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**Aesthetic medicine treatments and products for diabetes:
reports of dangerous products purchased from unauthorized channels are on the rise**

AIFA invites patients to pay attention to the dangers associated with the purchase of medicines through unauthorized websites, as previously done (<https://www.aifa.gov.it/-/medicinali-online-in-aumento-le-segnalazioni-di-prodotti-contraffatti-acquistati-da-canali-non-autorizzati>), also through the creation of information campaigns such as the one launched by the Agency last December (https://www.youtube.com/playlist?list=PL5_GT4uemfv9tYuxVv9Ww0STPJYmsv5Sr).

On the basis of the reports and information brought to the attention of AIFA by citizens, associations, companies and other national and international authorities, concerning cases of sale of medicines on illegal channels, such as unauthorized websites, it was possible to detect some emerging cases which concern, in particular, products used in aesthetic medicine treatments and semaglutide-based drugs, indicated for the treatment of adults suffering from type 2 diabetes mellitus.

With regard to aesthetic medicine products, the reports of cases of illegal sale and/or falsification are, in most cases, related to injectable solutions for the face. For example, botulinum toxin, a neurotoxic protein used for therapeutic and aesthetic purposes, and dermal fillers based on hyaluronic acid (HA), a natural substance that gives volume to the skin, fall into this category.

From the investigations carried out, it was found that these products, advertised through non-authorized channels, including media platforms, have been used (and therefore purchased) by doctors without qualifications in numerous unauthorized clinics throughout the country.

It is important to highlight that botulinum toxin is a prescription-only medicine and must be administered by doctors with the qualifications required by law and specific professional skills.

With regard to dermal fillers, although they are medical devices and not medicines, these must likewise be prescribed and administered by qualified doctors with specific professional skills.

Aesthetic medicine is a branch of medicine and, therefore, should only be practiced by professional and expert doctors.

Botulinum toxin medicines cannot be purchased online by individuals or individuals without authorisation. It is therefore important that the sale of these medicinal products by telematics is carried out exclusively through official channels (such as pharmacy, wholesaler or pharmaceutical company that holds the marketing authorisation/concessionaire in Italy), which are not advertised to the general public and that have systems that guarantee the recognition of the licensing of the specialist and expert medical practitioner, for which the sale is reserved for sale. As already pointed out, the analyses carried out on these products purchased online, on unofficial channels, have detected their falsification.

With regard to semaglutide-based drugs, their falsification represents another emerging case study that is just as dangerous as the one described above.

In Italy, this active ingredient is contained in the medicine Ozempic, owned by Novo Nordisk A/S, marketed with a prescription requirement (and therefore not salable or purchasable online) in various packaging and indicated for the treatment of adults with diabetes mellitus inadequately controlled type 2, as an adjunct to diet and exercise.

This type of medicine is also used off label for weight loss.

An increase in the demand for this medicine by patients would have led, on the one hand, to states of shortage, as reported in the AIFA note (link; <https://www.aifa.gov.it/-/nota-informativa-importante-su-ozempic%C2%AE-semaglutide>), and, on the other, to an increase in the illegal offer of non-original products on the web: recently WHO informed its network of national regulatory authorities (Threat Assessment 2/2023 -June 2023) on an increase in reports of the discovery of falsified versions of medicines containing semaglutide, and warned that falsified versions could be sold through unauthorized channels, including social media platforms.

National authorities, not just European ones, have also shared alerts on these products.

In July 2023 Swissmedic, the Swiss regulatory authority, announced, also through its institutional website [Swissmedic warns against falsification of Ozempic pens] that in Switzerland there have been numerous hospitalizations caused by taking falsified versions of the medicine Ozempic, purchased by patients through websites that are not licensed to sell medicines.

The investigations highlighted, in one case in particular, that the Ozempic package purchased online did not contain the original medicine, i.e. the pre-filled pen containing the active ingredient semaglutide, but a pen containing the insulin, the administration of which has led to acute hypoglycaemia due to insulin overdose: a very life-threatening event which requires immediate treatment.

The regulatory authorities of Croatia, Poland, Brazil and South Africa have also issued alerts and information notes following the discovery of falsified packages of semaglutide-based medicines.

Although the cases illustrated above concern two different types of products, the same considerations apply to both products purchased illegally online through non-authorized channels including social media platforms: it is not possible to establish where they come from, who produced them, through which processes/substances and how they were stored. They therefore represent a serious danger to health.

At the same time, it is important to underline that the structure of the Italian legal production and distribution chain makes the infiltration of falsified products almost impossible, which instead find space only in illegal channels such as unauthorized websites and social platforms.

The primary purpose of this information note is to ensure transparent information on illegal phenomena, aware that correct communication, raising awareness of sometimes little-known cases, represents an important tool for protecting public health and every single citizen-patient.

The collaboration of everyone is essential - private citizens, health professionals, companies and associations - so that suspicious cases are constantly reported to AIFA and to the Carabinieri NAS, so that they can take any measure necessary to counter any illegal phenomenon that poses a risk to public health.

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