India–UK FTA May Boost Pharma Exports, But Experts Warn Of Side Effects On Patent Safeguards

Rajesh Kumar | Aug 01, 2025

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While the India-UK FTA opens new doors for Indian pharma, experts caution that subtle shifts in intellectual property norms could weaken safeguards on access to affordable medicines

The recently signed India-UK Comprehensive Economic and Trade Agreement (CETA) is being welcomed by the pharmaceutical industry in India for protecting provisions in the Patent Act, 1970 and

increasing export opportunities. However, experts fear that the agreement may weaken India's safeguards on compulsory licensing and tilt the balance toward big pharmaceutical companies.

According to the Ministry of Commerce and Industry, the CETA does not mandate provisions that extend patent terms or introduce data exclusivity. These are the two common tools used to prolong monopoly rights over drugs beyond the original patent period. This is seen as a major win for India's USD 25 billion generic drug industry, which exports about half of its output globally. The ministry said that Section 3(d) of the Patent Act remains intact and fully protected.

Section 3(d) prohibits companies from extending their patent monopoly by making minor modifications to existing drugs (like changing the form, dosage or salt composition) and claiming them as new inventions, unless they show a significant improvement in therapeutic efficacy.

Commenting on this, **Dr. Milind Antani**, Lead, Pharma, Healthcare, Medical Device and Digital Health Practice at Nishith Desai Associates, says,

> **"The India-UK CETA does not override Section 3(d) of the Patent Act and does not specifically mandate patent term extensions, data exclusivity, or the dilution of Indian patentability criteria, which will also aid Indian generics to enter the market post patent expiry.**

He, however, points to Article 13.47 of the agreement which outlines three categories of patentable subject matter that may be excluded from patent protection. These exclusions cover subject matter whose commercial exploitation would conflict with public order or morality, diagnostic, therapeutic, and surgical methods for treatment of humans or animals, and biological processes for the production of plants and animals (other than micro-organisms). "This could have a soft impact on the pharmaceutical industry," Dr. Antani cautions.

Adding to this, **Ankit Sahni**, Partner at Ajay Sahni & Associates, emphasises that:

> **"The India-UK CETA maintains India's sovereign discretion in patent law by respecting existing flexibilities under the TRIPS Agreement, including vital public health safeguards such as Section 3(d) of the Indian Patents Act. This ensures that while enhanced IP protection is promoted, there remains no dilution of India's carefully calibrated threshold for pharmaceutical patentability**

Article 13.3 of the CETA states that either country retains the right to adopt or amend domestic laws to safeguard public health, nutrition, and the public interest in areas critical to their socio economic and

technological development. Article 13.5 reaffirms both countries' commitments under the World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as well as the Doha Declaration on TRIPS and Public Health.

TRIPS requires countries to provide patent protection for inventions in all fields of technology, including pharmaceuticals, for a minimum of 20 years.

Compulsory Licensing and Voluntary Licensing

Article 13.6 addresses concerns related to access to medicines. It states that both India and the UK recognise voluntary licensing as the preferred mechanism for improving access to medicines. It also clarifies that the agreement does not prevent either country from adopting public health measures and must be interpreted in a manner that supports the protection of public health and the promotion of access to affordable medicines. Importantly, the agreement gives each party the sovereign right to determine what qualifies as a "national emergency" or "circumstances of extreme urgency."

Therefore, this in some sense, although not explicitly, allows for the government to push for compulsory licenses. Compulsory licensing allows the government to permit a domestic company to manufacture a patented drug without the consent of the patent holder during health crises.

Dr. Antani explains, "The CETA recognises and promotes voluntary licensing as the optimal and preferable route for licensing terms to promote access to medicine. There's no explicit reinforcement of India's right to issue compulsory license, which might signal a soft shift in tone or priorities. However, the CETA does emphasise the flexibilities under the Doha Declaration on TRIPS and Public Health adopted in November 2001, which reaffirms each member's right to grant compulsory licences and to determine the grounds upon which they are issued."

As given under Article 13.6, the right to grant compulsory license has not been removed, Dr. Antani notes that the structural and rhetorical preference for voluntary license could "undermine India's flexibility and assertiveness in using compulsory license when needed." He warns that voluntary licenses often carry restrictions, such as territorial limitations, limited licensees, or supply conditions, that could delay access to affordable medicines, limit price competition, or reduce treatment coverage.

Disclosure and Innovation

Article 13.56 modifies the long standing requirement for annual working statements from patent holders. Under the CETA, neither party shall require annual disclosure on the working of patents; instead, if such disclosure is mandated, it must occur at intervals no shorter than three years. According to **Neha Khanduri**, Associate Partner at Singhania & Co:

> **"The India–UK CETA strives to strike a balance between access to medicine and bolstering innovations. The provision entailing disclosure of examination reports relating to the patent application, relevant prior art, related patents and non-**

> **patent literature, shall enable stakeholders to minimise the effort to access the state of art with respect to the invention in question.**

However, Khanduri also points out that the CETA could have gone further. She noted the absence of requirements to disclose divisional applications, patents of addition, or continuation-in-part filings, which could have enhanced transparency. Further, she expresses concern over the dilution of India's traditional disclosure standard through Article 13.56. The shift from annual to triennial reporting limits the availability of timely data.

Soft TRIPS-Plus Shift

When asked whether the CETA introduced any TRIPS-plus standards, Dr. Antani was cautiously analytical.

TRIPS-plus standards go beyond the minimum requirements set in TRIPS. These are typically pushed by countries to protect their pharmaceutical, biotechnology or entertainment industries.

"The CETA does not impose outright TRIPS-plus standards such as patent term extensions, removal of Section 3(d), data exclusivity or automatic patent linkage, which were initially sought by the UK," he says.. "However, it promotes regulatory cooperation and technical alignment, which raises concerns about functional harmonisation."

He further explains that while the text does not codify new TRIPS-plus rules, provisions around voluntary licensing, streamlined opposition rules, and compensation for patent holders could amount to a "soft TRIPS-plus shift" by increasing procedural or economic hurdles to exercising India's existing flexibilities.

Dr. Antani says that increased reliance on voluntary licensing under CETA may dilute India's sovereign policy tools in the long run. "India heavily relies on sovereign IP tools such as compulsory licensing, pre- and post-grant oppositions, and price controls," he says. "The CETA's soft emphasis on voluntary mechanisms subtly reframes compulsory liscenses as a last resort rather than a routine public health safeguard."

He warns that since voluntary licenses are private contracts, they are often negotiated under terms favourable to patent holders. These could include pricing restrictions, supply caps, or export prohibitions.

Working Group on IPRs

Article 13.15 establishes a bilateral Working Group on IPRs composed of government representatives from both sides. This Working Group is required to monitor and review the implementation of safeguards.

Dr. Antani sees both potential and risk in this initiative. "The Working Group could offer important benefits such as providing a formalised venue for ongoing discussions. If India actively participates, it

could ensure that its public health priorities, such as access to affordable medicines, are consistently articulated."

The Working Group, he notes, could also serve to clarify ambiguous provisions in the CETA, prevent disputes, and ensure technical support is tailored to India's developmental needs. However, he remains cautious: "While it appears neutral on the surface, it carries a high risk of serving as a mechanism to align India's IP regime with stricter global norms and become a vehicle for functional harmonisation and incremental TRIPS-plus alignment."

He warns that constant engagement in such a forum could lead to subtle but powerful shifts in policymaking, particularly if driven by international commercial interests. "Commercial interest of global stakeholders might steer Indian policymaking toward global industry expectations, rather than local developmental or public health realities," he says. "The implementation of guardrails for the functioning of the Working Group remains to be seen."

The CETA is expected to help Indian companies grow their presence in the UK's USD 45 billion pharmaceutical market. Around 99 percent of Indian pharma exports now qualify for zero tariffs in the UK.

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This analysis is primarily based on responses prepared by the team at Nishith Desai Associates. The contributing experts also include:

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