PMCPA | Prescription Medicines Code of Practice Authority

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 and changes to and impact on the 2019 ABPI Code of Practice for the Pharmaceutical Industry

The new regulations

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (2020 No 1125) were laid on 16 October 2020 and certain regulations came into operation on 17 October and the remainder by 7 November 2020.

Subject to various exceptions, medicines for human use may only be sold or supplied if they have been granted a marketing authorisation by the licensing authority One of those exceptions is that, in certain types of public health emergency, the licensing authority may temporarily authorise the sale or supply of medicines without marketing authorisations. Conditions may be attached to those temporary supply authorisations, including classifying the product as a prescription only medicine (POM) or a pharmacy medicine and requirements in relation to qualified persons. The Human Medicines Regulations 2012 already provided for some of the restrictions to be set aside by an approved protocol in a pandemic situation, where the POM was for the treatment of the pandemic disease. The new regulations amend those earlier arrangements so they can be used for POMs that prevent, as well as POMs that treat, the pandemic disease.

Under UK law persons are only allowed to advertise medicines if they have marketing authorisations, or some equivalent regulatory approvals, and this is extended by the new regulations to allow advertising of medicines covered by the temporary authorisations described above. The requirements that would normally be placed on the marketing authorisation holder are instead placed on the person responsible for placing the product without a marketing authorisation on the market – and some of these are adapted to take account of the fact that there is no marketing authorisation in place. Advertising of medicines to the public, for example of POMs, is significantly restricted by The Human Medicines Regulations, but there are exceptions for approved vaccination campaigns, and a parallel exception is created in the new regulations for approved campaigns relating to the sort of public health emergencies that may lead to the temporary authorisations described above (although approved campaigns would not be limited to medicines covered by temporary authorisations). There are special requirements for advertisements wholly or mainly directed at persons qualified to prescribe the medicines in question, and these are also adapted to take account of the new arrangements for temporary authorisations. A person may not publish an advertisement for a medicinal product in relation to which there is in force an authorisation by the licensing authority on a temporary basis unless it is part of the campaign that has been approved by the Ministers.

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ABPI Code of Practice for the Pharmaceutical Industry

The 2019 ABPI Code prohibits the promotion of medicines without marketing authorisations and requires that promotion is not inconsistent with the summary of product characteristics (Clauses 3.1 and 3.2). The prohibition on advertising prescription only medicines to the public has an exemption for vaccination campaigns approved by the health ministers.

The new regulations mean that changes were needed to the ABPI Code to ensure that if companies are to promote medicines with temporary supply authorisations then such activities are not inconsistent with the requirements of the ABPI Code. The approach is to ensure that the ABPI Code permits advertising of products with temporary supply authorisations. This is set out below in relation to application of the 2019 ABPI Code. The agreed 2021 ABPI Code takes account of the recent legislation.

2019 ABPI Code – additional guidance

If a complaint is received relating to matters recently permitted by the introduction of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, in particular the advertising of medicines with temporary supply authorisations to health professionals and other relevant decision makers under Regulation 174 of The Human Medicines 2020 as amended and the company concerned has the relevant approval from the Ministers as set out in Regulation 280 as amended then by exception Clause 3 of the 2019 ABPI Code will not apply. Companies in such circumstances are expected to continue to comply with the Code. When a temporary supply authorisation has been granted, companies promoting such products to health professionals and other relevant decision makers must provide information similar to prescribing information as required by Clause 4.1 and ensure that material is not inconsistent with the temporary supply authorisation, the agreed product details and the agreed information for patients.

Similarly if a complaint is received relating to advertising to the public of medicines under Regulation 284 of The Human Medicines 2020 as amended and the company concerned has the relevant approval from the Ministers as set out in Regulation 292 as amended then by exception the limitation in Clause 26.1 of the 2019 ABPI Code will apply to vaccination and other campaigns as approved by the health ministers. Companies in such circumstances are expected to continue to comply with all other relevant requirements of the Code. In addition such campaigns should include a general reference to the reporting of side effects as it is unlikely that the requirements of Clause 26.3 will apply as the relevant material is not intended for patients taking a particular medicine.

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The PMCPA position as outlined above has been discussed with the Advertising Standards Unit, Vigilance and Risk Management of Medicines, MHRA and the Code of Practice Appeal Board.

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