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# nds ND&CT Rules 2019 ew drugs, trials norms

in the ND&CT Rules, in Rule 8, Sub Rule 3(ii), a provision shall be inserted that if there is no communication received from the CLA to the applicant within the forty-five working days period, the registration of ethics committee shall be deemed to have been granted by the CLA and such registration shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules.

The applicant who has taken deemed approval under the above said provision shall before initiating the functions of the EC, inform the CLA in Form CT-02A and the CLA shall on the basis of this information, take on record the Form CT-02A which shall become part of the official record and shall be called deemed registration of the CLA.

The next provision to be inserted is under Rule 22, Sub-Rule (2), wherein if there is no communication from the CLA to the applicant within the 90 working days period, the permission to conduct all clinical trial shall be deemed to have been granted by the CLA and such permission shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trial in accordance with these rules.

In Rule 24, a provision to be added under which if there is no communication from the CLA to the applicant within 90 working days period, the permission to conduct all clinical trials shall be deemed to be legally valid for all purposes and the applicant shall be authorised to initiate clinical trials in accordance.

In Rule 34, Sub-Rule (2), a provision is added that if no communication has been received from the CLA to the applicant within the 90 working days period, the permission to conduct bioavailability or bioequivalence study of the new drug or investigational new drug shall be deemed to have been granted. ◆

# Global API market entering into new growth phase

Dr. Sanjay Agrawal

The market for active pharmaceutical ingredients (API) was estimated to be worth over US$ 177.05 billion in 2021 and is anticipated to grow to US$ 258.60 billion by 2027, registering a CAGR of nearly 7.50 per cent over the forecast period of 2022-2027.

The Covid-19 epidemic had a positive market impact in 2020 because the key players and countries are producing large quantities of ingredients to meet the ongoing demand for Covid-19 treatment. Drug producers have changed their business strategies to concentrate on a bigger patient base due to the Covid-19 epidemic. For instance, the US asked India to import hydroxychloroquine (HCQ) to treat coronavirus. The virus has also hampered Canada's pharmaceutical supply chain, which might harm patients there. Canadian pharma giants are expanding their partnerships with nations other than China to reach new markets.

The increasing drug research and development efforts for drug manufacturing, the growing significance of generics, and the rising adoption of biopharmaceuticals are the main drivers of the active pharmaceutical ingredients market's growth. The market's expansion is anticipated to be hampered by many countries' unfavourable medicine price control policies and high manufacturing costs.

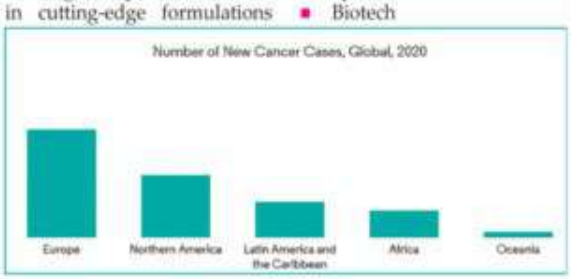
The demand for medications is anticipated to rise due to the rising prevalence of chronic diseases, accelerating the market growth for active pharmaceutical ingredients. The World Health Organization (WHO) estimates that cardiovascular illnesses claim 17.9 million lives annually, making them the top cause of mortality worldwide.

According to the Alzheimer's Association, 5.8 million Americans will have Alzheimer's disease in 2020. The sixth biggest cause of death in the US is this illness, which is more common in persons over 65 (and approximately 5.6 million patients fall in this age bracket).

This number is anticipated to reach 14 million as the baby-boomer generation ages, and the situation worsens over the projection period as they approach the age of 65. A new case of the illness is predicted to emerge every 33 seconds by 2050.

In addition, introducing fresh pharmaceutical and biological products, purchases, joint ventures, and geographical expansions are some of the strategic actions to maintain market stability. This will probably encourage market expansion shortly. As an illustration, Quartic.ai and Bright Path Labs worked together in 2020 to build AI-based technology to continuously manufacture essential APIs that are required for generating essential small-molecule medications.

Drugs for diabetes, cardiovascular disease, analgesics, and pain treatment have historically dominated the market for active pharmaceutical ingredients (API). However, according to R&D trends, the focus is on creating complex APIs used in cutting-edge formulations targeting specialized therapeutic fields.


Drug price controls in several countries, severe competition among the market's participants, and strict regulatory standards are the main factors limiting market expansion.

### Market segments

The API market is divided into different market segments based on the following:

- Business model (captive API and merchant API)
- Synthesis type (synthetic and biotech)
- Drug type (generic and branded)
- Application (cardiology, pulmonology, oncology, ophthalmology, neurology, orthopaedic
- Geography (North America, Europe, Asia-Pacific, Middle-East and Africa and South America)

### Purpose & scope of report

Any drug's active pharmaceutical ingredient (API) causes its effects. Many active substances are present in some medications, such as combination medicines, which treat various symptoms or work in many ways. Both during the R&D and commercial production phases, they are generated by employing highly technical industrial procedures.

### By business mode

- Captive API
- Merchant API

### By synthesis type

- Synthetic
- Biotech

### By type of drug

- Generic
- Branded

### By application

- Cardiology
- Pulmonology
- Oncology
- Ophthalmology
- Neurology
- Orthopaedic
- Other Applications

### Market trends

Since the pharmaceutical industry is leading the fight against Covid-19 and has responded to this worldwide challenge by ensuring the availability of medicines despite supply chain disruptions, the pulmonology segment has been enjoying a high peak in growth.

Due to the large population using various CVD medications due to the high prevalence of cardiovascular disorders, the cardiology segment commands a sizable market share. Cardiovascular diseases (CVD) continue to be the main cause of morbidity and the leading cause of mortality in Europe, according to the European Society of Cardiology's 2019 Statistics. There are about six million new cases of CVD in the EU and over 11 million cases in Europe annually. With about 49 million sufferers in the EU, the disease has a significant economic cost of EUR 210 billion annually.

CONTINUED ON p4 |▶

# Biological medications being used to treat chronic illnesses

CONTINUED FROM p6

Due to the increased frequency of cancer over the past several decades and the expectation that the disease would affect a larger percentage of the population throughout the projection period, the oncology segment is also anticipated to rise significantly during that time. To meet the global oncology market's needs, players are constantly creating new APIs.

A generic version of Velcade, manufactured by Millennium Pharmaceuticals, called Bortezomib for Injection, was introduced to the US market by Dr. Reddy's Laboratories in December 2019. Adult patients with multiple myeloma or mantle cell lymphoma undergoing at least one prior therapy are treated with bortezomib.

### North America dominates market

North America now dominates the market for active pharmaceutical components, and this dominance is anticipated to last for a few more years. Due to rising disease rates and an aging population, this area is anticipated to see a gain in market share in the future. We control the majority of the market in North America.

The country had to import many APIs from other countries because of the drastic Covid-19 outbreak, and domestic producers also had to ramp up production to meet the demand. The majority of its API needs are satisfied by imports from Asian markets.

According to the US trade statistics, China and India account for roughly 75–80 per cent of all APIs imported into the US since they have well-established production bases and a big labour force that caters to the pharmaceutical industry.

Recent political and trade initiatives of the US government to raise import levies and taxes are anticipated to increase operational expenses and put more pressure on manufacturers' pricing. To guarantee the supply of high-quality goods to the US market, the FDA has raised the application costs for brand-new medicine approvals and increased the frequency of periodic inspections carried out at various offshore contract manufacturing facilities.

### Competitive environment

The market for active pharmaceutical ingredients is extremely competitive and has several significant companies, which suggests a fragmented market environment. Due to their extensive industrial footprints, several manufacturers from China and India enjoy a prominent market position in the API market. Due to a thriving pharmaceutical and life sciences industry, Italy, Germany, and the UK are the primary regions for API commerce in Europe.

The majority of APIs made by well-known MNCs are utilized for captive production. A small number of businesses, though, have emerged as contract manufacturers with a wide range of customers. Furthermore, small and midsize businesses are expanding their market position by releasing new ingredients at competitive costs in response to rising technology breakthroughs and product improvements.

In the market for active pharmaceutical ingredients, organizations like Teva, Pfizer, Aurobindo, Sun Pharmaceuticals, Novartis, Mylan, and Boehringer Ingelheim hold sizable market shares.

### New phase of growth

The active pharmaceutical ingredients (API) market is transitioning into a new growth stage on a global scale. The API sector is expanding at a never-before-seen rate due to the intensifying market dynamics of rivalry and consolidation, including new regulations, patent expirations, and Para IV focus.

According to a recent market analysis released by Global Market Research, the global API market, estimated to be worth US$119.7 billion in 2013, is predicted to grow to US$185.9 billion by 2020, developing at a CAGR of 6.5 per cent from 2014 to 2020.

During the anticipated period of 2014 to 2020, the global API market is anticipated to expand significantly, with the oncology and central nervous system medication sectors playing a key role. During the projected period from 2014 to 2020, these segments are anticipated to expand at the highest CAGR.


Due to the increasing frequency of cardiovascular illnesses, sedentary lifestyles, and the aging population, cardiovascular medications accounted for the greatest market revenue share in 2013. In all market divisions, the tendency of top-selling brands to lose their market exclusivity has given rise to chances for generic products. In particular therapeutics segments, this raises the demand for APIs.

Biological medications are now being used more frequently to treat chronic illnesses like diabetes and cancer. Due to their rigorous production requirements and difficult duplication when compared to chemical APIs, these medications are more expensive. The ability to produce biosimilars that are not perfect replicas of innovator medications but are extremely equivalent in terms of safety and efficacy has been made possible by advancements in production technology—the WHO has also established comparable rules established by the European Union. Europe has been the leader in the approval of biosimilars. The development of regulatory frameworks for biosimilars in several countries portends a significant market opportunity for pharmaceutical firms.

CONTINUED ON p42

# How new technology is transforming patient care

Saurabh Kochhar

The integration of technology into the Indian economy is revolutionary and has impacted every sector and healthcare is no exception. It continues to drive forward and streamline the healthcare operations that were earlier hard to be handled manually. Spurred by the outbreak of the covid-19 pandemic, the adoption of digital technologies in healthcare is playing a pivotal role in developing novel treatments for improved delivery at lower costs.

Today, technology companies are making strategic investments in the healthcare potential to transform the patient experience with a customer-centric healthcare approach. The intervention of new technologies in healthcare is focusing on creating data-driven delivery models that are different from traditional models, making bold moves for the sector's growth. As per the market data – the revenue in the Indian digital health market is projected to touch US $9.22 billion in 2022, at an annual growth rate of 22.7 per cent CAGR.

The intervention of technology solutions is posing as a key enabler in utilising agile innovations. It takes into consideration the needs of patients and healthcare providers, imperative to fill the existing gaps in the healthcare landscape.

**Cloud computing – enabler of HER**

To achieve universal healthcare access, the government renewed its focus to improve the way healthcare providers approach medical treatments. For holistic and digitally enabled patient care, it becomes imperative for healthcare providers to embark on a digital journey to record patients' data electronically and deliver holistic care. Among the most prominent digital healthcare solutions, electronic health records are one of the most sought-after solutions in replacing the antiquated process of recording patients' medical data and history.

Considering the many health tech innovations, cloud computing is considered at the forefront and key enabler of electronic health records. The post-pandemic world not just requires cutting-edge tools to replace traditional care solutions, but needs a technology intervention that can create a holistic healthcare environment to improve doctor and patient collaboration.

For both the care receiver and the provider, cloud technology has provided a significant advantage in bringing accessibility and affordability to their tablet – anywhere and whenever one needs to access the medical record.

The expedited move of healthcare towards digitally driven solutions has impacted the way healthcare providers and patients communicate for refined healthcare delivery

**Paperless prescriptions**

The expedited move of healthcare towards digitally driven solutions has impacted the way healthcare providers and patients communicate for refined healthcare delivery. With digital interventions, the concept of paper Rx i.e., paper prescriptions have moved to e-Rx, electronic/digital prescriptions that are generated, transmitted and stored digitally as a patient's EHR. The concept of e-RX is fast replacing conventional prescriptions, outpacing the benefits of doctors' handwritten prescriptions, cross-checking the medicines and finding alternatives at pharmacies in case of unavailability.

Since e-Rx are generated electronically, they are legible and clear to understand the treatment and dosage. Unlike handwritten prescriptions, e-Rx has a negligible scope of human errors that eliminates misinterpretation of medicines and ensures patient safety in initiating medicine-based treatment. As e-Rx is saved on the cloud, chances of misplacing or losing a prescription are minimized and directly transferred to pharmacists, without having to keep a track of the hard copy.

Electronic records or e-Rx, both are digitally generated that play a crucial role in eliminating the forgery of prescriptions. Often handwritten prescriptions are forged or misused to obtain more drugs from the pharmacy. However, e-Rx puts an end to several illegal practices such as obtaining drugs illegally or drug abuse.

**Streamlining of medical data**

Throughout the patient's treatment journey, a huge amount of medical data is generated from his hospitalization to post-recovery treatment. Before the digital transformation, healthcare providers collected patient data only in the form of hard copies. However, the challenges to access and analyze the data remained unresolved. Every time, someone from the hospital's staff has to enter the data manually into the system for record-keeping.

The digital makeover of healthcare data provides faster access to patient's medical history while promoting easier collaboration between doctor and patient. It reshapes the patient's journey by streamlining the data – accessing, storing and exchanging healthcare data more efficiently. Cloud-based technology simplifies storage that dramatically reduces maintenance costs, improves accessibility and adds transparency.

**Bottomline**

Digital adoption in the healthcare scenario is continuing to gain major traction with the implementation of new technologies. With a lot of disruption coming from the healthtech entrepreneurs to rethink patients' perspectives, the healthtech start-ups are leading the sector towards digital innovation, redefining the way patients engage with healthcare providers and reshaping the patient care experience. ◆

*(The author is Founder & CEO of Meddo Health)*

# Cost-competitiveness of Indian APIs, a major advantage

CONTINUED FROM p1 ▶

With the introduction of poly pills, the API business would see an additional boost in creating a solid product pipeline. Numerous Indian API players are working on cutting-edge research on the chemicals that go into making a combination tablet for high blood pressure and cardiovascular disease.

Angiotensin II receptor antagonists or sartans, utilized in medications for hypertension, diabetic nephropathy, and congestive heart failure, are also a significant market opportunity for Indian APIs. Osartan, candesartan, irbesartan, telmisartan, olmesartan, valsartan, and eprosartan are a few of the APIs.

Additionally, India is an expert in dental and dermatological APIs. The Indian API business might directly compete with China by 2020 and become a favoured partner for major international firms in the sector.

The industry is currently in an advantageous position and is acting quickly to corner the orders from the patent-expiring medications valued at more than $60 billion. The firms also hope to capture a sizable portion of the regulated US and EU markets, where pricing pressure is growing due to the availability of low-cost suppliers in emerging nations, surplus big pharma capacity, and backward integration by certain generic firms.

The cost-competitiveness of the Indian API business is a major advantage in the international market. India has a high level of expertise based on the chemical knowledge of its scientific ability. According to the Karnataka Drugs and Pharmaceutical Manufacturers Association, with the growth of contract manufacturing and research services in India, businesses like Anthem Biosciences, Syngene, a Biocon subsidiary, and Jubilant are now more prevalent there than in Western nations.

The involvement of Indian API manufacturers in the synthesis and production of late-stage intermediates and APIs has led to a progressive evolution of their role in the global pharmaceutical supply chain. Historically, innovators have typically chosen to outsource early-stage intermediates to Indian manufacturers while doing the final phases of API synthesis in-house or collaborating with specialized European suppliers. However, in recent years, the reputable track record of Indian businesses in providing high-quality products and their ability to perform complex synthesis has increased participation in supplying late-stage intermediates to innovative businesses, according to the ICRA report. ◆

*(The author is leading Pharmaceutical Consultant)*