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Dear Mr Ali

GPhC Response to the Call for Evidence ACMD Diversion & Illicit Supply of Medicines Inquiry

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmaceutical services in England, Scotland and Wales.

The GPhC sets the standards for education and training, conduct, ethics and performance and continuing professional development for the pharmacy professions. We have also developed standards for registered pharmacies. Our standards are intended to provide a workable framework for pharmacy professionals to practise safely and effectively. Our standards can be found at www.pharmacyregulation.org/standards.

Among healthcare professional regulators the GPhC is unique because it also regulates registered pharmacies as well as individual pharmacy professionals. The GPhC also has its own long-standing Inspectorate. In addition to our responsibilities in relation to pharmacy professionals, our inspectors visit all registered pharmacies in Great Britain to ensure that they comply with all legal requirements and regulatory standards. The inspector will examine how the pharmacy operates with the aim of securing and promoting the safe and effective practice of pharmacy at the registered pharmacy.

As part of our ongoing routine inspection of registered pharmacies, on a day to day basis, our Inspectors monitor and secure compliance with relevant legal requirement that include requirements for the sale and supply of medicines in general, and controlled drugs in particular. Much of the following feedback we have provided has been gathered from discussions with our inspection and investigation teams.

Some of this is data from cases and some of it includes anecdotal information, as we do not

routinely collect this type of information in this way about the medicines involved in cases.

We welcome the opportunity to respond to the ACMD's call for evidence on the diversion and illicit supply of medicines, predominantly controlled drugs. Thank you for the invitation to take part in the Evidence Gathering Meeting / Inquiry on 12th June, however given our limited role in this area we believe that this written submission constitutes the bulk of our evidence and beyond this we would have little to elaborate on in a public setting.

We have limited our responses and evidence to where we feel our work is relevant to the particular questions posed and are happy to clarify any areas as necessary.

Q.2 Do you know of medicine diversion and illicit supply, and if so where are these medicines coming from?

In the course of our work we have become aware, and have investigated, a number (less than 10 cases) of concerns raised about allegations of unlawful sales and supplies through registered pharmacies. We have recently established a number of memoranda of understanding (MOU) with other regulatory bodies and authorities, to share information about concerns, and we continue to develop further arrangements with other bodies. Where we have found areas of concern that fall outside our remit we have shared this information, and have worked, with the other relevant regulators and bodies such as the Home Office, the Medicines and Healthcare products Regulatory Agency (MHRA), the Care Quality Commission (CQC), Healthcare Improvement Scotland (HIS) and Healthcare Inspectorate Wales (HIW).

Evidence from the cases we have investigated, and have previously discussed with bodies such as the MHRA, indicate the areas in which illicit supplies may be coming from include:

- internet sites both domestic and international;
- illicit imports;
- stocks obtained by theft from pharmacies, hospital wards and departments; and
- inappropriate prescribing, prescription fraud and prescription theft.

Q.3 Which medicines/drugs do you consider are being diverted and supplied illicitly?

Although we do not capture this information routinely, in the course of our investigations, we are aware that the following types of medicines have been diverted or supplied illicitly:

- Antibiotics and antivirals
- Lifestyle drugs (drugs for slimming, or to treat erectile dysfunction)
- Hypnotics (diazepam, flunitrazepam)

- Analgesics (codeine, dihydrocodeine, tramadol)
- Anti-epileptics (gabapentin, pregabalin)
- Antihistamines
- Controlled drugs (methadone)
- Abortifacients (mifepristone, misoprostol)
- Chemicals / cutting agents (vitamin C powder)

Some medicines are being diverted and exported due to their high cost and high demand (or unavailability) in other countries.

- Antineoplastics (Glivec, Tyverb, Votrient)
- Antivirals and antiretrovirals (Valcyte, valganciclovir, Copegus, Invirase, Atripla, Truvada)
- Antibiotics (tobramycin)
- Antidepressants (Cymbalta)
- Osteoporosis treatments (Bondronat, Aclasta)
- Others (peginterferon alpha, dornase alpha, Sandostatin and Exjade)

Q.5 What action should the healthcare and other relevant sectors take to resolve the issue of diversion and illicit supply of medicines?

Whilst it would not be for us to direct you on how this should be done, we are committed to joint working with the appropriate bodies, through our MOUs, for clarity on regulating legal and illegal supplies.

Through our existing joint working arrangements and positive working relationships we will continue to work with other regulatory bodies and authorities to assist where we can in minimising illicit supplies and diversion. If you would like further information on any of the points raised in this response, or any other aspects of the GPhC's work please do not hesitate to contact us on the details provided below.

Yours sincerely



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