3 - Jneħħi l-ħtieġa li tikseb permess speċjali mis-SSP biex tippreskrivi	Ir-regolament 3 jemenda r-regolament 13 tar-regolamenti prinċipali u jelimina l-kisba ta' awtorizzazzjoni minn qabel bil-miktub mis-Suprintendent tas-Saħħa Pubblika biex jippreskrivi l-amfetamini u jelimina l-ħtieġa li jitlaqqa' bord mediku ta' speċjalisti biex japprova tali preskrizzjoni.
4 - Jneħħi l-ħtieġa li min jippreskrivi jimla r-Raba' Skeda li tinsab mar-regolamenti prinċipali	Ir-regolament 4 jemenda r-Raba' Skeda li tinsab mar-regolamenti prinċipali u jneħħi l-ħtieġa li t-tabib jimla r-Raba' Skeda u jinforma lis-SSP fi żmien 24 siegħa minn meta jippreskrivi l-amfetamini.
5 - Jneħħi l-ħtieġa lill-ispiżjar li joqgħod jimla l-Ħames Skeda li tinsab mar-regolamenti prinċipali	Ir-Regolament 5 jemenda l-Ħames Skeda li tinsab mar-regolamenti prinċipali u jneħħi l-ħtieġa li l-ispiżjar jimla l-Ħames Skeda u li jinforma lis-SSP fi żmien 24 siegħa minn meta jiddispensa l-amfetamini.

5. Sezzjoni Konklużiva

Dawn ir-regolamenti emendatorjigħandhom jidħlu fis-seħħ mal-pubblikazzjoni tagħhom fil-Gazzetta tal-Gvern. Jekk tkun meħtieġa iktar informazzjoni, inti ġentilment mitlub biex tikkuntattja lis-SSP.

N.B. Dawn in-Noti ta' Spjegazzjoni mhumiex maħsuba biex ikunu deskrizzjoni eżawrjenti tal-istrument legali u lanqas sostitut tiegħu jew suppliment leġiżlattiv għall-istess. Dawn in-Noti ta' Spjegazzjoni mhumiex intiżi bħala deċiżjoni awtorevoli fuq l-interpretazzjoni tal-leġiżlazzjoni.

Is-6 ta' Ġunju, 2025

No. 875

MINISTRY FOR HEALTH AND ACTIVE AGEING

Explanatory Notes[1]

1. Introduction

Title of Regulations	Drugs (Control) (Amendment) Regulations, 2025 (hereinafter referred to as the "amending regulations")
Activity to be regulated	Prescribing of amphetamines by psychiatrists and doctors. The Drugs (Control) Regulations (S.L.31.18) (hereinafter referred to as the "principal regulations" are to be amended)
Responsible entity	Superintendence of Public Health (SPH)

2. Summary and background

2.1 Aims & Objectives of the legislation

To eliminate unnecessary bureaucracy in the current procedure for prescribing amphetamines (mainly dexamphetamine).

[1]These Explanatory Notes are for the purpose of and in accordance with article 3(2)(c) and Schedule III of Chapter 512 of the Laws of Malta.

2.2 Importance of legislation

Removing unnecessary bureaucracy will encourage prescribers to prescribe amphetamines more readily to patients who require them.

2.3 Consultation Process

The main stakeholder, the Mental Health Services within the Ministry for Health and Active Ageing (MHA – MHS) has agreed to eliminate such unnecessary bureaucracy.

3. Overview of the structure of the instrument

The amending regulations consist of five (5) regulations.

4. Commentary

Regulation No. of the amending regulations	Meaning & obligations placed on user
1 - Citation	Regulation 1 provides the title of these amending regulations.
2 - Prevents doctor shopping	Regulation 2 amends regulation 9 of the principal regulations whereby prescribers will not be permitted to prescribe urgent prescriptions for amphetamines, thus eliminating the scenario where patients would go to different doctors for repeated urgent prescriptions for amphetamines.
3-Removes need to obtain special permission from SPH to prescribe	Regulation 3 amends regulation 13 of the principal regulations and does away with obtaining the prior authorisation in writing by the Superintendent of Public Health to prescribe amphetamines and eliminates the need to convene a medical panel of specialists to approve such prescribing.
4 - Removes the need for prescriber to fill in the Fourth Schedule to the principal regulations	Regulation 4 amends the Fourth Schedule to the principal regulations and removes the requirement of the doctor filling in the Fourth Schedule and informing SPH within 24 hours of prescribing amphetamines.
5 - Removes the need for pharmacist to fill in the Fifth Schedule to the principal regulations	Regulation 5 amends the Fifth Schedule to the principal regulations and removes the requirement of the pharmacist filling in the Fifth Schedule and informing SPH within 24 hours of dispensing amphetamines.

5. Concluding Section

These amending regulations shall come into force upon their publication in the Government Gazette. Should more information be required, kindly contact the SPH.

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. These Explanatory Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

6th June, 2025