EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Medicines Regulations 2012 ("the 2012 Regulations"), which govern the arrangements, across the United Kingdom, for the licensing, manufacture, wholesale dealing and sale or supply of medicines for human use.

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 (which is either, or both, of the Secretary of State and the Minister of Health in Northern Ireland). 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. These Regulations make it clear that conditions may be attached to those temporary authorisations, including classifying the product as a prescription only medicine (POM) or a pharmacy medicine and requirements in relation to qualified persons. The changes also provide for the consequences of breach of those conditions (regulations 5, 6 and 31).

Subject to various exceptions in Part 12 of the 2012 Regulations but by virtue of restrictions in that Part, POMs may only be sold or supplied in accordance with a prescription of, or administered parenterally by, a health care professional classed as an appropriate practitioner. Also, subject to various exceptions in Part 12 of the 2012 Regulations but by virtue of restrictions in that Part, POMs and pharmacy medicines must be sold or supplied, by or under the supervision of a pharmacist, from a registered pharmacy. In a pandemic situation, these Regulations allow the Secretary of State, the Scottish Ministers, the Welsh Ministers or the Minister of Health in Northern Ireland to approve protocols setting aside the core Part 12 restrictions and allowing for the supply of coronavirus and influenza immunisations by persons of the classes specified in the protocol (that is, persons other than appropriate practitioners), elsewhere than at registered pharmacies – subject to compliance with the conditions set out in the protocol. As soon as is reasonably practical after one year after the first such protocol is approved, the Secretary of State must publish a report on the operation of the new protocol provisions (regulation 14).

The 2012 Regulations already provided for some of the core Part 12 restrictions to be set aside by a protocol in a pandemic situation, where the POM was for the treatment of the pandemic disease. These Regulations amend those earlier protocol arrangements so they can be used for POMs that prevent, as well as POMs that treat, the pandemic disease (regulation 13). The 2012 Regulations also already provided for some or all of the core Part 12 restrictions to be set aside by instruments known as Patient Group Directions (PGDs). PGDs can generally only be used for products that have been granted marketing authorisations (or some equivalent regulatory approvals). These Regulations amend some of the provisions allowing for PGD supply so that they can also be used for POMs covered by the temporary authorisations described above (regulations 7 to 11). Another route to exceptions from the core Part 12 restrictions are a series of exceptions set out in Schedule 17, which are targeted at various practical situations such as the needs on board ships or aircraft, and occupational health schemes. The current arrangements that would allow parenteral immunisations as part of occupational health schemes limit the administration of the POMs to doctors and nurses. These Regulations allow for other specified categories of registered health care professionals to administer coronavirus and influenza immunisations as part of the occupational health schemes of local authorities and specified NHS bodies. These arrangements are time limited to 1st April 2022 (regulations 3, 12 and 32).

The arrangements that allow for the supply under protocols of medicines covered by temporary authorisations mean that some persons who may not be registered health care professionals may be supplying or administering these medicines. Where a temporary authorisation is given to a medicine without a marketing authorisation for a recommended use – or, in a public health emergency, a new use is temporarily recommended for a medicine with a marketing authorisation – immunity from civil liability is given to specified persons in relation to loss or damage resulting from the use of the medicine in accordance with the licensing authority's recommendation. Prior to these Regulations, this immunity was given to registered health care professionals supplying or administering such medicines to patients but not to other individuals doing the same. These Regulations extend that immunity to persons supplying or administering such medicines under the relevant powers to issue protocols. Prior to these Regulations, this immunity already extended, in the case of medicines without marketing authorisations, to the manufacturer of the medicine but not to the person placing it on the market. These Regulations extend that immunity to the person placing the unauthorised medicine on the market. The immunity does not however extend to specified requirements under consumer protection legislation, nor to where a person who would otherwise be able to claim the immunity is responsible for a sufficiently serious breach of the conditions attached by the licensing authority to the product's supply (regulations 6 and 29).

Sale or supply of a medicine other than at the final stage of the medicines supply chain normally requires a wholesale dealer's licence. Both as part of a campaign for influenza or coronavirus immunisations, or in a case of a campaign for distribution of medicines for the prevention or treatment of pandemic disease for supply under protocols, the possibility exists that the NHS providers at the final stage of the supply chain will need to share stock between them to ensure the campaign runs as efficiently as possible. Subject to authorisation from the relevant NHS commissioners, these Regulations will allow such sharing without a wholesale dealer's licence until 1st April 2022 (regulation 4). Such campaigns may also require the delivery of medicines to persons who would not normally be supplying or administering medicines to patients, and these Regulations permit such unusual deliveries, if they are to persons who are able to supply or administer the medicines under the relevant protocols (regulation 15).

Part 14 of the 2012 Regulations contains a number of restrictions relating to the advertising of medicines. Persons are only allowed to advertise medicines if they have marketing authorisations, or some equivalent regulatory approvals, and this is extended 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 (regulations 16 to 19 and 25). Advertising of medicines to the public, for example of POMs, is significantly restricted by Part 14, but there are already exceptions for approved vaccination campaigns, and a parallel exception is created 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) (regulations 20 to 24). 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 (regulations 26 to 29 and 33).

The review provision in the 2012 Regulations has also been modified to take account of these Regulations (regulation 30).