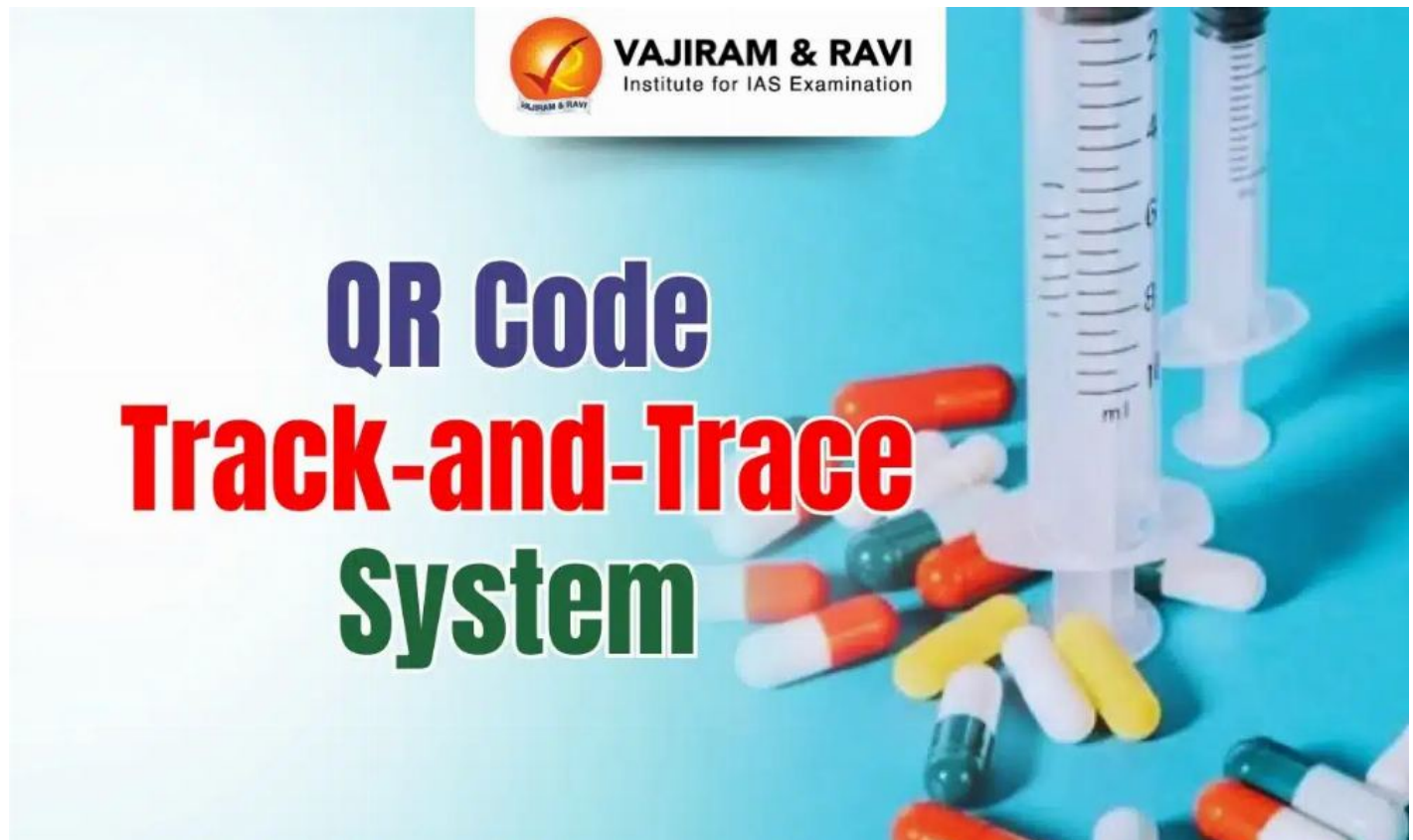


QR Code Track-and-Trace System: India's New Weapon Against Fake Medicines

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QR Code Track-and-Trace System Latest News

- The Centre has mandated that all vaccines, antimicrobials, narcotics and addictive drugs, and anti-cancer drugs must carry a **bar code or QR code** that enables tracking of every vial or blister pack.
- The system will be rolled out in phases: by July 2027 for vaccines, narcotics, and anticancer drugs, and by July 2028 for antimicrobials. The aim is to crack down on counterfeit and spurious medicines.

Track-and-Trace Mechanism

- It is a system that lets regulators and companies follow the entire journey of every single unit of a medicine — from the manufacturing plant right to the retail store.
- Each pack carries a unique code, making it possible to trace exactly where a product is at any stage.
- The system is not entirely new. It already applies to 300 top drug brands, including the gastric reflux tablet Aciloc and the fever medicine Calpol. The recent notification extends it to the four new categories.

How the System Works

- Manufacturers of all medicines listed under **Schedule H2** of the Drugs Rules must affix a unique bar code or QR code on the primary package (or on secondary packaging if space is short).
- A new Schedule H2 was created in the Drugs Rules, 1945 four years ago when tracking first began; it lists the top 300 brands and now the four new categories.
- Beyond the unique identification number for each blister pack or vial, the code must also carry:
 - Brand name and generic name of the drug
 - Name and address of the manufacturer
 - Batch number
 - Date of manufacturing
 - Date of expiry
 - Manufacturing licence number
- Crucially, the system requires manufacturers, wholesalers, distributors, and retailers to log these products on specialised track-and-trace platforms at each stage.

Why It Makes Counterfeiting Hard

- Because each unit carries a unique, one-time code, fraud becomes very difficult:
 - Even if counterfeiters use AI to generate similar-looking codes, the uniqueness of each unit makes large-scale faking hard.
 - Reusing original packaging to refill and sell fake drugs will not work, because once a code is registered on the platform, the same number cannot be re-registered.
- The Health Ministry stated that the enhanced traceability will help authenticate medicines across the supply chain and strengthen regulatory oversight against spurious drugs.

Why the System Is Needed

- The core aim is to **prevent counterfeiting**, which typically takes two forms: releasing products with no active ingredient, or diluting a drug to stretch quantities for sale.
- A track-and-trace mechanism helps regulators:
 - Distinguish whether a spurious drug came from a cost-cutting company or was a completely fake product packaged like a known brand.
 - Identify whether a product was contaminated at the source or tampered with later.
 - Locate every unit precisely in case of a product recall.

The Keytruda Case: Why It Matters for Cancer Drugs

- The relevance for expensive cancer drugs is stark. An investigation uncovered a ring that counterfeited the cancer immunotherapy drug Keytruda.
 - Unscrupulous players partnered with hospital staff to pilfer empty or used vials from cancer units.
 - These were refilled with anti-fungal medicine of similar consistency and sold to patients at a lower price.

- Keytruda can be highly effective — sometimes dissolving tumours — but remains largely inaccessible in India due to cost: around ₹2 lakh per cycle, with patients needing 12-17 cycles.
- Tracking every vial directly targets this kind of fraud.

Challenges in Implementation

- Two main difficulties stand out:
 - **Logging delays.** If a genuine product is logged late and a counterfeit gets registered first, the genuine drug could wrongly appear as counterfeit.
 - **Cost burden.** Companies must build systems to generate unique codes for every packet and log them at every stage. This may be affordable for makers of costly cancer drugs, but a heavy burden for smaller firms making everyday pills.
- Since many Schedule H2 drugs are essential medicines under price control, an expert suggested the government may need to provide monetary support or allow slight price increases during implementation.

Boosting Regulatory Credibility

- The system also aims to raise the maturity level of India's drug regulator. The **WHO** has a benchmarking tool that rates regulators on how drugs are approved, surveilled, tested, and recalled.
- For vaccines, the Indian regulator is already at Maturity Level 3 (the second-best level). Making each vaccine unit traceable is a step towards the highest rating, Maturity Level 4.
- A higher maturity level makes it easier for Indian medicines to be accepted in international markets, as their quality becomes more trustworthy.
- This links the anti-counterfeiting drive directly to the larger goal of strengthening India's standing as the "pharmacy of the world."

Source: IE

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