ROFEL SHRI G M BILAKHIA COLLEGE OF PHARMACY

AFFILIATED TO GUJARAT TECHNOLOGICAL UNIVERSITY, APPROVED BY PHARMACY COUNCIL OF INDIA
ISO 9001:2015 & ISO 29990:2010 CERTIFIED INSTITUTION

"Experience Innovation in Education"

HIGHLIGHTS OF MONTH

We have launched New website of our college.
link: www.rofelpharmacy.ac.in

Visit and explore the new layout.
For Information : info@rofelpharmacy.ac.in
For Administrative Office :admin@rofelpharmacy.ac.in
For Admission Enquiry : admission@rofelpharmacy.ac.in
To Contact Principal : principal@rofelpharmacy.ac.in

Feedback from our New students at ROFEL Campus.

"If your actions inspire others to dream more, learn more, do more and become more, you are a leader"

"HOW YOU FEEL AT ROFEL CAMPUS"

I am Niyati A.Pawar
B.Pharm Sem-1

I am a student of Rofel Shri G.M Bilakhia College of Pharmacy,Vapi . I am very greatful here to share the feedback about my college. My all-inclusive experience till now is astounding with very good facilities and other arrangements done for the students along with the teaching skills. I have perosnally found a healthy and postive surrounding with the teachers who are thoroughly supportive regarding every aspect.They motivate us and give us the push we need to get the best out of ourselves.The individual attention paid to each student is hard to get at any other colleges.

Thank you .

Hello , I'm Tiwari Shraddha from B.Pharm Sem 1 . With the advent of pharmaceutical sciences and its augmentation, ROFEL has led me to a whole new experience with education and learning. I can always count on the positive network of our faculties alongside the library book facility and laboratory practicals for clear reference. The atmosphere is discreet and encouraging. It has been a great opportunity to outgrow here. I look forward to further outgrowth in the following years.

I am glad to have taken admission in B Pharm in Rofel Shri G M Bilakhia college of Pharmacy. (We are extremely lucky that the classes had been started offline from the first day, When the cases started increasing back then, the college took more precautions, And all professors supported hybrid mode)Its fun to perform practicals, trust me when I say this. The professors and staff are very friendly & supportive. We have a number of books and journals in the library to dive into, and a nice botanical garden. Library & Botanical garden are my personal favourite in the college. I had personally dived into the library many times, there are a lot of book you can read other than the syllabus of main course, which may interest you. And Botanical garden which have a number of medicinal and ornamental plants to observe all day (if you are an autistic like me, you can). The second most loved is the Practical hours of the college.
Where you learn a lot of new things, and which give you a pleasure of knowing and doing something :)
-Nikhil (B.Pharm Sem -1)

Hello I am Srushti (B.Pharm Sem-1).
I like the environment of college, all the professors are very hard working and put great efforts for us... Library is very useful and I really like the college... 😇

Feedback From our ROFEL Alumni

"LETS REWIND BACK TOGETHER"

It's great to be back here. I can see the drastic change in infrastructure of college, definitely the positive growth. Thanks to ROFEL for such a huge contribution in my career development. Alumni association would benefit for new talent.

Mr. Falgun Shah (B.Pharm- 2002)
Currently working at-
Mercu Research,
West Point, PA,USA

Always good to be back here. ROFEL is a well growing college as I know. The management and teaching staff has very positive thinking for new ideas and culture development. I am glad that I have completed my graduation from this college. Good luck and best wishes.
Nakul Patel

(B.Pharm 2003)
Currently working-
Manager, Zydus Healthcare Ltd.
Ahmedabad.

It is a great privilege to me to say about my college ROFEL Shri G.M Bilkahia College of Pharmacy and Department of Pharmaceutics. I think I have made a best choice to join this department of this college. Those six years were phenomenal. The HOD, teaching and non-teaching staff were stupendous. I learnt a lot from curriculum as well as from different industrial visit we leart more about practical knowledge. I feel proud that I am a student of such an esteemed institution which focuses only on student career and well-being.
Jitendra Jaiswal
B.Pharm(2014) & M.Pharm (2016)

I am very happy to be a part of ROFEL from 2011-2017. My journey during college was really splendid and all credit goes to ROFEL Shri G.M Bilakhia College of Pharmacy. With my 6 years (UG & PG) of stay here I would honestly say that if you want to discover your potential , there is no better place than ROFEL. The dynamic management and professors put their trust on students and help them to reach new heights. That is how I came out with multiple placements on hand which includes my dream job.Our college also helps us to learn all soft skill training, other extra curricular activities and also industrial training. On the whole ROFEL pages of my life diary stands evergreen and my relationship with this place remain forever. Wholehearted thanks for everything ROFEL.

Ms. Velenti Chauhan
(B.Pharm 2015) & (M.Pharm 2017)

Attending college for the first time made me tense but it was great experience for me. The way in which I have grown up, mature, and found out who really I am, is something that I couldn't accomplish without going to ROFEL. ROFEL college of Pharmacy is much beyond just an "institution'. It actually donates a "culture'. Culture of excellence, empowerment and enrichment. Being a part of ROFEL, I felt blessed. My heartily thanks to all the professors, Principal and staff members in our institute who have helped me in my entire journey of college. The various co-curricular activities have build confidence and leadership qualities in me which will be helpful for me throughout my life.

Ms. Dimple Jain
(B.Pharm- 2019)
(M.Pharm- 2021)

OUR STUDENT ZIL PATEL (B.PHARM SEM-1) SPENDING HER DIWALI VACATION IN A CREATIVE WAY.

After Diwali Vacation, student have resumed their classes from 22 November ,followed by GTU exam of B.Pharm Sem 7.

PHARMA TALKS

With Omicron, the SARS-CoV-2 virus ups the ante

As Express Pharma's Anniversary marks the end of a tumultuous year, the WHO designated B.1.1.529/Omicron has emerged as a SARS-CoV-2 variant of concern (VOC). Countries have once again issued travel advisories and shut down flights to and from affected areas.

Sadly, the emergence of Omicron in southern Africa coincides with World AIDS Day on 1st December. Due to its "very unusual constellation of mutations," scientists are leaning towards the theory that it could have evolved during chronic infections among immunocompromised patients, most likely HIV/AIDS patients. Similarities are being drawn to the last year's beta variant, also identified first in southern Africa, which has the highest number of people infected with HIV.

As data on the Omicron variant increases by the day, cases have already been detected in Belgium, Israel and Hong Kong, in patients with travel histories including southern Africa. While our experience of the past two years of coping with COVID-19 will hopefully help us find the right treatments faster, one cannot deny the uncertainty that every variant brings to our world. Memories of last year's stock markets crashes, travel bans and supply chain shocks due to COVID-19 are already once again a reality and should serve as a wake-up call.

Because, even if Omicron proves to not be as infectious, countries cannot take chances. It is too early to be congratulating ourselves on rolling out vaccines, diagnostics tests and pills for the vaccine-hesitant and immunocompromised. Even as developing nations struggle to give their entire populations at least the first shot, fully vaccinated developed nations, initially complacent about their booster shots, may now prefer to wait for rejigged shots to combat these new variants.

Omicron's emergence led to the WTO postponing its in-person 12th Ministerial Conference (MC12), and while alternative arrangements are being worked out, this will definitely impact efforts to form a meaningful consensus on the two-year-old TRIPS waiver proposal. The operative word being 'meaningful.'

First proposed by India and South Africa, and now backed by more than 100 low-income developing countries, will the proposal to waive off certain intellectual property (IP) rights on COVID therapeutics for the duration of the pandemic, be once again relegated to 'simmer on the back burner'?

Ironically, if the waiver had been approved earlier, more vulnerable populations, like those in southern Africa, would have possibly had better access to COVID-19 vaccines and medicines. VOCs like Omicron are thus only to be expected as the divide between the vaccine haves and have-nots, and the Global North-South, widens.

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Mirroring COP-26, India was expected to become the voice of choice for the Global South at the MC12. It may seem strange that India is seeking an IP waiver, even while encouraging, and part-funding IP related to COVID-19 vaccines and medicines. Why fund IP in vaccine efforts like Bharat Biotech's Covaxin and Zydus Cadila's ZyCov-D, (and many more such candidates in the pipeline), only to agree to waive this IP when the demand is the highest? But this stance is being seen as proof that India is acting like a responsible global citizen.

A waiver will further enhance India's reputation as a global vaccine manufacturer, but this was India's calling card even before the pandemic. If there was scant interest in that responsibility pre-pandemic, then why are so many blocks being raised now? The fact is, COVID-19 therapeutics and vaccinations will remain important for at least the next few years.

It may be argued that a TRIPS waiver is no longer required, as voluntary licences (VLs) could serve the same purpose to improve access to COVID medicines. Recent examples include Merck's VL for molnupiravir and Pfizer's VL for Paxlovid, to Medicines Patent Pool (MPP).

But Médecins Sans Frontières/Doctors Without Borders (MSF) has highlighted many limitations in these VLs. Not only does the territory exclude nearly half of the world population and important upper-middle-income countries with manufacturing capacity, such as in Brazil and China, it also contains a provision undermining the right of generic companies who sign the licence to challenge patents to facilitate generic-drug production, as per an MSF release. Legal experts have since cautioned that these recent VLs for COVID-19 therapeutics, while being projected as replacements for compulsory licences (CLs), have actually served to "blunt" the true spirit and original intent of such agreements.

After successfully creating a world of COVID-19 vaccine haves and have-nots, we should expect many more situations of what's being termed "vaccines apartheid." For example, at the now postponed MC12, as per a 16th November circular from the WTO Secretariat, only participants vaccinated with European Medicines Agency (EMA)-approved vaccines could apply for the Swiss COVID certificate required to attend the Geneva-based MC12. This was a neat way to create logistical nightmares for representatives from the global south, who would need to undergo PCR tests every 72 hours to attend the meetings.

Do we dare look at 2022 with hope? It is worth remembering that this is a world without borders. And, none of us is safe, till everyone is safe.

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OPINION

New opportunities for India in global API market

V K Singh, Chief Operating Officer – Chemical SBU, Cadila Pharmaceuticals, traces the evolution of the API industry in India and the road ahead

Active Pharmaceutical Ingredients (APIs) are the building block of strategic architecture in the pharmaceutical value chain. More importantly, APIs provide therapeutic effect of a medicine and, are, therefore, the central innovation and, more often, the critical intellectual property that drives the industry. API manufacturing is not only about prowess in chemistry, but also the skill to navigate the maze of patents that inventors and others file to ring-fence and evergreen their invention, thus, prolonging the marketing exclusivity and concomitant commercial gain. It is generally believed that the API industry migrated to India from Europe where it thrived for more than a century due to cost arbitrage. However, India's skill in chemistry catalysed this migration and her dexterity in process design and engineering gave her the power to stay.

There is another myth that India's patent regime gave it a structural advantage. While that may be true for the domestic market for which APIs could be produced and sold even if under patent, it would certainly not have helped India become the hub of exports for regulated markets. Besides, like India, a host of other countries had the process patent regime till they all joined TRIPs in 1995.

In 2020, the global API value was $180 billion, and it is expected to grow at a CAGR of mid-single digits (five-to-six per cent) during 2021-2026 to $250 billion by 2026 and $300 billion by 2030 adding about $50 billion every five years. As per IMS 2020, the generic market for API has a share of 94 per cent by volume with the innovator's share of six per cent. This shows that the opportunity of penetration into the generic market is immense. Given the sheer size of the market, a whole lot of mollarisation, as it happened in the 50s in the automobile industry, is on the anvil, and we foresee a big stand-alone capacity for intermediates of APIs, the new star on the horizon.

API exhibits at the base of the value pyramid. The impact of genericisation is the highest on this segment. The price erosion is also the fastest. Hence, for mature APIs, the focus will shift from R&D process to excellence in engineering. Improved kinetics, improved process engineering, improved solvent recovery, optimal batch sizes, scale and minimal changeovers – all will be critical for cost efficiency. Companies will focus on fewer APIs, but manufacture more of them, for scale, procurement and cost efficiencies.

Dependence on China for APIs has been a big concern for the Indian pharma industry. From 0.5 per cent in 1987, the percentage of API imports from China shot up to around 78 per cent in 2020. India imports approximately 55 per cent of its API needs, and almost all imports are from China. Scale, subsidies, cheaper capital with cost of four-to-five per cent versus 12-15 per cent in India, lower logistics cost (0.9 per cent versus four per cent in India), cheaper power, all work to China's advantage.

However, the ride with China is always a roller coaster. Their implementation of laws is too capricious. In early 2018, several industrial parks and SEZs were shut due to environmental issues. The government launched a programme, '26+2' with 5,000 inspectors swooping on industrial parks and factories and closing more than 1,000 creating global shortages. Besides, wages in China are increasing. There is always an additional factor of geo-politics. Whether it is the Doklam Standoff of 2017 or the

skirmish in Galwan in 2020, peace with China is always tenuous. Several Indian companies have moved their requirement of APIs, KSMs and intermediates to Indian manufacturers who have ramped up their capacity rapidly to cater to this uptick in demand. Nevertheless, the dependence on China for basic chemicals continues. Therefore, to say that we have insulated and shock-proofed our supply chain from dependence on China would be an overstatement.

The COVID-19 pandemic, a Black Swan event in the real sense, came as an eye-opener for pharma manufacturers worldwide. Prices of several APIs shot up between 50 to 100 per cent. The world also witnessed medicine nationalism. Most importing countries saw the need for repatriating the pharma industry back to their shores and domiciling production. While the Indian API industry had capability, it lacked capacity. Noting this, the Government of India stepped in with the PLI scheme as a part of *Aatmanirbharta* (self-reliance) to encourage the industry to build capacity in India.

Post pandemic, there was a clear clamour for reshoring in the US. The government encouraged Pfizer Corp with aids from outfits like BARDA for reshoring several essential APIs back to the US with reliance on continuous manufacturing to keeping costs low. As the industry moves to fewer APIs with high scale and cost control, the migration to continuous manufacturing will become an imperative. The draft guidelines on continuous manufacturing are evoking under the sponsorship of USP.

The interchangeability of biosimilars, which, is the US, till a few months back was allowed only as follow-on-biologics, is another game-changing phenomenon on the firmament. Insulin has been the first to receive that status. The biologics market is expected to be around $150 billion to $170 billion going off patent by 2030. The market will grow in leaps and bounds once interchangeability is allowed for all of them. The products are all small volume and do not need scale. Many scientist-driven boutique companies are expected to come up with specialisation in few APIs to address this opportunity.

India is the largest manufacturer of drugs, next only to China and Italy in volumes, and, globally, 12th in terms of value. The Indian pharma sector is projected to reach $75 billion by 2024 and $130-138 billion by 2030. India has been a major contributing factor to global healthcare outcomes and is responsible for meeting 60 per cent of the global requirement of ARV (Anti-retroviral) drugs. About 38 per cent of ANDAs have been filed by Indian manufacturing sites in the last five years. India has the highest number of US FDA-approved plants outside that of the US, and has a reputation for meeting top-notch standards laid by FDA and EDQM.

Post-COVID, the Indian pharma industry is at an inflexion point. It is envisaged, that the contribution of pharma to the GDP will grow to 4.5-5 per cent from 1.8 per cent, at present. And, given the learning from India's contribution to TB and retroviral drugs, one can extrapolate that APIs to a very large extent will drive this aspiration and growth trajectory. The growing negative sentiment about China in large due to the pandemic and due to the growing unpopularity of its trade bullying and debt diplomacy has significantly increased the migration of interest to India and will help the API industry. As a consequence, we see huge PE interest in the Indian API industry. The top 10 or 12 global funds have created a war chest of about $5 billion to invest in the Indian industry. To keep in step with its own captive needs, growth aspiration and the market demand, Cadila Pharma has also created a blueprint for quadrupling its API manufacturing capacity in five years at its green field project at Dabej in Gujarat.

Pharma is one unique sector where the consumer is not the decision maker and the decision maker is not the payer. It is unique in another sense, that there is no product obsolescence. Aspirin, paracetamol and metformin still continue to be gold standards of front-line therapy. Hence, scale, quality, compliance and process excellence shall drive growth. The above said notwithstanding, India will have to create robust and resilient supply chains and fix infrastructure much faster than she plans, to ensure that she is not a bystander to this next phase of growth.