

28th April 2017

Subject: Misuse of Drugs Regulations 2017 become effective from 4th May 2017

Dear interested stakeholder,

Further to the HPRA communication in January 2017 regarding the Misuse Use of Drugs framework (attached), we wish to inform industry that the Misuse of Drugs Regulations 2017 is expected to become effective from the 4th May 2017.

The HPRA would like to take this opportunity to remind you that a number of substances that were previously not controlled will now fall under the scope of the Misuse of Drugs legislation including: zopiclone, zaleplon, lisdexamfetamine and phenazepam.

As a result of the new legislation, changes have also been made to the requirements for controlled drug import and export licences, see the table below illustrating 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)

As these changes are expected to be implemented from the 4th May 2017, your company is asked to review the products handled to ascertain if any of the proposed changes affect the company and to update procedures and authorisations as appropriate.