

AI-Powered QR Code Drug Information Systems

Transforming Medicine Pack-Based Education, Pharmacovigilance, Adherence and Patient Safety

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Hidoc Journal • Evidence-Informed Product Analysis • 5 August 2026

EVIDENTIARY POSITION This article does not report Hidoc product-performance data. It analyses a public product concept against external evidence and proposes a prospective evaluation framework.

STRUCTURED ABSTRACT

Background	Medication-related harm remains a major patient-safety burden, while medicine packs provide limited space for current, readable and multilingual information. Two-dimensional codes can connect a physical pack to electronic product information, but a scannable symbol alone does not establish authenticity, comprehension, adherence or clinical benefit.
Objective	To analyse an AI-enabled, pack-linked medicine information capability associated with the Hidoc MediBot concept and to define an evidence-based architecture, governance model and evaluation protocol for its responsible deployment.
Methods	A targeted narrative synthesis was conducted using peer-reviewed reviews and primary studies, official health-agency guidance, regulatory documents and technical standards available through 5 August 2026. The analysis separated public product descriptions from external evidence and from proposed, as-yet unvalidated functions.
Results	The literature supports QR and two-dimensional codes as low-friction access points for education, electronic leaflets and selected self-reporting workflows. Digital adherence interventions show small-to-moderate and heterogeneous effects, and recent QR-specific studies are principally feasibility studies. Regulatory examples from Japan, the European Union, Singapore, Australia and India demonstrate movement toward electronic information and traceability, while GS1 guidance requires careful distinction between product-identification carriers and consumer-facing links. Generative AI introduces additional risks of hallucination, inappropriate reassurance, privacy loss and promotional bias.
Proposed evaluation	A three-arm pragmatic trial comparing printed information, static electronic product information and a governed conversational layer should assess comprehension, retrieval accuracy, adverse-event report completeness, adherence, usability, equity and safety errors. Product-specific claims should follow prospective evaluation rather than be inferred from adjacent technologies.
Conclusion	A QR-linked MediBot could become a useful medication-safety interface if it is built on verified product identity, regulator-aligned content, retrieval-grounded responses, explicit escalation pathways, privacy-by-design and continuous human oversight. It should complement—not replace—printed statutory information, pharmacists, prescribers or emergency services.

Keywords: QR code; GS1 DataMatrix; electronic product information; patient information leaflet; medication safety; pharmacovigilance; adherence; generative artificial intelligence; MediBot.

1. Background

Medication use is an information-intensive process. A patient must identify the correct product, understand why it was prescribed, follow the dose and timing, recognise important interactions and adverse effects, store it correctly, and know when to seek help. Each step can fail. The World Health Organization (WHO) estimates that medicines and therapeutic options account for nearly half of preventable harm in medical care, which places communication and medication-use systems at the centre of patient-safety policy [1,2]. The problem is not confined to hospitals. Transitions between clinic, pharmacy and home are particularly vulnerable because the patient becomes the final operator of a complex regimen, often with incomplete recall and limited access to the prescriber.

The medicine pack is the most persistent physical object in that pathway, yet it is a poor medium for layered communication.

Space is limited; statutory text is dense; multiple languages compete for the same surface; and safety information can change after printing. Systematic and scoping reviews of patient information leaflets have repeatedly described problems with readability, navigation, risk communication and practical relevance [3-5]. A printed leaflet remains essential in many jurisdictions and for people without reliable digital access, but it cannot easily offer audio, large type, personal navigation, updated content, source tracing or a direct route to adverse-event reporting.

Two-dimensional codes create a bridge between the physical pack and a digital information environment. A scan can open authorised product information, a patient-friendly explanation, a video, an adherence tool or a reporting form. The code itself, however, is only a pointer or data carrier. It does not guarantee that the destination is current, that the medicine is genuine, that the patient understands the content, or that an artificial-

intelligence response is safe. Product design must therefore move beyond the common proposition of 'put a QR code on the pack' toward a governed scan-to-safe-action system.

This distinction is especially important in India. Bar- or QR-code requirements for specified medicines were introduced through amendments to the Drugs Rules and took effect for the initial group of major brands in 2023. Further Schedule H2 expansion was notified in June 2026 [6-8]. The mandated data elements are primarily oriented to identification and traceability: product code, generic and brand names, manufacturer, batch, manufacture and expiry dates, licence number and other prescribed details. These requirements create infrastructure that can support trusted information access, but they should not be interpreted as proof that every scanned code authenticates a pack or that a consumer chatbot is regulator-approved.

The public Hidoc Dr website describes MediBot as an AI medical chatbot that answers questions on drugs, diseases and treatments, links users to clinical resources, summarises research and supports users within the Hidoc environment [9,10]. Hidoc also publicly presents patient education and WhatsApp chatbot services. This article analyses a logical extension of those capabilities: a medicine-pack-linked interface that opens verified information, offers bounded conversational support, facilitates pharmacovigilance and supports adherence. No publicly available clinical evaluation of this specific pack-linked Hidoc capability was identified. Accordingly, the article treats the capability as a product concept and evaluation target—not as an established clinical intervention.

2. Aim and analytical approach

The aim is to define what an evidence-based QR-linked medicine information system should do, what it must not do, and how it should be evaluated. The paper uses a targeted narrative review rather than a systematic review. Sources were prioritised in the following order: official regulatory and health-agency material; peer-reviewed systematic or scoping reviews; primary feasibility or clinical studies; professional and standards-body guidance; and, only for product description, Hidoc public materials. Searches focused on QR codes, two-dimensional barcodes, electronic product information, electronic patient information leaflets, medication adherence, pharmacovigilance, falsified medicines, generative AI drug information, privacy and cyber security.

Three evidence categories are kept separate. First, 'documented product capability' refers only to functions described on public Hidoc channels. Second, 'supported design rationale' refers to findings from external literature that make a function plausible or useful. Third, 'proposed capability' refers to architecture or workflows recommended in this article but not demonstrated for Hidoc. This hierarchy is necessary because digital-health writing frequently converts technical possibility into implied effectiveness. A patient-safety publication should instead state the evidentiary status of each claim.

Table 1. Evidentiary hierarchy for product statements

Category	Permitted interpretation	Example
Documented capability	A function explicitly described in public Hidoc materials.	MediBot answers drug-related questions and links to clinical resources.
Supported rationale	External evidence suggests the function is feasible or potentially useful.	QR-linked electronic leaflets may improve access and navigation.
Proposed capability	A recommended design not yet demonstrated for the product.	Batch-aware adverse-event intake with regulator routing.
Validated outcome	A product-specific result shown in an appropriate prospective evaluation.	Not currently available for the pack-linked concept.

3. Product concept: from a QR destination to a medication-safety interface

The proposed experience begins when a patient, caregiver, pharmacist or clinician scans a machine-readable symbol on a medicine pack. The system resolves the encoded identifier, checks product and jurisdiction metadata, and retrieves the applicable authorised information. It then presents a layered interface: the statutory label; a patient-oriented summary; language, audio and accessibility options; a conversational question function; adverse-event reporting; reminders; and pathways to a pharmacist, clinician or emergency service.

The architecture should use a 'verified core, adaptive edge' model. The core consists of identity, label text, approved indications, contraindications, warnings, storage conditions and manufacturer or regulator updates. These elements require controlled source ingestion, versioning and approval. The adaptive edge changes presentation—not clinical meaning—by allowing search, plain-language explanation, translation, audio, teach-back and navigation. Generative AI may help the user locate and understand information, but it should not create a new dose, infer an indication, rank treatment options or contradict the authorised source.

A useful interface should also recognise that users have different intents. A patient may ask, 'Can I take this after food?', a caregiver may need a missed-dose instruction, a pharmacist may want the latest label, and a regulator may need a structured adverse-event report. The product must route these intents differently. Low-risk informational questions can be answered from a controlled knowledge base with citations. High-risk questions—overdose, pregnancy exposure, severe allergy, suicidal intent, paediatric dosing uncertainty, or a suspected life-threatening reaction—require immediate safety messaging and human escalation.

Hidoc's public terms describe AI content as informational and not a substitute for professional medical advice [11]. That boundary is appropriate but insufficient on its own. A disclaimer cannot repair a harmful answer. Safety must be implemented through product constraints: permitted sources, retrieval-only fields, deterministic rules for red flags, confidence thresholds, response templates, audit logs and independent clinical review.

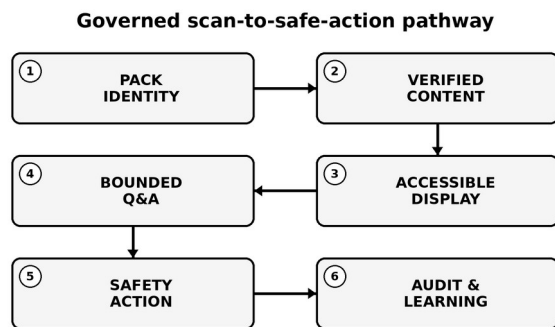


Figure 1. Proposed scan-to-safe-action architecture. The code is an entry point; safety depends on verified identity, controlled content, bounded AI, escalation and audit.

4. Core capability domains

4.1 Product identity and provenance. The first task is to establish what product the user has scanned. Identity should be derived from regulated or manufacturer-controlled data, not from free-text inference by a language model. Where a GS1 DataMatrix carries a Global Trade Item Number, batch, expiry and serial data, the system should parse those elements according to the applicable standard. A consumer-facing QR may use GS1 Digital Link to resolve the same identifier to online content. GS1 Healthcare cautions against using an additional, non-standard QR as the primary carrier for identification and traceability; when a separate QR is used, its role should be limited and unambiguous [12-14].

A critical limitation follows: a static web URL does not authenticate a pack. Counterfeiters can copy the visible code and redirect users to a genuine-looking page. Authentication requires a trusted serialised repository or other verification service capable of determining whether the identifier is valid, duplicated, recalled or otherwise anomalous. The European Union's falsified-medicines framework combines a unique identifier with an anti-tampering device, illustrating that digital identity and physical integrity are complementary controls [15]. The system should therefore use precise labels such as 'product information retrieved' or 'identifier verified' rather than the broader claim 'medicine is genuine' unless the underlying verification supports it.

4.2 Regulated product information. Electronic product information (ePI) is authorised statutory information in a structured electronic form. The European Medicines Agency defines it as the authorised product information that includes the summary of product characteristics, package leaflet and labelling [16,17]. A pack-linked platform should preserve jurisdiction, marketing-authorisation holder, product strength, dosage form, revision date and source URL. It should display the exact authoritative text and make any simplified explanation visibly subordinate to it.

Version control is a safety function, not merely a content-management feature. Each answer should be reproducible against the label version used at that time. Updates require effective dates, review status and rollback capability. A patient who scans an older pack should normally receive the current authorised safety information, while the system retains the ability to explain that the physical leaflet may reflect an earlier revision. Content should be archived for pharmacovigilance investigations and complaints.

4.3 Patient-centred explanation. The digital layer can address limitations of printed leaflets through headings, search, progressive disclosure, illustrations, audio, local-language navigation and adjustable type. The goal is not to shorten everything. It is to help users locate the information needed for a decision while preserving access to the complete authorised source. Evidence on leaflet comprehension indicates that layout,

plain language, numerical risk presentation and testing with target users matter [3-5]. Content should therefore be developed with health-literacy and human-factors methods rather than by automatically summarising the label.

Translation should follow a risk-tiered process. Frequently used patient text can be professionally translated and clinically reviewed. Machine translation may assist with low-risk navigation or draft generation, but high-risk content—contraindications, pregnancy, interactions, overdose and emergency warnings—requires validated terminology and human review. Audio can improve access for users with limited literacy or visual impairment, but it must be synchronised with the approved text and offer replay, speed control and a visual transcript.

4.4 Conversational medicine information. A chatbot can reduce the search burden by allowing natural-language questions and returning a concise answer with links to the exact source section. Retrieval-augmented generation is preferable to an unconstrained general model because it can limit the response context to the correct product, jurisdiction and approved sources. Still, retrieval does not eliminate hallucination. The model can misread a table, merge two strengths, overgeneralise a warning or provide a fluent answer when the source is silent.

Every response should therefore include product identity, a concise answer, source provenance and an action boundary. When evidence is absent or ambiguous, the chatbot should say so and route the user to a pharmacist or prescriber. It should not calculate an individual dose unless a regulator-approved calculator and required patient variables are available. It should not advise starting, stopping, splitting or substituting medicines. Recent evaluations of general-purpose AI for medicine questions have shown variable accuracy and occasional unsafe or inappropriate outputs, supporting the need for controlled knowledge sources and expert testing [18-20].

4.5 Pharmacovigilance access. Adverse-event reporting is often fragmented across manufacturer, regulator and hospital channels. A QR interface can reduce discovery friction by placing a 'report a suspected side effect' action beside the relevant product information. The form can pre-populate product, batch and manufacturer fields from the scan, while asking the reporter to confirm them. It can collect the four minimum elements of an individual case safety report—an identifiable patient, identifiable reporter, suspected product and suspected reaction—then route the report to the appropriate pharmacovigilance system [21].

Automation must not silently discard or causally adjudicate reports. An AI layer may help classify free text, detect seriousness criteria, identify missing information and draft follow-up questions, but trained pharmacovigilance personnel remain responsible for validation, duplicate management, coding and regulatory submission. The platform should clearly state whether the report has been transmitted to the manufacturer, the national programme, both or neither. In India, linkage should align with the Pharmacovigilance Programme of India and applicable marketing-authorisation-holder obligations [21].

4.6 Adherence and self-management. The scan event can launch reminders, dosing calendars, refill prompts, short videos or teach-back questions. Digital adherence interventions have produced positive results in some meta-analyses, but effect sizes are heterogeneous and depend on condition, intervention intensity, outcome measurement and follow-up [22-25]. A QR code is principally an access mechanism; it does not itself change behaviour. The intervention must address a specific cause of non-adherence—forgetfulness, misunderstanding, side-effect concern, regimen complexity, access or cost.

The safest initial design is voluntary and non-punitive. A patient can set reminders without sharing adherence data. Caregiver access requires explicit consent and should be revocable. Missed-dose advice must come directly from the authorised label or pharmacist-approved protocol; where instructions are absent or patient-specific, the interface should

not improvise. Adherence dashboards should distinguish user-reported intake from objectively observed ingestion and should avoid presenting estimated adherence as certainty.

4.7 Professional connection and escalation. A pack-linked system has value when it shortens the route from uncertainty to qualified help. Hidoc publicly describes access to specialists and continuous support within its platform [9,10]. In a patient-facing implementation, escalation should be role-appropriate: community pharmacist for common administration questions; prescriber for treatment changes; emergency services for acute danger; poison-control pathways where available; and manufacturer medical information for product-specific questions. Service hours, response times and jurisdiction should be visible before the user submits personal data.

5. What the evidence currently supports

QR codes have been studied across health education, clinical workflows and cardiology. Scoping reviews describe uses in just-in-time learning, patient information, procedure support, simulation and administrative processes, while also reporting barriers related to device access, connectivity, user familiarity and implementation quality [26,27]. These reviews demonstrate versatility and acceptability; they do not establish a uniform effect on patient outcomes.

More direct evidence is emerging for electronic patient information leaflets. A 2025 mixed-method feasibility study in a South African outpatient setting surveyed 330 patients and 16 pharmacy staff and found substantial practical willingness to use QR-linked leaflets, while identifying access and implementation concerns [28]. Another 2025 publication examined QR-coded patient leaflets as a route to reducing paper use, but environmental benefit depends on actual printing practices, device energy and user behaviour [29]. These studies support feasibility and user testing, not wholesale removal of paper.

QR-specific adherence research is similarly preliminary. The APOLLO-QR study evaluated a QR-based self-reporting method among patients receiving ticagrelor and reported encouraging feasibility and concordance for adherence estimation [30]. Earlier work in older adults with heart disease explored a simple scan-based feedback method [31]. A Taiwanese mHealth pilot linked QR scanning with medication and health management but experienced attrition, illustrating the gap between initial usability and sustained engagement [32]. The appropriate interpretation is that QR access can simplify logging or feedback; sustained adherence benefit remains an empirical question.

Broader mobile-health evidence offers cautious support for reminders and self-management tools. A 2020 systematic review and meta-analysis found an overall small-to-moderate improvement in medication adherence from mobile applications, while later reviews in cardiovascular and chronic-disease populations reported substantial heterogeneity [22-24]. In oral anticancer therapy, a 2024 meta-analysis found no clear pooled adherence advantage despite improvement in some symptom or toxicity outcomes [25]. Product claims should therefore specify the intervention, population, duration and measurement method rather than citing 'apps improve adherence' as a universal conclusion.

The evidence for AI medicine-information chatbots is evolving even faster. Some cross-sectional comparisons report high answer accuracy in controlled question sets, but other evaluations identify incomplete, unsafe or inappropriately confident responses [18-20]. General models may fabricate citations or answer beyond the label. Performance also varies by language and prompt. For a pack-linked system, the clinically relevant metric is not generic benchmark accuracy. It is the rate of correct, complete, source-concordant and safely escalated responses for the exact products, languages and user intents deployed.

6. International regulatory and implementation examples

Table 2. International examples and design lessons

Setting	Observed policy or infrastructure	Design lesson
Japan	Outer-pack code links to PMDA electronic package inserts and related documents.	Use a regulator-controlled destination and current version.
European Union	ePI development plus separate serialisation and anti-tamper safety features.	Do not conflate information access with authentication.
United States	Electronic approved labels, Medication Guides and human-factors labelling guidance.	Link simplified explanations back to approved labelling.
Singapore	Defined e-labelling and QR access to approved materials.	Show content currency and the authoritative source.
Australia	QR/data-matrix use is allowed within continuing printed requirements.	Retain immediately needed printed instructions.
India	Schedule H2 code and data requirements, expanded in 2026.	Build on compliant identity data and apply privacy controls.

Japan provides one of the clearest examples of pack-linked electronic information. Following amendments effective in August 2021, users can scan a barcode or two-dimensional code on the outer box to access the electronic package insert and related documents on the Pharmaceuticals and Medical Devices Agency platform. The policy was designed to improve access to the latest safety information, with paper inserts removed in principle after a transition period [33,34]. The model demonstrates the importance of a regulator-controlled destination and product-code linkage.

In the European Union, ePI is being developed as structured authorised information that complements existing channels. The initiative emphasises accessibility, interoperability and multilingual use while retaining the statutory status of the underlying content [16,17]. Separately, the Falsified Medicines Directive and delegated regulation require safety features for many prescription medicines, including a unique identifier and anti-tampering device [15]. A product interface should not merge these two functions conceptually: ePI provides information; repository verification and physical controls address traceability and tampering.

The United States maintains extensive electronic access to approved labels through Drugs@FDA and DailyMed, while certain medicines require Medication Guides, patient package inserts or instructions for use. The Food and Drug Administration treats labelling as a principal means of communicating safe and effective use and has issued human-factors guidance on carton and container design to minimise medication errors [35,36]. A consumer QR layer should link to, rather than rewrite or replace, the applicable approved source.

Singapore's Health Sciences Authority permits defined electronic-labelling approaches in selected contexts and has used QR codes for approved educational materials, while warning that online publication may lag an approval and directing professionals to the authority's current source [37,38]. Australia permits machine-readable codes under labelling rules but retains printed requirements for information that must be immediately available, including certain preparation instructions [39,40]. Both examples reinforce a hybrid model rather than an assumption of paperless equivalence.

India's Schedule H2 requirements create a major opportunity for standardised identity and consumer access, particularly after the 2026 expansion to additional medicine categories [6-8]. Implementation should, however, avoid three shortcuts: using a marketing QR that is visually indistinguishable from the regulated carrier; calling a successful URL lookup 'authentication'; and using patient interaction data for promotion without valid consent and purpose limitation. India-specific deployment must align with the Digital Personal Data Protection Act, the final rules and sectoral pharmacovigilance requirements [41,42].

7. Implementation considerations

7.1 Barcode and resolver strategy. A manufacturer should first map every stock-keeping unit to a persistent product identifier and the applicable label. The system should support GS1 DataMatrix parsing where present and a GS1 Digital Link-compatible resolver for web access. Redirects must remain stable over the life of the pack. A change in vendor or domain should not break codes already distributed. The visible pack should explain the code's purpose in plain language—for example, 'Scan for current medicine information'—and, where feasible, print the destination domain to help users detect overlays or malicious substitutions.

7.2 Content operating model. A cross-functional content board should include regulatory affairs, medical information, pharmacovigilance, pharmacy, patient communication, privacy and cyber security. Each content object needs an owner, jurisdiction, source, review date and risk class. The board should define which text may be generated, translated, summarised or personalised. Promotional claims and brand messaging must be stored separately from non-promotional safety and medicine information, with distinct approval workflows and analytics access.

7.3 Model and knowledge-base controls. The safest conversational design begins with deterministic answers for common high-risk topics and retrieval-grounded generation for lower-risk navigation. The system prompt alone is not a safety control because it can be bypassed or inconsistently followed. Controls should include product-level source whitelists, structured fields for dose and warnings, response-length limits, refusal and escalation rules, automated contradiction checks, citation verification, and post-deployment review of sampled conversations. Model updates require regression testing before release.

7.4 Human factors and accessibility. The scan page should open quickly on low-bandwidth mobile devices and should not force app installation or account creation merely to view statutory information. Key actions must remain usable with one hand, screen readers and enlarged text. Users need a language choice before consent. Older adults and people with limited digital literacy should be involved in testing. The code should be large enough, have adequate quiet space and contrast, and remain scannable on curved or reflective packaging.

7.5 Privacy and consent. Viewing general product information should not require identification. Consent should be granular for reminders, saved medication lists, caregiver sharing, specialist contact and research analytics. The platform should minimise data collection, define retention periods and allow deletion or withdrawal where applicable. Health information, adverse-event narratives and communication logs are sensitive even when the medicine name is not. India deployment must account for the Digital Personal Data Protection framework and any more specific legal or contractual duties [41,42].

7.6 Cyber security. QR systems are exposed to code replacement, malicious redirects, domain takeover, phishing, automated scraping and denial-of-service attacks. CERT-In has warned about QR-based phishing and recommends verification of domains and secure browsing practices [43]. Operational controls should include HTTPS, certificate monitoring, domain-lock procedures,

tamper-evident placement where feasible, short redirect chains, web-application security testing, rate limits, signed content manifests, real-time anomaly detection and a process to disable compromised destinations without losing access to essential information.

7.7 Integration and service reliability. The system may need interfaces with regulatory content repositories, manufacturer master data, safety databases, customer-relationship systems and pharmacist or clinician services. Each integration creates dependencies. A graceful-degradation design should show the authorised static content even when the chatbot, analytics or appointment service is unavailable. Outage messaging must never replace emergency information. Service-level objectives should cover resolver availability, content freshness and time to correct a safety-critical error.

7.8 Equity and hybrid access. Digital access is uneven by age, income, disability, language, geography and device capability. The presence of a QR code cannot justify removing a readable medicine name, strength, expiry, batch, critical warning or legally required leaflet from the pack. Pharmacies should offer printed or verbal alternatives, and the digital page should permit printing or offline saving. Equity metrics should be reported by language, age group, disability and rurality rather than as a single average engagement rate.

8. Governance, limitations and failure modes

The central governance risk is category error: treating a communication interface as a clinical decision-maker. A user may believe that an AI response is personalised because it is conversational. The product should repeatedly make clear whether it knows the user's age, pregnancy status, renal function, allergies or co-medications—and should generally avoid collecting these variables unless required for a defined, governed function. Without them, the system cannot safely individualise many answers.

Hallucination is not the only AI risk. A response can be technically true but incomplete, poorly prioritised or inappropriate for the user's urgency. It may cite an outdated label, mix a brand with another strength, omit a boxed warning, translate a negation incorrectly, or reassure a patient who needs emergency care. Safety evaluation must therefore examine critical omissions, actionability, escalation and calibration in addition to factual accuracy.

Pharmacovigilance integration creates both opportunity and legal risk. Once a platform receives a suspected adverse event, contractual and regulatory reporting clocks may begin. Social-media-style monitoring, free-text conversations and specialist messages can all contain reportable information. The operating model must define surveillance scope, responsible staff, reconciliation between systems and auditability. Users should not be asked to repeat information unnecessarily, but they must be told how the report will be used.

Promotional influence is another concern. A medicine-information page funded by a manufacturer may subtly favour benefit statements, hide class alternatives or direct patients toward brand engagement. The system should distinguish authorised information, independent education and promotional material visually and technically. Medical and safety content should not be ranked by commercial campaign objectives. Interaction data should not be used to infer disease status for targeting without a lawful, transparent basis.

Authentication claims require special restraint. A verified identifier can be copied; a valid serial can be reused; and a genuine page can be opened from a falsified pack. The system may detect duplication or location anomalies, but it cannot always determine physical authenticity. Pack verification should be described in probabilistic and process-specific terms, with a clear route for reporting suspicious products.

Evidence limitations should also be explicit. Much of the QR literature consists of feasibility studies, surveys, single-centre implementations and educational applications. Long-term adherence, clinical outcomes and cost-effectiveness are not established for a general pack-linked chatbot. Smartphone ownership does not equal willingness to scan, and initial curiosity may not translate into sustained use. Product evaluation must include non-users and failed scans, not only engaged users.

Finally, environmental claims require complete accounting. Replacing some paper may reduce printing and distribution, but a hybrid system still uses packaging, servers, networks and personal devices. Environmental benefit depends on whether statutory leaflets can legally be reduced, how often users print, and the carbon intensity of digital infrastructure. Sustainability should be measured rather than used as an assumed co-benefit.

Table 3. Principal failure modes and minimum controls

Failure mode	Potential consequence	Minimum control
Wrong product or strength match	Incorrect instructions	Identifier parsing, pack confirmation and product-level test cases
Copied or malicious QR	False reassurance or phishing	Trusted resolver, visible domain, monitoring and tamper checks
Outdated label	Missed warning or changed instruction	Version control, effective dates and update alerts
Hallucinated answer	Unsafe action	Restricted sources, deterministic red flags, citations and human escalation
Unreported adverse event	Regulatory breach and lost safety signal	Continuous monitoring, routing rules and reconciliation
Digital exclusion	Unequal access	Printed alternatives, no-login statutory content and accessibility testing
Promotional contamination	Biased medicine information	Separated repositories, approval workflows and audit access

9. Proposed evaluation methodology

9.1 Study objective and design. The first evaluation should test whether the system improves safe understanding and access without increasing misinformation or inequity. A pragmatic, multicentre, three-arm cluster-randomised or stepped-wedge study could compare: (A) usual printed pack information; (B) printed information plus a QR link to static authorised ePI and a reviewed patient summary; and (C) the same content plus the governed MediBot conversational, reporting and reminder functions. Randomisation by pharmacy or clinic would reduce contamination between participants.

9.2 Population and products. The study should include adults receiving medicines for chronic and acute conditions, deliberately oversampling older adults, users with limited health literacy, multiple-language users and people taking high-risk medicines. Initial products should have clear authorised information and manageable clinical pathways. Paediatric dosing, anticoagulation, insulin, oncology, pregnancy-sensitive medicines and controlled substances may require separate protocols or exclusion from the first deployment.

9.3 Primary outcomes. Co-primary outcomes should be (1) objective medication comprehension measured by a validated or pretested questionnaire and teach-back, and (2) safety of information delivery, defined as the proportion of test and real-world interactions with no critical factual error, no critical omission and appropriate escalation. A successful scan is not a

patient-safety outcome. The study should predefine clinically important error categories and use blinded reviewers.

9.4 Secondary outcomes. Secondary measures should include time to locate the authorised answer; successful product match; recall of dose, major warning and missed-dose action; user trust; System Usability Scale score; language and accessibility performance; pharmacist contacts; complete adverse-event reports; reminder uptake; adherence measured through proportion of days covered, pharmacy refill data or electronic monitoring where feasible; health-service utilisation; and cost per successfully informed user. Engagement should be presented as a funnel: packs dispensed, codes visible, scans attempted, destinations loaded, content viewed, questions asked and actions completed.

9.5 AI-specific validation. Before live deployment, a product-by-intent test set should cover common questions, adversarial prompts, spelling variants, local-language expressions and high-risk scenarios. Independent clinicians and pharmacists should rate correctness, completeness, relevance, source concordance, urgency and potential harm. The test should include label updates and intentionally ambiguous product names. Non-inferiority margins for critical-answer accuracy should be stringent, and any unsafe high-severity answer should trigger root-cause analysis rather than being diluted in an average score.

9.6 Pharmacovigilance evaluation. Simulated and real reports should be assessed for successful pre-population, minimum-case completeness, correct seriousness flagging, duplicate detection, routing time, acknowledgement and reconciliation with the safety database. The analysis should compare the proportion of reports that require follow-up and the time required by pharmacovigilance staff. AI coding can be evaluated separately from regulatory submission to avoid conflating assistance with accountability.

9.7 Adherence evaluation. Adherence should be measured only where the intervention contains an explicit behaviour-change component. Self-reported scans should not be treated as confirmed ingestion. Where refill data are available, proportion of days covered can be compared between arms over six to twelve months. Qualitative interviews should investigate why the intervention was ignored, disabled or abandoned. The trial should be powered for the chosen adherence outcome rather than relying on post hoc engagement correlations.

9.8 Equity and privacy analysis. The protocol should compare outcomes by age, gender, language, disability, socioeconomic position, smartphone type and connectivity. Researchers should record whether participants required assistance and whether paper or pharmacist alternatives were used. Privacy outcomes should include consent comprehension, data minimisation, withdrawal success, unauthorised access incidents and the proportion of users able to obtain statutory information without creating an account.

9.9 Statistical and reporting plan. Primary analysis should follow intention-to-treat at the cluster level using mixed-effects models that account for site and product. Missing data and failed scans are outcomes, not exclusions. Safety analyses should report absolute counts and severity. Product updates, model versions and knowledge-base revisions during the trial must be documented. Reporting should follow applicable digital-health trial guidance and include the complete intervention specification so that results can be reproduced.

9.10 Post-market surveillance. After launch, a standing safety dashboard should track wrong-product mapping, broken links, outdated source documents, hallucinations, emergency escalations, suspected counterfeit alerts, adverse-event routing failures, cyber incidents and disparities in access. Thresholds for pausing a product, language or model version should be defined in advance. A public-facing change log and periodic independent audit would strengthen trust.

Table 4. Proposed evaluation domains and decision thresholds

Domain	Illustrative measure	Decision principle
Identification	Correct product/strength/batch mapping	No critical mapping errors in validated deployment set
Comprehension	Teach-back score and critical-warning recall	Superiority to usual information or prespecified clinically meaningful gain
AI safety	Critical error, omission and escalation rates	Stringent non-inferiority; zero tolerance for unmitigated severe errors
Pharmacovigilance	Minimum-case completeness and routing time	Improved completeness without reporting delay
Adherence	PDC/refill or electronic monitoring	Prospectively powered; self-report kept distinct
Equity	Outcome gaps by language, age, disability and connectivity	No material worsening; accessible alternative available
Privacy/cyber	Consent failure, incident and malicious redirect rates	Predefined pause and remediation thresholds

10. Discussion

A pack-linked medicine interface is attractive because it uses an object already present at the point of need. It can reduce search friction and connect fragmented functions—authorised information, education, adverse-event reporting, adherence support and professional contact. The strongest near-term use case is not an autonomous AI pharmacist. It is a reliable resolver and navigation layer that helps the user reach the correct, current source and recognise when human help is needed.

The design creates value by combining multiple modest improvements. Product data can be pre-populated rather than retyped. A patient can hear a reviewed explanation in a preferred language. A pharmacist can verify the current label. A suspected reaction can be reported with the batch captured. A reminder can be created without downloading a full application. Each function is plausible, but their integration increases governance complexity and the possibility of unintended use.

For Hidoc, the strategic advantage is that MediBot already sits within a medical-knowledge and professional-engagement environment described publicly by the company [9,10]. The responsible product path is to use that ecosystem for source governance, specialist escalation and evaluation—not to infer efficacy from platform scale. The first launch should focus on a limited formulary, defined languages and a small set of high-frequency questions. Expansion should follow evidence of safe performance and operational capacity.

The system also offers a useful distinction between information personalisation and treatment personalisation. Presentation can be tailored to language, literacy, sensory needs and the user's question. Treatment advice should remain anchored to authorised content and qualified professionals. This separation allows the interface to become more usable without drifting into unregulated prescribing or diagnosis.

A successful deployment would not be measured primarily by scans, conversation length or campaign engagement. The meaningful outcomes are whether users identify the correct medicine, understand critical instructions, avoid harmful actions, report suspected problems efficiently and reach an appropriate professional when needed. Commercial analytics should remain subordinate to these patient-safety outcomes.

11. Conclusion

AI-enabled QR medicine information systems can convert the pack from a static container into a governed access point for current information and support. The evidence justifies further development and prospective testing, particularly for electronic leaflets, multilingual navigation, adverse-event reporting and defined adherence workflows. It does not justify claims that a QR code or chatbot independently prevents medication errors, authenticates every pack or improves clinical outcomes.

The proposed Hidoc MediBot extension should be built on five non-negotiable foundations: verified product identity; regulator-aligned and version-controlled content; retrieval-grounded, bounded AI; explicit human and emergency escalation; and privacy, cyber security and post-market surveillance by design. Printed and professional channels must remain available. With those controls and a rigorous evaluation programme, pack-linked conversational information could become a useful component of medication safety rather than another unverified digital layer.

Declarations

Author contributions: Both authors contributed to the conception, evidence interpretation, critical revision and approval of the manuscript.

Funding: No external funding is reported for this manuscript.

Conflicts of interest: Varun Gadia is associated with Hidoc Dr. The manuscript is a product and evidence analysis and reports no product-specific clinical outcomes. Dr Sadhana Gadia declares no additional conflict stated for this manuscript.

Data availability: No original patient-level dataset was used. Sources are listed in the references.

Ethics: Ethics approval was not required because the manuscript contains no human-participant research or identifiable patient data.

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