AUGUST MEDIA COVERAGE

INDEX

S. No	Date	Publication	Edition	Headline
Financials				
1.	6-Aug-24	The Economic Times	Online + Print	Pharma industry urges govt for stable drug pricing policy
2.	8-Aug-24	The Financial Express	Online	CDSCO waives local clinical trials for new drugs approved in developed countries
3.	8-Aug-24	Hindu Business Line	Online	India notifies rule for rapid launch of breakthrough drugs in the country bypassing local clinical trials
4.	8-Aug-24	Business Standard	Print + Online	Clinical trial waiver only if drugs have greater benefits, says govt
5.	19-Aug-24	Hindu Business Line	Print + Online	Clinical trial waiver a step to improve patient access in need of guardrails
Mainlines				
6.	8-Aug-24	The Hindu	Print + Online	Government announces waiver for several drugs approved from select countries
Online and Trade				
7.	8-Aug-24	The Print	Online	Govt notifies rule for rapid launch of breakthrough drugs in India, bypassing local clinical trials
8.	8-Aug-24	ET Pharma	Online	India waves local clinical trials for certain drugs approved in well-regulated markets
9.	8-Aug-24	Express Pharma	Online	DCGI waives off local trials for drugs approved in well-regulated markets
10.	8-Aug-24	Biovoice	Online	OPPI welcomes Indian govt's move to waive off local clinical trials for certain drugs
11.	10-Aug-24	ET Pharma	Online	Fostering Innovation and Growth: The Need for a Robust Intellectual Property Framework
12.	14-Aug-24	BW Healthcare	Online	Building a Healthier Future: India's Vision on Innovation & Research

13.	17-Aug-24	The Tattva	Online	Government simplifies drug approval process with new waiver
14.	28-Aug-24	ET Brandequity	Online	A booster dose for marketing in pharma and healthcare

FINANCIALS

Publication	The Economic Times
Date	6-Aug-24
Edition	Online
Headline	Pharma industry urges govt for stable drug pricing policy

Pharma industry urges govt for stable drug pricing policy

Teena Thacker, ET Bureau • Last Updated: Aug 06, 2024, 12:40:00 AM IST

Synopsis
The Organisation of Pharmaceutical Producers of India (OPPI) has called for a stable and predictable drug pricing policy, urging the government to avoid using Para 19 of the Drug Pricing Control Order (DPCO), which allows significant price reductions in the public interest.

The Organisation of Pharmaceutical Producers of India (**OPPI**), which represents prominent multinational **pharma** companies, has asked the government for a "predictable" pricing policy for drugs and not to resort to Para 19 of the Drug Pricing Control Order (**DPCO**) that authorises the **regulator** to reduce prices significantly in public interest for a period as it deems fit.

The National Pharmaceutical Pricing Authority-India's drug pricing regulator-had earlier invoked Para 19 of DPCO to slash prices of **cardiac stents** and **knee implants** to make them affordable.

"Pricing policy should be predictable. There should be no change in the pricing policy like it was done by resorting to Para 19 of DPCO 2013, in 2014 and 2019," it said in a pr esentation to the Department of Pharmaceutical (DoP).

Publication	The Economic Times
Date	6-Aug-24
Edition	Print
Headline	Global Pharma Cos Push for Predictable Drug Pricing Policy

Global Pharma Cos Push for Predictable Drug Pricing Policy

Teena Thacker

Mumbai: As the government moves to set up a new pricing framework for drugs and medical devices, MNC lobby Organisation of Pharmaceutical Producers of India (OPPI) has sought a "predictable" pricing policy for drugs and not to resort to Para 19 of the DPCO that authorises the price regulator to reduce the prices significantly in public interest for a period as it deems fit.

The National Pharmaceutical Pricing Authority (NPPA) had earlier invoked Para 19 of Drug Pricing Control Order (DPCO) to slash the prices of cardiac stents and knee implants to make them affordable.

"The pricing policy should be predictable. There should be no change in the pricing policy like it was done by resorting to Para 19 of DPCO 2013, in 2014 and 2019," it said in a presentation to the Department of Pharmaceutical (DoP).

The DoP has been holding meetings with the stakeholders to discuss reforms in the pricing framework for drugs and medical devices. Several meetings have taken place last month. Presentations have been made so far by the OPPI, Indian Drug Manufacturers Association, Indian Pharmaceutical Alliance, All India Drugs Action Network (AIDAN) and the Laghu Udhyog Bharti.

PARA 19 ISSUE

Cos urge govt not to resort to Para 19 of the DPCO that authorises regulator to reduce prices significantly in public interest

Earlier, the drug pricing regulator had reduced the prices of stents by 87% and orthopaedic knee implants by invoking Para 19 of Drugs Prices Control Order (DPCO) 2013 and that was subsequently extended since then.

"Para 19 should be invoked only for a defined period and in truly extraordinary circumstances requiring government intervention in public interest," the OPPI further said in its presentation.

The government's move of price control on stents had become a contentious issue between the US and India. It led to a price cut of up to 85% resulting in many MNCs withdrawing their products from the country.

The US has since then been pressing India not to extend price caps on other medical devices.

Publication	Financial Express
Date	8-Aug-24
Edition	Online
Headline	CDSCO waives local clinical trials for new drugs approved in developed countries

CDSCO waives local clinical trials for new drugs approved in developed countries

According to the circular, the waiver has been granted under Rule 101 of the New Drugs and Clinical Trials Rules, 2019.

Written by Sushmita Pande
August 8, 2024 16:03 IST

The decision has been taken to fast-track the availability of new drugs. (Image Credits: Pixabay)

In a significant move, the Central Drugs Standard Control Organisation (CDSCO) on Wednesday that it has waived off local clinical trials for certain categories of new drugs that have already been approved in the United States, United Kingdom, Japan, Australia, Canada and the European Union.

According to the circular, as seen by *Financial Express.com*, Clinical trial waivers will also be considered for new drugs for rare diseases, drugs used in pandemic situations or for special defence purposes, new drugs having significant advances over the existing standard of care and gene and cellular therapy products that are approved in these developed markets.

Publication	Hindu BusinessLine
Date	8-Aug-24
Edition	Online
Headline	India notifies rule for rapid launch of breakthrough drugs in the country bypassing local clinical trials

India notifies rule for rapid launch of breakthrough drugs in the country bypassing local clinical trials

Updated - August 08, 2024 at 09:41 PM. | New Delhi

Move expected to make drugs manufactured outside India more accessible and affordable in the local market

BY OUR BUREAU

COMMENTS SHARE READ LATER

Five category of drugs will be waived off from the clinical trial requirements. | Photo Credit: Reuters

The Centre has decided to waive clinical trial requirements in India if the drugs are approved in the United States, United Kingdom, Japan, Australia, Canada, and the European Union. The move is expected to make drugs manufactured outside India more accessible and affordable in the local market.

Five category of drugs will be waived off from the clinical trial requirements. These include orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in case of a pandemic, new drugs used for special defence purpose, and those having therapeutic advance over the current standard care.

Sources said , more country names may be added to the list or existing ones taken-off the list, if required.

Publication	Business Standard
Date	8-Aug-24
Edition	Online
Headline	Clinical trial waiver only if drugs have greater benefits, says govt

A senior official from the health ministry noted that this rule aims to make essential drugs with major therapeutic advancements over existing treatments more readily available.

Under this rule, the central drug regulatory body will grant full approval to these drugs rather than emergency use authorisation, simplifying the approval process for critical drugs and molecules already available in Western markets.

Anil Matai, director general of the Organisation of Pharmaceutical Producers of India (OPPI), welcomed the move, saying it would benefit both domestic and international drug manufacturers by expediting the approval process and improving access to essential medications for Indian patients.

OPPI, which represents multinational drugmakers in India, has urged the government to extend these waivers to a broader range of therapeutic categories, further enhancing access to cutting-edge treatments.

Publication	Business Standard
Date	8-Aug-24
Edition	Print
Headline	Clinical trial waiver only if drugs have greater benefits: govt

Clinical trial waiver only if drugs have greater benefits: Govt

SANKET KOUL
New Delhi, 8 August

The Ministry of Health and Family Welfare announced on Thursday that while it has waived the precondition of local clinical trials for certain drugs already approved in well-regulated markets, the subject expert committee will still assess whether these drugs offer greater therapeutic benefits than those available in India.

This decision follows a government order on August 7 that lifted the local clinical trial requirement for drugs approved in the US, the UK, Australia, Canada, Japan, and the European Union.

Senior officials at the health ministry indicated that this change would open the door to the introduction of several drugs to the Indian market, potentially saving three to four years by bypassing the need for clinical trials.

A senior official from the health ministry noted that this rule aims to make essential drugs with major therapeutic advancements over existing treatments more readily available. Under this rule, the central drug regulatory body will grant full approval to these drugs rather than emergency use authorisation, simplifying the approval process for critical drugs and molecules already available in Western markets.

This follows a government order which lifted local trial requirement for drugs approved in the US, the UK, Australia, Canada, Japan, and the EU

Anil Matai, director general of the Organisation of Pharmaceutical Producers of India (OPPI), welcomed the move, saying it would benefit both domestic and international drug manufacturers by expediting the approval process and improving access to essential medications for Indian patients. OPPI, which represents multinational drugmakers in India, has urged the government to extend these waivers to a broader range of therapeutic categories, further enhancing access to cutting-edge treatments.

According to the government order, the waiver currently applies to categories such as orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, those for special defence purposes, and new drugs with major therapeutic advancements over current standards of care that address critical and unmet medical needs.

Ruchi Sogarwal, head of corporate affairs at Takeda Biopharmaceuticals India, commented on the impact of this move on patients, saying that the selected categories address high unmet medical needs.

"Accelerating the regulatory process for these therapies could have a big impact on patients and communities at large," she said.

Publication	Hindu BusinessLine
Date	19-Aug-24
Edition	Online
Headline	Clinical trial waiver, a step to improve patient access, in need of guardrails

Progress with caution. Clinical trial waiver, a step to improve patient access, in need of guardrails

PREMIUM

Updated - August 18, 2024 at 07:04 PM.

Experts call for ensuring patient safety while expanding access to new drugs

BY PT JYOTHI DATTA

COMMENTS SHARE READ LATER

The affordability question: New policy may speed up access but must address high costs and local testing concerns | Photo Credit: istock.com

Also read

Breaking down 'patent thickets' without smothering innovation

Last year, patient families from India took part in an international "right to breathe" campaign seeking access to cystic fibrosis (CF) therapy Trikafta, from the American biotech company Vertex Pharmaceuticals.

Cystic Fibrosis causes sticky mucus to build up in the lungs and digestive system, and the undiagnosed often die in their infancy, patient families said, in their letter to the Government. Besides India, campaigns were mounted from South Africa, Ukraine and Brazil, coordinated by a United Kingdom-based campaigner for patient rights, along with other international organisations.

Publication	Hindu BusinessLine
Date	19-Aug-24
Edition	Print
Headline	Clinical trial waiver, a step to improve patient access, in need of guardrails

Clinical trial waiver, a step to improve patient access, in need of guardrails

PROGRESS WITH CAUTION. Experts call for ensuring patient safety while expanding access to new drugs

PT Jyothi Datta

Last year, patient families from India took part in an international "right to breathe" campaign seeking access to cystic fibrosis (CF) therapy Trikafta, from the American biotech company Vertex Pharmaceuticals.

Cystic Fibrosis causes sticky mucus to build up in the lungs and digestive system, and the undiagnosed often die in their infancy, patient families said, in their letter to the Government. Besides India, campaigns were mounted from South Africa, Ukraine and Brazil, coordinated by a United Kingdom-based campaigner for patient rights, along with other international organisations.

The experience, though, repeats itself with different illnesses — where patients seek access to newer therapies that are still to come to India.

THE AFFORDABILITY QUESTION. New policy may speed up access but must address high costs and local testing concerns ISTOCK.COM

LANDMARK WAIVER

Earlier this month, the Centre took a step to address such situations, by waiving clinical trials in five categories, if the drugs had been approved in stringent regulatory markets including the US, UK, Japan, Australia, Canada and the European Union.

The waiver covered drugs and vaccines falling into categories including orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes and new drugs having significant therapeutic advances over the current standard care. The waiver was facilitated under Rule 101 of the New Drugs and Clinical Trial Rules, 2019.

The move was welcomed in sections of civil society as being in the interest of patients. However, some industry-watchers have expressed caution, concerned about introducing a therapy without local trials. There are drugs approved by stringent authorities sitting on the periphery, while patients cannot access or afford it, says Chetali Rao, legal and policy advisor with Third World Network.

Earlier, drugs made it to India only if the country was part of the multinational company's global trials. The waiver decision takes it a step ahead by making these drugs available to the local population if countries with stringent authorities approve it, she explains. However, she adds, this may not do much to reduce the high prices (running into lakhs of rupees) of these drugs. "Affordability is still an issue," she says, noting that some of these new therapies are not even registered in India.

Drug companies, especially multi-nationals, point to their patient assistance programmes as avenues to improve patient access. But Rao says they come with conditions that makes it difficult for all patients who may need the medicine.

Besides, in the absence of patient registries, there is no clear picture on the number of patients who actually need the therapy. Only local production by indigenous companies will help to make these drugs more accessible, she says.

CALL TO EXPAND

Following the Government's decision, the Organisation of Pharmaceutical Producers of India (OPPI) said, the move was progressive and would benefit domestic and foreign drug manufacturers "by expediting the approval process and facilitating faster access to essential medications for Indian patients."

Calling it a "commendable beginning", the OPPI called for the waivers to be extended to a broader range of therapeutic categories, to enhance access to cutting-edge treatments. "We urge the Government of India to consider additional therapeutic areas where similar waivers could significantly impact patient access. Moreover, it is pertinent to understand how the criterion for 'new drugs having significant therapeutic advance over the current standard care' is defined and implemented. This could set a precedent for recognising and adopting breakthrough therapies that offer superior clinical benefits," the platform, largely for multinational companies, said.

PATIENT SAFETY

A report by the Global Trade Research Initiative, however, raised patient safety concerns, if there was a waiver. "By overlooking India's unique genetic diversity, the waiver could lead to unexpected safety and effectiveness issues," says the report.

Ajay Srivastava, former Indian Trade Service Officer and founder of GTRI, further points to the lack of reciprocity in the move, besides the high costs Indian companies incur in undertaking trials abroad. Also, insisting on post marketing surveillance after a drug is launched, will result in mere data collection, he says, without a local trial.

While it's true that patients need quicker access to break-through drugs, S Srinivasan of LOCOST (a producer of less-expensive drugs) and representative of Aidan (All India Drug Action Network), says, it should not involve dilution of governance. He calls for "bridging trials" to evaluate therapies in a local population, adding that the option of waivers can be adopted in special cases. The process to make new drugs available to patients, he says, should be both simple and safe.

MAINLINES

Publication	The Hindu
Date	8-Aug-24
Edition	Online
Headline	Government announces waiver for several drugs approved from select countries

Clinical trial: Government announces waiver for several drugs approved from select countries

The Central Government has specified a set of five categories for new drugs that will be considered for the Indian market.

Updated - August 08, 2024 03:07 pm IST Published - August 08, 2024 02:51 pm IST - NEW DELHI

BINDU SHAJAN PERAPPADAN

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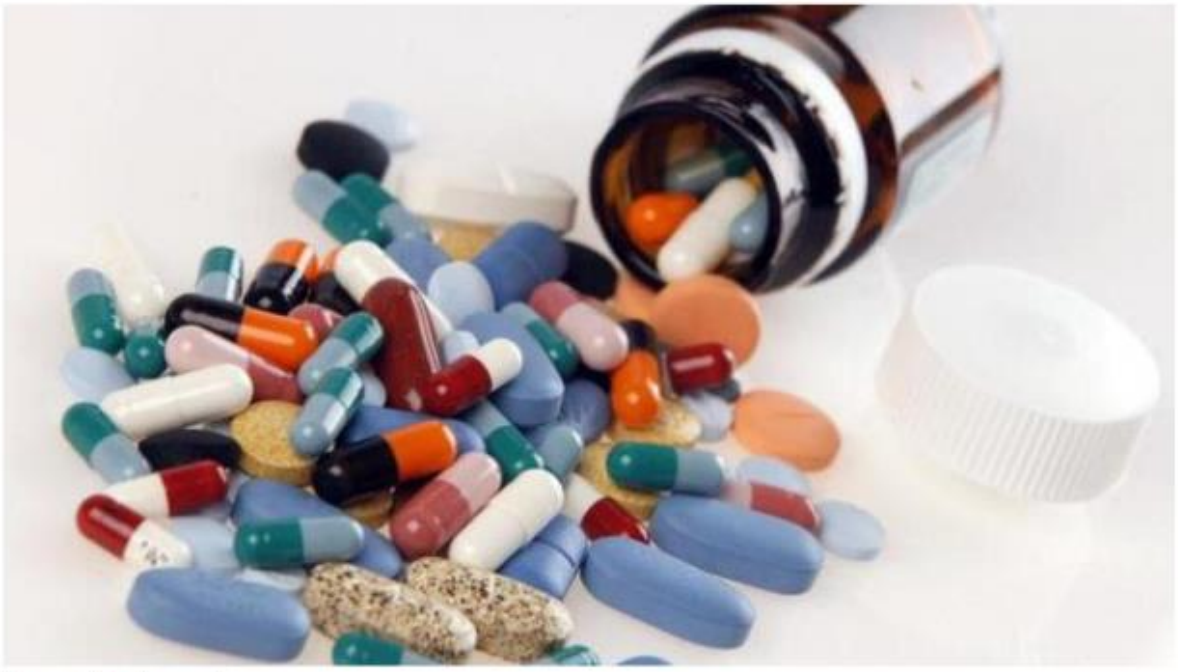

Representational image only.

In a decision that would make drugs manufactured outside India more accessible and affordable in the local market the Central government has decided to waive the requirement for clinical trials in India if the drugs are approved in the United States, United Kingdom, Japan, Australia, Canada, and European Union.

Publication	The Hindu
Date	8-Aug-24
Edition	Print
Headline	No clinical trial for drugs approved in select nations

No clinical trial for drugs approved in select nations

Centre waives the requirement if drugs are approved in U.S., U.K., Japan, Australia, Canada and EU; it specifies five categories for new drugs that will be considered for the Indian market

Bindu Shajan Perappadan
NEW DELHI

In a decision that will make drugs manufactured outside India more accessible and affordable in the local market, the Union government has decided to waive the requirement for clinical trials in India if the drugs are approved in the U.S., the U.K., Japan, Australia, Canada, or the European Union.

The government has specified a set of five categories for new drugs that will be considered for the Indian market.

Drugs for rare diseases and new drugs used in pandemic situations are among those that will be considered for the waiver. AP

Rare disease drugs

Drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, new drugs used for special defence purposes, and new drugs having significant therapeutic advances over the current standard care will be considered for waiver, said a senior Health Ministry official, adding that names of the countries on the current list can be taken off and new ones added.

The order issued by India's drug regulatory agency, Central Drugs Standard Control Organisation, on Wednesday said the Union government had authorised the exemption of local clinical trials for approval of new drugs under Rule 101.

Govt. Rules

"As per Rule 101 of the New Drugs and Clinical Trial Rules, 2019, the Central licensing authority, with approval of the Union government, may specify by an order, the name of the countries from time to time for considering waiver of local clinical trial for approval of new drugs under Chapter X and for grant of permission for conduct of clinical trial under Chapter V of the said rules," reads the order.

Meanwhile, another official at the Union Health Ministry noted that the order has been a long-standing demand of the pharmaceutical companies and health experts who have been advocating for enhanced drug accessibility for patients and for research.

'Progressive move'

Anil Matai, director-general, Organisation of Pharmaceutical Producers of India (OPPI), reacting to the announcement, said that this a welcome and progressive move that will significantly benefit both domestic and foreign drug manufacturers by expediting the approval process and facilitating faster access to essential medications for Indian patients.

"The OPPI has been advocating for this notification, recognising its potential to transform both the pharmaceuticals, and the healthcare landscape in India. The inclusion of specific categories such as orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, those for special defence purposes and new drugs with significant therapeutic advance over the current standard care would address critical and unmet medical needs. This strategic alignment is particularly crucial for accelerating access to innovative therapies to the patients in India," he said.

The group has, however, maintained that extending these waivers to a broader range of therapeutic categories will further enhance access to cutting-edge treatments. It has asked the Centre to consider additional therapeutic areas where similar waivers could significantly impact patient access.

ONLINE AND TRADE

Publication	ThePrint
Date	8-Aug-24
Headline	Govt notifies rule for rapid launch of breakthrough drugs in India, bypassing local clinical trials

Industry suggests removing conditions

In response to a query by ThePrint, the Organisation of Pharmaceutical Producers in India (OPPI), a network of global pharma companies, said that it welcomes the decision to grant waiver of requirement of local clinical trials for drugs, subject to conditions.

"OPPI and its member companies remain committed to collaborating with the government to ensure that Indian patients benefit from the latest advancements in medicine as swiftly as possible, maintaining a balance between safety, efficacy, and expedited access," said Anil Matai, OPPI Director General. "This progressive move will significantly benefit both domestic and foreign drug manufacturers by expediting the approval process and facilitating faster access to essential medications for Indian patients."

The organisation, Matai said, has been advocating for this notification.

The inclusion of specific categories like orphan drugs and gene and cellular therapy products, would address critical and unmet medical needs, he addded.

Publication	Express Pharma
Date	8-Aug-24
Headline	DCGI waives off local trials for drugs approved in well-regulated markets

The move is expected to accelerate access to innovative therapies within the country.

Lauding the decision, **Anil Matai, Director General, OPPI,** says that this move will significantly benefit both domestic and foreign drug manufacturers by expediting the approval process and facilitating faster access to essential medications for Indian patients.

He added, "OPPI has been advocating for this notification, recognising its potential to transform both, the pharmaceuticals, and the healthcare landscape in India. The inclusion of specific categories like orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, those for special defence purposes and new drugs with significant therapeutic advances over the current standard care would address critical and unmet medical needs. This strategic alignment is particularly crucial for accelerating access to innovative therapies for patients in India.

However, while this is a commendable beginning, we believe that extending these waivers to a broader range of therapeutic categories will further enhance access to cutting-edge treatments. We urge the Government of India to consider additional therapeutic areas where similar waivers could significantly impact patient access. Moreover, it is pertinent to understand how the criterion for 'new drugs having significant therapeutic advance over the current standard care' is defined and implemented. This could set a precedent for recognising and adopting breakthrough therapies that offer superior clinical benefits."

Publication	BioVoice
Date	8-Aug-24
Headline	OPPI welcomes Indian govt's move to waive off local clinical trials for certain drugs

Home › Biotech › BioPolicy › OPPI welcomes Indian govt's move to waive off local clinical trials for...

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OPPI welcomes Indian govt's move to waive off local clinical trials for certain drugs

This will be applicable to a few select drugs already approved in well-regulated markets like the USA, UK, Japan, Australia, Canada, and the EU

By **Rahul Koul** - August 8, 2024 64 0

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New Delhi: The Government of India has waived off local clinical trials for certain drugs already approved in well-regulated markets like the USA, UK, Japan, Australia, Canada, and the EU, under Rule 101 of the New Drugs and Clinical Trial Rules, 2019.

Anil Matai, Director General, Organisation of Pharmaceutical Producers of India (OPPI) welcomed the Government of India's decision to notify the list of countries under Rule 101 of the New Drugs and Clinical Trial Rules, 2019 that would, subject to other conditions, enable waiver of the requirements of local clinical trials for several drugs if already approved in well-regulated markets, including the USA, UK, Japan, Australia, Canada, and the EU.

Publication	ET Pharma
Date	8-Aug-24
Edition	Online
Headline	India waves local clinical trials for certain drugs approved in well regulated markets

India waives local clinical trials for certain drugs approved in well-regulated markets

The policy specifically addresses critical and unmet medical needs by including categories such as orphan drugs for rare diseases, gene and cellular therapy products, new drugs used in pandemic situations, those for special defense purposes, and new drugs that offer significant therapeutic advancements over current standards of care. This strategic alignment is seen as crucial for accelerating the availability of innovative therapies to Indian patients.

Online Bureau · ET Pharma
Updated On Aug 8, 2024 at 04:48 PM IST

Read by:
851 Industry Professionals

New Delhi: Informing that both domestic and foreign drug manufacturers will be benefit by the significant policy shift, as the Government of India has waived the requirement for local clinical trials for specific drugs that have already received approval in well-regulated markets such as the US, UK, Japan, Australia, Canada, and the EU. The Organisation of Pharmaceutical Producers of India (OPPI) stated that its a progressive move and it is expected to benefit both domestic and foreign drug manufacturers by expediting the approval process and facilitating faster access to essential medications for Indian patients.

Publication	ET Pharma
Date	10-Aug-24
Edition	Online
Headline	Fostering Innovation and Growth: The Need for a Robust Intellectual Property Framework

Fostering Innovation and Growth: The Need for a Robust Intellectual Property Framework

An effective IP framework serves as both a guardian and an enabler. It guards the results of ingenuity, ensuring that inventors are duly rewarded for their contributions. Simultaneously, it acts as an enabler, fostering an environment where businesses can confidently invest in research, development, and manufacturing, knowing that their IP rights are secure.

Anil Matai · ET Pharma
Updated On Aug 10, 2024 at 11:03 PM IST

In the dynamic tapestry of modern medicine, where technological breakthroughs and disruptive innovations constantly redefine health outcomes, the role of Intellectual Property (IP) framework emerges as not just pivotal, but foundational. A robust IP framework is essential to foster innovation and growth by providing the necessary protection and incentives for pharmaceutical companies, researchers, and developers.

An effective IP framework serves as both a guardian and an enabler. It guards the results of ingenuity, ensuring that inventors are duly rewarded for their contributions. Simultaneously, it acts as an enabler, fostering an environment where businesses can confidently invest in research, development, and manufacturing, knowing that their IP rights are secure.

Publication	BW Healthcare
Date	14-Aug-24
Edition	Online
Headline	Building a Healthier Future: India's Vision on Innovation & Research

Building A Healthier Future: India's Vision On Innovation & Research

Mr Anil Matai | Aug 14, 2024

research # innovation # pharma # India # healthcare # patents # R&D # biotechnology # pharmaceutical # technology # trade

The Government of India's Amrit Kaal blueprint -Vision Pharma 2047 – which envisages India as 'Vishwaguru' (global leader) in innovation & research underscores the Government's commitment to nurture an innovation-driven ecosystem

Research and innovation are the cornerstones upon which the future of medicine is built. Healthcare systems are able to thrive because of continuous research & innovation in the fields of science and technology that result in finding new treatment outcomes to address unmet medical

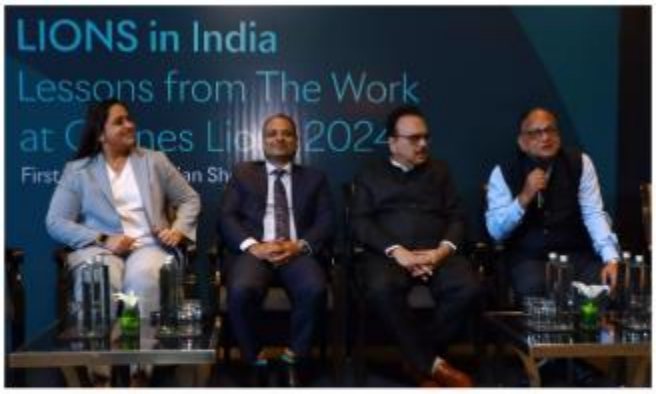
Publication	The Tattva
Date	17-Aug-24
Edition	Online
Headline	Government simplifies drug approval process with new waiver

Impact of Drugs Approved from Foreign Countries on India's Pharmaceutical Landscape

The waiver order, issued by the Central Drugs Standard Control Organisation (CDSCO) on August 7, aligns with Rule 101 of the New Drugs and Clinical Trial Rules, 2019. This rule grants the Central Licensing Authority the power to exempt certain new drugs from local clinical trials, provided that such exemptions are approved by the Central Government. The CDSCO's order specifies that the names of the countries eligible for this waiver can be updated periodically to reflect changes in international regulatory standards and global health needs.

Anil Matai, Director General of the Organisation of Pharmaceutical Producers of India (OPPI), has praised the government's decision, highlighting its potential benefits for both domestic and international pharmaceutical companies. Matai described the move as "welcome and progressive," noting that it will facilitate a more efficient approval process and enable faster access to essential medications for Indian patients. He emphasized the significance of this waiver in addressing unmet medical needs, particularly for rare diseases, advanced gene and cellular therapies, and treatments related to pandemics.

Publication	ET Brandequity
Date	28-Aug-24
Edition	Online
Headline	A booster dose for marketing in pharma and healthcare



Anil Matai, director general, Organisation of Pharmaceutical Producers of India spoke about the importance of public-private partnership in improving this access to universal health care. "It has to be a public private partnership when it comes to infrastructure development of all kind, whether it is physical infrastructure, the E-infrastructure and so on," he said.