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France Puts The Brakes On Launch Of Anti-COVID Nasal Spray

by Tom Gallen

COV-Defense nasal spray, claimed to inactivate the SARS-CoV-2 virus, will no longer launch in France after regulator ANSM demanded rigorous efficacy and safety data.

France's National Agency for Medicines and Health Products Safety, ANSM, has blocked the launch of an OTC nasal spray marketed to inactivate the virus which causes COVID-19 due to lack of efficacy and safety data.

Pharma & Beauty (P&B) Group had been set to roll out across France on 1 March the COV-Defense spray as a class I medical device, claiming that the product, which contains "ionized water", "ensures the inactivation of the SARS-CoV-2 virus at more than 99%."

"Despite the manufacturer's claims," noted ANSM, "we have not yet received any clinical validation data demonstrating the performance and safety of use of this spray, an essential condition for a medical device to be placed on the market according to European regulations."

As a result, the agency has banned the marketing, distribution, advertising and use of COV-Defense until P&B Group presents an "appropriate level of clinical evidence" for the performance and safety of the product.

In Vivo Trial Required

To date, the company has only carried out in vitro tests of COV-Defense, which ANSM noted had not been designed nor intended to determine the potential viricidal action of a product sprayed on the nasal mucosa.

Responding to ANSM's decision, P&B Group said it had postponed the launch of COV-Defense and committed to carry out in vivo clinical trials in the coming months. The company insisted that its nasal spray "was never intended to replace the vaccines or the barrier procedures in

force.”

In preparation for the now aborted launch, COV-Defense had already been listed on a number of French e-commerce sites, marketed as an “additional barrier” against the virus, at a price of €14.90 (\$18) for a 30ml bottle. “COV-Defense nasal spray contains ionized water obtained by a patented electrolytic process,” notes the product listing. “This alkaline water is enriched with minerals and negative ions.”

French firm Adwatis, which supplies the product to P&B, claims the ionized water in the spray “penetrates, encapsulates all kind of particles, molecules, micro-organisms, (...), and removes them by repulsion force (due to same polarity) from all kind of even or uneven microscopic surfaces. Isolated particles and pollutants are [then] easily removed by rinsing.”

Despite the intervention by ANSM, P&B’s partner GFF Medical Group is still seeking distribution partners for COV-Defense. In a LinkedIn post, GFF says the product is “coming to the UK soon” and offers “daily protection at school, work, play travel.”

OTCs For COVID-19?

COV-Defense is not the first nasal spray claimed to help prevent SARS-CoV-2 infection. UK researchers claim they have developed a nasal spray that can provide protection against the virus which causes COVID-19 and are seeking an industry partner to commercialize the device as a consumer health product.

Comprising an antiviral agent, λcarrageenan, and a gellan polysaccharide, the nasal spray has been shown in the laboratory to “prevent and slow” transmission of the SARS-CoV-2 virus, according to a pre-print study by scientists at the University of Birmingham. (Also see "[UK Researchers Seek Commercial Partner For Nasal Spray Shown To ‘Prevent’ COVID-19](#)" - HBW Insight, 24 Nov, 2020.)

Regulators on both sides of the Atlantic are yet to approve any drugs or other medical products which can be marketed with indications to prevent or treat COVID-19.

The UK’s Advertising Standards Authority has warned marketers not to reference COVID-19 or coronavirus in ads for dietary supplements after a number of firms fell foul of the law. (Also see "[COVID-19 Mentions Prohibited From Supplement Ads - UK Regulator](#)" - HBW Insight, 20 Jul, 2020.)

While in the US, industry self-regulation group BBB National Programs Inc. has referred a number of firms to the Federal Trade Commission for making fraudulent claims for products labeled as dietary supplements to prevent or treat COVID-19. (Also see "[Risking FTC Scrutiny. Direct Seller Ignores Industry Self-Regulation Group On COVID-19 Claims](#)" - HBW Insight, 19 Nov,

2020.)