Medicines & Healthcare products Regulatory Agency

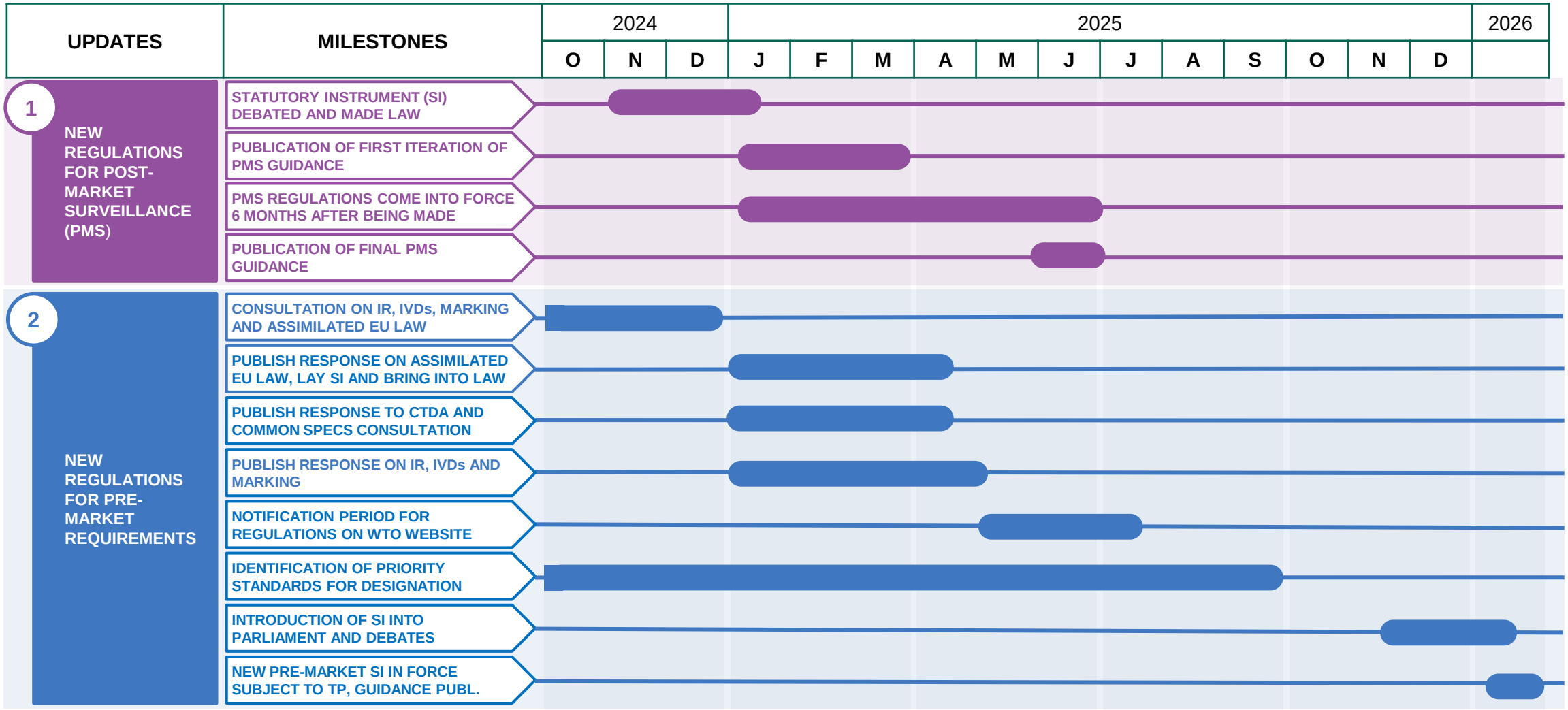
Medical Devices Regulatory Reform

Roadmap to implementation

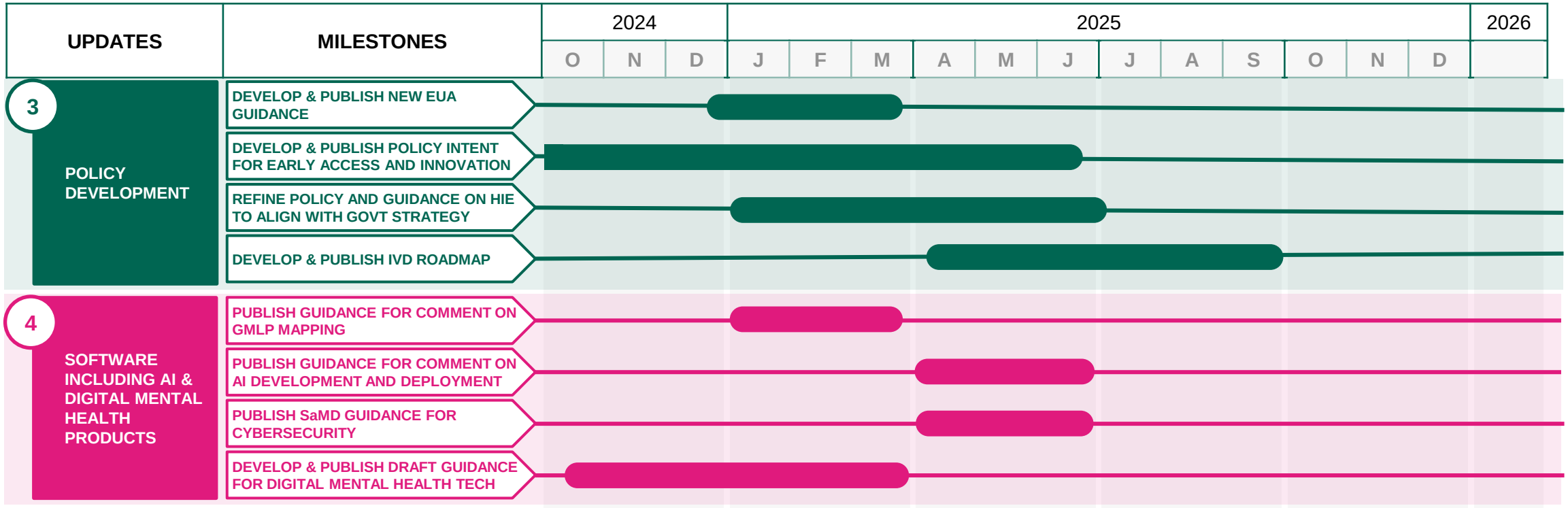
Version 2.0 (December 2024)

This is a ‘living’ document that is subject to updates

Medical Devices Regulatory reform roadmap (1 of 2)



Medical Devices Regulatory reform roadmap (2 of 2)



Glossary			
EUA	Exceptional Use Authorisation	IR	International Reliance
GMLP	Good Machine Learning Practice	SaMD	Software as a Medical Device
HIE	Health Institution Exemption	TP	Transitional Provisions
IVD	*In Vitro* Diagnostics		

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