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EU Regulators Clarify Rules On Nasal Spray Claims Ahead Of Cold & Flu Season

by Tom Gallen

The EU's medical device regulators have joined forces to remind consumer health firms of the rules which must be followed when marketing a nasal spray offering protection from viruses, such as influenza and SARS-CoV-2.

Consumer health firms looking to capitalize on Europe's upcoming cold and flu season by launching protective nasal spray products are being reminded to familiarize themselves with regulations governing classification, clinical data and claims.

National medical device regulatory authorities across the EU have jointly issued guidance to manufacturers planning to place on the market nasal sprays which claim virucidal and antimicrobial actions, for example against SARS-CoV-2.

The regulators felt compelled to act following a proliferation of nasal sprays promising protection from COVID-19 infection without the required clinical evidence to support such claims. During the height of the pandemic this led to product recalls, advertising bans and blocks placed on launches. (Also see "*France Puts The Brakes On Launch Of Anti-COVID Nasal Spray*" - HBW Insight, 24 Feb, 2021.)

Across the pond, US regulators dealt with similar fraudulent COVID-19 claims from a range of products including nasal sprays, herbal remedies and intravenous drips. (Also see "*Michigan Firm's Nasal Spray Neither A COVID-19 Treatment Nor For Nasal Use*" - HBW Insight, 13 Apr, 2022.)

To improve compliance with the new Medical Devices Regulation (EU) 2017/745, the latest guidance sets out essential points to be considered before placing nasal sprays on the European market.

Classification

First, manufacturers must ensure that their product is appropriately qualified and classified in line with the relevant legislation, and in accordance with the intended purpose and the principal mode of action of the product.

Nasal sprays which achieve their principal intended action by physical or mechanical means are medical devices, whereas those which achieve their principal intended action by pharmacological, immunological or metabolic means may be classed as medicines, and require a marketing authorization.

If the nasal spray is medical device it will be classified as class IIa at a minimum, the guidance notes, requiring a conformity assessment by a notified body before it can be placed on the market for the first time. Under the old medical device directives, manufacturers could launch nasal sprays as class I enabling them to self-certify conformity.

Clinical Data

As part of the assessment process, manufacturers must provide the clinical evidence necessary to demonstrate the nasal spray conforms with safety and performance requirements set out in the MDR and to support product claims. High risk devices or claims require a more extensive clinical evaluation. "Claims against a human pathogenic virus in the context of a global health crisis should be considered as a high-risk situation," the guidance notes.

Given the notable number of nasal sprays launched during the pandemic relying on in vitro studies to support their COVID claims, the regulators emphasize that such tests are not sufficient and must be supplemented by substantial clinical data.

"The clinical data should verify not only the safety of the device, but also its clinical effectiveness and performance, whilst there should also be sufficient evidence to support the mode of action and the site where the action is performed," the guidance says. Substandard investigations which lack of statistical robustness or adequate controls are not considered to have scientific validity for demonstration of adequate clinical performance.

Manufacturers seeking a conformity certificate for their nasal spray by demonstrating the equivalence of their product to another comparable reference device should tread carefully. Clinical data for a nasal spray acting against seasonal influenza cannot be used as clinical equivalence to demonstrate clinical performance against COVID-19, the guidance warns.

Claims

Claims regarding the proven device benefit should be listed on the product's label, along with a description of the expected performance of the device and its intended purpose.

Noting that it is prohibited in the MDR to mislead the user with regard to the performance of the

device, in the labeling, instructions for use and also in advertising, the guidance stresses that COVID-19 claims can only be used if the performance of the nasal spray has been proven specifically on the SARS-CoV-2 virus.

MDR Hurdles

While manufacturers may welcome clear guidance for this increasingly popular class of medical devices, launching a compliant product may take some time.

Notified bodies have been placed under significant strain as manufacturers look to ensure their existing products are compliant with MDR ahead of the 2024 deadline. The workloads of notified bodies have increased significantly without a corresponding jump in capacity. (Also see "*AESGP Regulatory Conference: EU Pharma Strategy, Med Devices Regs, European Green Deal And GCSF Sustainability Charter Launch*" - HBW Insight, 26 Nov, 2021.)