



Capsulas

The QR code to include the SmPC in promotional materials

New information note from the Directorate General for the NHS Shared Service Portfolio

At the end of last month, the Ministry of Health released a briefing note on the use of QR codes in promotional materials aimed at healthcare professionals, enabling a link to the SmPC of medicines.

Background

The use of QR codes to link SmPC has been widely used, especially after the pandemic, to comply with the requirement to include the minimum content in promotional materials set out in Article 10 of the Royal Decree on the Advertising of Medicines for Human Use (Royal Decree on Advertising).

However, the explicit inclusion of the option to provide the minimum content through this means was lacking until now. The Ministry of Health acknowledged that this had been a recurring request from pharmaceutical companies during the public consultation leading up to the draft of the new legislation regulating advertising of medicines for human use.

Content of the information note

In the light of this briefing note, the use of the QR code in promotional material is now expressly permitted. However, it is limited to directing to the technical specifications, in compliance with article 10(1)(a) of the Royal Decree on Advertising (which mandates the inclusion of the essential product information in all promotional material). Notably, QR code are not permitted to redirect users to the information outlined in paragraphs 1(b), 1(c) and 2 of the same article 10. In simpler terms, information on the prescription and dispensing regime, available

product presentations (including dosage and pharmaceutical form), as well as information about the price and financing of the medicinal product must be included in the promotional material itself (without any cross-reference to the QR).

Additionally, alongside the QR code graphic, there should be a clear indication that it leads to the SmPC medicinal product.

Catalan guidelines on the advertising of medicinal products

According to the Catalan guidelines, the minimum content must be accessible in a direct, rapid and comprehensible manner. In fact, in order to avoid any doubt, the guidelines specifies measures such as the font size or the specific ways in which the minimum content must be distributed in optical, magnetic, audiovisual or interactive media (although these references are becoming increasingly outdated).

The Catalan guidelines explicitly prohibit providing the minimum content through QR codes or URL addresses. This is considered not to meet the accessibility requirement, since both promotional information and the minimum content shall be equally accessible. The guidelines only allow these means in “exceptional cases where it can be demonstrated that the information in the SmPC is subject to frequent changes”. Considering the new briefing note from the Ministry of Health, which we believe should prevail, one might anticipate an update to the Catalan guide to, at the very least, align positions with the Ministry of Health.

