General Pharmaceutical Council

GPhC response to Consultation on implementing 'safety features' under the Falsified Medicines Directive

Thank you for the opportunity to respond to this key consultation. Having carefully reviewed your consultation document and considering our regulatory role and functions, we have focused our response on one of your questions:

Question 1: What form of sanctions regime do you think would be the most effective to enforce the regulations across the UK medicines supply chain?

As the regulatory body for pharmacists, pharmacy technicians and registered pharmacies in England, Scotland and Wales, we support the enforcement approach and the sanctions regime proposed in the consultation.

The approach to use a mixture of criminal and civil sanctions, whereby civil sanctions (such as written warnings, stop notices and civil fines) would be used before applying criminal sanctions (such as fines and imprisonment, reserved for intentionally fraudulent breaches) is consistent with the General Pharmaceutical Council's (GPhC) own approach to regulation.

The GPhC aims to be consistent and proportionate in its approach to the regulation of pharmacy professionals and registered pharmacies. This means that we will consider both statutory and non-statutory enforcement action to ensure compliance with the standards for registered pharmacies, and we will select the appropriate action that is necessary to safeguard patients and the public.

During our inspections we look carefully at how the pharmacy is meeting our **standards for registered pharmacies**, which include the safe and appropriate management of medicines. Where we identify a registered pharmacy that is not meeting our standards, we will consider various options to secure compliance.

In the first instance we use improvement action plans, to ensure that the necessary changes are made to comply with the GPhC standards. We take the specific pharmacy context into account when determining what level of enforcement action is appropriate. Further statutory enforcement powers are only considered in situations where a pharmacy owner does not complete an improvement action plan, or in situations where there is a serious risk to patient safety.

We have formal arrangements in place for working with other enforcement agencies and whenever another organisation is better placed to manage the concerns, we would refer the matter to them.

We have chosen not to provide comments to the remaining consultation questions because we consider that they fall outside our regulatory scope. However, we would welcome the opportunity to continue our ongoing engagement with the MHRA on this and related issues.