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Chennai,
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APIs are central to drugs' pharmacological action

DR SANJAY AGRAWAL

In the intricate and ever-evolving world of pharmaceuticals, one term holds foundational importance: Active Pharmaceutical Ingredient, or API. It may not be as widely recognised as brand names like Aspirin or Paracetamol, but APIs are what truly drive the efficacy of any medication. Without APIs, pills are just fillers and capsules are empty shells.

This article unpacks the essential role of APIs in modern medicine- exploring what they are, how they are made, global supply dynamics, regulatory frameworks, challenges in manufacturing, and the emerging trends that are shaping their future.

What Is an API?

An Active Pharmaceutical Ingredient is the biologically active component in a drug product that produces the intended therapeutic effect. For example, in a common pain relief tablet like ibuprofen, ibuprofen itself is the API. The rest of the tablet - excipients, binders, preservatives, colourants - are inactive ingredients used to deliver the API effectively.

APIs are central to drugs' pharmacological action. Whether the medication relieves pain, lowers blood pressure, or fights infections, it's the API doing the real work.

API vs Formulation: A Quick Breakdown

While the API is the powerhouse of the medicine, the formulation (also known as the finished dosage form or FDF) is how the drug is presented- tablet, injection, syrup and so on. The formulation combines the API with other substances that help it get absorbed by the body, improve stability, and make the drug easier to use.

For instance:

- **API:** Amoxicillin
 - **Formulation:** Amoxicillin 500 mg capsule with excipients, preservatives, and stabilisers
- Understanding the difference between the two is key in both drug development and regulation.

How Are APIs Made?

API production is a complex and highly regulated process, typically carried out in multiple steps:

1. **Chemical Synthesis-** For most synthetic drugs, the API is produced through multi-step chemical reactions. This requires precise conditions, catalysts, solvents, and strict control over impurities.
2. **Biotechnology-** Biopharmaceuticals like insulin or monoclonal antibodies are made using living organisms such as bacteria or yeast through fermentation or recombinant DNA technology.
3. **Extraction-** Some APIs are derived from

natural sources like plants, fungi, or animal glands. Morphine, for instance, is extracted from the opium poppy.

After synthesis or extraction, the API undergoes purification, crystallisation, drying, and milling to meet the required quality and potency.

The Global API Supply Chain: Who Makes What?

India and China dominate the global API manufacturing landscape, accounting for more than 60% of global production. This shift to Asia happened over the past three decades due to:

- Lower production costs
- Availability of skilled labour
- Government incentives
- Less stringent environmental regulations (though this is changing)

India, known as the "pharmacy of the world," is a leading producer of generic APIs. China, meanwhile, is the top supplier of raw materials and intermediates used to make APIs.

However, this overdependence has created supply chain vulnerabilities, highlighted starkly during the Covid-19 pandemic. Countries like the US, Germany, and Japan have since been working to revive domestic API manufacturing through "reshoring" strategies and incentive schemes.

Regulation and Quality Control

Because APIs directly impact patient health, they are subject to stringent quality and regulatory standards worldwide. Major regulatory agencies include:

- USFDA (United States Food and Drug Administration)
- EMA (European Medicines Agency)
- DCGI (Drugs Controller General of India)
- PMDA (Pharmaceuticals and Medical Devices Agency, Japan)

APIs must meet standards for:

- Purity and potency
- Residual solvents
- Stability and shelf-life
- Microbial contamination
- Heavy metals and impurities

Every batch of API must be manufactured according to GMP (Good Manufacturing Practice) standards, and facilities are regularly audited. Any deviation can lead to product recalls, licence suspension, or legal penalties.

Challenges in API Manufacturing

API manufacturing isn't a walk in the park. It involves intense capital investment, regulatory compliance, environmental responsibility, and supply chain management. Key challenges include:

- **Stringent environmental norms:** Especially in Europe and India, managing chemical waste and emissions is becoming a high-cost priority.

- **Volatile raw material prices:** Many APIs depend on imported intermediates whose prices fluctuate due to geopolitical or logistical issues.

- **Counterfeit APIs:** In the black market, fake or substandard APIs are a serious threat to global health, especially in low-income countries.
- **Antibiotic resistance:** Improper production and disposal of antibiotic APIs can lead to environmental contamination and resistant strains.



Emerging Trends in the API World

1. **Green Chemistry-** Eco-friendly synthesis methods are being developed to reduce the environmental footprint of API production.
2. **Continuous Manufacturing-** A shift from batch to continuous processing for APIs is improving efficiency and quality.
3. **Biologics & Biosimilars-** As demand for precision therapies grows, biotech APIs (like peptides, proteins, and gene therapies) are booming.
4. **Domestic API push-** India's PLI (Production-Linked Incentive) scheme and the US's BARDA support are boosting local API capacity to reduce import dependence.
5. **AI & Automation-** Artificial intelligence is being used to optimise reaction conditions, predict impurity formation, and maintain regulatory compliance in real-time.

Why APIs Matter More Than Ever

APIs are not just the chemical essence of a drug- they are strategic assets for public health and economic independence. As the world witnessed during the pandemic, disruptions in API supply can paralyse entire healthcare systems.

Securing a robust, ethical, and sustainable API industry is no longer just a pharmaceutical concern- it's a matter of national security. Governments, private players, and academia must collaborate to future-proof this vital link in the healthcare chain.

Conclusion

From everyday medications to cutting-edge therapies, APIs are the unsung heroes behind every successful treatment. Their manufacture, regulation, and distribution form the heartbeat of the global pharmaceutical industry. As new diseases emerge and personalised medicine becomes mainstream, APIs will continue to evolve- becoming more complex, more targeted, and hopefully, more accessible. So the next time you pop a pill, remember- it's the API inside that's making the magic happen. ○

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