Notification to manufacturers and wholesalers

Overview

The Misuse of Drugs (Amendment) Act 2016 was passed through the Houses of the Oireachtas in July 2016. The primary purpose of the Act is to protect public health by bringing certain substances which are open to misuse and known to be traded on the illicit market under the scope of the Misuse of Drugs legislation, thereby aiding the law enforcement activities of An Garda Síochána. The Act will come into operation on foot of commencement orders and will enable the Minister for Health to introduce new regulations. The Health Products Regulatory Authority (HPRA) would like to inform industry of the implications that the new Act and Regulations will have to the licensing of controlled drugs.

New substances added

A number of substances that were previously not controlled will now fall under the scope of the Misuse of Drugs legislation. Some of the new substances intended to be controlled that may impact on stakeholders are listed below:

- Zopiclone
- Zaleplon
- Lisdexamfetamine
- Phenazepam

One of the consequences of these substances being controlled is that if your company handle any of these substances or products containing these substances, you will have to obtain a controlled drug authorisation in respect of the activity performed (e.g. production or supplying).

For wholesale distribution authorisation holders, another potential consequence is the need to vary the company's authorisation to include the category of narcotic or psychotropic substances to the authorisation, if not present already.

With respect to companies that may require authorisation in relation to these proposed changes, the HPRA will work with these companies and use a pragmatic approach.

Regulations introducing changes to import and export licences

You will be aware that in 2013 a public consultation proposed a variety of amendments to the Misuse of Drugs Regulations 1988, as amended. It is anticipated that the Minister for Health will soon introduce Regulations to amend the current framework for some controlled drugs.

The new controls will require an import or export licence (as appropriate) for all substances listed in Schedule 3 (including flunitrazepam and temazepam) and listed in Part 1 of Schedule 4 (which will include many benzodiazepines, zopiclone and zaleplon). A Letter of No Objection will therefore no longer apply to the importation/exportation of these substances. The table below may help to illustrate the impact of the changes.

Activity	Current requirements	New requirements
Each import or export of controlled drugs listed in Schedule 1, 2 or 3	Import or export licence (as appropriate)	No change
Each import or export of temazepam and flunitrazepam	Letter of no objection	Import or export licence (as appropriate)
Each import of controlled drugs listed in Schedule 4 part 1 (e.g. alprazolam, diazepam, nitrazepam, zolpidem)	Letter of no objection	Import or export licence (as appropriate)
New controlled drugs such as zopiclone and zaleplon	No requirement	Import or export licence (as appropriate)

In anticipation of the proposed changes, your company is asked to review the products handled to ascertain if any of the proposed changes affect the company in advance of the implementation of the Regulations.