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A REVIEW ON COMPARATIVE STUDY OF NEW DRUG APPLICATION (NDA) REQUIREMENTS FOR PHYTOPHARMACEUTICALS AND SYNTHETIC DRUGS

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ABSTRACT

Phytopharmaceuticals sit somewhere between traditional herbal medicine and synthetic new chemical entities (NCEs), and the New Drug Application (NDA) or marketing authorisation requirements built around them differ greatly from those for synthetic drugs, with these differences shifting depending on which jurisdiction you're looking at. This review compares NDA-equivalent requirements for phytopharmaceuticals and synthetic drugs across three major regulatory systems: India's Central Drugs Standard Control Organisation (CDSCO), the US Food and Drug Administration (FDA), and the European Medicines Agency (EMA). Working from primary regulatory texts, the New Drugs and Clinical Trials Rules 2019, 21 CFR Part 314, and Directive 2004/24/EC, alongside peer-reviewed literature found through a structured search of PubMed, ScienceDirect, Google Scholar, and the agencies' own databases, the analysis maps out the preclinical, clinical, CMC, and post-marketing data each pathway actually demands. India turns out to be the outlier among the three: it's the only jurisdiction that requires full Phase I–III clinical trial data for phytopharmaceuticals on terms close to those a synthetic NCE would need. The US, by contrast, channels botanical products mainly through a dedicated Botanical Drug Guidance pathway that comparatively few products make it through (just two approved Botanical NDAs against more than 800 Investigational New Drug submissions), while the EU leans heavily, 71.1% of registered products, on a simplified traditional-use registration that asks for no clinical trial data at all. This divergence carries real consequences for development cost, timeline, and where a company chooses to launch a plant-derived medicine first. The review also points to specific gaps in India's current framework, among them the absence of phytopharmaceutical-specific toxicological thresholds and clearer standardisation guidance, and argues that closer alignment with ICH and WHO principles, paired with something like the EU's tiered evidentiary model, could make India's approval process more predictable and more productive without loosening patient safety standards.

KEYWORDS: Phytopharmaceuticals, New Drug Application, synthetic drugs, CDSCO, FDA, EMA, regulatory comparison, botanical drugs, drug approval pathway, NDCT Rules 2019.

1. INTRODUCTION

What kind of product a medicine is largely decides how it gets to market. A synthetic new chemical entity (NCE) follows a well-worn path: defined chemical structure, reproducible synthesis, and a fairly linear run of preclinical and clinical studies that ends in Phase III confirmatory trials, whether the application is called an NDA in the US, an MAA in the EU, or a New Drug application under India's rules. Phytopharmaceuticals don't fit this mould as neatly. India defines them as purified, standardized fractions of a medicinal plant carrying at least four identified bioactive or phytochemical markers,[1] but a plant extract is not a single molecule. Its composition shifts with geography, season, and how it was cultivated, and yet regulators

have, over time, come to expect evidence packages that look a great deal like those required of synthetic drugs.[9]

Three jurisdictions have answered this tension in three quite different ways. India folded phytopharmaceuticals into the same "new drug" category as synthetic NCEs in 2015, putting them under CDSCO and, broadly, the same clinical burden.[4,6] The US never created a separate legal category at all — botanical products simply move through the FDA's existing IND/NDA machinery, helped along since 2016 by a Botanical Drug Development Guidance that makes room for partially characterized, multi-constituent mixtures.[11] The EU went a third way, building a tiered system under Directive 2004/24/EC where most registered herbal products rely on a simplified traditional-use route that asks for no clinical trial data at all, reserving the full marketing-authorisation burden for a smaller subset of products.[7]

No single piece of existing literature lines these three models up side by side at the level of individual data requirements. Some work examines India's framework on its own [8]; other work surveys herbal medicine regulation globally without zeroing in on NDA-specific comparisons [6]; still other work looks closely at EU registration patterns in isolation.[7] This review tries to close that gap directly, by building a structured comparison rather than treating each jurisdiction as a separate story.

1.1 OBJECTIVES

- Compare, data element by data element, what India, the US, and the EU actually ask for from a phytopharmaceutical submission versus a synthetic drug submission.
- Where the numbers exist, quantify how each pathway actually performs in practice — not just what the rules say, but how many products move through each route.
- Identify specific gaps in India's current phytopharmaceutical framework relative to its international counterparts.
- Propose concrete, evidence-grounded recommendations for improving regulatory clarity and approval throughput in India.

2. METHODOLOGY

This is a literature-based comparative review. No primary clinical, laboratory, or survey data was generated. The search covered PubMed/MEDLINE, ScienceDirect, Google Scholar, and SpringerLink, alongside the official repositories of CDSCO (cdsco.gov.in), the US FDA (fda.gov, ecfr.gov), and the EMA (ema.europa.eu). Search terms combined "phytopharmaceutical," "botanical drug," "herbal medicinal product," "New Drug Application," "NDCT Rules 2019," "21 CFR 314," "Directive 2004/24/EC," and "regulatory comparison" in various pairings. Primary legal texts, Gazette notifications, the Code of Federal Regulations, EU directives, were pulled directly from official government and agency sources rather than secondary summaries. Peer-reviewed sources published in English between 2014 and 2026 were given priority, though foundational regulatory texts were cited regardless of age where they remain in force. An article made the cut if it directly addressed phytopharmaceutical or synthetic drug regulatory requirements in at least one of the three jurisdictions. Sources dealing only with complementary or alternative medicine systems outside formal drug regulation, AYUSH-only products not classified as phytopharmaceuticals, for instance, were left out of the core comparison, though a few are referenced for context.

3. Regulatory Framework for Synthetic Drugs (NDA Pathway)

3.1 India — New Drugs and Clinical Trials Rules, 2019

India regulates new chemical entities through the New Drugs and Clinical Trials Rules (NDCT) of 2019, which replaced Part XA and Schedule Y of the older Drugs and Cosmetics Rules, 1945. Spanning 13 chapters and eight schedules, the NDCT brought in fixed review timelines and a more risk-based approach to monitoring clinical trials.[10] For a synthetic NCE, the Central Licensing Authority wants the full package: pharmacognostic and chemical characterization, preclinical pharmacology and toxicology, Phase I through III clinical data, and a complete CMC dossier, before granting marketing permission. Once approved, a drug keeps its "new drug" status, and the regulatory obligations that come with it, for four years unless the rules say otherwise.[5]

3.2 United States — 21 CFR Part 314

The content and format expected of a US New Drug Application sits in 21 CFR Part 314, particularly Section 314.50. A complete NDA needs an application form, an integrated safety and effectiveness summary in tabular and graphic form, the full nonclinical pharmacology and toxicology record, CMC information sufficient to pin down identity, strength, quality, and purity, complete clinical study reports across every trial phase, proposed labeling, patent certification, and pediatric use data where relevant.[2] Applications filed under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act generally need a sponsor's own, independently generated safety and effectiveness data; 505(b)(2) applications can lean on the FDA's prior findings or published literature for parts of that package instead.

3.3 European Union — Centralized Procedure

The EMA runs a centralized marketing authorisation procedure under Regulation (EC) No 726/2004. A single application, built in the internationally standard Common Technical Document (CTD) format, can earn a marketing authorisation good across every EU member state at once. As in the US and Indian systems, a centralized application for a synthetic NCE needs complete preclinical pharmacology and toxicology data, Phase I–III clinical data, and a CMC dossier, reviewed

by the EMA's Committee for Medicinal Products for Human Use (CHMP) before the European Commission makes its final call.

3.4 Structural Convergence Across Jurisdictions

The legal architecture differs across all three systems, but the actual shape of a synthetic-drug submission doesn't differ all that much, because India, the US, and the EU are all either ICH members or substantially aligned with ICH's standards. The ICH M4 guideline is what gives the CTD format its common shape across NDA, NDA-equivalent, and MAA filings worldwide. That convergence on the synthetic-drug side makes the divergence on the phytopharmaceutical side, covered next, stand out more sharply: none of the three jurisdictions had a comparable harmonization mechanism to lean on when they each built their own botanical regulatory approach.

4. Regulatory Framework for Phytopharmaceuticals

4.1 India — CDSCO Phytopharmaceutical Pathway

India gave phytopharmaceuticals their own legal identity through Gazette Notification G.S.R. 918(E), the 8th Amendment to the Drugs and Cosmetics Rules, 1945, dated 30 November 2015. Under that amendment, a phytopharmaceutical drug is a purified, standardized fraction of a medicinal plant, or a part or extract of one, carrying at least four bioactive or phytochemical markers that have been both identified and quantified, meant for therapeutic use.[6] The notable part is jurisdiction: this puts phytopharmaceuticals under CDSCO rather than the Ministry of AYUSH, which still governs classical Ayurvedic, Siddha, and Unani formulations under a much lighter framework.[1]

Rule 122E treats a phytopharmaceutical as a "new drug," which pulls in the data requirements set out in Appendix IB of Schedule Y: botanical identification and authentication, standardized extracts with quantified markers, preclinical safety and pharmacology work, and Phase I through III trials to show safety and efficacy. In practice, this tracks fairly closely with the synthetic NCE pathway described in 3.1.[8] There is some relief built in, though: phytopharmaceuticals already on the market for more than five years, or backed by enough published safety data, can qualify for abbreviated requirements.[6]

4.2 United States — FDA Botanical Drug Pathway

The US never built a category equivalent to India's. Botanical products aiming for drug status simply go through the standard IND/NDA process, though the FDA has put out specific guidance, most recently the 2016 revision of its Botanical Drug Development Guidance, to handle the particular headaches of multi-constituent, only partially characterized plant mixtures, especially when it comes to designing late-phase trials.[11] Products that skip the drug-approval route altogether can instead be sold as dietary supplements, which need no FDA premarket approval for safety or efficacy. That's a materially easier bar, and one that simply isn't on the table in India once a product makes a therapeutic claim.

The numbers here are worth sitting with. FDA Botanical Review Team records show a steady stream of botanical development activity, upward of 800 IND and pre-IND meeting requests logged by the end of the study period, spread across almost the full range of the agency's review divisions. Set against that volume, actual approvals have been rare: at the time of writing, the agency had cleared only two botanical products for marketing, sinecatechins (Veregen) in 2006 and crofelemer (Fulyzaq/Mytesi) in 2012 (Figure 1).

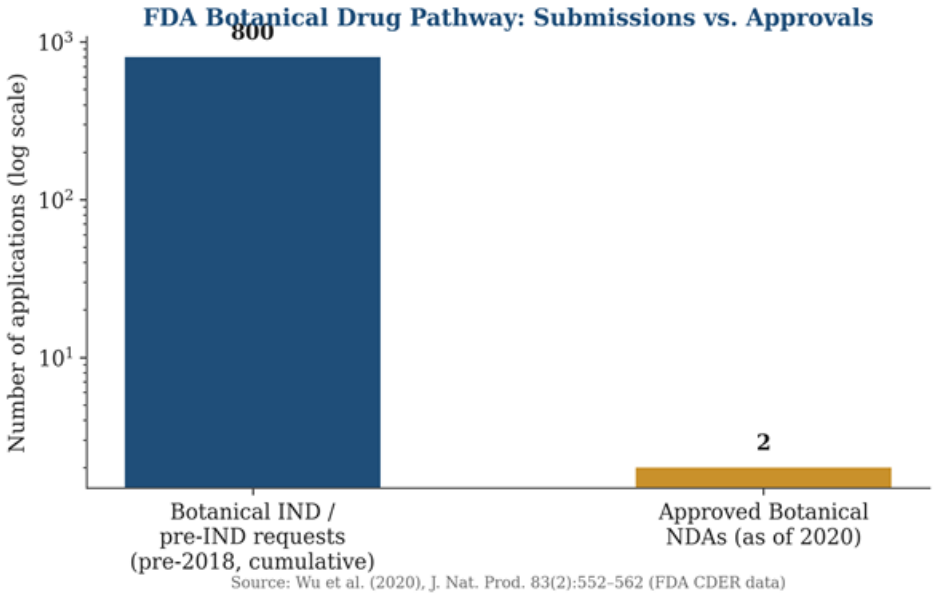

Figure 1: FDA Botanical Drug Pathway: cumulative Botanical IND/pre-IND submissions (pre-2018) versus approved Botanical NDAs as of 2020. Note logarithmic y-axis. Source:. [11]

4.3 European Union — Traditional Herbal Medicinal Products Directive (THMPD)

The EU took a third path entirely. Directive 2004/24/EC, which amended the earlier Directive 2001/83/EC, sets up three parallel routes rather than one single track. A product can register as a Traditional Herbal Medicinal Product (THMP) on the strength of at least 30 years of documented use, 15 of them within the EU, leaning on bibliographic safety and efficacy evidence instead of fresh trials. It can instead seek Well-Established Use (WEU) status, which does require safety and efficacy data, whether from the sponsor's own studies, the published literature, or some mix of the two, though generally regarded as a lighter lift than full clinical development. Or it can go for full marketing authorisation, held to the same standard as any synthetic NCE, complete preclinical and clinical data included.[3,7]

Looking at how the EMA has actually processed herbal substances shows just how much the simplified route dominates in practice. Between 2004 and the end of 2016, the EMA assessed close to 190 herbal substances at European level, and the great majority were resolved through the light-touch route: 150 monographs issued, against just 13 list entries and 19 public statements.[7] Over that same period, EU Member States granted 1,719 traditional-use registrations and 859 full marketing authorisations for herbal products (Figure 2).[7] In other words, most plant-derived medicines on the EU market are processed through the traditional-use pathway that India's framework has no real equivalent of.

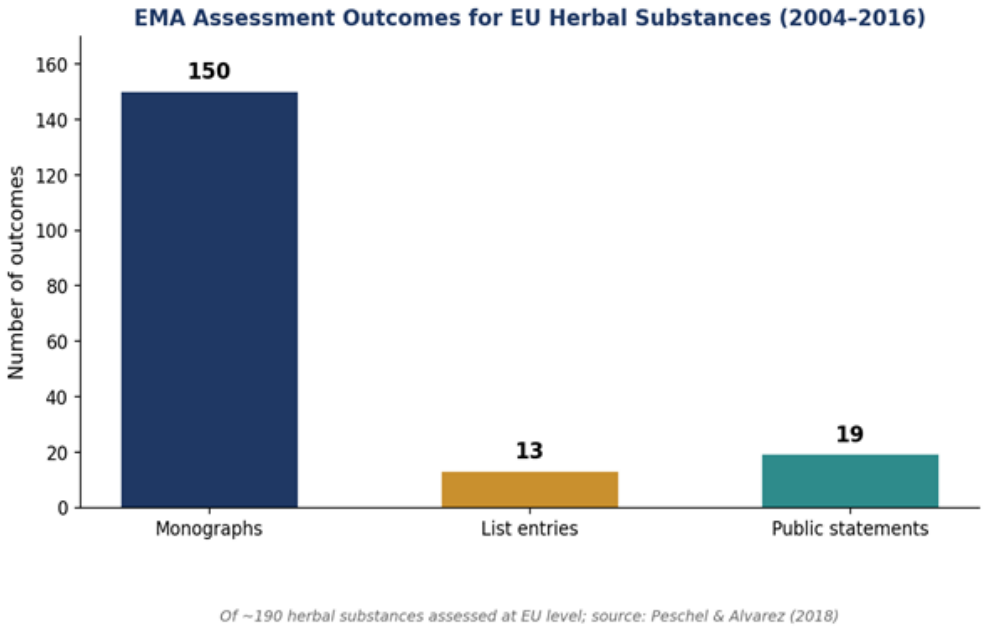

Figure 2: EMA assessment outcomes for herbal substances evaluated at EU level, 2004–2016. Source: Peschel & Alvarez (2018).[7]

5. Comparative Analysis

Table 1 takes everything laid out in Sections 3 and 4 and lines it up side by side, across all six combinations of phytopharmaceutical and synthetic pathways in the three jurisdictions. As far as the authors can tell, this particular comparison hasn't been assembled in one place before.

Table 1: Comparative data requirements for phytopharmaceutical and synthetic drug regulatory submissions across India, the USA, and the EU. PV = pharmacovigilance; API = active pharmaceutical ingredient. Compiled by the authors from the primary and secondary sources cited in Sections 3 and 4.

Data Element	India Phytopharma-ceutical	India Synthetic NCE	USA Botanical Drug	USA Synthetic NDA	EU THMP / Synthetic MAA
Governing regulation	NDCT 2019; G.S.R. 918(E)	NDCT 2019	21 CFR 314; Botanical Guidance 2016	21 CFR 314	Dir. 2004/24/EC; Reg. 726/2004
Botanical/chemical identification	Mandatory	N/A (single API)	Mandatory	N/A (single API)	Mandatory (THMP & MAA)
Minimum bioactive markers	≥4 markers	N/A	No fixed minimum; case-by-case	N/A	Per Ph. Eur. monograph

Preclinical toxicology	Required (28–90 day, 2 species)	Required	Required	Required	Not required (THMP); Required (MAA)
Clinical trials (Phase I–III)	Generally required	Required	Required for Botanical NDA	Required	Not required (THMP); Required (MAA)
Bibliographic/traditional-use evidence accepted in lieu of trials	Limited (>5 yrs market use)	No	No formal provision	No	Yes (THMP: ≥30 yrs use)
CMC / quality dossier	Required	Required	Required	Required	Required (all pathways)
Pharmacovigilance / post-market surveillance	Phase IV; ADR reporting	Phase IV; ADR reporting	Standard FDA PV requirements	Standard FDA PV requirements	Required (all pathways)
Regulatory authority	CDSCO / DCGI	CDSCO / DCGI	FDA – CDER	FDA – CDER	EMA – HMPC / CHMP

Three patterns stand out from Table 1. First, India is the only one of the three jurisdictions where the default phytopharmaceutical route carries a clinical trial burden roughly on par with a synthetic NCE, and there's no formal tiered alternative like the EU's traditional-use registration to fall back on. Second, the US, having no dedicated phytopharmaceutical category, effectively forces plant-derived products into one of two extremes: the comparatively easy dietary-supplement route (no premarket approval, but no therapeutic claims either) or the full Botanical NDA route (synthetic-drug-level burden), with nothing in between. That binary setup may well explain the steep gap between submissions and approvals seen in Figure 1. Third, the EU's three-tier system is the only one of the three that formally lets traditional-use evidence substitute for clinical trial data rather than merely supplement it, and its own registration numbers (Figure 2) show this option getting used by a clear majority of products.

There's a practical implication buried in this for an Indian phytopharmaceutical developer thinking about where to launch first: the EU's well-established-use pathway may, for a botanical with decent published safety and efficacy literature behind it, actually turn out to be a less demanding route to market than CDSCO's own domestic pathway. That's a counterintuitive point, and one that doesn't seem to have been spelled out explicitly elsewhere in the comparative literature.

5.1 Visual Synthesis of Comparative Regulatory Rigor

Figure 3 turns the qualitative comparison in Table 1 into a visual summary, scoring each pathway's relative data demands on a 0–3 scale (0 meaning not required, 3 meaning full synthetic-NCE-equivalent requirement) across five core regulatory domains. It's worth being clear about what this scoring is and isn't: it's an analytical synthesis the authors built from the qualitative descriptions in Sections 3 and 4, not a number reported directly by any one source. Treat it as an interpretive aid, not a precise index.

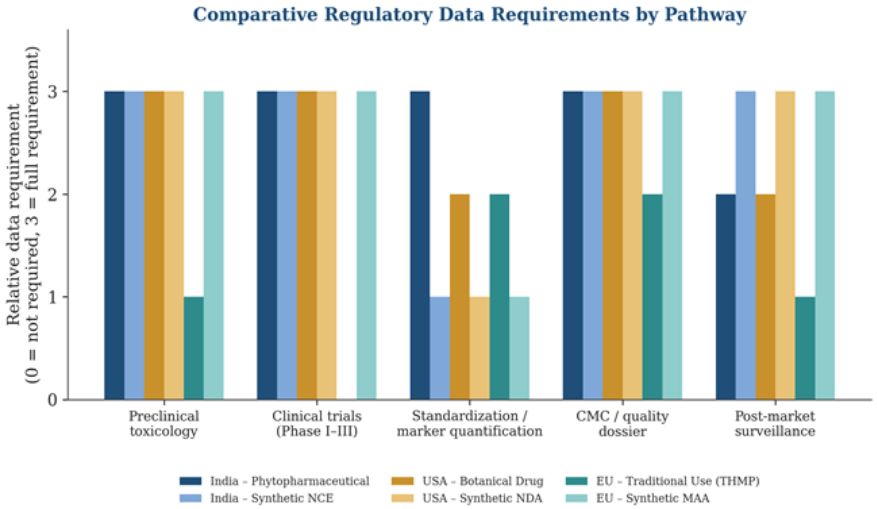

Figure 3: Author-constructed comparative scoring of relative regulatory data requirements by pathway and domain, synthesized from the qualitative requirements described in Sections 3 and 4. Scale: 0 = not required, 3 = full synthetic-NCE-equivalent requirement.

One thing the chart makes visually obvious: standardization and marker quantification is the single domain where every phytopharmaceutical pathway imposes a requirement that simply has no parallel in synthetic drug regulation, which makes sense given the basic difference between one fully characterized molecule and a multi-constituent botanical mixture. On the other end, the EU's traditional-use pathway is the only phytopharmaceutical-type route here that scores at or near zero on both preclinical toxicology and clinical trials, which is really what marks it out as the outlier among the models examined.

6. Key Differences and Regulatory Gaps

6.1 Evolution of India's Phytopharmaceutical Framework

India's phytopharmaceutical framework didn't appear all at once. The term first showed up in Indian regulatory discourse in 2013, the legal category followed in 2015, and a string of institutional and quality-standard developments have trailed along in the years since (Figure 4).

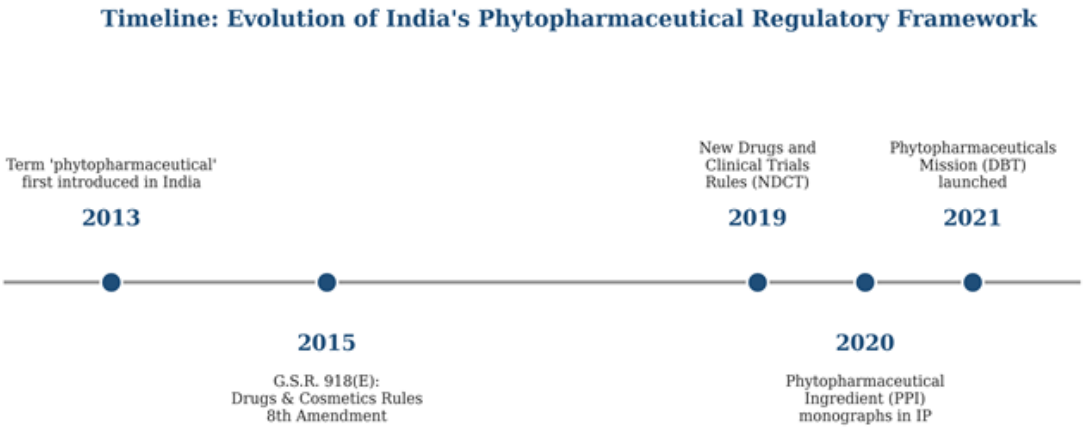

Figure 4: Timeline of key milestones in the evolution of India's phytopharmaceutical regulatory framework, 2013–2021. Compiled from. [6,8]

6.2 Specific Gaps Identified in India's Framework

Even with a decade of development behind it, India's framework still falls short of its US and EU counterparts in a few specific ways:

- No phytopharmaceutical-specific toxicological thresholds. Where the FDA has its own Botanical Drug Guidance, CDSCO hasn't issued anything comparable that spells out toxicological endpoints distinct from default synthetic-NCE expectations, so sponsors end up applying synthetic-drug standards by analogy.[8]
- No tiered evidentiary pathway. India has nothing resembling the EU's traditional-use registration, so a botanical with decades of documented safe use gets no regulatory credit for that history, unlike its EU counterpart.[7]
- Overlap and ambiguity with AYUSH. Similar botanical products can land under either AYUSH or CDSCO depending on formulation and marketing claims, a classification problem the more cleanly tiered EU system doesn't really have.[6,8]
- Limited regulatory throughput. Despite the 2015 legal recognition, the number of phytopharmaceutical applications actually submitted to and approved by CDSCO has stayed modest, something the literature attributes more to high development costs, perceived AYUSH-equivalence, and general regulatory uncertainty than to any shortage of viable candidates.[8]

6.3 Comparative Standardization Burden

As Figure 3 shows, standardization and marker quantification is where phytopharmaceutical pathways pull furthest away from synthetic drug regulation across all three jurisdictions, simply because no synthetic NCE pathway has anything to compare it to. Within that domain, India is more procedurally specific than either the US or the EU: it asks for at least four quantitatively assessed bioactive markers, where neither of the other two sets a fixed minimum, judging standardization instead on a case-by-case or monograph basis.[6,7] That specificity cuts both ways. It gives sponsors clearer guidance, but the literature also points out that it can act as a barrier for botanicals whose activity doesn't reduce neatly to four or more discrete, measurable markers, a limitation CDSCO guidance acknowledges but hasn't yet resolved.[9]

7. Challenges and Industry Perspective

Beyond the text of the regulations themselves, the literature points to several practical issues shaping how these three frameworks actually work day to day. In India, high development costs paired with a clinical burden close to that of a synthetic NCE hit smaller

manufacturers and academic-origin candidates hardest, since they typically lack the capital reserves of larger pharmaceutical firms.[9] And the geographic, seasonal, and cultivation-dependent variability built into plant-derived raw material makes the kind of consistent batch-to-batch standardization that all three systems demand genuinely difficult, no matter which evidentiary route a sponsor takes.[6]

In the US, not having a dedicated phytopharmaceutical category leaves sponsors choosing between two extremes: dietary supplement status, easy market entry but no therapeutic claims allowed, or full Botanical NDA development, which costs about as much as developing a synthetic drug. The wide gap documented between IND-stage botanical activity and approved Botanical NDAs.[11] lines up with the idea that many sponsors simply find that binary choice commercially unappealing next to the supplement route.

In the EU, the THMPD's traditional-use pathway has clearly lowered the bar for products with a long history of use, but that same feature has drawn its share of criticism. Implementation hasn't been even across member states; registrations cluster heavily in a handful of countries. And some analysts have pointed out that leaning on bibliographic rather than experimental evidence can, in certain cases, create a level of regulatory confidence in efficacy that the underlying clinical evidence doesn't really back up.[7]

One more challenge cuts across all three systems: phytopharmaceutical regulation has barely been touched by ICH harmonization. Synthetic drug regulation benefits from the CTD format giving India, the US, and the EU a shared submission architecture; nothing equivalent exists for phytopharmaceutical or botanical submissions specifically, so each jurisdiction has had to work out its own evidentiary model independently. That absence of harmonization adds real cost and complexity for any phytopharmaceutical program aiming for simultaneous or sequential approval across more than one of these markets.

8. Future Directions and Recommendations

Based on the comparison above, a few recommendations follow, aimed mainly at strengthening India's CDSCO framework while drawing on what's worked, and what hasn't, in the US and EU systems:

- Issue phytopharmaceutical-specific toxicological and clinical endpoint guidance. CDSCO could build a dedicated guidance document, along the lines of the FDA's Botanical Drug Development Guidance, spelling out acceptable toxicological thresholds and clinical endpoints that don't simply default to synthetic-NCE expectations. This alone would cut down a lot of current interpretive ambiguity.[8]
- Consider a tiered evidentiary pathway. A formal mechanism similar to the EU's well-established-use or traditional-use registration, letting bibliographic or long-term-use evidence substitute for new clinical trials under defined conditions, could meaningfully improve approval throughput for phytopharmaceuticals that already have a substantial safety history, without India needing to adopt the EU's lighter-evidence model wholesale for every product.
- Clarify the AYUSH/CDSCO boundary. Clear, product-level classification criteria would cut down the current ambiguity that lets similar botanical products end up under very different regulatory burdens depending on formulation and marketing claims.
- Strengthen quality infrastructure. Continuing to expand Indian Pharmacopoeia phytopharmaceutical ingredient monographs, and building out dedicated drug testing laboratory capacity on top of the existing CSIR-IIIM initiative, would support more consistent standardization assessment across applications.[8]
- Pursue selective international harmonization. Engaging directly with ICH and WHO on phytopharmaceutical-specific guideline development, instead of relying on synthetic-drug ICH guidelines applied by analogy, would cut duplicative data requirements for Indian manufacturers chasing approval in more than one market at once.

  These are offered as directions worth considering, not a finished policy prescription. Working out which of them matters most, and how feasible each really is, would need real engagement with CDSCO, industry, and academic regulatory science groups, not just a literature review.

9. CONCLUSION

This review set out to compare, data element by data element, what India, the US, and the EU each require for a phytopharmaceutical New Drug Application versus a synthetic one. Prior literature has covered pieces of this ground, single-jurisdiction deep dives, broader surveys, but not, as far as could be found, in this consolidated, side-by-side form. What comes through clearly is that the three jurisdictions have landed on genuinely different answers to the same underlying problem: how do you evaluate the safety and efficacy of a complex, naturally variable, multi-constituent plant product using a regulatory architecture that was really built with single, fully characterised synthetic molecules in mind.

India's CDSCO framework, with its synthetic-NCE-equivalent clinical burden and few tiered alternatives, is the most demanding of the three systems looked at here. The US's binary structure, supplement status on one side, full Botanical NDA development on the other, has produced a wide gap between development-stage activity and actual market authorisation. The EU's three-tier model, where most products lean on simplified traditional-use registration, is the most permissive of the three, though not without its own well-documented limits

around evidentiary rigour and uneven implementation across member states. For India specifically, closer engagement with international harmonisation, dedicated phytopharmaceutical technical guidance, and a real tiered evidentiary pathway all look like concrete, evidence-grounded ways to improve regulatory clarity and approval throughput, building on a decade of real but still unfinished progress since the phytopharmaceutical category was first established in 2015.

Declarations

Conflict of Interest

The author(s) declare no conflict of interest.

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Ethical Approval

Not applicable; this is a literature-based review involving no primary data collection from human or animal subjects.

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