



## **STATEMENT ON THE NEED TO OBTAIN AN APPROPRIATE LICENSE FROM THE MHRA**

Currently a pharmacy premises registered with the RPSGB /PSNI may make limited wholesale supply of licensed medicines without a Wholesale Dealer's License (WDL).

Advice from the MHRA is that in order to comply with the exemption, wholesale dealing of licensed medicinal products by a registered pharmacy should, in any 12 month period, amount to no more than 5% of the total financial value of sales or supplies of licensed medicinal products made by that registered pharmacy." This is commonly known as the 'de minimis' rule.

Whilst those hospitals that have registered their pharmacy premises with the RPSGB / PSNI may wholesale licensed medicines to separate legal entities, this registration should not be undertaken to circumvent the wholesale requirements.

This exemption from the requirement for registered pharmacies to hold a Wholesale Dealer's Licence is currently under consideration as part of the wider Supply Chain Review see MLX 357: consultation on measures to strengthen the medicines supply chain and reduce the risk from counterfeit medicines. Further consultation on the scope and conditions of the exemption is due to be issued by the MHRA. In order not to pre-empt the outcome of this consultation, the MHRA suggests that hospital pharmacies may wish to consider the scale and nature of any wholesaling activities of licensed medicines conducted, and participate in the consultation process.

Whilst this review of the de minimis rule takes place, hospital pharmacies that are currently wholesaling licensed medicines to other healthcare organisations may continue without an MHRA licence. Further questions about this may be addressed to the MHRA direct on a case by case basis.