

Detailed Legal, Ethical, and Regulatory Compliance Checklist

This project adheres to UK regulations for software in healthcare contexts, ensuring it remains a pure informational/navigation tool.

Aspect	Regulatory Requirement	Compliance Measure Implemented	Evidence/Source (as of December 2025)
Non-Diagnostic Status	Must not qualify as a medical device (no diagnosis, treatment, or clinical decision support)	Pure rule-based navigation using public pathways; no interpretation of symptoms as diagnoses; always redirects to professionals	MHRA Guidance: "Software and AI as a Medical Device" (2025); tools providing general information only are not regulated as devices
Medical Device Classification	Avoid qualification under UK MDR 2002 (as amended)	Intended purpose: Signposting only; no monitoring, prediction, or alleviation of disease	MHRA Flowchart for Standalone Software/Apps (2025)
Privacy and Data Protection	Compliance with UK GDPR	No user accounts, no data storage/logging; all processing local to device; anonymized simulations for testing only	UK GDPR Principles; no personal health data handled
Content Accuracy	Based on reliable, public sources	Pathways aligned with NHS Pharmacy First (7 conditions) and urgent red-flag lists	NHS England Pharmacy First Service Specification (2025)
Disclaimers and Safety Netting	Prominent warnings required	Mandatory disclaimers on every page/result; red-flag immediate escalation to 999	Best practice from NHS 111 online and MHRA guidance
Accessibility	Inclusive design for all users	Full WCAG 2.1 Level AA compliance planned and audited	Web Content Accessibility Guidelines 2.1
Post-Market Monitoring	Voluntary for non-regulated tools	Planned user feedback collection (anonymous); monitoring for improvements	MHRA post-market guidance (voluntary for non-devices)
Adverse Incident Reporting	Report if serious issues arise	Not mandatory (non-device), but voluntary reporting pathway established	MHRA vigilance guidance

Additional Notes:

- Confirmed non-medical device status per MHRA 2025 guidance: Informational/navigation apps without diagnostic intent are out of scope.
- Ethical focus: Promotes equitable access, reduces health inequalities by guiding to free NHS services.
- Updates: All sources reviewed as of December 2025; pathways will be maintained if public NHS guidance changes.