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Making pharmacy law – an insider's view

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Structure of Legislation

- Primary legislation – Acts
- Secondary legislation – Regulations, Directions, Determinations
- Medicines Act 1968
 - Can't do anything – series of exemptions
- NHS Act 2006
 - Contrasting provisions for secondary and primary care
- Misuse of Drugs Act 1971
 - Framework Act, detail in 2001 Regulations
 - Supervision of management and use in NHS legislation¹

► 1. The Controlled Drugs (Supervision of Management and Use) Regulations 2013.

Medicines vs NHS Legislation (1)

- Patient group directions
 - Medicines legislation – criminal offence
 - NHS legislation – pharmaceutical services arrangements, eg flu vaccination
- Emergency hormonal contraception
 - Medicines legislation – POM to P reclassification 2000
 - Prayed against in both Houses of Parliament
 - Partnership working, minimum standards, guidance and training
 - Now NHS Pharmacy Contraception Service

Medicines vs NHS Legislation (2)

- Dispensing errors
 - Medicines legislation – defence to criminal offence if conditions met, eg duty of candour
 - Crown Prosecution Service – victims of crime – cultural differences
 - Balance public protection and patient safety
 - NHS – encourage reporting and learning
 - Hospital chief pharmacist – statutory recognition

Controlled drugs

- The law vs myths
 - eg hospitals and digitalisation of drug distribution and storage
- Keeping the law up to date can be slow
 - Balancing HO (harm) and Health (patient care) perspectives
- Managing risk
 - NHS England best practice guidance – Health Building Note 14-2: Medicines storage in clinical areas
 - CQC – supports digitalisation; understand basis of enforcement action
 - Risk assessment

NHS Pharmaceutical Services Regulations

- 2005 Regulations so thick the title was printed on the spine
- Mistakes happen
- Contract vs contractual framework
- Issues with wider policies to reduce regulatory burden

Conclusion

- Complexity and interplay of pharmacy and medicines related legislation
- Making pharmacy law is just one element of enabling change
- The law provides a framework
- Matters are rarely black and white
- Professional practice requires judgment and risk assessment