorities around the globe have issued differing, and sometimes conflicting, requirements for the control of nitrosamine impurities in medicines causing uncertainty for manufacturers.

To ensure the latest science will guide decisions about the potential risks of nitrosamine impurities, and that regulatory guidance on nitrosamines appropriately facilitates the use of science- and risk-based approaches while preserving patient access to safe, effective and quality medicines; regulators and biopharmaceutical companies must continue to collaborate and share scientific learnings to advance the common knowledge around nitrosamine impurities and their potential impact on patients.

PhRMA is committed to working with medicine regulators around the world to support global harmonization of nitrosamines standards, ensure that regulatory guidance is appropriately science- and risk-based, advance the common knowledge around nitrosamine impurities and their potential impact on patients, and help ensure the uninterrupted supply of quality medicines to patients around the world.

[i] https://www.fda.gov/drugs/news-events-human-drugs/rigorous-detection-nitrosamine-contaminants-metformin-products-balancing-product-safety-and-product

[ii] https://www.fda.gov/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications