

Annex C - Legislative Frameworks Comparator

Dimension	Misuse of Drugs Act 1971 (MDA)	Misuse of Drugs Regulations 2001 (MDR)	Pregabalin & Gabapentin 2018-19 control changes	Human Medicines Regulations 2012 (HMR)	MHRA regulatory regime	Clinical governance & prescribing	CBPM packaging & pharmacy labeling (patient-facing)	Road Traffic Act 1988 (drug-driving)	Equality Act 2010 / PSED
Position in patient journey	Primary criminal law framework (baseline offences)	Regulatory exemption framework to the Misuse of Drugs Act 1971	Comparator: controlled-drug "tightening" model	Medicines law (lawful access)	Medicines safety oversight	Clinical decision-making	Primary patient interface	Specific criminal context	Cross-cutting assessment
Primary purpose	Control of harmful drugs through criminal law	Specify exemptions and permissions from MDA offences	Increase controls on specified medicines in response to misuse	Regulate medicines safety, supply, and use	Ensure medicines quality and safety	Support safe clinical practice	Communicate clinical use instructions to patients	Protect road safety by regulating drug-driving	Prevent discrimination; ensure equality
Impact assessment / equality analysis (including protected characteristics)	No impact assessment identified within Annex A document set	Impact assessments and explanatory memoranda produced in connection with primary and secondary legislation; equality and wider impacts summarised in documentary material	Operates within established medicines regulatory impact assessment processes within licensing and pharmacovigilance functions	Embedded impact and safety assessment processes within licensing and pharmacovigilance functions	Equality considerations embedded through clinical standards rather than legislative impact assessment	Impact assessment supporting SI 2018/1055 produced; no assessment identified of patient-facing communication of criminal-law consequences linked to route of administration. No explicit assessment identified of impacts on protected characteristics arising from such communication gaps	Impact assessment accompanying introduction of section 5A explicitly considers equality and disability impacts arising from lawful prescribed drug use	Impact assessment supporting SI 2018/1055 (A15) produced; no explicit assessment identified of impacts on protected characteristics under the Equality Act 2010, including disability, within the Annex A document set.	
What it regulates	• Drug classification (A/B/C) • Core criminal offences	• Schedules 1-5 • Lawful possession, prescribing, supply	• Class C classification (MDA) • Schedule 3 controls (MDR)	• Licensing • Prescribing • Labelling • Patient information	• Product standards • Pharmacovigilance • Labelling content	• Routes of administration • Dosing • Risk management	• Directions for use • Dose • Route (clinical) • Storage	• Driving with specified controlled drugs present • Statutory medical defence	• Disparate impacts • Reasonable adjustments
Parliamentary scrutiny route (procedure + debate)	Primary legislation subject to full parliamentary scrutiny	Secondary legislation subject to standard statutory instrument procedures	Primary legislation (affirmative procedure) and secondary legislation accompanied by parliamentary debates	Primary legislation subject to full parliamentary scrutiny	Operates under delegated regulatory powers	Not applicable	Not applicable	Secondary legislation implementing section 5A accompanied by parliamentary debate on specified-limits regulations	Equality considerations subject to parliamentary scrutiny where raised
Who it applies to	General public	Clinicians, pharmacists, patients	Prescribers, dispensers, handlers, patients	Manufacturers, prescribers, patients	Manufacturers, licence holders	Clinicians and patients	Patients	Drivers	Public authorities
Normal treatment of non-compliance	Criminal offence	Loss of exemption may expose conduct to criminal law under the MDA	Controlled-drug requirements (prescribing, dispensing, supply/handling) may trigger criminal liability	Regulatory or clinical consequences	Regulatory sanctions	Clinical review or adjustment	Treated as clinical non-compliance	Criminal offence (with statutory medical defence where conditions are met)	Legal compliance duties
Explicit statutory safeguard for prescribed patients	None	No explicit statutory safeguard addressing route-specific withdrawal of exemption or resulting criminal exposure for prescribed patients	Controlled-drug safeguards established through Schedule 3 placement, including recognised prescribing, dispensing, and safe-custody frameworks	Clinical and regulatory safeguards inherent in medicines law	Safety and licensing safeguards through regulatory oversight	Clinical discretion and professional standards govern prescribing decisions	No patient-facing safeguard or warning addressing criminal liability arising from route of administration	Statutory medical defence for prescribed drugs taken in accordance with medical advice	Equality duties apply; no CBPM-specific statutory safeguard for prescribed patients identified within the Annex A document set
Role in CBPM / medicines framework	Cannabis remains Class B	Establishes CBPM category (introduced in 2018) and conditions via Regulation 16A	Applies controlled-drug framework to specified medicines	Governs lawful prescribing and supply of CBPMs once recognised	Oversees product quality and safety	Advises on clinical administration	Provides patient-level instructions	Addresses prescribed drug use in driving context	Disabled patients form a distinct cohort
Visibility to patients	Explicit (criminal law)	Indirect (exemption-based; not patient-facing through medicines systems)	Medium (explicit controlled-drug status is not prescribing/dispensing systems; patients experience tighter supply controls)	High	Medium	High	Very high	High	Indirect; no patient-facing equality assessment identified within the Annex A document set
Operational guidance / circular issued (existence + timing)	No operational guidance specific to prescribed patient use identified	Home Office Circular 018/2018 issued following CBPM rescheduling; limited patient-facing content	Home Office Circular 019/2018 issued ahead of commencement, setting out implementation and transition expectations	Medicines guidance issued through established regulatory channels	MHRA guidance and safety communications issued as required	Professional and clinical guidance issued via established bodies	Pharmacy labelling provides clinical instructions; no guidance identified addressing criminal-law consequences	Department for Transport and cross-government guidance issued in advance of commencement	Public authorities subject to PSED when issuing operational guidance
How inhalation / use is treated	No route distinction	Route relevant to exemption conditions	Route not central to control mechanism	Route-neutral	Route-neutral	Vapourisation generally preferred	Packaging may state "for inhalation"; pharmacy label states "for vapourisation"	Not relevant	No explicit assessment identified within the Annex A document set of impacts on protected characteristics, including any differential impact arising from route-specific criminalisation.
How smoking is treated	No route distinction	Regulation 16A(3) withdraws exemption if smoked	Not relevant to control mechanism	No criminal distinction by route	No criminal distinction by route	Smoking discouraged on health grounds	May be discouraged clinically or not mentioned	Not relevant	No explicit assessment identified within the Annex A document set of impacts on protected characteristics, including any differential impact arising from route-specific withdrawal of exemption under Regulation 16A(3).
Nature of instruction	Legal prohibition	Legal exemption subject to conditions, including route-specific condition for CBPMs (Reg 16A(3))	Standard Class C controlled-drug requirements	Clinical and regulatory	Clinical and safety	Clinical advice	Clinical instruction (route and dose), without reference to criminal consequences	Explicit criminal rule with statutory safeguards	Equality safeguard
Criminal liability triggered?	Yes (baseline offences)	Yes, where exemption is withdrawn and MDA offences re-engage	Yes, where role-specific controlled-drug requirements are breached (typically prescriber/dispensing/supply duties; patient liability mainly where possession/supply is unlawful)	No	No	No	No indication criminal liability is engaged	Yes, subject to statutory medical defence	N/A
Is criminal risk communicated here?	Yes	Not directly patient-facing	Yes, through explicit controlled-drug status and associated prescribing/supply requirements	No	No	No	No (packaging and dispensing labels do not indicate criminal consequences linked to route of administration)	Yes	No
Safeguards for prescribed patients	None	None explicitly addressing route-specific criminal exposure for prescribed patients	Schedule 3 controls, recognised prescribing safeguards, and established controlled-drug handling framework	Clinical safeguards	Safety safeguards	Clinical discretion	None relating to criminal law	Statutory medical defence	PSED duties apply; no CBPM-specific patient safeguard identified within the Annex A document set.
Policy framing at time of change	No change	Presented as enabling lawful medical access to cannabis-based medicines, following creation of a new CBPM category	Presented as tightening controls due to misuse and harm	Continuity of medicines regulation	Continuity of regulatory oversight	Continuity of clinical practice	Continuity of patient-facing clinical instructions	Presented as a public-safety measure	Equality duties unchanged
Commencement / transition arrangements	Standing criminal law; no specific transitional arrangements	Immediate effect on satisfaction of exemption conditions on commencement	Staged approach: announcement, legislative amendments, and operational guidance issued ahead of commencement	Continuous regime; no CBPM-specific transition	Continuous regulatory oversight	Continuous clinical practice	Continuous patient-facing practice	Defined commencement date following legislative and regulatory preparation	Equality duties apply continuously
Pre-2018 legal status of subject matter	Cannabis long classified; criminal status unchanged	No CBPM category prior to 2018	Licensed medicines prior to control changes	Existing medicines regime; no CBPMs	No CBPM oversight prior to 2018	No lawful plant-based cannabis prescribing prior to 2018	Category did not exist prior to 2018	No CBPM-specific application prior to recognition	No CBPM-specific equality assessment identified prior to recognition within the Annex A document set.
Resulting criminal-law exposure for patients	Unchanged	Conditional: lawful use dependent on continued satisfaction of exemption conditions	Expanded and explicit: additional controlled-drug obligations	Unchanged	Unchanged	Unchanged	No patient-facing reference to criminal exposure	Explicit offence with statutory medical defence	No assessment identified within the Annex A document set of impacts on protected characteristics arising from resulting criminal-law exposure.
Interaction with Regulation 16A(3)	Unchanged by 2018 amendments	Provides mechanism by which MDA criminal liability may re-engage	Provides comparator for standard approach to increasing controls	Operates independently	Operates independently	Provides clinical guidance	Does not reference criminal consequences	Illustrates explicit criminal-law treatment in a defined context	No assessment identified within the Annex A document set of equality or protected-characteristic impacts arising from Regulation 16A(3).