

**Supplementary Information on Wholesale Dealer and Controlled Drugs Licences in the Health and Justice system in England**

**Purpose**

1. This document has been prepared to provide further advice as to what NHS commissioners and NHS healthcare providers, including pharmacy service providers, should do regarding the requirements for the sale or supply of stock medicines, including controlled drugs (CDs).
2. It supplements the information set out in a recent letter from Dr Keith Ridge (Chief Pharmaceutical Officer). This is attached as an appendix.
3. A case study giving an example of the effect of the changes is at page 9 and a section on frequently-asked questions and answers is at page 10 onwards.

**Background**

1. Prior to 14 August 2012, Section 10(7) of the Medicines Act 1968 provided a pharmacist in a registered pharmacy or someone acting under their supervision in that pharmacy, who sells, supplies or offers for sale or supply a medicinal product by way of wholesale dealing, with an exemption from the requirement to hold a wholesale dealer’s authorisation for medicines for human use (“WDA(H)”).
2. The exemption only existed on the basis that the wholesale dealing activity constituted no more than an inconsiderable part of that business. For a long time, the Medicines and Healthcare products Regulatory Agency (MHRA) had generally regarded this to be 5% of the total turnover of licensed medicinal products at that registered pharmacy or less.
3. This exemption was repealed under the Human Medicines Regulations 2012 (S.I. 2012/1916), which were laid on 24 July 2012 and came into force on 14 August 2012. The exemption was outside the European Directive 2001/83/EC (6 November 2001) on medicines for human use within the community. The Human Medicines Regulations 2012 provide that any person who wishes to engage in the wholesale supply of medicines is entitled to do so only if holding a WDA(H).
4. This means that **any** wholesale supply of stock medicines on a commercial basis by a pharmacy now requires a WDA(H). **Please note that these licensing requirements do not apply to individually labelled medicines dispensed by the pharmacy against a prescription or the exchange of stock between pharmacies that are part of the same legal entity.**
5. This change does not affect certain pharmacies that provide stock medicines to another legal entity, whether a formal contract or agreement is in place or not, as long as the supply is to meet patient needs and is consistent with MHRA guidance. This includes those pharmacies:
* in NHS Trusts;
* that are registered community pharmacies; or
* located in other settings such as community hospitals or prisons.
1. The MHRA has published guidance on this issue. This recognises the valuable work that pharmacies (both hospital and community) provide within their local health economies in respect of supplying medicines to others who need to hold them to pass on to their patients. The guidance is available at: <http://www.mhra.gov.uk/home/groups/comms-ic/documents/regulatorynews/con394660.pdf>.
2. By way of an example, the MHRA guidance provides that pharmacists in a pharmacy needing to obtain small quantities of a medicine from another pharmacy to meet a patient's individual needs may do so without the need for the supplying pharmacy to hold a WDA(H). However, the transaction must meet all of the following criteria:

* it takes place on an occasional basis;
* the quantity of medicines supplied is small and the intention is to meet

 the needs of an individual patient; and

* the supply is made on a not for profit basis.

**MHRA Wholesale Dealer licences**

1. Any company or individual wishing to wholesale deal (defined as selling, supplying or procuring to anyone other than the end-user) medicinal products within the EU must hold a WDA(H).
2. The administrative procedures for issuing and maintaining a WDA(H) licence are carried out by the Process Licensing (PcL) section in the Inspection, Enforcement and Standards Division of the MHRA. In fulfilling this role, PcL works very closely with the MHRA Medicines Inspectorate responsible for inspections.
3. Further information, including relevant fees, is available from the PcL enquiry line on 020 3080 6844 or email: pcl@mhra.gsi.gov.uk. Please also see the section on frequently asked questions and answers starting on page 10.

**Controlled Drug Licences**

1. Companies and individuals need to apply for Home Office domestic licences if they wish to produce, supply or possess CDs. Applications are subject to fees.
2. It should be noted that, prior to 14 August 2012, Section 10(7) of the Medicines Act 1968 did not provide any exemption for wholesale dealing of CDs under relevant misuse of drugs legislation. In addition, the Home Office regulatory requirements did not change as a result of the Human Medicines Regulations 2012. They have always come into play when a WDA(H) is needed.
3. The Home Office has therefore worked closely with the MHRA to ensure policy alignment in these matters. If a WDA(H) is required, this also means that, if supplies include CDs in Schedules 2 - 5 to the Misuse of Drugs Regulations 2001 (the “2001 Regulations”), then it is likely that a corresponding Home Office CD licence is also needed by the pharmacy to legalise this supply.
4. The 2001 Regulations do provide certain limited legal authorities that allow the possession, supply and production of drugs controlled under the Misuse of Drugs Act 1971 without the need for a Home Office CD domestic licence. This is known as a limited licensing “exemption”.
5. For example, pharmacists, when acting in their professional capacity, may benefit from licensing exemptions for drugs in all Schedules except Schedule 1, as outlined in regulations 8, 9 and 10 of the 2001 Regulations. Similar provisions exist for persons conducting a retail pharmacy business. The Home Office believes that the majority of retail pharmacies will continue to benefit from this “exemption”.
6. However, the longstanding requirement for pharmaceutical wholesalers to hold the relevant Home Office and MHRA licences is unchanged by this, irrespective of whether the wholesaler employs a pharmacist.
7. Further information about Home Office CD licences, including relevant fees, can be obtained by contacting the Duty Compliance Officer on 020 7035 8972 in the first instance. Please also see the section on frequently asked questions and answers starting on page 10.

**Supply of CDs by NHS Trusts to NHS and private providers delivering contracted-out services**

1. The use of “contracted out” services in NHS hospitals may also give rise to the need for a Home Office licence **for possessing CDs** to be held by the provider to which the NHS Trust is providing stock CDs.
2. This also applies where wholesale dealers and other pharmacy service providers supply CD stock to (private) healthcare providers.
3. As a general rule, it is the “organisation” or “function” which gives rise to any exemption from the CD licensing requirement, not the physical location or building where the service is provided.
4. Therefore, a “contracted out” service operating on NHS premises would not derive any licensing exemption solely on account of its physical location at NHS premises.
5. Any “supply” of CD stock from an NHS body or wholesaler to a (private) contracted out service provider would result in a change of legal ownership and physical possession of the drugs and therefore be an activity requiring Home Office licensing held by the (private) contracted out service provider.
6. A number of questions have arisen from NHS commissioners and providers - in particular hospitals and community pharmacies who have been supplying stock medicines and CDs to hospices, care homes, prisons, secure units etc., as to whether a WDA(H) or Home Office CD licence is required and what action commissioners, healthcare providers and pharmacy service providers should take.
7. These are addressed in the following sections:
* implications and suggested actions for NHS Trusts, NHS healthcare providers and other organisations receiving stocks of medicines, community pharmacies and NHS and local authority commissioners;
* a case example; and
* a list of frequently asked questions and answers that help to clarify the licensing requirements further.

**Implications and actions for NHS Trusts supplying medicines**

1. An NHS Trust can continue to supply stock medicines, including CDs, to healthcare professionals within that hospital or its satellites (which are part of the Trust), but cannot do so to organisations that are not part of the legal entity, which constitutes the Trust. Such organisations may include hospices, secure environments, ambulance trusts, GP practices or community health trusts.
2. A WDA(H) would be required where a Trust pharmacy is supplying to organisations outside that Trust a larger quantity of stock medicines on a more regular basis than the guidance set out by the MHRA allows.
3. Where a WDA(H) is required, there is a corresponding need for a Home Office CD licence where stocks supplied involve CDs (Schedules 2-5 of the Misuse of Drugs Regulations).
4. This requirement does not apply to any drugs, including CDs, which are dispensed by a hospital pharmacy on a named patient basis. Such supplies are exempt from the need for a Home Office CD licence by virtue of Regulation 10(2) of the 2001 Regulations.
5. However, this exemption does not apply to “over-labelled” medication (see also paragraph 34 below) which would be regarded as a supply of stock. A Home Office CD licence would be required as above.

***Suggested actions:***

* NHS Trust pharmacies supplying other legal entities with stock medicines should take action to confirm whether an MHRA WDA(H) is required;
* Should the stock transactions include Schedules 2-5 CDs then the Trust should additionally contact the Home Office to establish whether a CD licence is needed;
* NHS Trusts supplying (private) contracted out organisations with CDs should also confirm that the (private) organisation has the necessary licences to possess stock CDs;
* If the NHS Trust decides not to apply for the required MHRA and/or Home Office CD licence then the NHS Trust should notify the organisation being supplied with stock medicines and/or CDs as soon as possible. That provider will have to make arrangements to source medicines and/or CD stock from an alternative licensed provider; and
* In the interests of patient safety, the NHS Trust should not suddenly cease to supply stock medicines but manage the situation in partnership with the healthcare provider, the MHRA and Home Office to ensure that the healthcare provider is able to continue to access supplies of stock medicines until alternative arrangements for sourcing supplies from licensed wholesalers are in place.

**Implications for NHS healthcare providers and other organisations receiving medicines and/or CD stocks**

1. Healthcare providers commissioned to deliver NHS services **in any setting** that involves the use of stock medicines sourced from a community or hospital pharmacy which is a different legal entity to the healthcare provider may be affected by the wholesale dealer and CD supply licensing requirements.
2. This includes medicines that are over-labelled for supply (i.e. after adding the patient name and date) under a Patient Group Direction or are for emergency use (for example, during out of hours periods). **Please note that a pharmacy that over-labels medicines for supply as described above requires a manufacturer’s licence from the MHRA.**
3. The organisation supplying the healthcare provider with medicines stock will need to have the appropriate MHRA WDA(H) and Home Office CD licences. It is the responsibility of the healthcare provider to establish that the required licences are in place and in date.
4. If the MHRA guidance on when a WDA(H) is not required does not apply and the current pharmacy service provider does not have the required licences, the healthcare provider needs to confirm with the pharmacy service provider that they are:
* taking the necessary action to acquire the appropriate WDA(H) and/or CD supply licence and will keep the healthcare provider informed of progress in writing; or
* **not** applying for a WDA(H) and/or a CD supply licence so that the healthcare provider can take steps to acquire medicines and/or CDs from alternative licensed providers.
1. Some healthcare providers have considered or may be considering changing the use of stock medicines (including CDs) to a named-patient basis where supplies are dispensed against individual prescriptions. Any review of these arrangements should be carefully and formally considered. A full risk assessment is likely to be needed that takes account of:
* delayed and omitted medicines due to longer timeframes needed for dispensing and delivery;
* mis-selection of medicines where a large number of patients are receiving the same individually labelled medicine which are all stored in the same location (for example, a CD cupboard); and
* the impact on safe medicines storage due to the increased space needed to store individually labelled medicines.

***Suggested actions***

* Healthcare providers and other organisations receiving medicines and/or CD stock are advised to check that the organisation they receive this stock from has the necessary licences or is in the process of applying for them;
* Where the supplying organisation does not have the required MHRA WDA(H) and/or Home Office CD licences and is not in the process of applying for them, then the healthcare provider must take **immediate** steps to source medicines and/or CD stock from an alternative licensed provider;
* In the interests of patient safety, it is advisable that the healthcare provider does not cease acquiring stock from the current supplying organisation until new procurement and delivery arrangements are in place;
* Healthcare providers that experience difficulties in sourcing stock medicines from a licensed provider should contact the MHRA and/or the Home Office for advice and also notify their NHS commissioner;
* Any review of the use of stock versus patient-specific medicines should be undertaken using a formal risk assessment that takes account of the risks to patient safety and timely access to medicines; and
* If the healthcare provider is not an NHS Trust (i.e. a contracted-out or private provider) and receives and uses stock CDs, then the provider should check whether Home Office CD licences to possess CDs are required.

**Implications and actions for community pharmacies and persons conducting a retail pharmacy business**

1. Paragraphs 8 – 10 above set out the circumstances under which a community pharmacy is not required to hold a WDA(H) when wholesale dealing. It is also expected that the majority of retail pharmacies will continue to benefit from the Home Office CD licensing exemptions within the 2001 Regulations as they provide certain limited legal authority that allows the possession, supply and production of drugs that are controlled under the Misuse of Drugs Act 1971.
2. Some retail pharmacy businesses provide contracted pharmacy services to NHS healthcare providers which includes the supply of stock medicines (via a signed order) and CDs (via a legal requisition).
3. The types of healthcare providers that can be supplied in this way include:
* care homes;
* GP practices;
* hospices;
* prisons and other secure environments; and
* community services providers, such as those employing district nurses.
1. These NHS contracted services fall outside the scope of national NHS pharmaceutical services contractual arrangements and are likely to require the retail pharmacy organisation to have the necessary MHRA wholesale dealers and Home Office CD licences.

***Suggested actions***

* Community pharmacists and persons conducting a retail pharmacy business who are supplying other legal entities with stock medicines should take action to confirm whether an MHRA WDA(H) is required;
* Should the stock transactions include Schedules 2 - 5 CDs, they should additionally contact the Home Office to establish whether a CD supply licence is needed;
* Pharmacies supplying private (contracted out) organisations with CDs should also confirm that the private organisation has the necessary licences to possess stock CDs;
* Should the community pharmacy or retail pharmacy business decide not to apply for an MHRA and/or Home Office CD licence (the latter being required for every branch) then the pharmacy organisation should notify the healthcare provider being supplied with stock medicines and/or CDs as soon as possible as the provider will have to make arrangements to source medicines and/or CD stock from an alternative licensed wholesaler; and
* In the interests of patient safety, the pharmacy should not suddenly cease to supply stock medicines but manage the situation in partnership with the healthcare provider, MHRA and Home Office to ensure that the healthcare provider is able to continue to access supplies of stock medicines until alternative arrangements for sourcing supplies from licensed wholesalers are in place.

**Implications and actions for NHS and Local Authority commissioners**

1. NHS England, clinical commissioning groups (CCGs), local authority commissioners and other personnel, such as CD Accountable Officers in NHS or private facilities, need to take these licensing requirements into account and will wish to assure themselves that adequate plans and arrangements are in place locally due to the licensing implications for the different healthcare providers detailed above.
2. Commissioners will wish to assure themselves that the licensing requirements concerned with the supply of medicines, including CDs, are adequately and fully reflected in commissioning arrangements and contractual documentation.
3. Current contract monitoring and future commissioning processes and contracts will need to take account of the wholesale dealing and CD licensing requirements to assure the commissioner that legal processes are being followed.
4. Commissioners may also need to support pharmacy services providers, other healthcare providers and NHS Trusts in handling the changes in the medicines stock and CD supply routes that ensue as providers take the necessary steps to implement the different licensing requirements.
5. Due to the complexity of these requirements, commissioners may need to liaise with and gain advice from a senior pharmaceutical adviser and in the case of CDs, the relevant NHS England CD Accountable Officer.

***Suggested actions***

* Share this document with local healthcare or pharmacy service providers;
* Establish that pharmacy services providers, healthcare providers, including NHS Trusts, have the necessary MHRA and Home Office CD licences, for example via contract monitoring processes;
* Support providers and ensure that in the absence of the required licences that appropriate steps are taken to correct this without compromising patient safety and access to medicines in a timely manner;
* Review service specifications and other commissioning documentation used to commission healthcare services and pharmacy services and adjust these as necessary to include the revised MHRA and Home Office CD licence requirements;
* Link with NHS England CD Accountable Officers as they can provide support directly and via their Local Intelligence Networks; and
* Access pharmaceutical advice to support commissioners and providers as necessary to maximise medication safety and confirm legal arrangements.

**Case study**

**Case study from a Secure Environment (adapted from an actual case)**

This case study is adapted from an actual case where the details were identified as a result of a HMIP inspection of the prison.

In October 2013, a prison healthcare provider delivering substance misuse services to the prison discovered that the pharmacy they were accessing their CD stock from did not have the necessary MHRA wholesale dealer and Home Office CD licences to supply them. The healthcare provider had over 100 patients that were receiving prescribed methadone and buprenorphine and other CDs administered daily under supervision by nurses from stock supplies (in line with national guidance).

The healthcare provider was faced with the possibility, once the current stock of methadone and other CDs had been exhausted, of not being able to supply CDs to their patients.

Therefore, the healthcare provider and pharmacy service provider decided to supply a measured dose of methadone in a medicine bottle for each individual with a supply for one week. In other words, around 800 tiny bottles all individually labelled arrived once per week.

As the CD cupboard was not big enough, the healthcare provider used a metal four drawer filing cabinet to store them in. This interim process had been going on for six weeks. In the first week, glass bottles were supplied, which caused a major headache. Used bottles were disposed of by nurses washing the bottles out in front of a witness, removing labels, and then disposing of them as normal waste.

Once the licences had been acquired, the healthcare provider and pharmacy went back to using stock supplies.

Clearly the interim arrangement was very unsafe with potential harm due to mis-selection from CD cupboards being significant. Even though the nurses perceived that the named patient system was better, it is clearly less safe to have 800 bottles that all look the same being stored and selected from a CD cabinet for supervised administration of the methadone to patients.

This scenario could apply equally should the need for CD possession licences be identified and where MHRA licences are needed for other high volume non-CDs that had been supplied from stock supplies.

**Frequently asked questions**

**Need for licence**

1. We source our stock medicines, including CDs, from a local community pharmacy and some medicines from the local hospital pharmacy. Can we still do this?

*Only if the community pharmacy has a WDA(H) and Home Office CD licence for the site from which it makes the supply.*

*If the hospital pharmacy does not supply CDs, then no CD licence is required. Please check MHRA guidance as to whether the supply is exempt or not from the need to hold a WDA(H).*

1. I am the senior partner in a non-dispensing GP practice. We usually buy medicines needed for our surgery from our local community pharmacy using a signed order or CD requisition. Can we still do this under the revised legislation if the pharmacy does not have a WDA(H) or Home Office CD licence?

*Following the repeal of Section 10(7), the MHRA recognises the work of pharmacies and has* *taken a risk based approach in order to try and ensure the continuity of supplies of medicines to patients.*

*MHRA’s advice, which is in relation to the supply of original licensed whole patient packs of medicine, requires the supply to be limited to an occasional basis, a small amount, and not for profit in order not to require a WDA(H).*

*However, the wholesale supply of original licensed whole patient packs of medicines, including CDs, on a commercial basis will require a WDA(H) and Home Office CD licence.*

1. We are a healthcare company providing out of hours services in our CCG area at specific premises. We have a contract with a separate company that provides us with the medical workforce for the service. At the moment we supply medicines to the sites that are used to deal with the immediate supply and administration of medicines to patients by the doctor where the provision of a written prescription would result in harmful delays in treatment. Do we now require a WDA(H) and/or Home Office CD licence for the sites (owned by us) as the medicines are actually supplied and administered by a practitioner from another legal entity?

*If the healthcare company supplies medicines to another legal entity – in this case, the company providing the medical workforce - for further supply or administration, the healthcare company will require a WDA(H). This is not a new requirement.*

*If the supply includes CDs, the healthcare company will also need a Home Office licence to possess and supply, unless the requirement to hold one is specifically exempted by part of the Misuse of Drugs Regulations 2001. Please note that the exemptions to CD licensing frequently apply only in limited circumstances, so may cover some but not all of the activities undertaken and a licence therefore would still be needed.*

*The company providing the medical workforce will not need a WDA(H) but will need to hold a Home Office CD licence for possession of stock CDs, again, unless the requirement to hold a licence is specifically exempted.*

1. We are a healthcare provider in a prison. We subcontract pharmaceutical services to a registered pharmacy which is off-site and does not plan to apply for a WDA(H). We have found a licensed wholesaler who is able to meet our needs. Within the requirements for licence holders of a WDA(H), is the wholesaler allowed to deliver the ordered medicines to a registered pharmacy for short-term storage and onward delivery to us along with, but separated from the named patient items, we have ordered from them? This would enable us to continue to receive pharmaceuticals via one delivery that minimises operational risks of medicines transfer.

*The pharmacy may act as a courier and collect the medicine from the licensed wholesale dealer for same day delivery to the prison. However, if the pharmacy takes possession of the medicine and holds it on its site, the pharmacy will need a WDA(H).*

1. I work in a hospital trust and the pharmacy holds a Manufacturer “specials” and WDA(H) licence. The CDs products manufactured are only used within the Trust. The only occasion that CDs are transported outside the Trust is when samples of manufactured products are sent to a contract laboratory for analysis. Does this require a Home Office licence?

*Yes - a licence could be required for this supply; unless the CD content and formulation of the “sample” is considered to be an “exempted product” in accordance with Regulation 2 of the Misuse of Drugs Regulations 2001.*

1. I understand that the supply of CDs in Schedules 2-5 of the Misuse of Drugs Regulations 2001 is exempt from the requirements for holding a Home Office CD licence when otherwise the requirements to hold a WDA(H) licence are required. Is this true?

*No – the presumption should be that a licence is required, unless the requirement to hold one is specifically exempted by a part of the Misuse of Drugs Regulations 2001. Please note that the exemptions to licensing frequently apply only in limited circumstances, so may cover some but not all the activities undertaken, and a licence therefore would still be needed.*

1. Are there any requirements for me to ensure that the organisation I am supplying stock to holds the necessary Home Office CD licence to be in possession of CDs (or ensuring they are exempt from doing so)?

*Yes - a wholesaler will need to ensure the provider has the necessary CD possession licences prior to supply of CDs to the provider.*

1. Do the changes to legislation affect the ability for GPs to carry any drugs - CDs or otherwise - in their bags?

*The changes in the medicines legislation will not affect the ability for GPs to carry medicines for administration or supply to their patients as this will constitute administration, retail supply or circumstances corresponding to retail supply. This change does not affect the general possession authority (Schedules 2-5 inclusive) for CDs afforded to General Medical Council registered doctors, when acting in their capacity as such, afforded by virtue of their professional competence.*

*However, where GPs provide a requisition to a pharmacy they should ensure that if the pharmacy does not hold a WDA(H), the supply by the pharmacy falls within MHRA guidance, which requires the supply to be limited to an occasional basis, a small amount, and not for profit in order not to require a WDA(H).*

1. I applied for a Home Office CD licence in December 2013 and am still waiting to hear in May 2014. Can I continue to supply CDs legitimately?

*No. A supplier cannot lawfully possess and supply CDs until such time as they are in receipt of a licence from the Home Office. Licences are only issued upon receipt of payment, and payment is not sought until such time as the licence has been approved in principle.*

1. Can I be assured that I will not be prosecuted whilst the Home Office decide my application?

*We recognise the need to ensure continuity of care, and delivery of medicines and pain relief to patients and wish to enable the continuation of this.*

*Unfortunately, a blanket and categorical assurance of the nature sought cannot be given in respect of an activity which is unlawful without a licence.*

*However, where an organisation has applied to regularise its position and is actively pursuing that application and complying with requests for information, Disclosure and Barring Service Checks etc., it would be highly unlikely that an enforcement agency would seek to effect a prosecution.*

1. When did this change come into effect?

*There have been no changes to the Home Office Misuse of Drugs Regulations 2001 in this regard. However, section 10(7) of the Medicines Act 1968 was repealed under the Human Medicines Regulations (S.I. 2012/1916) on 24 July 2012 as it was outside the European Directive 2001/83/EC on medicines for human use within the community. The Regulations came into effect in August 2012.*

**MHRA WDA(H) Licence applications**

1. Who do I apply to?

*Application forms and guidance on applying are available at*

[*http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Manufacturersandwholesaledealerslicences/index.htm*](http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Manufacturersandwholesaledealerslicences/index.htm)

[*http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm*](http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Informationforlicenceapplicants/Licenceapplicationforms/Wholesaledealerslicencesapplicationforms/index.htm)

*These should be sent to the Process Licensing Section (PcL) by e-mail* ***pcl@mhra.gsi.gov.uk***

1. How much does this cost, when do I have to pay it and how long does the licence last?

*The fee is £1,803 for an initial licence, which is payable with the application.*

*An inspection fee of £1,936 is also payable prior to any inspection being carried out.*

*Special reduced rates apply to:*

 *1)  Wholesale dealers handling GSL products only;
2)  Registered retail pharmacies where wholesaling of licensed products does not exceed 15% of total turnover in licensed products; and
3)  Small wholesale dealers where wholesaling of licensed products does not exceed £35,000 of total turnover in licensed products.*

*The initial licence is continuous.*

1. How long will it take before I know whether my application is successful?

*The MHRA aims to respond to WDA(H) licence applications and either accept or reject them within 90 working days.*

**Home Office CD Licence applications**

1. Who do I apply to?

*Home Office Controlled Drug Licence applications must be made online at:* [*https://eforms.homeoffice.gov.uk/outreach/DrugsConsole.ofml*](https://eforms.homeoffice.gov.uk/outreach/DrugsConsole.ofml)*.*

*New users and first time licensees must register to use the system at:* [*https://eforms.homeoffice.gov.uk/outreach/drugs\_registration.ofml*](https://eforms.homeoffice.gov.uk/outreach/drugs_registration.ofml)*.*

1. How much does this cost, when do I have to pay it and how long does the licence last?

*Licences are issued for a period of one year.*

*Fees are payable for the issue of a licence and the fees most likely to be applicable are summarised as follows:*

*New/first-time licences:*

* *possess CDs - £3,133*
* *possess and supply CDs - £3,655*

*Subsequent years (renewals) licences:*

* *where the application is decided on papers - £326*
* *where a compliance visit is required - £1,371*

*As a general guide, the Home Office will always inspect new/first time licensees before a licence is issued and expect to make a return visit, when the fee of £1,371 would apply, every 3-5 years.*

*Further details on Home Office fees and application handling can be found at:* [*https://www.gov.uk/government/publications/drug-licensing-handling-fee-guidance*](https://www.gov.uk/government/publications/drug-licensing-handling-fee-guidance)*.*

*Fee payments will be requested once the application has been approved “in principle”, but a licence will only be issued when payment has been received.*

1. How long will it take before I know whether my application is successful?

*All applications are triaged upon receipt to determine whether all information has been provided and whether a compliance visit is necessary.*

*The aim is to do this within two weeks of receipt.*

*Applications will not be allocated for a visit/assessment until all Disclosure and Barring Service (DBS) checks have been completed on individuals to be named on the licence. This must be done via Capita RVS - Home Office Drug Licensing does not do this on behalf of applicants.*

*Where there is a genuine need to expedite an application, and all information has been supplied, the Home Office will aim to expedite. First time or new licence applications can take up to 12-16 weeks to complete after the case has been allocated.*

*Renewal licence applications, which are considered on the papers, are usually processed within 4-6 weeks.*

**Hospitals/Hospices**

1. I work in a hospital trust and we supply stock medicines and stock CDs to a local hospice/mental health ward/trust etc. Do we need to hold a WDA(H) licence and Home Office CD licence?

*Yes - if the hospice is a separate legal entity either on or off the hospital site. No - if the hospice or ward is part of the same legal entity as the hospital.*

1. What can hospices do if they are having difficulty obtaining medicines supplies from usual sources?

*MHRA has published guidance for pharmacists on the repeal of the exemption from a WDA(H). This guidance sets out conditions whereby a WDA(H) may not be required. These conditions are set out in this information sheet at paragraph 10 on page 2 and are also available on the MHRA website:* [*http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON394659*](http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON394659)*.*

1. Does this provision cover supplies of CDs as well?

*No. A CD licence to cover supplies of CDs to hospices would likely still be needed.*

1. Where can I find who is authorised to supply medicines as a wholesale dealer?

*A list of current WDA(H) holders is available on MHRA website at http://*[*www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2025604.pdf*](http://www.mhra.gov.uk/home/groups/is-lic/documents/publication/con2025604.pdf)*. This includes licensed NHS Trusts.*

1. Is a similar list available for those licensed to supply CDs?

*Home Office licensee details are not publicly available, so a similar list is not available for those that are licensed to supply controlled drugs. However, it is likely that most wholesale dealers will also be licensed to supply controlled drugs.*

1. We use an NHS Trust for most of our medicines supplies but they are supplied from separate parts of the Trust, which are on different sites. Is it likely we need to check that each site has a WDA(H)?

*Provided all the sites are part of the same legal entity, only one WDA(H) is required. If the sites are not part of the same legal entity, then separate WDA(H)’s may be needed unless the particular provisions, which enable supplies to be made without a WDA(H), apply – see paragraph 10 on page 2*

1. Does the same hold true for supplies of CDs from NHS Trusts?

*NHS Trusts, which supply CDs, but from different sites, would generally only need one CD licence provided these sites are part of the same legal entity. However, if the sites are widely dispersed, it is possible that each site may require a CD licence as appropriate.*

1. Do hospices need to apply for a licence to possess CDs to give their patients?

*Hospices do not need a licence to possess controlled drugs listed in Schedules 2 to 5 to the Misuse of Drugs Regulations, where these are supplied against a named-patient prescription.*

*However, where stocks of controlled drugs are held for general supply to patients, a Home Office licence may be required.*

*Stocks of controlled drugs listed in Schedules 3, 4 and 5 can generally be possessed without a licence.*

*A hospice may possess stocks of controlled drugs listed in Schedule 2 without the need for a Home Office licence in limited circumstances. A licence is not required where the hospice is wholly or mainly funded directly from charitable or public funds.*

*The exact provisions authorising hospices to possess and supply Schedules 2 to 5 controlled drugs are set out in Regulations 8(2)(d) and 9(3)(b) to the Misuse of Drugs Regulations 2001 as amended.*

*Hospices will wish to assure themselves whether any of these provisions apply to their activities. If in doubt, hospices should seek their own legal advice as necessary.*

**Other matters**

1. What did the European Directive say about medicines supplies?
2. *Recital (35) of the Directive stated:*

*(35) “It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.”*

*Recital (36) went on to state:*

*(36) “Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorization. Pharmacists and persons authorized to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorization.”*

*Article 77 of the Directive stated that:*

1. *“Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.*
2. *Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1.”*

**Appendix**



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| All-England Chief Pharmacists Group | Strategy, Finance & NHSSkipton House80 London RoadLondonSE1 6LH | T 0207 972 2833www.dh.gov.uk |
| 21st February 2014Dear Colleague |  |

**CONTROLLED DRUGS AND WHOLESALE DEALER’S AUTHORISATION FOR HUMAN USE/WHOLESALE DEALERS’ AUTHORISATIONS**

Following recent exchanges with a number of pharmacist colleagues, this letter summarises the circumstances in which it is necessary for pharmacies, which are supplying controlled drugs, to hold a wholesale dealer’s authorisation for human use (WDA(H)).

It follows the repeal of the exemption from the requirement to hold a Home Office Controlled Drug licence (Section 10(7) of the Medicines Act 1968) and the need for NHS Trusts and pharmaceutical services providers to obtain such licences.

The Home Office, MHRA and DH previously provided an explanatory note on this subject in May 2013. This is attached as an Annex. A fuller information sheet is being prepared on this subject, which I intend to circulate by the end of March 2014.

*Summary*

The previous professional exemption for pharmacists in a particular healthcare setting, that allowed the supply of low volumes of stock medicines (i.e. those not supplied to an individual patient by a pharmacy via a dispensed prescription) by way of wholesale dealing to other legal entities without a WDA(H), has been removed.

**Any** supply of stock medicines on a commercial basis by a pharmacy now requires a WDA(H) to be held by the supplying pharmacy.

This change has affected pharmacies providing stock medicines to another legal entity with or without a formal contract in place. This includes those pharmacies:

* in NHS Trusts;
* that are registered community pharmacies; and
* located in other settings such as community hospitals and prisons.

If a WDA(H) is required, this also means that if supplies include controlled drugs in schedules 2 - 5 to the Misuse of Drugs Regulations 2001, then it is likely that a corresponding Home Office Controlled Drug licence is also needed by the pharmacy to legalise this supply. The Home Office regulatory requirements have not changed and have always come into play when a WDA(H) is needed.

MHRA has previously given guidance that in situations where there is a specific patient need, a pharmacyneeding to obtain small quantities of a medicine **from another pharmacy** may do so without the need for the supplying pharmacy to hold a WDA(H). This is subject to the supply meeting all of the following criteria:

* it takes place on an occasional basis;
* the quantity of medicines supplied is small and the intention is to meet the needs of an individual patient; and
* the supply is made on a not for profit basis.

Pharmacy service providers need to take account of this change arising from the Human Medicines Regulations (2012) (SI 2012/1916) and the relevant MHRA guidance when considering whether they need to apply for the necessary licences (MHRA/HO) should they continue to supply stock medicines to other legal entities.

Commissioners and healthcare service providers will also wish to assure themselves whether contracted pharmaceutical service providers have or have not applied for such licences.

In the meantime, if you have any queries on:

* MHRA wholesale dealer’s authorisation for human use, please contact PcL enquiry line on 020 3080 6844 or email: pcl@mhra.gsi.gov.uk
* Home Office Controlled Drug licences, please contact the Duty Compliance Officer on 020 7035 8972 in the first instance.

I am happy for this letter to be circulated to your networks, with the proviso that this is an interim statement pending the circulation of a fuller information sheet.

Yours sincerely



**Dr Keith Ridge CBE**

**Chief Pharmaceutical Officer**

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**Annex A: May 2013 e-mail sent out and agreed by the Department of Health, Home Office and MHRA providing information on the Wholesale Dealer’s Licence and CD Licence requirements**

Prior to 14 August 2012, Section 10(7) of the Medicines Act 1968 provided a pharmacist in a pharmacy (hospital or registered) or someone acting under their supervision, who sells, supplies or offers for sale or supply a medicinal product by way of wholesale dealing, with an exemption from the requirement to hold a Home Office (HO) Controlled Drugs licence. The exemption only existed on the basis that the wholesale dealing activity constituted no more than an inconsiderable part of that business, which for a long time had been generally regarded by the Medicines and Healthcare products Regulatory Agency (MHRA) as 5% of the total turnover of licensed medicinal products at that registered pharmacy.

This exemption was repealed on the 14 August 2012 as it was outside the European Directive 2001/83/EC on medicines for human use within the community.

The MHRA guidance recognises the valuable work that pharmacies (both hospital and registered) provide within their local community in respect of supplying medicines to others who need to hold them to pass on to their patients. The exemption did not provide any prohibition in relation to misuse of drugs legislation. The HO worked closely with MHRA to ensure policy alignment in these matters.

By way of an example, the MHRA guidance provides that **pharmacists** needing to obtain small quantities of a medicine **from another pharmacist** to meet a patient's individual needs may do so without the need for the supplying pharmacy to hold a wholesale dealer's licence only if the transaction meets all of the following criteria:

* it takes place on an occasional basis;
* the quantity of medicines supplied is small and the intention is to meet the needs of an individual patient; and
* the supply is made on a not for profit basis.

This restriction does not apply to exchange of stock between pharmacies that are part of the same legal entity. It also provides that conversely, pharmacists who wish to engage in commercial trading in medicines are entitled to do so only if they hold a wholesale dealer's licence and comply with all the relevant HO requirements. However it is advisable that the MHRA’s guidance should be read in its entirety rather than just certain elements of the guidance. Furthermore, organisations are encouraged to have recourse to their own independent legal advice, in respect of legislative interpretation as neither the HO, MHRA or DH are in a position to offer a legal advice service, but can instead provide general information on the interpretation of regulations and how they might apply in individual situations.

The position and view of the HO remains unchanged since the repeal of Section 10(7) of the Medicines Act. NHS registered hospitals are, in certain circumstances, exempt from HO Controlled Drugs licensing in respect of Schedule 2-4 Controlled Drugs, under Regulation 8 and 9 of the Misuse of Drugs Regulations 2001 (the “2001 Regulations”).This is, and has been the position since the implementation of the 2001 Regulations; **there has been no change to the requirement for licensing in 2010.**

An NHS Trust can continue to supply controlled drugs to healthcare professionals within that hospital or its satellites but not to organisations that fall outside that hospital such as hospices, or community health trusts. Therefore, an MHRA wholesale dealer licence would be required when the hospital pharmacy is supplying a larger quantity of controlled drugs on a more regular basis than the guidance set out by the MHRA reports, where the supply is made outside of the hospitals legal entity, and it appears likely that there would be a corresponding need for a Home Office Controlled Drug licence. The above would not apply to any drugs dispensed by a hospital pharmacy on a named patient basis - Regulation 10(2) of the “2001 Regulations” would allow this practice to occur without the need for a licence, but this would not apply to “over labelled” medication which would be regarded as a supply of stock and licensing therefore could be required as above.

We are aware that the use of “contracted out” services in NHS hospitals may also give rise to the need for a Home Office CD licence to be held by both the provider to whom the service is contracted, and any (NHS) body intending to provide those services. As a general rule, it is the “organisation” or “function” which gives rise to any 2001 Act “exemption” from licensing, not the physical building. Therefore, a “contracted out” service operating on NHS premises would not derive any licensing exemption solely on account of its physical location (on NHS premises) and any “supply” from an NHS body to the (private) contracted out service provider would result in a change of legal ownership and physical possession of the drugs and would appear to be an activity requiring Home Office license.