

## ePI/mobile technologies for product information

The use of mobile technologies, e.g., QR-codes, to convey information on medicinal products, such as the labelling and patient information leaflets, is associated with benefits but also potential risks.

Benefits of these technologies include the reduction of paper and the immediate introduction of new information after a regulatory decision has been taken, e.g., following a variation approval, thereby avoiding delays in getting updated information to the user. Additional media can also be included, e.g., instructional videos. For those visually impaired or illiterate, embedded audio recordings can make the information more accessible. Other benefits include shipping and marketing of medicines without the need to adapt the packs to different languages or other country-specific requirements.

Conversely, potential downsides to these technologies include the need for internet connectivity, availability of a smartphone, and familiarity with digital techniques.

To overcome these disadvantages both printed information and the mobile technology may be used during a transition period, although this may lead to discrepant information if accessing both modalities. Furthermore, the printed labelling of the pack would still need to meet the requirements of the country where the product is to be marketed.

PQT/MED supports the use of mobile technologies, where appropriate, provided local regulations in each target country are considered. The decision on whether mobile technologies are acceptable therefore rests with the National Regulatory Authorities (NRAs). The NRAs may decide whether the patient information leaflet should be available in paper format, electronically, or both. The NRAs would also have to undertake review of the electronic information.

PQT/MED emphasizes the importance of unrestricted access to the product information for any user of a medicine.

Further guidance may be issued by PQT/MED in due course.