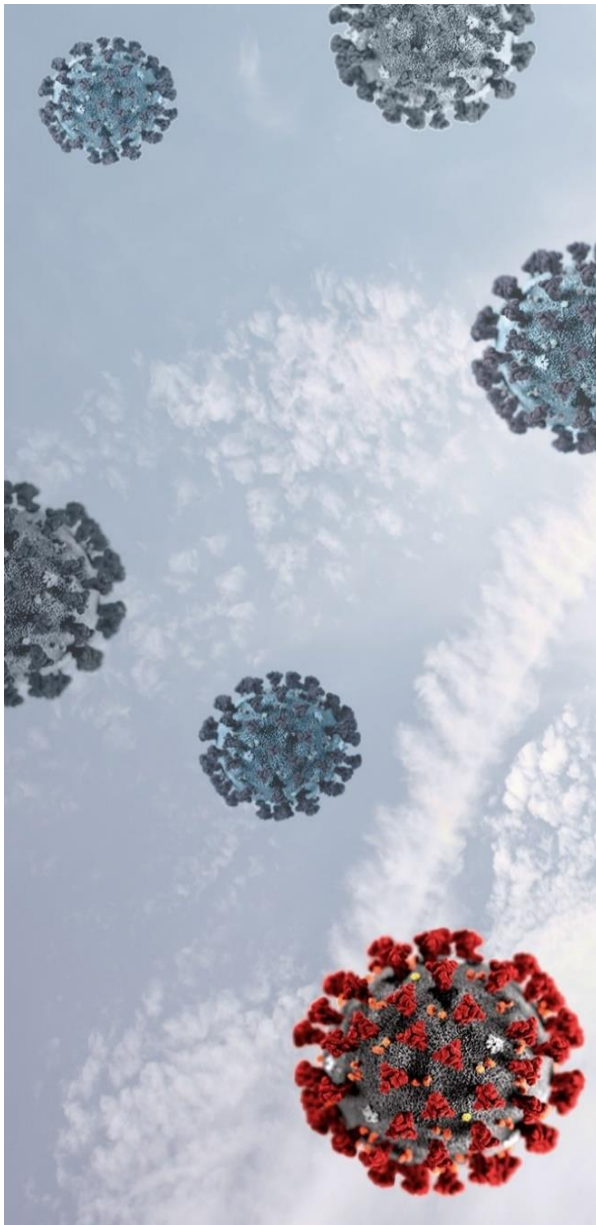

Measures for setting maximum prices for certain products

Legal Flash

April 22, 2020



Order SND/354/2020, of April 19, establishing exceptional measures to guarantee people access to the products recommended as hygiene measures to prevent COVID-19 infection (“**Order SND/354/2020**”) has been published. Its main objectives are:

- > To establish the procedure for setting the maximum retail price of medical devices and those products necessary to protect the health of the population against COVID-19;
- > To determine the information to be included on face mask labels; and
- > To define the conditions in which surgical masks not packaged individually may be sold separately to the public.

Order SND/354/2020 can be appealed before the Administrative-Contentious Chamber of the Supreme Court within two months of its publication.



To achieve its purposes, the Order contains the following provisions:

Procedure for setting the maximum retail price:

The **affected products** are:

Category	Specific product
Medical devices	surgical masks.
	nitrile gloves.
	other medical devices determined in a Resolution of the Secretary of State for Health.
Products (other than medicinal products and medical devices)	Face masks, both single-use and reusable, meaning masks that cover the mouth, nose and chin, fitted with a head harness and meeting the requirements of technical specifications UNE 0064-1:2020, UNE 0064-2:2020, UNE 0065:2020 or any equivalent standard that meets the accepted criteria established in those specifications.
	Antiseptic healthy skin washes authorized by the Spanish Agency of Medicinal Products and Medical Devices (“AEMPS”), and cosmetic alcohol hand sanitizer gels temporarily authorized by the AEMPS.
	Other products that will be determined in a Resolution of the Secretary of State for Health.

(hereinafter, the “**Products**”)



The **procedure** for setting the maximum retail price is as follows:

- > The General Directorate of the Portfolio of Shared Services of the National Health and Pharmacy System of the Ministry of Health will call the Inter-Ministerial Medicines Pricing Committee to an extraordinary online meeting in 48 hours.
- > The General Directorate of the Portfolio of Shared Services of the National Health and Pharmacy System will also propose a maximum retail price for the Products to the Committee, which will deliberate and make a decision in that extraordinary meeting.
- > The Inter-Ministerial Medicines Pricing Committee will pass the appropriate resolution, and the General Directorate of the Portfolio of Shared Services of the National Health and Pharmacy System, as the Committee's administrative support body, will prepare the document including that resolution, which may be a certificate issued by the secretary of that collegiate body.
- > That resolution will be notified or, as appropriate, published in the Official Gazette of the Spanish State (*Boletín Oficial del Estado* or *BOE*).

General Directorate of the Portfolio of Shared Services of the National Health and Pharmacy System

Inter-Ministerial Medicinal Product Pricing Committee





Consumer information obligations on face masks:

The information must be visible on the label or, if there is no space on it, in the instructions, pamphlets or documents included with the product. If they are sold online, the information must be visible on the website:

- > Company details: corporate name and registered office.
- > Usual product name: the name by which it is known, allowing full identification of its nature.
- > Contents of the package: number of units if the package contains several masks.
- > Composition.
- > Recommended period of use.
- > Essential product characteristics, including size if relevant, and whether it is reusable or single-use.
- > Warnings, including: “This product is not a personal protection equipment or a medical device.”
- > Batch, when the manufacturing process includes identifiable series.
- > Usage instructions on positioning, use and storage, handling and disposal.
- > Place of origin or provenance, if omitting it could mislead the consumer.
- > Whether it meets technical specifications UNE 0064-1:2020, UNE 0064-2:2020 or UNE 0065:2020, establishing minimum requirements for single-use and reusable face masks regarding the materials used to design, produce, manufacture, brand and use them, or any equivalent standard.
- > The test data on bacterial filtration efficiency (BFE) and breathability (differential pressure) (Pa/cm²), if a test has been conducted, including the test number and the laboratory used.
- > Reusable masks must indicate a maximum number of washes, as well as a cleaning or sterilization method.
- > Full final price under section 20.c) of the consolidated text of the Spanish General Consumer and User Rights Act (*Ley General para la Defensa de los Consumidores y Usuarios*), approved by Royal Legislative Decree 1/2007, of November 16.



Other aspects to consider:

- **Efficacy:** The bacterial filtration efficacy (BFE) and breathability (differential pressure) (Pa/cm²) must be laboratory certified based on technical specifications UNE-EN 14683:2019+AC:2019 or an equivalent standard. If a maximum or continuous use period is indicated, it must be well-founded. If neither the masks nor the material has undergone any laboratory testing with regard to their filtration efficacy and breathability, their label may not claim characteristics suggesting that the product possesses properties that have not been verified (“virus protection”). Furthermore, if this type of mask claims to be “washable”, it must be made of a fabric or combination of fabrics that can be washed according to the instructions provided without damaging the product. If a maximum number of washes is attributed, it must be well-founded.
- **Masks for children:** In case of masks for children, under Royal Decree 1801/2003, of December 2, on general product safety, technical specifications UNE-EN 14682:2015 Safety of children's clothing, adjustable cords and drawstrings on children's clothing must be taken into account with regard to head harnesses for children's face masks. They must be attachable without knotting, unattached ends or three-dimensional elements. It is also advisable to include a warning that the mask should be used under adult supervision.
- **Reusable masks:** Reusable face mask manufacturers must ensure that the masks maintain their properties after washing or sterilization. The mask properties should, therefore, be verified and confirmed through testing, according to the maximum number of washes stated on the label.
- The labels of **antiseptic healthy skin washes and cosmetic gels and alcohol hand sanitizers** that have not been authorized by the AEMPS cannot claim on the label characteristics suggesting that the product possesses properties that have not been verified, such as “virus protection/disinfection”.
- **Surgical masks** not individually packaged can only be sold separately in pharmacies.



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