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Indian Biosimilars Industry - Roadmap to Actualize Global Leadership

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Contents

Indian Domestic Market for Biosimilars: Success thus Far and Roadblocks Ahead

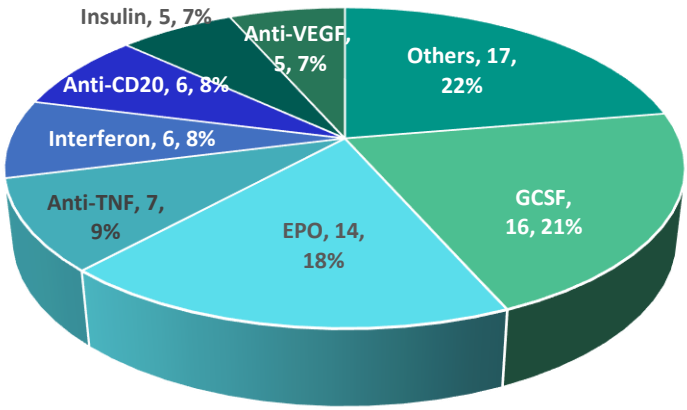
Indian Domestic Market for Biosimilars

Success thus far & Approval Track Record

The Indian pharma industry has come a long way in elevating itself from a large volume low cost manufacturer of small molecule generics to being an active participant in the higher value biosimilars segment. With India being one of the earliest markets to open for similar biologics, there has been a long track record of approvals in the country. Currently there are over 70 biosimilars approved in India. While the first biosimilar draft guidance was released in 2012, first approved biosimilar in India dates back to 2000, and approvals prior to the biosimilar guidance were through an abbreviated new drug pathway dealt on a case-to-case basis.

The most popular biosimilars in India by number of current approvals are first generation Granulocyte Colony Stimulating Factors (GCSF) and Erythropoietin (EPO) products. Molecules wise, Epoetin alpha for anemia, filgrastim for low blood neutrophil and rituximab for oncology and autoimmune indications are some of the most crowded biosimilars in India, with 11, 10 and 6 biosimilar brands approved respectively.

New-Innovator Biologicals and Similar Biologicals Approved in India by Drug Class



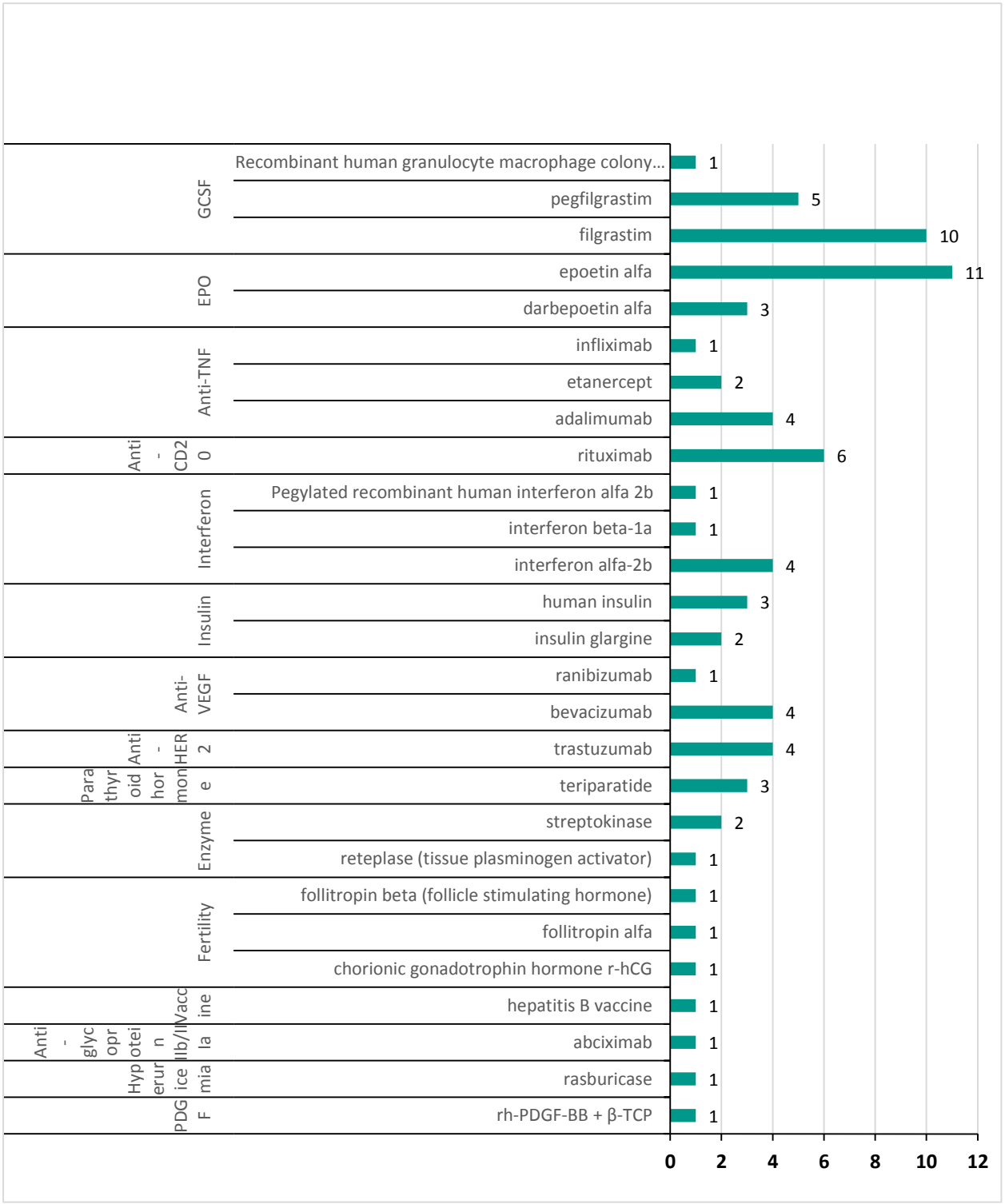
While there is large diversity in approved biosimilar products, there is just a handful of companies holding noteworthy number of product registrations, with a long tail of companies with lesser number of product approvals.

# Product Approvals	Companies
20	Reliance Lifesciences, Intas Pharma
7	Biocon
12	Cadila Healthcare, Wockhardt, Dr Reddy's Laboratories
7	Hetero, Emcure, Shantha Biotechnics
12	Claris Lifesciences, Torrent, Zenotech Labs, USV, Virchow Biotech, Lupin
8	Cadila Pharma, Bioviz Technologies, Biocad, Epirus BioPharma, Ranbaxy, Gland Pharma, Serum Institute, Cipla

However, the competition gets more intense at the commercial end, with several manufacturers also exploring a contract manufacturing business model for their biosimilars, resulting in larger number of marketers for many of the above products. Pertinent examples[1] include Filgrastim with 10 product registrations, but 33 marketers and Pegfilgrastim with 5 product registrations and 15 marketers.

[1] Source: IPSOS data, June 2017

Non-Innovator Biologics & Similar Biologics Approved in India by drug class & molecule[2]



[2] Source: Company websites and other publically available documents

2016 Revised Guidelines – Key attributes and implications for industry

Although biosimilar guidance in India has been in existence since 2012, there has been excessive global criticism on the lax regulatory requirements of the guidelines. With many of the currently approved biosimilars having gone through this old pathway, Indian-made biosimilars are viewed in an inferior lens in global markets. India released its revised biosimilar guidelines in 2016, which overcomes several pitfalls in the earlier guidelines with respect to patient safety. The main changes in the revised guidelines include

- Allowing use of reference drug approved in India or any other ICH country
- Minimum study sizes of 100 patients for clinical studies and single arm studies ae no longer permitted
- Post-marketing studies are mandated for additional safety validation with a minimum study size of 400 patients

The new guidelines have been widely appreciated in the global biopharma community as being suitable to the developing country context but having sufficient safeguards and threshold of validation required to ensure patient safety. With the new guidelines, Indian companies are now better-placed competitively to leverage India as a hub for development and manufacturing of biosimilars.

Roadblocks Ahead for Sustainable Success

Although there is an active engagement landscape in biosimilars as demonstrated by the sheer number of approved products in the country, there are several roadblocks hindering the market from reaching its true potential.

i. Relatively Small Market Size and Poor Volume Penetration despite Price Control

Biologic drugs in general has remained sub-optimal in penetration in developing markets such as India, mainly due to affordability qualms. Lack of national insurance schemes also render the market to be largely out of pocket in nature, which exacerbates the problem multifold. Although the advent of biosimilars was expected to overcome affordability barriers, the same has not been translated to reality, as exemplified in the below case study on Trastuzumab.

Being the largest biosimilar market in India, market size for the drug is relatively lower than one would expect, at ***INR 286 crores***[3] in 2017 (including originator sales). With the first Trastuzumab biosimilar launched in 2013, the pace of growth and market development is glaringly unimpressive for such a crucial drug compared to other benchmarks in Indian pharma market, such as gliptins/insulin in chronic care setting or private market vaccines such as varicella. As outlined below, this poor market development is not for want of price rationalization but is rather attributable to extremely low volume penetration.

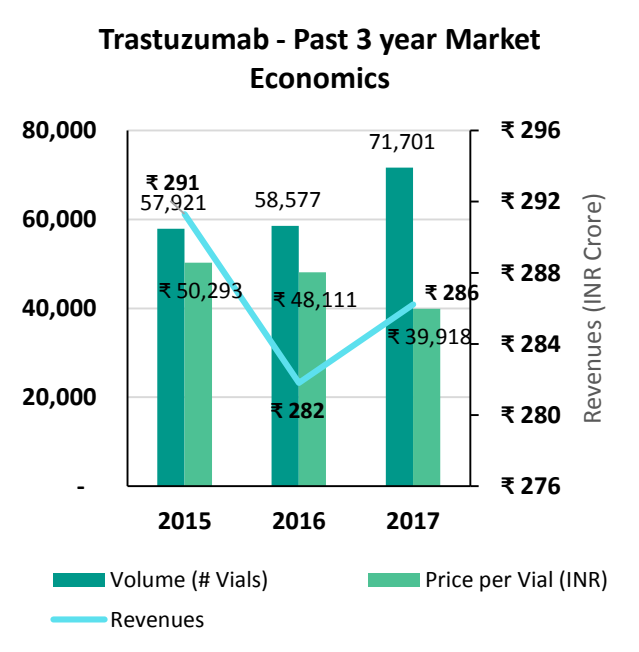
[3] Source: IPSOS data, June 2017

Volume Penetration of Trastuzumab in India: A Case Study

Trastuzumab is prescribed for HER 2 positive breast cancer as neoadjuvant/ primary systemic therapy as well as Adjuvant therapy. Neoadjuvant chemotherapy refers to medicines that are administered before surgery most probably to reduce the size of the tumor prior to surgery, while adjuvant therapy refers to administration of trastuzumab after surgery, mainly to prevent recurrence of the disease. Apart from these breast cancer indications, trastuzumab is also prescribed for HER 2 positive metastatic gastric cancer.

	Breast Cancer	Gastric Cancer	Total
5 year prevalence in India -2012	3,97,000	45,000	
Incidence of Disease in India	1,45,000	63,000	
HER 2 Positive Cases - Target market for Trastuzumab	15%	22%	
Target Population for trastuzumab treatment (based on incidence and prevalence)	Adjuvant Therapy: 37,800 Neoadjuvant Therapy: 21,750	9,900	69,450
Annual Volume Requirement of Trastuzumab (based on dosing regimen) (kg)	Adjuvant Therapy: 262.5 kg Neoadjuvant Therapy: 75.5 kg	36.8 kg	374.8 kg
Annual Volume Sales of Trastuzumab (kg)[4]			29.2 kg
Volume Penetration of Trastuzumab			7.8%
Volume Penetration of Biosimilar Trastuzumab			4.7%

As seen in above table, the current market penetration of trastuzumab in India is abysmally sub-optimal at less than 10%. It is evident that, at the ***current cost of care for overall therapy estimated at close to INR 7 lakhs per patient per year***, access to care is a looming challenge. Moreover, market data shows that although prices have eroded significantly in the past 3 years, it has only contributed to marginal volume expansion. This further evidences that the market has reached an equilibrium state with respect to affordable population at the current price economics. Hence, substantially expanding market access



[4] Source: IPSOS data

hereon and enhancing ROI for manufacturers is contingent on expanding access to population where overall therapy is currently unaffordable.

Analyzing current pricing economics, we note that prices for most biosimilars in India, are at their lowest globally, with many essential drugs including trastuzumab already price capped by the National Pharmaceutical Pricing Authority (NPPA). On top of this, there are about 10 competitors for trastuzumab in India (Source: IPSOS data, public resources) competing on price, which further brings the prices down. However, considering that most biosimilars including trastuzumab are IV infusions, dispensing of drugs is heavily controlled by hospital channels. While companies provide discounts on list price to win business of hospitals, pricing benefit is not necessarily transferred to the patient, and potentially has no impact on expanding access. Even if prices were to be slashed any further to enable better affordable access, there is negligible scope for expanding value realization for manufacturers without additional initiatives covering overall cost of care. Thus, biosimilar manufacturers lack the incentive to further rationalize price to expand market penetration in this landscape. Thus, concerted multi-stakeholder efforts involving clinical education, expansion of adoption net and most importantly, coverage for overall cost of care in oncology is needed to rescript the current landscape.

ii. Slow Pace of Portfolio Development and Sunk Costs as Deterrents to Investment

Indian biosimilar companies also lag behind their global peers in terms of pace of portfolio development. Time to market is of crucial essence in biosimilars as rapid price erosion implies that only the first few companies to market reap maximum benefit. In this backdrop, most Indian companies continue to chase first generation assets, while the global peer group is embarking on second and third generation biosimilar opportunities. This lag in contemporariness of portfolio stems from problems at multiple levels. Firstly, even larger companies lack the risk appetite to invest substantially in yet-to-open high value markets due to the high degree of binary risk. The quantum of investment required for a biosimilar development is twenty to hundred times the investment required for a small molecule generic. While this is a significant leap for even large companies, smaller companies lack the financial wherewithal to pursue assets at a pace aligned with global peers. At this pace, by the time Indian made assets reach markets, markets erode significantly, making ROI questionable. Thus, there is an urgent need for Indian companies to upgrade portfolio robustness to match global standards.

Market access and scale-up in RoW markets has also been slower than anticipated. Several assets approved under the earlier regulatory framework don't necessarily have robust data packages as needed for registration in several RoW countries. This has further delayed market entry in export markets and has limited RoI for early entrants.

Given this context, several companies are straddled with sunk investments in first and second generation biosimilars (including monoclonal antibodies) in assets that have limited merit to

advance into clinical validation and approved products that have not reaped financial returns as expected. In most cases, this serves as a deterrent to expansion of corporate investment commitment. Supporting creation of more attractive market dynamics and tangible comfort on RoI will be critical to address this investment bottleneck and catalyze greater level of corporate engagement.

iii. Need for improving manufacturing competency

Manufacturing competency and technical expertise is the cornerstone for success and long-term sustainability in the biosimilars market. Another key challenge in the road to biosimilar success in the country is lack of access to state of the art manufacturing technology for bio-manufacturing competence. Although biosimilar development in India dates back close to two decades, several companies still grapple with issues related to high performance clones that ensure lean and efficient manufacturing capability. Yield maximization is key in boosting value generation and sustained competitiveness in both domestic and export markets. As prices erode, yield becomes paramount for viable business continuity. This needs attention early on as it is complex to make upstream technology changes for marketed products. Hence, upstream technology development needs greater focus (especially cell line and clone development) across the industry. While technology access from global sources can address the problem in the near term horizon, in-country capacity building is needed for a long term solution.

ROW Markets:
Need For Expanding Markets and Value Realization Potential

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Semi-regulatory markets with regulatory rigor similar to that of India have so far been the next logical step for the biosimilar portfolio for most Indian companies. ROW markets have been attractive for companies with lower risk appetite or capital allocation to the segment as they demand relatively lower regulatory rigor.

However, the real risk profile is far from acknowledged, with multiple levels of market entry as well as access concerns in semi-regulated markets. Although these markets present lower investment profiles and thus appear to be near term low hanging markets, they also present lower rewards, making ROI questionable.

Lack of Regulatory Harmony, a Market Entry Risk

Regulatory pathways are highly country specific and un-harmonized with country level approvals needed for most markets. This in turn makes the entire commercialization effort heavily time consuming, thereby delaying market entry and value realization. The time and efforts laid in gaining market access in multiple small opportunity countries result in high sunk costs and also rob companies of precious time, investment and resources.

Low Market Maturity, a Significant Risk for Market Access and Realization of Return

While regulatory approvals present a market entry risk, lower market maturity presents an added layer of market access risk. High price of biologics have always limited penetration in emerging markets; and biosimilars hold the promise of smashing affordability barriers and expanding access. However, in reality, penetration of biosimilars have been sub optimal in many ROW markets. This is similar to the concerns discussed above on uninspiring levels of market expansion in India. Most ROW markets have high level of out-of-pocket payments with lower level of payor influence. The multi-stakeholder approach needed for market creation has been largely amiss. The low level of market maturity implies relatively smaller markets in each geography.

Bridging Studies for Indian-made Assets

Apart from the above market entry and access related challenges, difficulties also persist in the level of market readiness of Indian-made assets for approval in these semi-regulated markets. Considering very few Indian biosimilars are approved under the new biosimilar guidance released in 2016, most of the molecules approved under the old regulatory framework are likely to need significant bridging studies for semi-regulated markets. Even under the new guidance, significant differences could exist for marketability in other markets. For instance, at least one repeat dose in-vivo toxicity study is sufficient in either rodent or non-rodent models for approval in India, with adequate justification on choice of species under the new guidelines, while repeat-dose toxicity studies in two species (one rodent and one non-rodent) are required by some countries. Additionally, some countries such as Mexico also require clinical bridging studies to be done in the local population. Such requirements

warrant additional investments and combined with uncertainty stemming from low market maturity, decrease the overall value realization potential for Indian companies.

Regulated Markets: The Need to Catalyze Greater Market Thrust

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While there are close to 70 biosimilars approved in India, and more than 20 companies are active participants in product development for domestic market, only a few companies have as of now committed critical level of investment for foray into regulated markets. Several factors such as disparity in regulatory rigor, quantum of investment and uncertainty about the levels of market maturity have served as deterrents for Indian biosimilar players to actively pursue regulated markets. Europe has been a pioneer in the biosimilar regulatory landscape; and with greater expanse of single payor markets triggering the shift, markets in Europe have evolved to a greater degree. The US market for biosimilars is relatively more nascent given long-standing FDA reticence that has only recently started to recede. As the regulated markets embrace biosimilars and move towards higher market maturity, it is optimal time for the industry to expand thrust on regulated markets, that will constitute majority of the near term global markets by value.

European Landscape: More Established Markets, yet Mixed Levels of Penetration

Biosimilar usage is growing rapidly in Europe but the market penetrations of different biosimilars varies considerably across European countries due to the varied incentives, purchasing policies, distribution channels and awareness of concerned authorities such as physicians and pharmacists.

The European Medicines Agency (EMA) established a set of harmonious rules and guidelines that manufacturers must follow in order to get their biosimilar evaluated and approved centrally. This was a major first step that Europe adopted in increasing patient access to biologic medicines at affordable prices.

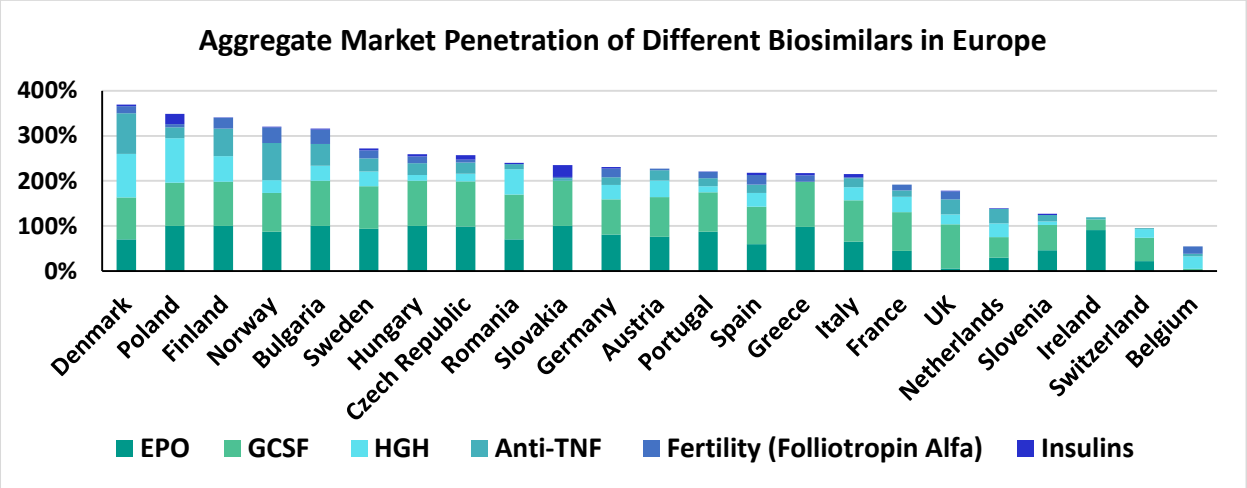
Although there is a central governing body that makes decisions regarding the approval and indications of new biosimilars, the decisions of interchangeability are left to individual countries. In addition to this, countries also specify their own policies regarding pricing, purchasing and utilization of biosimilars and their originator medicines. Since incentive policies applied to biosimilars are heterogeneous across countries, it leads to unique market access regimens. These vastly different environments in European countries has resulted in highly varied levels of penetration for the same biosimilar in different countries. The level of penetration, along with other factors, determines the level of competition and price erosion.

Table in the subsequent page shows data published by Quintiles IMS for European Commission services[5], for biosimilar penetration across countries and therapy classes.

[5] https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf

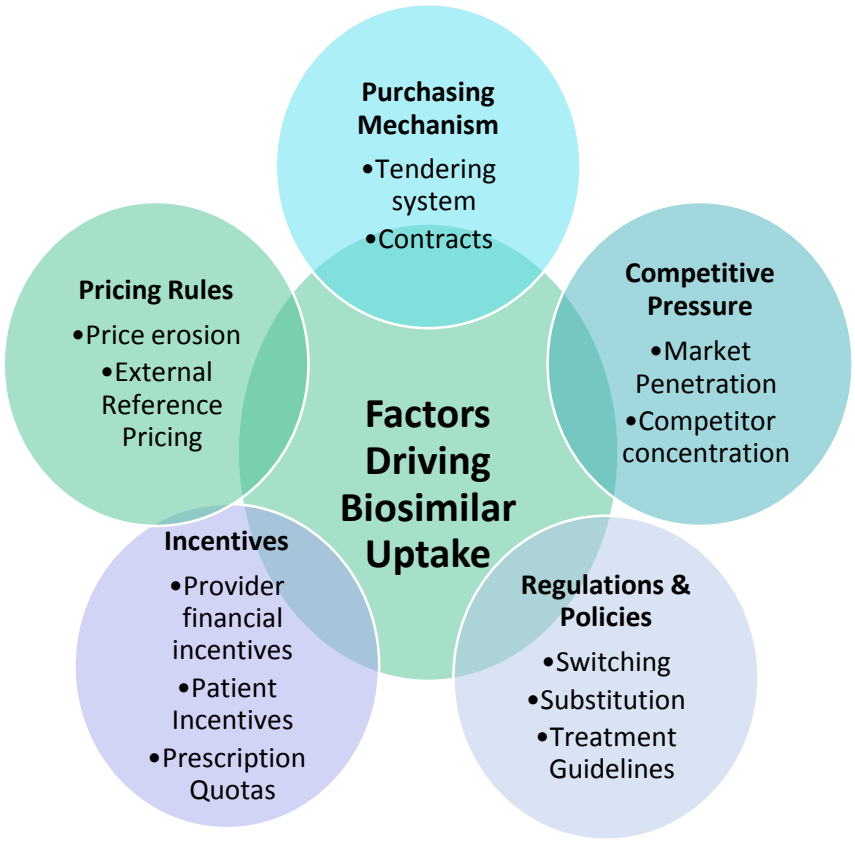
Country	EPO	GCSF	HGH	Anti-TNF	Folliotropin Alfa	Insulins
Denmark	70%	93%	97%	90%	16%	3%
Poland	100%	96%	99%	24%	7%	23%
Finland	100%	98%	57%	61%	24%	1%
Norway	87%	86%	29%	82%	35%	1%
Bulgaria	100%	100%	34%	48%	32%	2%
Romania	70%	100%	56%	11%		3%
Sweden	94%	94%	33%	29%	18%	4%
Greece	98%	100%	0%		14%	5%
Hungary	100%	100%	13%	26%	15%	5%
Czech Republic	99%	100%	17%	25%	6%	10%
Slovakia	100%	100%	0%	6%	3%	26%
Germany	81%	78%	32%	17%	19%	4%
Austria	76%	88%	37%	23%	3%	0%
Portugal	87%	88%	13%	18%	14%	1%
Spain	60%	83%	30%	19%	21%	5%
Italy	65%	92%	29%	20%	2%	7%
France	45%	86%	34%	14%	13%	0%
UK	6%	98%	22%	33%	18%	1%
Netherlands	30%	45%	31%	32%	0%	1%
Slovenia	46%	56%	8%	14%	0%	3%
Ireland	91%	23%	0%	5%	0%	0%
Switzerland	22%	52%	19%	2%		0%
Belgium	2%	3%	28%	5%	17%	0

As seen in the chart, the range of biosimilar uptake can vary vastly from country to country in Europe, with some countries such as Denmark, Finland, Poland and Bulgaria witnessing much higher penetration across products than many of the other developed countries such as Germany, France and UK.



Wide ranges of market penetration can also be observed between different therapy areas in a single country, such as UK which has only a 6% share for Epoetin alfa and a high 98% for GCSF. Another trend observed is that Insulins and Follitropin Alfa biosimilar have a low market penetration in most countries in Europe, with the highest being 35% and 26%, respectively.

Analysis of the varying uptake levels points to many intercrossing factors playing a significant role in driving biosimilar adoption at the country level:



Purchasing Mechanism

Purchasing policies play a significant role in driving biosimilar adoption at the country level. Firstly, it is important to note that the retail sector and hospital sector in most European countries vary as the hospital sector is more stringently regulated and controlled through the use of tenders and contracts. Single winner tenders, such as national tenders reflect very high uptake levels soon after the launch of the biosimilar. This is exemplified in the case of rituximab biosimilars which reached 80% volume share in less than 6 months in Norway[6]. Other countries such as Germany have contract based purchasing in which negotiations occur directly between manufacturer and insurer. Such contracts and other multiple tender models (hospital tenders, regional tenders) lead to multiple biosimilars entering the market at the same time. As such, single authority/single payor tendering has led to benchmark levels of adoption in an accelerated manner with lower levels of adoption in multiple tendering markets.

Competitive Pressure

Given the lower expanse of out of pocket markets in Europe, competitive pressure could result in greater price erosion in a tendering or contracted buying context and faster price rationalization resulting in wider adoption. In markets where there are multiple payors, more number of competitors could imply greater share of voice for stakeholder engagement and hence could help push the boundaries of adoption.

Regulations & Policies

Favorable regulations and policies can provide a custom tailored path for biosimilars to enter the market quickly and efficiently. Across Europe, switching of biologicals is allowed at the physician level; intensity of encouragement differs in the hospital and retail market. While switching is acceptable, substitution at pharmacy level without recommendation of the physician is not allowed in most countries in Europe; one of the exceptions seen is in Poland.

Incentives

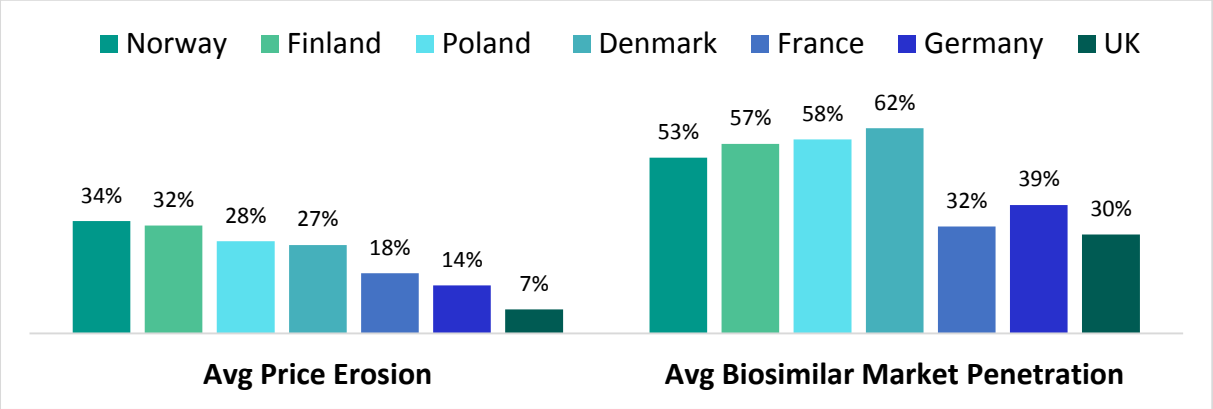
Direct incentives are offered by payers to different stakeholders to influence product choice and there are also indirect incentives relating to funding, and reimbursement.

Pricing Rules

Pricing rules are in place to ensure that there are sufficient price drops in biosimilars across all products, maintain a healthy competition and also level the playing ground between originator product and biosimilars. Level of price erosion has a direct correlation with adoption, as seen in the chart below. In countries where there is a higher level of price erosion (Denmark, Norway, Finland and Poland), there is also higher level of biosimilar uptake compared to countries with lower level of biosimilar penetration (Germany, France, UK).

[6] Advancing Biosimilar Sustainability in Europe, IQVIA Institute for Data Science, September 2018

External reference pricing is present in around half of the European countries which provides guidelines on price slashing for new biosimilars and is another factor that could potentially drive uptake.



US Markets: Nascent Market Backdrop, with newfound Regulatory Clarity

While the US is the largest near term market for biosimilars, the USFDA has been slow to warm up. US FDA's historically slower pace of embracing biosimilars is a known point of debate in the pharma world, with just one approved biosimilar (Sandoz's filgrastim) until early 2016. The US market for biosimilars has truly opened only in 2016 and the year 2017 was a landmark year with back to back biosimilar approvals, ushering in an era where the biosimilar opportunity is more tangible. As of October 2018, there are a total of 13 approved biosimilars in the US which is a highly commendable feat, considering the short time span in which this has been achieved.

Medicine Name	Active Substance	Marketing Authorization Holder	Authorization date
Zarxio	filgrastim	Sandoz	06-03-2015
Inflectra	infliximab	Celltrion	05-04-2016
Erelzi	etanercept	Sandoz	30-08-2016
Amjevita	adalimumab	Amgen	23-09-2016
Renflexis	infliximab	Samsung Bioepis	21-04-2017
Cyltezo	adalimumab	Boehringer Ingelheim	25-08-2017
Mvasi	bevacizumab	Amgen	14-09-2017
Ogivri	trastuzumab	Biocon/ Mylan	01-12-2017
Ixifi	infliximab	Pfizer	13-12-2017
Retacrit	epoetin alfa	Pfizer	15-05-2018
Fulphila	pegfilgrastim	Biocon/ Mylan	04-06-2018
Nivestym	filgrastim	Pfizer	01-07-2018
Hyrimoz	adalimumab	Sandoz	31-10-2018

Challenges Limiting Market Potential in US Biosimilars

While the past 2 years have been extremely fruitful in terms of regulatory openness in US, tangible commercial success of biosimilars in the market has been limited by several factors:

i. High investments amid high competitive threat to market share in regulated markets

The cost of development of a single biosimilar for regulated markets ranges north of $100 million, ranging anywhere between $ 150 million – $ 200 million. With such high investments, and price erosions in Europe having breached 60% thresholds, even for billion dollar markets, financial viability and ROI is bleak beyond the first 5 competitors. Considering such high criticality in time to markets, the business case and profitability weakens for later entrants, thus limiting value realization and commercial success. For instance, Sandoz's recent decision to abandon rituximab biosimilar after FDA required generation of additional data is a classic example of how any stretch on time to launch threatens value realization in the high investment regulated markets.

ii. Concerns surrounding interchangeability and automatic substitution

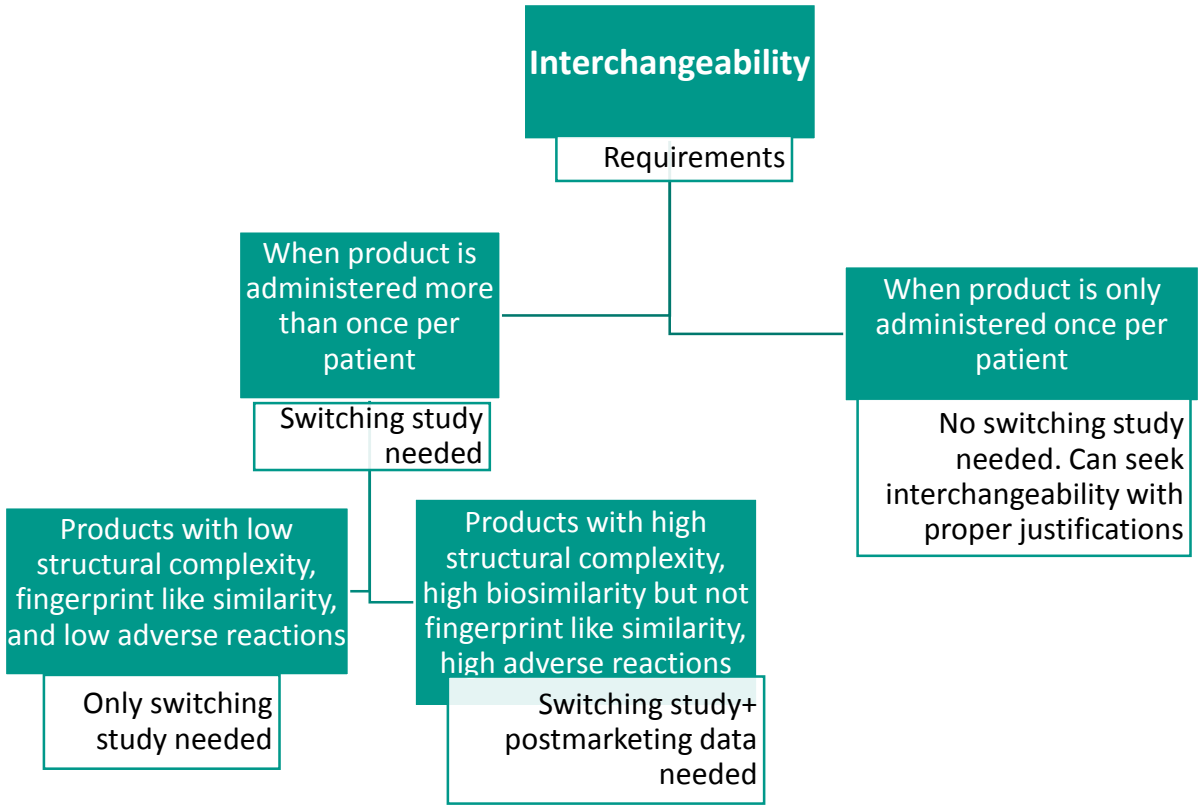
Automatic substitution of originator drug with biosimilars and switching between originator drugs and biosimilars are critical considerations that can impact uptake of biosimilars. While automatic substitution does not yet prevail in EU for any approved biosimilar, EMA, per its revision of the 2005 guidelines, leaves the decision on interchangeability to the EU Member States. On the other hand, in US, the regulatory uncertainty on biosimilar substitution has long been a big market access concern for manufacturers because, although an interchangeable biosimilar product can be substituted for the reference product without provider intervention, no approved biosimilars were deemed interchangeable so far by the USFDA. A welcome development in this direction was the Biosimilars interchangeability guidance issued in 2017.

Biosimilars Interchangeability Guidance

The Biosimilars Interchangeability Draft Guidance was issued in early 2017 specifying data and information required from switching studies by sponsors to establish interchangeability. The additional requirements to establish interchangeability are summarized in the image in subsequent page.

The switching study is expected to be designed in a way that there is a study with a lead-in period of treatment with the reference product, followed by a randomized two-arm period—with one arm incorporating switching between the proposed interchangeable product and the reference product (switching arm) and the other remaining as a non-switching arm receiving only the reference product (non-switching arm). This guidance is still in draft status and there is some level of manufacturer concerns with respect to some terminologies such as "fingerprint-like" which are quite subjective. However, the guidance has lifted some level of

ambiguity surrounding biosimilar substitutability and if executed will foster better consumer confidence on biosimilars.



iii. Slow-evolving co-operation from the payor and prescriber communities

Patient influence in brand choice is very limited and there is no incentive to shift from originator drug to biosimilars as long as insurance covers the drug. Thus, payors and providers/ prescribers play a larger role in influencing switching. Considering no approved biosimilars in the US are deemed interchangeable so far, prescriber comfort is heavily lacking for switching patients to biosimilars and this is a serious factor affecting biosimilar uptake. There are no signs of immediate change as interchangeability guidance is still new, remains a draft and the prescribed switching studies are time-consuming. On the other end, while there is significant cost benefit from biosimilars warranting substantial payor thrust on biosimilars, with interchangeability being a clinical decision, payers remain apprehensive about providers pushing back. With oncology being a high risk disease category, payers are also apprehensive about mandating switching without stamp of the regulator. Additionally, some large payers have heavy discount contracts on innovator drugs linked to not favoring biosimilars. This causes an additional layer of complexity in biosimilar adoption. With such challenges hampering true potential of biosimilars in the US, future market access is heavily dependent on how interchangeability evolves and level of discount provided by biosimilar manufacturers to large payors to incentivize switching.

iv. Innovator counter strategies to circumvent biosimilar competition

Given large single product revenue contribution of blockbuster biologics to originator companies, it is only natural that they do everything in their power to sustain their market positioning and prolong commercial exclusivity. Such roadblocks include aggressive direct to consumer marketing and legal settlements. Innovator companies have well-structured television ads promoting biologics (Ex: Enbrel, Humira, Remicade), and some go to the extent of advising superiority of innovator brand over biosimilars. At the other end, innovators exert financial muscle in waging hard-hitting legal battles against biosimilar companies, pushing for legal settlements delaying biosimilar market entry. Examples of such settlements are highlighted in the table below:

Drug	Innovator	Biosimilar	Biosimilar Manufacturer	Approval	Nature of Settlement
Humira	Abbvie	Amgevita Hyrimoz Imraldi Hulio MSB11022	Amgen Sandoz Samsung Bioepis Mylan Fresenius Kabi	US - Sep2016 EU - Mar2017 EU – July2018 US – Nov2018 EU – May2018 EU – Sep2018 Pipeline asset	To launch in US in July/ September/ November 2023 and in Europe upon approval
Enbrel	Amgen	Erelzi	Sandoz	US - Aug2016 EU - June2017	Ongoing patent suit
Herceptin	Roche	Ogivri	Mylan-Biocon	US - Dec2017	Global settlement at confidential terms for withdrawal of patent challenges

While such challenges have impacted commercial success of biosimilars in the US market so far, it is clear that the regulator has already taken cognizance of the prevailing issues, as the new Biosimilars Action Plan (BAP) issued by FDA acknowledges many of these issues.

FDA Biosimilars Action Plan

A new Biosimilars Action Plan (BAP) was announced by the US FDA in July 2018, which is yet another milestone to ease market access of biosimilars in the US. Below, is a summary of the key elements outlined in the BAP and the expected market impact for biosimilar manufacturers.

Key Element of BAP	Initiatives to be Undertaken	Expected Impact for Biosimilar Competitors
1.Improving biosimilar development & approval process	• Developing application templates specifically for 351 K BLA • Transitioning to Office of Therapeutic Biologics & Biosimilars (OTBB) • Develop tools for efficient biosimilar development - in silico modeling tools for PK & PD correlation vs expected clinical responses using existing clinical data	• More streamlined development & approval process for biosimilars • In-silico models can reduce development cost of biosimilars in the long term
2.Maximizing scientific & regulatory clarity for biosimilar development community	• Additional guidance - for applicants who seek approval for lesser number of conditions than reference product because of patent protection; • Enhancing purple book with exclusivity info & additional info, with an interactive user interface • Strengthening partnerships with EU, Japan, Canada regulatory authorities & data sharing agreements with possibility of using non US licensed comparator products in biosimilar applications and for real world evidence against safety, efficacy	• More regulatory clarity & competitive intelligence available for biosimilar manufacturers • Improved regulatory reciprocity for biosimilar assets approved & in pipeline for other more mature regulated markets
3.Communications to improve perception among payers, clinicians patients	• To develop audience-appropriate innovative and effective educational material including videos that can clarify key scientific concepts of biosimilars	• Will enhance confidence on biosimilars among payers, providers & patients expected
4.Supporting competition by reducing gaming of FDA requirements by innovators	• Co-ordinate with FTC to address anti-competitive behavior • Work with legislators to close any regulatory loopholes that prevent biosimilar entry even after exclusivity • Address instances where drug makers refuse to sell samples	• Prevent anti-trust activities from the innovators • Better commercial viability & value realization potential

Indian Industry Participation in Regulated Markets

Europe: There is relatively more encouraging level of engagement in European markets, with some Indian made biosimilars having already secured EMA approval and a few others under registration (Biocon/Mylan - positive opinion issued by CHMP for Trastuzumab and Pegfilgrastim under registration). The relatively more open European market itself can be divided into 2 distinct segments based on current level of market receptiveness for biosimilars. On one end, there are markets like Denmark and Finland with landmark levels of biosimilar adoption but higher than anticipated levels of price erosion. At the other end are markets such as Germany and France, where true market potential is yet to be tapped and there is scope for multifold expansion of market adoption. Overall, the region presents an active partnership landscape, high regulatory support for biosimilars and expanding levels of market maturity. While Indian companies have successfully launched first generation biosimilars, there is substantial need to expand level of thrust of Indian industry to realize potential of the biosimilar segment.

Medicine Name	Active Substance	Marketing Authorization Holder (Indian)	Authorization date
Accofil	filgrastim	Intas Pharmaceuticals	18-09-2014
Semglee	insulin glargine	Biocon/ Mylan	23-03-2018
Pelgraz	pegfilgrastim	Intas Pharmaceuticals	21-09-2018

US: While the wave of Indian made biosimilars have already seen the light of day in US, with FDA approval of Biocon-Mylan's biosimilars, there is great need to expand level of industry engagement in targeting this opportunity.

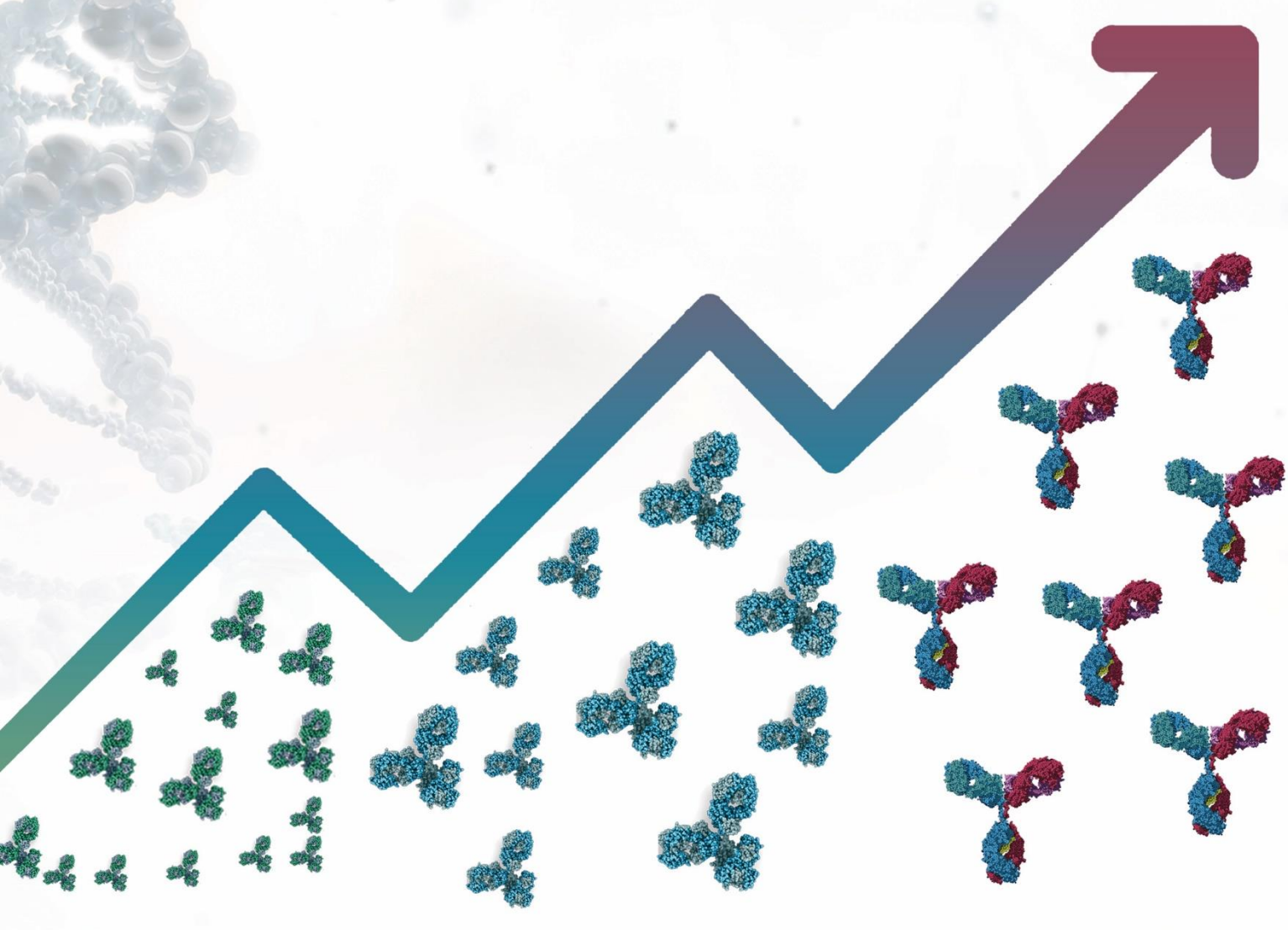
Today, the regulatory environment is more conducive, and there is high thrust from the regulator to streamline approvals. With about 12 biosimilars approved so far, there are enough precedents for Indian companies to equip themselves with knowledge of regulatory requirements. Each new approval has also paved the way for greater regulatory clarity, with the long-awaited draft guidance on biosimilars interchangeability and the new Biosimilars Action Plan being two milestone regulatory developments that can make commercial markets more accessible.

Medicine Name	Active Substance	Marketing Authorization Holder (Indian)	Authorization date
Fulphila	pegfilgrastim	Biocon/ Mylan	04-06-2018
Ogivri	trastuzumab	Biocon/ Mylan	01-12-2017

There is greater regulatory guidance now on designing clinical programs for extrapolation and interchangeability. With more efficient program design, there is also great potential for level of investment per asset to get optimized in the mid-term horizon.

Recommendations and Way Forward for Indian Industry:

Road to a Sustainable Future



Recommendations and Way Forward for Indian Biosimilars Industry: Road to a Sustainable Future

Tectonic shift of global healthcare from small molecules to biologics is hard to ignore anymore and considering the imminent problems biologic drugs bring forth in terms of drug pricing and affordability, role of biosimilars has never been more important. While there has been no significant engagement in novel biologics from Indian pharma majors, biosimilars are a hard to ignore growth opportunity for Indian companies going beyond small molecule generics ridden with intense competition and price pressures. There is growing interest in the Indian landscape and is evidenced by increasing number of new companies jumping on the biosimilars bandwagon. The segment is critical if Indian industry is to obtain the targeted $100 billion bio-economy.

Based on currently approved biologic drugs and pipeline analysis for anticipated approvals during the period, in the most optimistic scenario, we estimate the global biosimilar market will be north of ***$ 240 Billion*** and Indian biosimilars market to be north of ***$ 40 billion by 2030.***

With record number of domestic approvals, active engagement in semi-regulated markets and growing footprint in regulated markets, the Indian biosimilar industry is poised at the cusp of growth. There is an active pipeline in the country today, with many companies marching towards regulated markets. Below table indicates pipeline of some of the leading players in the segment.

Company	Pipeline Info	Target Markets	Stage of Development[7]
Intas Biologicals	5 biosimilars in the pipeline for India, and 5 for regulated markets of EU and USA		
Biocon	Adalimumab		Global Phase 3 completed
	Trastuzumab	Approved in USA, Under review in EU, Canada & Australia, Filed/Marketed in Emerging markets	
	Pegfilgrastim	USA, EU, Canada, Australia, EM	Filing
	Bevacizumab	Marketed in India	Global Phase 3
	Filgrastim	-	Early Development
	Etanercept	-	
	Pegfilgrastim	EU, USA	Approval enabling studies initiated
	Rituximab	EU, USA	

[7] Source: Company annual reports, investor presentations and other public disclosures

Dr. Reddys	Bevacizumab	EU, USA	
	2 new molecules entering clinical development in coming months		
Zydus Cadila	8 biosimilars in the pipelines for regulated markets and India		
Reliance Life Sciences	14 biosimilars in global pipeline		
Lupin Pharma	5 biosimilars in global pipeline		
Wockhardt	4 biosimilars in global pipeline		

It is imperative to nurture the vibrant industry landscape and support the industry in value realization. It is important to equip participants with the right arsenal to combat commercial challenges around market entry and access in domestic as well as international markets.

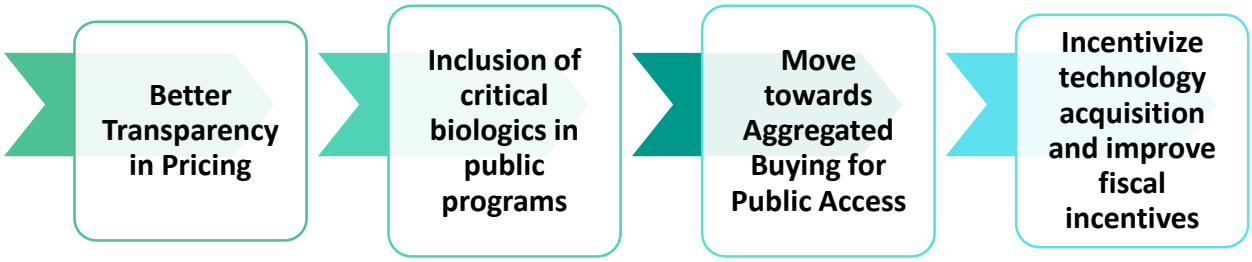
Major areas of challenges to combat in order to secure a sustainable future for Indian-made biosimilars and key recommendations are summarized below.

Expanding Markets in Domestic Landscape: Need For A Multi-Stakeholder Approach

As highlighted in earlier sections of the publication, the volume penetration of biosimilars within the country is appallingly low, with less than 10% for the largest biosimilar market of trastuzumab. Despite price control of key biosimilar drugs, overall penetration of drugs remains sub-optimal. Wielding price control as an arsenal has always been a double-edged sword and high caution needs to be exercised to ensure right balance between affordable access and reward for innovation. In the case of biosimilars, it has mostly resulted in shrinking of markets without a corresponding impact on expansion of access to care due to overall cost of care still being unaffordable for more than 80% of the target population. The market has reached a point of limbo where value realization has saturated at a very low level of market penetration and there is negligible commercial incentive for companies to expand markets further.

Thus, there is an urgent need for government intervention and a multi-stakeholder approach for expanding volume penetration and propelling the domestic biosimilars market towards success.

Recommendations



i. Better Transparency in Pricing

Price competition in Indian biosimilars market mostly prevails at hospital level to win business vs competitors and the price benefit is not being transferred to the patients, despite the drugs being price controlled. This is a significant concern in a landscape where overall cost of care for indications such as cancer is already unaffordable for more than 80% of the population. Transparency in pricing and margins at different stages of value chain is thus need of the hour, in order to trigger market expansion to patients who are currently out of the affordability net.

This recommendation, if accepted will pave way for benefits of price competition to be transferred to patients.

Margin caps across the value chain is one way of tackling this issue and the government has already taken the initial steps in this direction. In the meeting held in April 2018 at the Prime Minister's office, NITI Aayog has recommended an upper limit of 24% for scheduled drugs and 30% for non-scheduled drugs at the first point of sale which includes stockists, wholesalers, distributors and hospitals.

ii. Inclusion of Critical Biologics In Public Programs

Considering the largely out-of-pocket nature of the Indian market, affordability qualms heavily limit market penetration, as the cost of care for biologic drugs remain a lofty luxury for majority of the population. In the case of oncology, in addition to cost of the drug itself, there has been high concern on patient drop-outs due to overall cost of care not being affordable. For instance, trastuzumab in the case of breast cancer is used as a primary systematic therapy and also as neo-adjuvant or adjuvant therapy. In the case of the latter, in addition to cost of the drug, overall cost of care includes cost of hospitalization and cost of surgery and/or chemotherapy. To expand access, we need to address access issues for both, overall cost of care and the drug itself. In the current landscape, even in the few states where cancer care is paid for, Government schemes don't cover biosimilars or peptide drugs and only cover traditional small molecule drugs.

If we need to push the boundaries on adoption to achieve meaningful impact of affordable biologics on health outcomes, their inclusion in Government schemes is critical. At the current price levels, such inclusion is also likely to be supported by sound health-economic justification. More importantly, expanding coverage of healthcare schemes to biosimilars will be doubly rewarding for the nation - doing so will significantly enhance access to healthcare for the population while also building in financial viability for biosimilar makers in their home turf.

As India is now at a threshold where the government is laying the foundation for universal coverage with the Ayushman Bharat program, a very refreshing development for a developing economy such as India, the timing is ripe for considering inclusion of affordable biosimilar drugs in public health schemes.

iii. Move Towards Aggregated Buying For Public Access

Current price control mechanisms do not factor in the large economic diversity of the Indian population and are exercised as one-size-fits-all approach for capping prices to all sections of the population. The upper economic tiers have several times more propensity to pay than the fixed prices while the lower tiers come nowhere near affording the same price. In effect, this could have even resulted in shrinking the overall addressable market size for biosimilars, without substantially expanding the market size and overall level of penetration.

Cross-subsidization models in the vaccine industry in India, for instance, is a clear success story of achieving sustainable pricing economics ensuring both affordable access as well as value realization for manufacturers. While substantial pooling of volume procurement in the public immunization system has driven volume based price economics for affordable access, freedom of pricing in private markets has ensured reward for innovation and value realization for manufacturers without compromising affordability. ***Inclusion of biosimilars in programs such as Ayushman Bharat will open windows for the government to explore similar models for biosimilars well.*** Considering the futuristic importance of large molecule drugs in allaying healthcare burden, it is critical to think of prudent ways to expand access in India and ensure our population does not lose out on such frontier medical advances, especially after being made more affordable through availability of biosimilars.

Thus, it is time to rethink such blanket price control measures and graduate to a more pragmatic approaches such as aggregated public procurement and cross-subsidization that more tactically solve the issue of affordability.

iv. Incentivize Technology Acquisition and Improve Fiscal Incentives

Although many Indian companies have cracked the complex production know-how in biosimilars in microbial as well as mammalian platforms, there is a need to enhance focus on upstream technology development. Even companies that are ahead of the game in domestic markets are still grappling with issues related to manufacturing performance and production

yield and are exploring organic as well as inorganic ways to improve manufacturing performance. Considering criticality of time to markets in the biosimilars market, it is important to support timely access of technologies that enable companies to forge a competitive market entry. High performing clones will be a critical competitive factor for companies as sustainable success hinges largely on production economics, especially as prices erode and unit cost and enhanced capex recovery become critical. Moreover, in an environment where prices crash with every additional competitor entering the market, companies without significant success in yield and manufacturing economics will lose competitiveness, and companies with better yields, even if late to markets, can quickly aggregate and consolidate market share due to better price competitiveness.

A multifold approach is essential for improving upstream technology development through

- **Nurturing effective clone development within the country**
- **Bilateral Government programs to create Public-Private Centre of Excellence**
- **De-risk and Incentivize technology acquisition**
- **Facilitate globally comparable fiscal incentives**

- Much of global R&D begins in academia and thus capacity building for clone development can also be nurtured within the country via pooling scattered skilled resources through competent academia-industry collaboration through creating PPP consortiums for collaboration in core technology development.
- Bilateral government programs are another avenue to trigger capacity building within the country. It is time to take a leaf from legendary programs such as Indo-US Vaccine Action Programme (VAP), which has resulted in upstream development of safe and efficacious vaccines against some of the major communicable diseases through concerted efforts from eminent scientists, institutions and policymakers from both countries.
- Current non-dilutive funding mechanism from the Government do not fund technology acquisition. Even current fiscal incentives are limited to in-house research and development and revenue from out-licensing of Indian patents. To equip the Indian biosimilar industry to be globally competitive in the near-term, it is critical that such fiscal incentives be extended to corporate investments in technology acquisition. Korea sets a good global benchmark for incentivizing technology acquisition. Tax incentives are provided for M&A activities that furthers innovation potential of the country. When a domestic Korean firm merges with a technology-led SME, the merging/ acquiring company is eligible to avail a 10% tax credit on the payment made, up to the value of the acquired technology. Technology acquisition is the starting point of risk investments made by companies and it is important that de-risking support be extended to the point of technology acquisition.

Establishing Competence in Global Markets

The global biosimilars industry is at the cusp of transition, with regulatory framework evolving and streamlining in multiple countries. Much of Indian made biosimilars are yet to see light of the day in global markets, although initial momentum is seeded by a couple of frontrunners such as Biocon and Intas with their initial approvals in US and European markets. Considering much of future value lies in global markets, it is important to consider ways to accelerate engagement and trigger value realization in these markets. Such participation in high value markets and value realization will also be a critical precursor to expanding level of industry engagement, catalyzing further investments, and setting in motion the cycle of portfolio investments.

Recommendations

i. Nurture Strategic Partnerships for Market Access

High levels of binary risk and unsurmountable levels of investment are the main factors hindering active engagement of Indian companies in global markets. Considering existence of large stalwarts in the domestic market, pooling of resources will help in significantly defraying risks and yield more bandwidth for shouldering investments. Strategic collaborations with global counterparts could also achieve the same goal and additionally provide access to their regulatory and marketing strength in global markets. Such collaborations also elevate the quality confidence and reputation of Indian-made assets, which is much needed in the current landscape, where assets approved from India and the Indian biosimilar regulations are still perceived inferior to global ones. Leveraging co-investment collaborations will be critical to accelerate path to markets and translate current level of active engagement in Indian industry to significant value realization.

Biocon's partnership with Mylan is a trailblazing success story in the history of Indian biosimilar industry. Signed in 2010, it is a joint development agreement with cost-sharing model. While Mylan holds rights to commercialize biosimilars developed under the partnership in regulated markets with profit sharing with Biocon, the partnership allows for co-exclusive commercialization in Rest of the world (ROW) markets. Approved products from the collaboration include

- **Ogivri: First FDA-approved biosimilar to Herceptin and the first biosimilar from Mylan and Biocon´s joint portfolio approved in the U.S**
- **Semglee: EMA approved biosimilar for Insulin Glargine**
- **Fulphila: First FDA-approved biosimilar to Pegfilgrastim**

ii. Foster Support Ecosystem to Drive Confidence In Assets

While solutions for more optimal value realization are very externally dependent on regulator and market forces, a more conducive export environment as well as more consolidated effort by industry can potentially make this engagement sustainable and scalable. Small molecule formulation exports from India are a formidable example of multiple ministries and industry working together to create a forthcoming export ecosystem and receptiveness for Indian products globally. Pharmexcil has played an instrumental role in driving export success of Indian-made generic drugs and in establishing their quality reputation in regulated markets. Given the expanse of investments with limited realized return, and the continuing misconception about inferiority of Indian biosimilar approval pathways, a similar thrust and a support framework is called for even in the biosimilars segment.

iii. Establish Regulatory Reciprocity In ROW markets

While the regulatory rigor between Indian National Regulatory Authority(NRA) approved products and US and EU regulations is hard to bridge, it is quite comparable with other emerging markets, yet different regulatory pathways in different countries call for significant bridging work to be done for approvals. Regulatory reciprocity for Indian National Regulatory Authority approved products will enable greater scalability in these markets. One such development that could help in better harmonization of country-level requirements is the WHO Prequalification Program.

The WHO prequalification pilot is an encouraging global development in this direction and the industry will greatly benefit from concerted effort to ease market access and creation of any aggregated procurement mechanisms akin to Antiretroviral drugs and vaccines. In the interim, facilitated regulatory guidance and advisory support for Indian companies pursuing this path for the first time would also greatly facilitate more efficient market access in this complex landscape.

- **WHO has kicked off a pilot pre-qualification program for biologic and biosimilar drugs for 2 key biologic products – *rituximab and trastuzumab*, in order to facilitate affordable access of these critical drugs in low and middle income countries. As part of this effort, the organization has recently invited manufacturers to express initial interest and also rolled out the guidance for the requirements for pre-qualification process. WHO-PQ process has proven to be a great boon for the Indian vaccine industry in creating a common platform for validation of products and procurement by multiple countries, Such an effort in biosimilars could provide the much needed boost for Indian made biosimilars to be competitive in other ROW markets**
- **Other mechanisms to alleviate market access concerns in ROW markets could be via triggering government-to-government liaison to create industry-friendly negotiated models on bridging studies required for assets**

Nurture the Start-up Ecosystem to Encourage Newer Ventures

The biosimilars game being a tough one to crack even for established Indian players, the challenges are multiple times more complex for aspiring young ventures looking to tap into the evolving market opportunity. There are a handful of Indian start-ups venturing in biosimilars, some of which are highlighted in the table

Company	Product Pipeline Details[8]
Apcegen Technologies Private Limited	Portfolio information undisclosed
Clonz Biotech Private Limited	Rituximab, Trastuzumab and Ranibizumab under preclinical development; Bevacizumab, Denosumab and Ustekinumab under clone development stage
Enzene Biosciences Private Limited (with strategic investment from Alkem Laboratories Limited)	Advanced stage of clinical development for 6 molecules for domestic market; One recombinant molecule and one monoclonal antibody in developmental pipeline for global markets
Epygen Biotech Private Limited	Advancing a biosimilar for Streptokinase licensed from Institute of Microbial Technology (IMTECH), Chandigarh, expected to launch in 2018. Pipeline includes Bevacizumab and Pegfilgrastim
Genesys Biologics Private Limited	Insulin Biosimilars
Imgenex India Private Limited	Trastuzumab in preclinical stage; adalimumab, bevacizumab, ustekinumab, and nivolumab in R&D
Levim Biotech	Streptokinase and GLP-1 biosimilar in pipeline

Firstly the investment-heavy nature of the segment is a deterrent in multiple stages of the product lifecycle. Start-ups that are incubated well typically tend to be able to manage costs until early analytical work at lab scale, as bulk of the costs till then comprise of cost of consumables and small animal experiments which could be covered under grant funding. Early stage programmatic investments from DBT and other grant providers has been instrumental in catalyzing these ventures. Costs skyrocket in subsequent stages where products enter preclinical animal testing and clinical stage. There is a huge valley of death in terms of scale-up infrastructure at this stage characterized with negligible level of early stage venture capital.

[8] Source: Company websites

Challenges also prevail in accessing quality genetically modified animal models for research. There is no domestic capacity in the country for GM animals and the research ecosystem today completely depends on imports for this critical need. Average waiting period for import ranges from 1.5 to 2 years thus unduly stretching time to markets.

Additionally, there is a near void of affordable cGMP pilot facilities in India for manufacturing clinical grade material, which is a critical deterrent in advancing these programs towards market. Considering high binary risk in commercialization, upfront investments on manufacturing facilities is a risk factor even for established companies with strong balance sheets. Globally, even innovators tend to outsource manufacturing of biomaterial for clinical trials to reputed contract organizations, which could cost as high as $ 2M for a single batch. Companies either work out larger CMO contracts or operationalize commercial facility investments only post product approval, in order to minimize sunk costs, should the product fail regulatory approvals. The same challenge prevails in biosimilar markets as well, especially affecting smaller ventures, with a clear market need for shared infrastructure in the country for manufacturing of clinical material.

The current situation is such that younger ventures that embarked on biosimilar development have eroded in value and face highly uncertain future due to slow pace of portfolio development. The most significant impediment in the path of younger ventures has been dearth of investments especially in context of exalting level of capex for CGMP facilities for clinical trial lots in the absence of a strong CMO ecosystem or shared facilities in the country. While early stage programmatic investments from DBT and other grant providers has been instrumental in catalyzing these ventures, it is critical that scale-up infrastructure and follow-on investment ecosystem is nurtured with urgent attention.

Recommendations

i. Non-Dilutive Funding For Clinical Development

While India has a strong base of non-dilutive grant funding opportunities, thanks to DBT and BIRAC, for initial de-risking of technology, the quantum of such funding is insufficient in light of the long lifecycle of biosimilar product development and validation. While current non-dilutive funding mechanisms from Indian Government can support young ventures in the first few steps of development, a well-structured funding to de-risk the most capital intensive step

of clinical validation for global markets could truly be instrumental in Indian industry carving global presence in biosimilars. To be truly impactful, such funding mechanism needs to be of sizeable quantum and take cognizance of time sensitivity of the biosimilar commercialization process. DBT's $250 million i3 program or the National Biopharma Mission is a step in this direction, and such platforms need to be expanded to sustain the startup ecosystem engaged in biosimilars and novel biologics.

ii. Common cGMP Infrastructure for Clinical Trial Material

In the absence of a strong CMO ecosystem for bio manufacturing in the country, creation of common cGMP infrastructure for manufacturing of clinical trial material is the need of the hour. With several competitors struggling to make their mark in global markets, India's competence lies largely in low cost manufacturing and it is important to nurture a competent bio manufacturing ecosystem to achieve it. This could be facilitated through PPP models or strategic buying of private sector capacity. Both Indian as well as international companies can be employed to operate these facilities, to trigger local bio manufacturing competency. As a challenge that also impacts ventures developing vaccines and novel biologics, this challenge calls for immediate attention. Again, DBT's i3 program includes the mandate of creating such common manufacturing capacity and when operationalized could provide great respite to ventures pursuing biosimilars.

NOTES

NOTES

Confederation of Indian Industry

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