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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 51 Issue No. 44 22 to 30 November 2020

IDMA ACTIVITIES:

IPR MATTERS:

GOVERNMENT COMMUNICATIONS:

CBIC MATTERS:

PARLIAMENT NEWS:

NEW DEVELOPMENTS:

NATIONAL NEWS:

INTERNATIONAL NEWS:

FEATURE:

MBA-STYLE INTERNATIONAL EDUCATIONAL PROGRAM FOR POTENTIAL LEADERS

Empowerment
Through Education
Living A Dream,
Building A Future

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

A VIRTUAL TRAINING PROGRAM - SERIES 2 Commences 1st February 2021

For further information / queries, please open the below links on our website www.idma-assn.org:

Circular / Covering Note | NSF Presentation | WHY APPQM? By Mr S M Mudda | APPQM 5 Modules | APPQM Series 1 FEEDBACK | REGISTRATION FORM

APPQM FOR DEVELOPING CHANGE AGENTS FOR QUALITY EXCELLENCE

APPQM - Program Modules

1. **Pharmaceutical Quality Management Systems – Best Industry Practices**
   (How to ensure your QMS drives business improvements)
2. **Managing Change: Change Control and Deviations**
   (Advanced problem solving, deviation management, report writing and change management)
3. **Human Factors – Getting people to follow the rules**
   (How to improve performance, reduce human error, embed a quality mind-set & keep your people)
4. **Transforming Data into Information – the Practical Application of Statistics to Transform your Business**
   (The practical application of statistics to transform your business)
5. **Quality by Design, Process Validation and Technology Transfer**
   (Building a foundation for Product Quality and Knowledge Management)

Advantages of NSF's Virtual Training

- NSF's virtual training combines live instructor-led virtual classrooms and self-paced learning online (easy to navigate e-learning) to provide participants with an interactive and engaging learning experience.
- Enhanced Virtual Interactivity – such as polls, etc.
- Virtually managed Break-out rooms - These are as good as physical break out groups
- Use of Team works – specially smaller group sizes
- Use of Tasks and Case Studies
- Courses managed Brilliantly by NSF - Each course is managed on NSF Learning Management System (LMS), with electronic course material
- Time for self-study each day.
- Guest Speakers (including MHRA, US FDA ex-regulators) enhance the modules and motivate the delegates

Additional Benefits:

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees **(from £8000 to £3300)**
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Why APPQM in INDIA?*

When launching the first series of the APPQM, we at IDMA along with NSF, UK reflected on the perceived trust deficit with international regulators despite being regarded as a 'Pharmacy of the World' and offered a global education program APPQM, in collaboration with NSF Health Sciences, UK, as a collective proactive response from the industry. We boldly stated APPQM would be Unique, World-Class and transform the operation efficiency of companies attending. Well, did series one live up to expectations?

Over 40 delegates attended series one.

This is what they thought:

"Transformative", "world-class", "best business investment we've ever made", "life changing", "worth every penny and more", "my company will be sending more delegates to series two", "has helped transform our quality culture" are just some examples of the feedback we've received from APPQM delegates.

Nearly 30 'work placement projects' have been completed by APPQM delegates.These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

*Please visit IDMA website for details of benefits

Current Challenges & APPQM

In this challenging times, the pharmaceutical industry will become competitive only if the 3 factors - **Legacy & Reputation** (License to Operate), **Profit & Efficiency** (Cost Control) and **Customer service** are balanced and managed well.

The COVID-19 pandemic has created unique challenges as well as opportunities for the industry. In the absence of any regulatory inspections happening until quarter III of 2021 and reduced physical oversight by the corporate QA functions, the external interventions on the site will be reduced. There is an urgent need to use this time for building a strong leadership at the site for quality and compliance.

We recommend the virtual APPQM for the site teams for keeping themselves updated with the changing regulatory expectations in the post COVID-19 phase, once the physical inspections start.

The need of the hour is to focus on long term preventive measures aimed at achieving continual improvements rather than short term Compliance-Oriented approach.

Please don't get left behind and register for the second series of APPQM to have a competitive edge in the global market and to be future ready.

REGISTRATION FEE FOR SERIES TWO

The Registration Fee for **APPQM SERIES 2** is restructured at

Rs.3,15,000/- (Rupees Three Lakh Fifteen Thousand Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the Registration Form and send it to

Melvin Rodrigues actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

For further information / queries :

You may also contact **Mr. S. M. Mudda**, @ **mudda.someshwar@gmail.com** / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M MUDDA Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**MAHESH H DOSHI** National President, IDMA	**DR. GEORGE A PATANI** Hon. General Secretary & Vice Chairman, Industry Institution Interaction Committee, IDMA	**DAARA B PATEL** Secretary – General, IDMA

IDMA, BDMA, FOPE, FICCI joint Representation on new PLI Scheme for Pharmaceuticals

Indian Drug Manufacturers' Association (IDMA) jointly with Bulk Drug Manufacturers Association of India (BDMA), Federation of Pharma Entrepreneurs (FOPE) and Federation of Indian Chambers of Commerce & Industry (FICCI) submitted the following representation on 19th November 2020 to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi on Proposed Phase II PLI Scheme for Pharmaceutical Sector:

"At the outset, we thank you for the kind opportunity given to BDMA, FOPE, FICCI and IDMA for the web meeting on 17th November 2020 to discuss the proposed Production Linked Incentive (PLI) Scheme.

We have attached two separate notes for your kind perusal as under:

1. Suggestions from our 4 Associations for the new PLI Scheme.
2. Record Note of the Minute of Meeting held under your Chairmanship on 17th November 2020.

Looking forward to your favorable consideration. Thanking you and with best regards."

Suggestions of the 4 Associations for Phase II PLI Scheme for Pharmaceutical Sector

MSMEs are backbone of the Industry and need handholding. Many Global Leaders of today were MSME companies of yesterday. Giving opportunity to MSME will help in creation of Champion Companies of Future.

As Pharmaceutical is already 3rd in volume and 13th in value, the Focus needs to be on self-reliance & Value creation. We BDMA, FOPE, FICCI, and IDMA wish to submit the followings for your kind consideration:

Criteria:

- We wish to suggest that **net worth, investment and selling price** should not be the only criteria for the selection of applicants.
- We suggest that instead of turnover (domestic + exports), knowledge, technology, experience and the capacity be the criterion for the scheme.
- Focus shall be on technology innovation and value creation.
- Scheme should be as simple as possible without any ambiguities and cumbersome procedural requirements.
- Since the scheme is all about Self Reliance and *Atmanirbhar Bharat* limiting this to Greenfield investments only should not be the focus. INSTEAD, Brownfield investments, Existing Unutilized capacity/ Old/Second-hand Machinery should be permitted to be used to ensure optimum utilization of National Resources.
- We suggest that there should be no reservation for any specific Sector and value creation and innovation should be key criteria.
- MSMEs are capable of producing most items listed in Category 1 & 3 of the PLI scheme, namely:
  - (1). Repurposed drugs,
  - (2). Autoimmune drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, and ARVs,
  - (3). *In vitro* diagnostic devices,
  - (4). Phyto-pharmaceuticals,
  - (5). Other drugs not manufactured in India,
  - (6). Other drugs as approved. Anti-cancer drugs only may be considered out of their capabilities

(7). Orphan Drugs,

(8). Patented Drugs nearing expiry patent Expiry, etc.

- For the success of the PLI scheme, present and planned, it is very important that major relaxations are accorded to the Industry by MoEF&CC from the present outdated Guidelines.

    1. For complete flexibility in product mix change, all permissions (EC/CFE/CFO) should be given Category wise such as "API & Intermediates",

    2. Pollution load (Quality & Quantity of Effluent) based permissions for discharge and not on the quantity of production inside the plant, Strengthen and support CETPs for effective and full proof treatment of effluent.

We, also suggest setting up of the following:

- National Level Authority to be constituted for advance Research in Chemical Drug Development and Biotech based products.
- Contract Manufacturing Organisation (CMO) to be developed in association with Academic Labs for DI and KSM, API, etc.
- Early-stage Government R&D support to be provided to Academia for pilot development of API for establishing the viability.
- Approval of Research-based products has to be given the topmost priority. Change your policies accordingly.
- Creation of New Centre of Excellence for API Development.
- Ease of Doing business, Single Window, Deemed approval, Pricing Policy, R&D Incentive withdrawal, regulatory dimension, simplification all loose ends to be tightened.

Other miscellaneous points:

1. **Gene therapy/Stem Cells –** Medium Enterprises can perform well in this area. There is not much land needed for these projects. At present 700 Clinical Trials are going on in this area and it has a market worth USD 2 Billion and is growing at a rate of 16%.

2. **Orphan Drugs –** Since the number of patients is limited in the world, it may not be viable for many manufacturers to produce these products. Special focus is needed on this aspect so that patients do not suffer and die for want of such medicines. We feel Government should incentivize R&D, Clinical Trials & Bulk production to create Industry interest in these products. Guaranteed purchase programs at fair market price may be initiated by Government to protect the manufacturer and to ensure the drugs availability to patients at affordable price. Sector Specific discussions may be initiated with dedicated NGO's such as IORD, (International Organization of Rare Disease) to ensure that advantage to the scheme reaches patients.

3. **Repurposed Drugs –** Government funded Research Institutions such as CSIR labs shall be involved for identification of known drug for New Application. Investments in Information Technology (Artificial Intelligence) shall be encouraged to identify the Drug targets and Drug Development.

4. **Excipients –** Excipients can also be produced by the MSMEs along with reagents, solvents, Hard Gelatin Capsules, etc. While considering excipients, chemicals, solvents, reagents, etc may be included in the list of products at the time of deciding the proposed PLI Scheme.

5. **FDI –** To attract Foreign Direct Investment; Department of Pharmaceuticals may kindly organize a web meeting for the PLI Scheme with the Global Investors by involving of Indian Missions abroad. DoP may also consider inviting Global Investors in India Pharma & Medical Devices summit.

6. **Support for R&D –** Large amount of expenditure is necessary for development of processes, particularly for the complex molecules and advanced drug delivery systems. Similarly, advanced technologies may need to be outsourced for which payments can be either upfront as lump sum amount, or by way of Royalty over a specified period. Part of the Rs.15,000 cr incentive needs to be earmarked for both these expenses incurred by the investors.

7. For creating new markets, FTAs may be encouraged, as necessary, keeping India's interest in Pharma Sector in mind.

8. **Environment –** Environmental permissions from the Ministry of MoEFCC has been the major hurdle for the industry. The project cannot be implemented unless the Environment approval is obtained before. We suggest blanket environment permission from the Ministry of Environment for the molecules to be produced in the existing PLI Scheme and in the proposed PLI Scheme subject to compliance with the permitted Pollution loads.

9. **Compulsory License –** Domestic manufacture of Patented Drugs can be achieved by utilizing the flexibility available to developing countries under TRIPS for grant of Compulsory License.

10. **Value Addition –** For the fermentation, we suggest retaining domestic content as 90% and for the synthetic molecules 70%.

11. **Business Security –** As repeatedly pointed out by the Associations, this is one of the major apprehensions faced by the prospective investors of PLI Scheme, particularly for the high-value investments needed for the fermentation-based products. This is because of the past experience from the onslaught of low-priced imports from China which ultimately wiped out the local fermentation industry. We feel the inclusion of a Para as under in the Guidelines would go a long way to assuage the investors:

    "Empowered Committee will keep a watch over import prices and in case of any sharp the predatory downward movement will recommend to Ministry of Finance for the proportionate increase in import duty within the framework of International Trade Agreements. Alternatively, compensation can be by way of increase in the incentive on a pro-rata basis to the investor under the Scheme."

12. We request industry be taken in confidence in advance for all decisions to be taken by the Government. Some decisions like restrictions on exports during the COVID time had an adverse impact on the credibility of the Indian Pharmaceutical Industry as a reliable supplier.

Record Note of the Minutes of Meeting held virtually under the Chairmanship of Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals on 17th November 2020 at 6 pm

You, very rightly pointed out that of all manufacturing sectors across the country, Government has chosen 10 specific Sectors to provide special impetus through the proposed PLI scheme. Pharmaceuticals have been chosen as one of these important manufacturing Sectors. This sector deserves special consideration, as any disruption in the supply chain would have direct impact on health of the population of the country. Unlike other Sectors this Sector is purely science driven & value creation can only be done by focus on Science and Technology. Priority and objective of the PLI Scheme for this Sector should be to reduce dependence on China and Value Creation. "Investment" and "job creation" should be secondary objectives. This is to achieve the objective of '*Atmanirbhar Bharat'* as envisioned by our Hon'ble Prime Minister.

You had very kindly elaborated the entire Scheme for the creation of **Global Champions**, namely the Sunrise Sectors, Key Sectors, and Labour Incentive Sectors. The Pharma sector is chosen to create **Potential Champions** in terms of scales, accessibility and affordability in domestic markets and higher value in Global Value Chain. The proposed PLI for the Pharma envisages a new investment of Rs.25,000 Crore, employment generation of 1,00,000 jobs and incremental exports of Rs.30,000 Crore with domestic value addition.

You also explained the timelines for the new proposed PLI scheme, starting from the Cabinet approval of 13th November 2020 and the closure of the application window by 15th March 2021 and approvals by 15th April 2021.

● ● ●

Aptar Pharma-IDMA Webinar on Ocular Drug Delivery; A Therapeutic Area with an Interesting Past and a Fascinating Future: A Report

Indian Drug Manufacturers' Association (IDMA) & our esteemed Member Aptar Pharma organised a Webinar on "***Ocular Drug Delivery; A Therapeutic Area with an Interesting Past and a Fascinating Future"*** on 5th November 2020. The Webinar was well-attended with over 92 participants from about 54 pharmaceutical manufacturing companies, mostly senior management level, with most of them involved in manufacturing and marketing of ophthalmic products and solutions. There were three speakers from Aptar Pharma, Germany, who spoke about different aspects of ocular drug delivery.

Mr Mahesh Doshi, National President, IDMA in his Welcome Address said "It gives me great pleasure to welcome you all to the Webinar on "*Ocular Drug Delivery: A Therapeutic Area with an Interesting Past and a Fascinating Future".*

It is my pleasure to especially welcome Mr Kanwal Tikoo, President India & South East Asia, Aptar. Dr Deven Parmar, Sr Director & Head, Clinical R&D, Zydus Cadila, Dubai and Chairman, IDMA Medical Committee. Mr Daara Patel, Secretary-General, IDMA, who will set the tone for the Webinar. We have Expert Speakers from Aptar Germany namely, Mr Matthias Birkhoff, Vice President, Business Development, Mr Mathias Leitz, Head of Product Management and Dr Degenhard Marx, Director, Scientific Affairs.

We generally are familiar with Drug Deliveries through topical, systemic, Oral, Transdermal, Intra-nasal routes etc. Eye Diseases are generally treated by medications administered via the topical or systemic route, though the topical route is increasingly preferred.

But the eye is an isolated very intricate specialised organ that is highly protected and hence delivering a drug directly to the eye is hugely complex though very beneficial. Hence the major challenge faced by today's pharmacologists and formulation scientists is ocular drug delivery.

We are indeed fortunate that Aptar Pharma, our esteemed Member, is a global leader in preservative-free multi-dose eye care solutions.

There are many advancements in ocular drug delivery that our expert Speakers from Aptar will educate us and improve our understanding of this complicated therapy.

We look forward to hearing them. I am sure that you all will benefit from this webinar as this webinar would highlight prevailing options available and also discuss future developments, in particular about innovative ideas like "Connected Eye Care", an issue which is more significant due to the current pandemic situation.

I once again thank Aptar Pharma & IDMA Secretariat for organizing an interesting and useful Webinar and welcome you all to the Webinar

Mr Daara B Patel, Secretary General, IDMA in his Opening Remarks said "It is my great pleasure to address you and set the tone to this webinar *'Ocular Drug Delivery: a therapeutic area with an interesting past and a fascinating future'* being organised by APTAR & IDMA jointly".

In setting the tone he said Human eyes are the most sensitive part of the body. The chronic ophthalmic diseases are mostly treated by daily eye drop application and to maintain the stability and efficacy over the period of time is the big issue for such medicine. Ophthalmic diseases such as AMD and Glaucoma are potentially blinding chronic conditions, requiring life-long medical therapy. Failure to adhere to proper treatment may lead to disease progression and loss of vision. One drop delivered correctly is sufficient, but the issue of delivering it correctly is largely patient dependant. Therefore the innovative Ocular drug delivery system is the need of the hour.

Sometimes self-medication/dispensing the drop has some degree of difficulty, especially in geriatric patients; issues with hand eye coordination. Poor compliance is widespread. It is often a cocktail of many ingredients, including stinging drops and the difficulty of applying drops accurately. Preservatives play a prominent role in this unfavourable mixture. The use of preservatives in eye drops has known glory at the beginning, but the direct and indirect side effects that they have on the ocular surface have led to a decrease of their popularity. The recent studies show the toxicity in the cell membrane, eye dryness, allergic inflammatory & hypersensitivity reactions, Ocular hyperaemia, were reported and several studies on pathophysiological mechanism of the role played by preservatives in ophthalmic drops were analysed in the past.

To preserve the eye drops from the ambient air, especially after opening of the bottle for longer time without getting it contaminated is challenging. Nobody must accept any compromise when it comes to microbiological integrity. Overcoming this issue was long awaited from a stability perspective, regulatory perspective and from the patient's perspective. Regulatory changes and increased scrutiny continue to challenge pharmaceutical companies to improve their quality functions. The pharmaceutical industry is always in the need of novel ideas and innovative products which are not only efficacious but also regulatory approved.

We mostly concentrate on new products and innovation, but we forget that being a patient centric company, we should ensure that a new drug delivery system is available to patients. Aptar is doing exactly the same, through their innovations ensuring patients benefit from a new drug delivery system. We must give importance to innovation of new drug delivery system as it is more convenient to the patients.

Aptar Pharma is mainly involved in innovative drug delivery system, components, active packaging solutions across the widest range of delivery routes including nasal, pulmonary, ophthalmic, dermal and injectables and has introduced several novel products in the Indian market such as Metered Dose Inhalers for Asthma & Chronic Obstructive Pulmonary Disorder, Metered Dose Pumps for Allergic Rhinitis, Airless Systems and Preservative Free Systems.

This webinar will address the most common preservatives used and their limitations for the maintenance of the eye sterile drops. This webinar is going to present available options and discusses future trends, in particular preservatives, debatable additives, but also novel ideas like "connected Eye Care", an issue that gains even more importance in the pandemic situation we are all in.

You will learn about the strategies to address patient compliance in both clinical settings and in home care as well as limitations and regulatory hurdles. We do encourage healthy interaction with the speakers to ensure that you take the skills and the knowledge to enable you and your team to perform to the peak of your abilities. I am sure you will all benefit greatly from this Webinar.

Mr Matthias Birkhoff, Vice President, Business Development, Aptar Pharma, spoke about the global ophthalmic drug market as it is today, the forecast for 2026 and also the forecast for the Indian ophthalmic drug market in 2026. He then went on to highlight the various challenges of ocular drug delivery like compliance and adherence to long term therapies like glaucoma, ease of use and dispensing, use of preservatives and how preservatives cause more problems than they can solve. He then ended the first part of his talk by introducing the new treatment ideas for various chronic retinal diseases.

Mr Matthias Leitz, Head of Product Management, Aptar Pharma took over from Matthias Birkhoff and gave the delegates an insight into the technology options available on the market. He went on to explain that Aptar Pharma uses a purely mechanical system, a filter and a tip seal, to maintain the integrity of the eye drop. He then detailed the various services provided by Aptar Pharma to support a Pharma company in their development of preservative free eye drops.

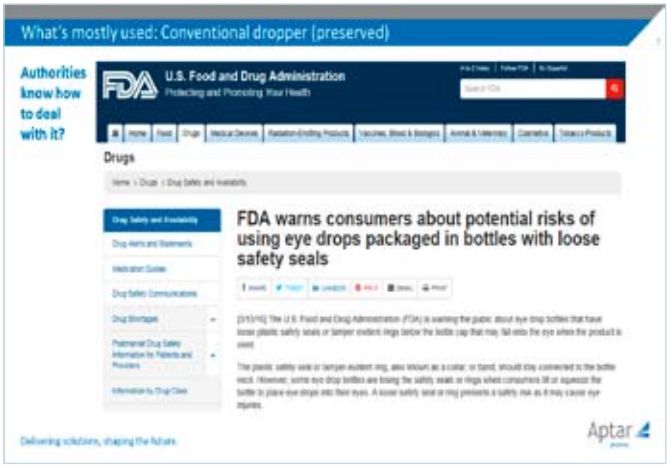
Moving forward, **Dr Degenhard Marx, Director, Scientific Affairs, Aptar Pharma**, the importance of designing the right tests for microbial integrity. He demonstrated how Aptar's OSD has been subjected to the most stringent of the microbial tests in order to prove its ability to maintain the integrity of the eye drop.

Questions & Answers Session were moderated by **Dr Deven Parmar**, Sr Director & Head Clinical R & D, Zydus Discovery, Dubai. He said that the webinar presentations and speakers were excellent, innovating and informative. Replying to a query, Mr Matthias Birkhoff explained the possibility of having a connected add-on device for the eye drop. This is one of the many steps Aptar Pharma has taken in the digital healthcare space and how connectivity can help solve the problem of adherence and compliance.

In Summing Up and Vote of Thanks **Mr Kanwal Tikoo, President India & S E Asia Aptar** thanked all speakers and participants for their active and lively participation. He also thanked Mr Daara Patel and the IDMA Secretariat for their support in successfully organising the Webinar.

Ocular Drug Delivery: a therapeutic area with an interesting past and a fascinating future

Presented by Matthias Birkhoff at the webinar jointly organised by APTAR and IDMA on 5 November 2020


What's mostly used: Conventional dropper (preserved)
Authorities know how to deal with it?
U.S. Food and Drug Administration
Protecting and Promoting Your Health
Drugs
FDA warns consumers about potential risks of using eye drops packaged in bottles with loose safety seals
Aptar

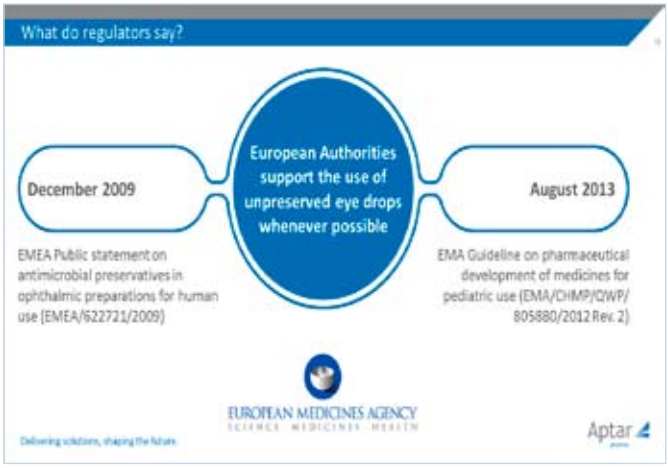

Do you know your target audience?
01
As the hand matures it starts to lose sensitivity and control
02
Finger dexterity degrades.
03
General loss of strength is a factor of aging, one area to lose more strength than others is the grip.
04
Squeezing motion/strength between thumb and index finger becomes more difficult / weaker
Aptar

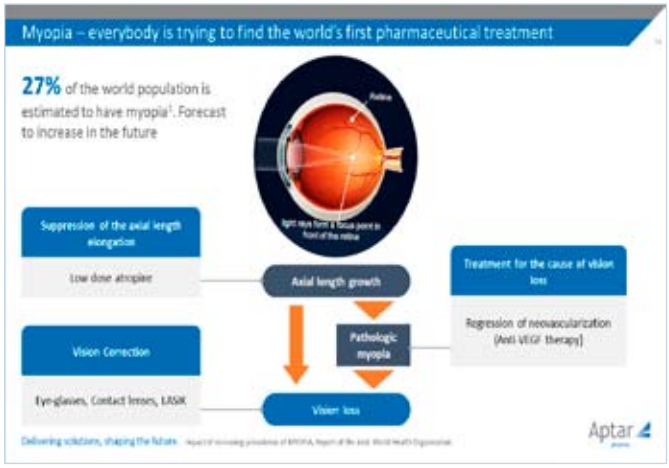

So how does your target audience comply?
Eye Care medications are often not easy to dose
Handling depends on product characteristics
Patients need training for correct use
Inconvenient dosing schedule if different eye drops need to be combined: application of different eye drops are to be separated by at least 15 min
Side effects related to preservatives in chronic conditions
Addition of preservative related side effects, if preserved eye drops are combined
Aptar


Challenge #2: preservatives in Eye drop formulations
Clinical studies suggest that preservatives in eye drops are associated with:
Ocular surface changes
Ocular discomfort
Tear film instability
Conjunctival inflammation
Subconjunctival fibrosis
Epithelial apoptosis
Corneal surface impairment
Potential risk of failure for further glaucoma surgery
Subclinical inflammation
Aptar

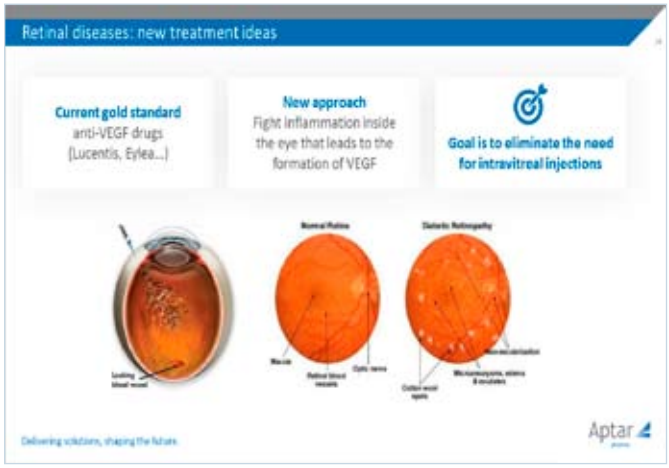

Are there alternatives?
Treatment of glaucoma and dry eye is dominated by eye drops
Alternatives: Inserts
Challenge for inserts:
– Need Highly Potent Drugs
– Controlled Release
– Long Term Tolerability May Become Challenging (No Sensitization, no irritation)
Need specialist for insertion/removal?
1st Generation
2nd Generation
3rd Generation
4th Generation
Aptar


How to increase compliance for long term treatment
01
Easy handling: handling steps similar to established devices will increase acceptance
02
Preservative-free systems will reduce ocular side effects (consider additive effects of preservatives if more than one drug is used) without affecting efficacy
03
Combination products (two or more active ingredients) will reduce dose frequency
04
Easy access: no specialist needed for application
05
Established distribution channels (pharmacies) reduce hurdles to get access


What do regulators say?
December 2009
European Authorities support the use of unpreserved eye drops whenever possible
August 2013
EMEA Public statement on antimicrobial preservatives in ophthalmic preparations for human use (EMEA/622721/2009)
EMA Guideline on pharmaceutical development of medicines for pediatric use (EMA/CHMP/QWP/805880/2012 Rev. 2)
EUROPEAN MEDICINES AGENCY
Aptar


Myopia – everybody is trying to find the world's first pharmaceutical treatment
27% of the world population is estimated to have myopia[1]. Forecast to increase in the future
Suppression of the axial length elongation
Low dose atropine
Axial length growth
Treatment for the cause of vision loss
Regression of neovascularization (Anti VEGF therapy)
Vision Correction
Eye-glasses, Contact lenses, LASIK
Pathologic myopia
Vision loss
Aptar


Retinal diseases – everybody is trying to find better treatment options
Wet Age-related Macular Degeneration (wetAMD)
Diabetic Retinopathy (DR) Diabetic Macular Edema (DME)
Central Retinal Vein Occlusion (CRVO) Branch Retinal Vein Occlusion (BRVO)
Posterior Uveitis
Anti-VEGF therapy
Anti TNFα therapy
Laser photocoagulation
Steroid
Photodynamic therapy (PDT)
Steroid
Anticoagulant (Oral)
Aptar

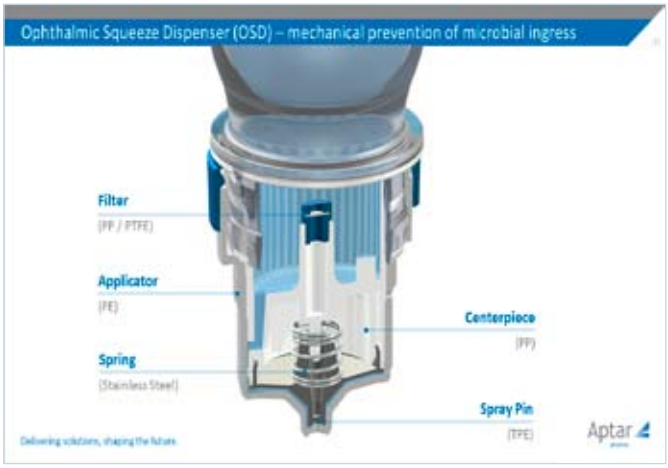

Retinal diseases: new treatment ideas
Current gold standard
anti-VEGF drugs (Lucentis, Eylea...)
New approach
Fight inflammation inside the eye that leads to the formation of VEGF
Goal is to eliminate the need for intravitreal injections
Aptar

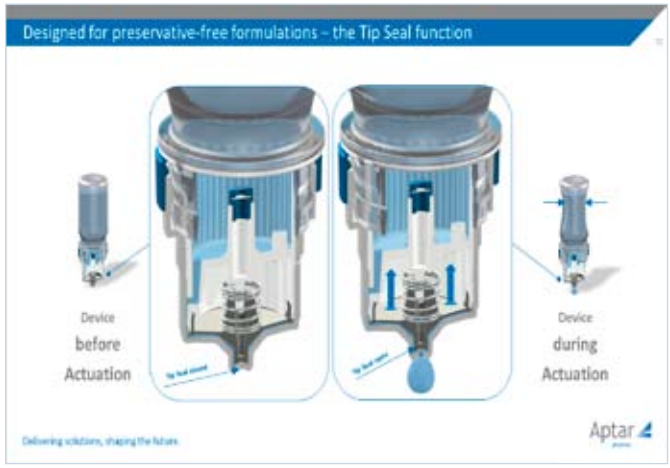

Diabetic Macular Edema: new treatment ideas
Strong headwind in the US
Ophthalmologists generate substantial part of their income with intravitreal injections
Estimated US Average of procedure is
$1,107
(drug not included!)
Aptar


Aptar Pharma
Preservative-free technologies in eye care treatments
Matthias Leitz
Head of Product Management
Delivering solutions, shaping the future.
Aptar


Ophthalmic drug delivery landscape
Unpreserved unit-dose
Preserved multi-dose
Unpreserved multi-dose
• Blow-Fill-Seal Technology
• Well-known technology
• Wide spread
• "Three-Component-Droppers"
• Cheap and reliable
• Debatable preservatives
• Pump technology based
• Squeeze container systems
• Different barrier systems
Aptar


Preservative-free multi-dose technologies
Chemical prevention of microbial ingress
Purely mechanical prevention of microbial ingress
Aeropump - 3K/COMOD
Nemera - Novelia
Aptar - OSD
Aptar

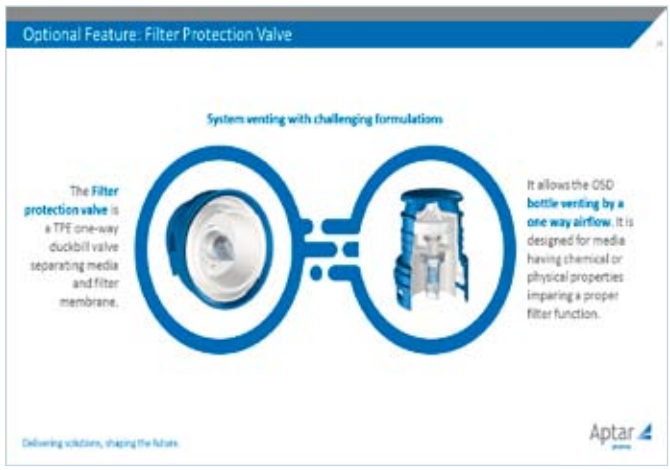

Ophthalmic Squeeze Dispenser (OSD) – mechanical prevention of microbial ingress
Filter
(PP / PTFE)
Applicator
(PE)
Spring
(Stainless Steel)
Centerpiece
(PP)
Spray Pin
(TPE)
Aptar


Designed for preservative-free formulations – the Tip Seal function
Device before Actuation
Device during Actuation
Aptar


Designed for preservative-free formulations - Tip Seal & filter
The tip seal mechanism closes the orifice immediately when releasing the pressure, thus preventing contamination through the tip
Suitable for oxidizing formulations due to metal free fluid path
The air required to compensate the volume loss in the bottle after the actuation is filtered through a PTFE multilayer membrane
Aptar


Aptar Pharma provides multilayered services to support product realizations
A properly functionning OSD
Nothing easier than that?!
Upcoming challenges
Hard to squeeze
Jetting
Restricted ventilation
Crystallization
Lab Evaluation: OSD performance test
Flow Control Determination & Actuation Force
Dose Weight & Consistency
Ventilation Stress Tests
Crystallization Stress Test
Aptar

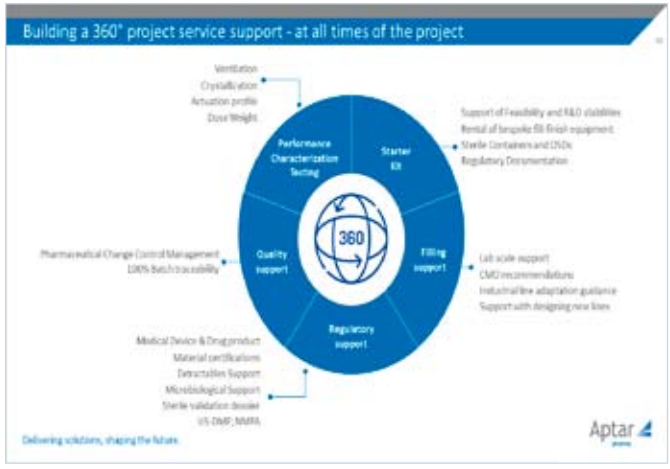

Flow control for various viscosities
• Varying formulation characteristics
• One design
• Length of flow channel inside the OSD → Flow control
– 0 % Flow control → Short flow channel – e.g., Gel
– 100 % Flow control → long flow channel – e.g., Water
• Ensures convenient product use
• Set up of Flow Control by orientation of Applicator and Centerpiece
• Determination of optimal Flow Control during OSD Performance Test with customer's formulation
Applicator
Centerpiece
0 %
37.5 %
100 %
Aptar


Optional Feature: Filter Protection Valve
System venting with challenging formulations
The Filter protection valve is a TPE one-way duckbill valve separating media and filter membrane.
It allows the OSD bottle venting by a one way airflow. It is designed for media having chemical or physical properties impairing a proper filter function.
Aptar

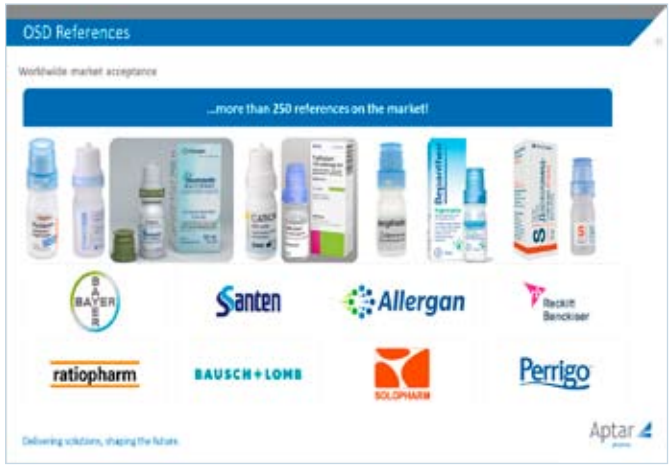

Optional Feature: Liner Cap
Avoiding issues related to crystallization
• The Liner Cap is a special cap featuring a specific fabric made of a non-woven PP/PE blend intended to wipe off the residual drop with each use
• This cap reduces or even completely avoids formulation crystallization extending OSDs range of application.
• Same color range as for Standard Cap
Functional principle:
Remaining Drop
Device Turned
Remaining drop is drawn into non-woven material
Evaporation of moisture from Liner through venting holes
OSD with dried Liner Cap after evaporation
Aptar

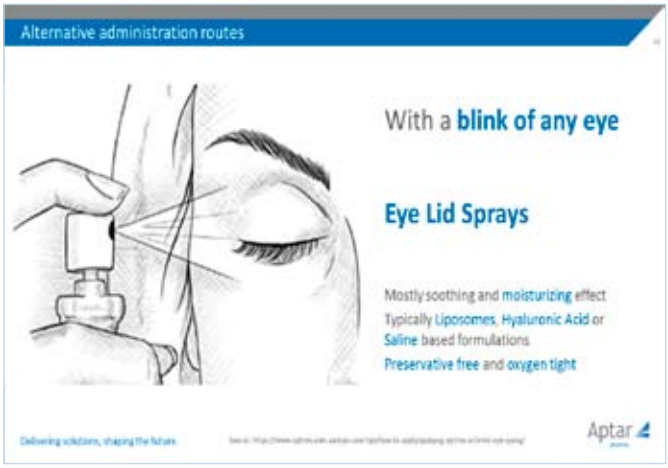

Optional feature upon request: Pure Cap
Sterility of the OSD tip prior first use
• Requirement on highly restricted markets: Regulatory authorities may ask for sterility of the Applicator Tip before first usage
• The Pure Cap is a special cap featuring a hermetic sealing of the cap (tip area) before first use
• By releasing the tamper evident flap, the venting hole in the cap is opened within the same motion
• In this way the drying of the residual drop on the tip is ensured during in-use period
• Proven machinability on filling lines
• Liner is an optional feature
Temper evident flap, to be removed before the first use
Venting hole is open after removal of the tamper evident flap
Aptar

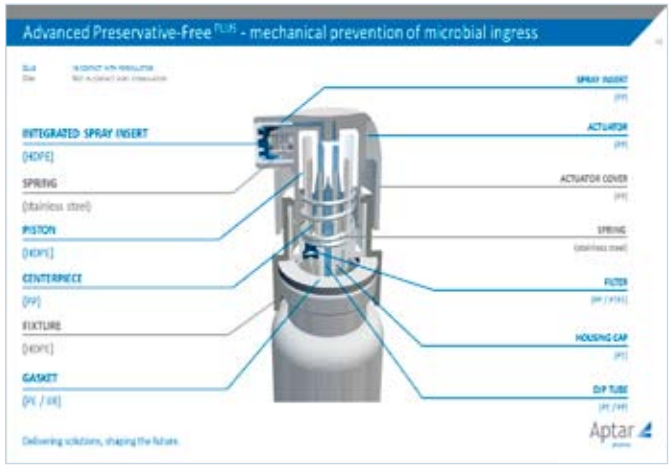

Product portfolio
Cap Options
Functional Options
Bottle Options
Liner Cap
Filter Protection Valve
Aptar


Building a 360° project service support - at all times of the project
Performance Characterization Testing
Starter Kit
Quality support
Filling support
Regulatory support
360
Aptar

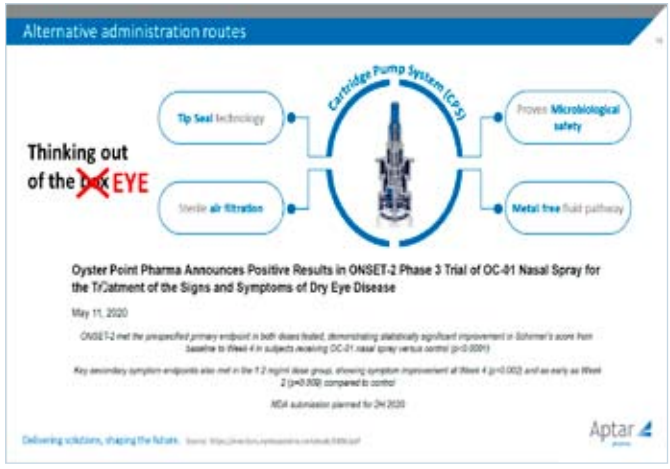

Pharma compliance*: Materials in contact
Part
Material
US Food Contact (21 CFR sections for resins / additives)*
EU Food Contact (starting materials listed in (EU) 10/2011)*
European Pharmacopoeia (composition according Monograph 3.1.3)*
Biological Reactivity Type testing
Spray Pin
Applicator
Filter
Centerpiece
Container
Filter Protection Valve
Aptar


OSD References
Worldwide market acceptance
...more than 250 references on the market!
BAYER
Santen
Allergan
Reckitt Benckiser
ratiopharm
BAUSCH+LOMB
SOLOPHARM
Perrigo
Aptar

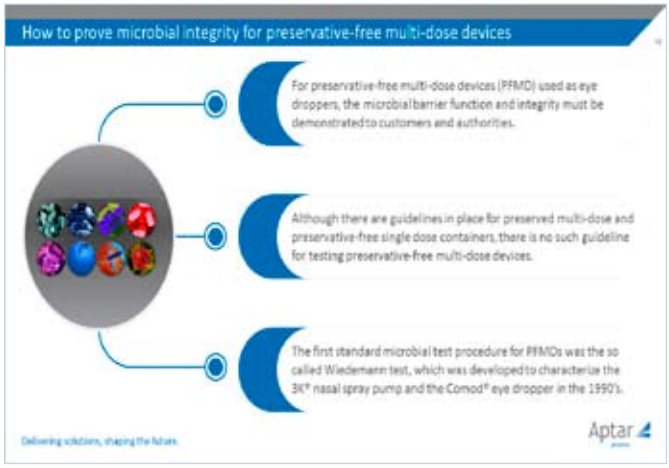

Alternative administration routes
With a blink of any eye
Eye Lid Sprays
Mostly soothing and moisturizing effect
Typically Liposomes, Hyaluronic Acid or Saline based formulations
Preservative free and oxygen tight
Aptar


Advanced Preservative-Free PUSH - mechanical prevention of microbial ingress
INTEGRATED SPRAY INSERT
(HDPE)
SPRING
(stainless steel)
PISTON
(HDPE)
CENTERPIECE
(PP)
FIXTURE
(HDPE)
GASKET
ACTUATOR
ACTUATOR COVER
FILTER
HOUSING CAP
DIP TUBE
Aptar


Preservative-free eye lid sprays
VIVASAN
Reckitt Benckiser
INNOXA
OmniVision
optima
PHILOSET
SCOPE
Aptar

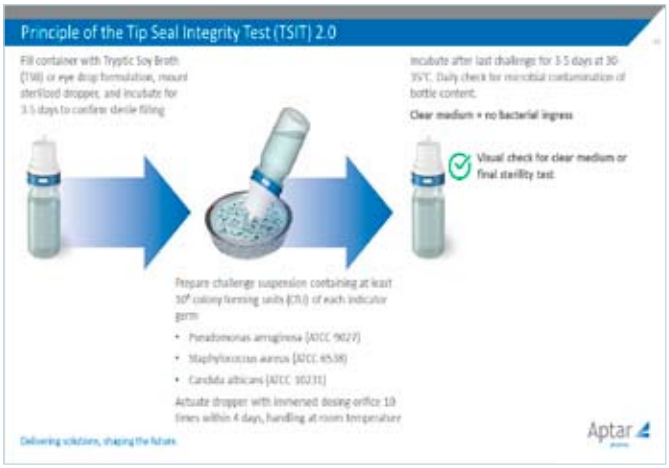

Alternative administration routes
Thinking out of the box EYE
Tip Seal technology
Sterile air filtration
Cartridge Pump System (CPS)
Proves Microbiological safety
Metal free fluid pathway
Oyster Point Pharma Announces Positive Results in ONSET-2 Phase 3 Trial of OC-01 Nasal Spray for the Treatment of the Signs and Symptoms of Dry Eye Disease
May 11, 2020
Aptar

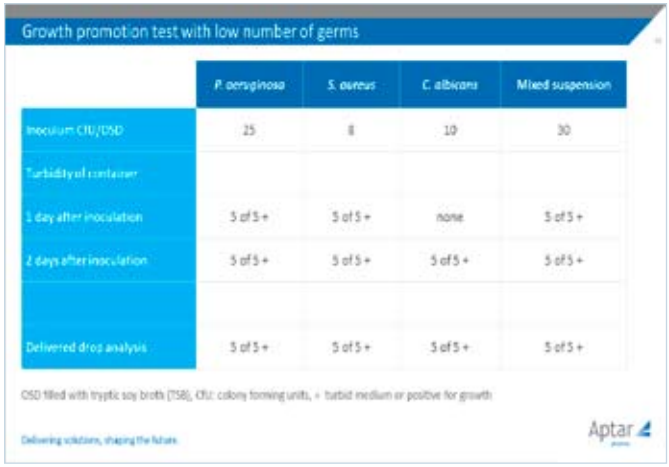

Aptar Pharma
Ensuring microbial integrity for the Ophthalmic Squeeze Dispenser (OSD)
Dr. Degenhard Marx
Scientific Affairs
Consumer Health Care Division
Delivering solutions, shaping the future.
Aptar


How to prove microbial integrity for preservative-free multi-dose devices
For preservative-free multi-dose devices (PFMD) used as eye droppers, the microbial barrier function and integrity must be demonstrated to customers and authorities.
Although there are guidelines in place for preserved multi-dose and preservative-free single dose containers, there is no such guideline for testing preservative-free multi-dose devices.
The first standard microbial test procedure for PFMDs was the so called Wiedemann test, which was developed to characterize the 3K® nasal spray pump and the Comod® eye dropper in the 1990's.
Aptar


Aptar Pharma established and evolved the Tip Seal Integrity Test (TSIT) method
Microbial integrity test for preservative-free multidose eyedroppers or nasal spray pumps
Aptar Pharma developed a new test design, published in 2019
Aptar


A broader microbial challenge is crucial in the eyes of European Authorities
TSIT 2.0 provides a much more stringent setup for microbial integrity testing
Wiedemann/established Aptar TSIT
TSIT 2.0
Rationale for test
Test medium
Indicator Germs
Challenge procedure
Incubation temperatur
Parameters analysed
Aptar


Principle of the Tip Seal Integrity Test (TSIT) 2.0
Fill container with Tryptic Soy Broth (TSB) or eye drop formulation, mount sterilized dropper, and incubate for 3-5 days to confirm sterile filling
Incubate after last challenge for 3-5 days at 30-35°C. Daily check for microbial contamination of bottle content.
Clear medium = no bacterial ingress
Visual check for clear medium or final sterility test
Prepare challenge suspension containing at least 10⁸ colony forming units (CFU) of each indicator germ
Pseudomonas aeruginosa (ATCC 9027)
Staphylococcus aureus (ATCC 6538)
Candida albicans (ATCC 10231)
Actuate dropper with immersed dosing orifice 10 times within 4 days, handling at room temperature
Aptar


Growth promotion test with low number of germs
P. aeruginosa
S. aureus
C. albicans
Mixed suspension
Inoculum CFU/DSD
25
8
10
30
Turbidity of container
1 day after inoculation
5 of 5 +
5 of 5 +
none
5 of 5 +
2 days after inoculation
5 of 5 +
5 of 5 +
5 of 5 +
5 of 5 +
Delivered drop analysis
5 of 5 +
5 of 5 +
5 of 5 +
5 of 5 +
OSD filled with tryptic soy broth (TSB), CFU: colony forming units, + turbid medium or positive for growth
Aptar

Growth media filled OSD maintained sterility following the TSIT 2.0 challenge procedure

Test day	Challenge total CFU/ml	Test samples	Positive controls	Negative controls
Number of samples		32	3	3
1	$4.3 * 10^3$	-	-	-
2	$6.8 * 10^3$	-	3 of 3	-
3	$5.1 * 10^3$	-	3 of 3	-
4	$8.6 * 10^3$	-	3 of 3	-
9	-	-	3 of 3	-
Sterility test		-	Not done	-
Dose analysis		32 of 32	3 of 3	-

(-) clear medium (n) number of samples positive for growth

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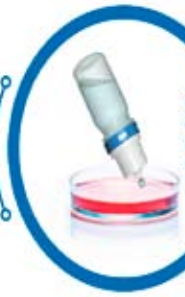
The next drop analysis cannot provide distinct information on microbial integrity of a PFMD

01

The analyzed drops at the end of the incubation period were positive for microbial growth for all test samples (including positive controls). This was mainly *Staphylococcus aureus* with partially delimited counts of colonies (approx. >100 CfU) on the agar plates.

This finding confirms, that an analysis of a delivered drop following the challenge procedure with *Staphylococcus aureus* is not useful as some germs may survive outside of the applicator without being able to contaminate the container content.

02



Check microbial contamination of the next delivered drops 72 h after last tip seal challenge

Aptar

How to define the impact of tip contamination on the next delivered eye drop

Bioburden determination in dosages of eyedropper devices after microbial tip contamination

Results from a study using preservative-free multi-dose artificial tear eyedroppers containing hyaluronic acid and marketed in the European Union with the CE mark

Study performed March 2020 in Labor Dr. Merk & Kollegen, Ochsenhausen, Germany

Aptar

The test set up measures the impact of microbial contamination on the tip surface

- The aim of this study was to determine the number of microorganisms present in subsequent dosages of eyedropper devices after high dose microbial contamination of the device tips
- Five commercial preservative-free multi-dose eyedropper products were investigated
- All eye droppers contain artificial tears with hyaluronic acid, marketed within EU as medical device (CE-marked)
- Test was performed at Labor Dr. Merk & Kollegen GmbH, Ochsenhausen, Germany
- The dosing tips of the products were challenged with a microbial suspension containing the test organisms Pseudomonas aeruginosa, Staphylococcus aureus and Candida albicans with more than 106 CFU/ml of each test organism (identical with TSIT 2.0 challenge procedure). Then the samples were stored at room temperature with reattached protection caps
- After 5-10 min, 4 h, 8 h and 24 h, the number of microorganisms within two delivered drops were determined using five replicates of each product

Aptar

A representative choice of preservative-free multi-dose hyaluronic acid eye drops were tested

Evolve HA	Hylo Gel	Hyabak	Hylo Vision HD plus	Hy-Opti
0.2 % sodium hyaluronate Novelia PFS dropper	0.2 % sodium hyaluronate Comod PFS dropper	0.15 % sodium hyaluronate Abak PFS dropper	0.2 % sodium hyaluronate preserved formulation	0.2 % sodium hyaluronate OSD PFS dropper

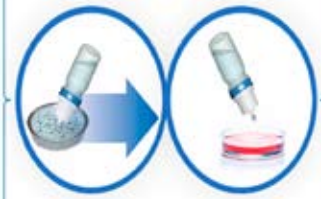
Aptar

Test design for next drop contamination study

Prepare a bacterial/fungal suspension containing at least 106 colony forming units (CFU) of each indicator germ:

- Pseudomonas aeruginosa (ATCC 9027)
- Staphylococcus aureus (ATCC 6538)
- Candida albicans (ATCC 10231)

Actuate dropper with immersed dosing orifice. Reattach protection cap and store at room temperature.



Check microbial contamination of the first two delivered drops within 5 min, 4, 8 and 24 hours after the tip contamination. 5 test samples per system and sampling point.

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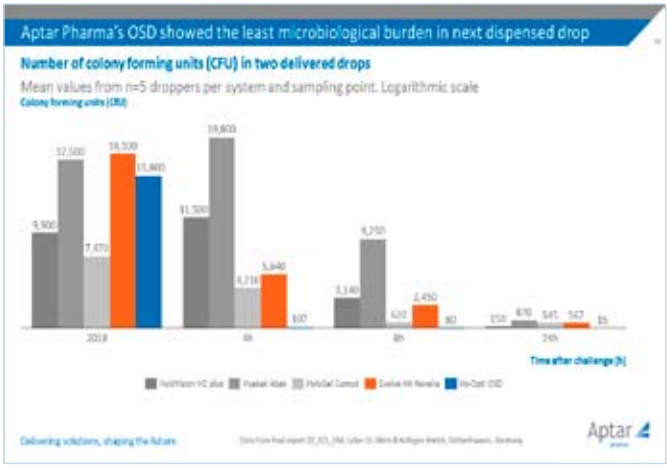
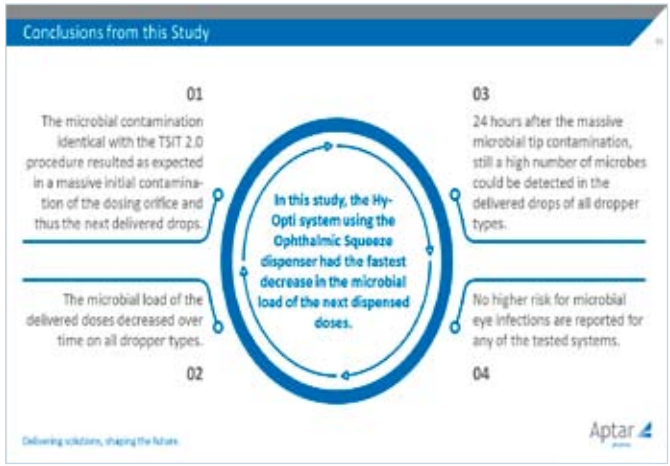
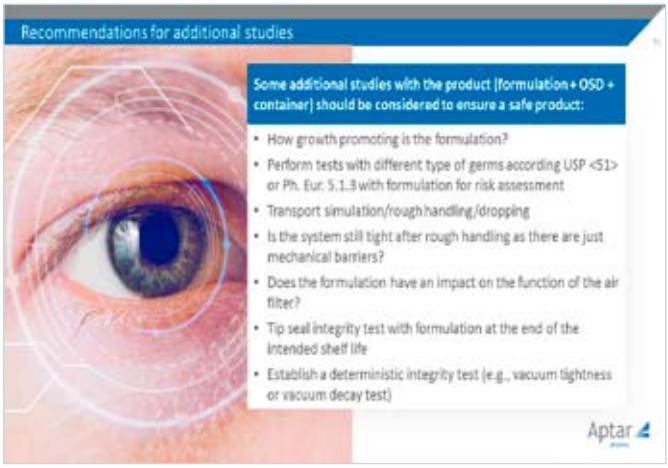
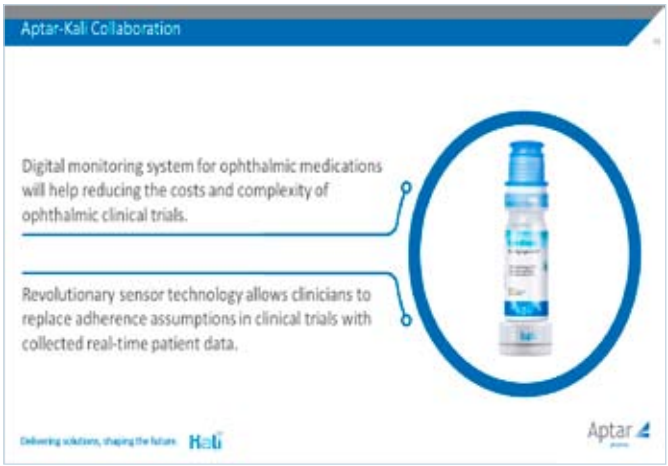
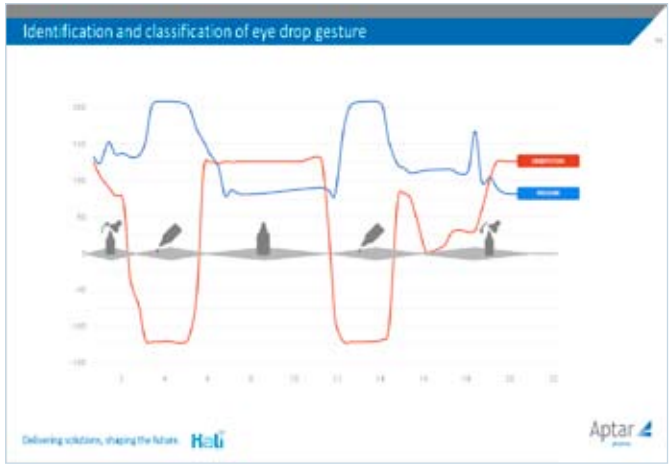

Aptar Pharma's OSD showed the least microbiological burden in next dispensed drop
Number of colony forming units (CFU) in two delivered drops
Mean values from n=5 droppers per system and sampling point. Logarithmic scale
Colony forming units (CFU)
Time after challenge [h]
Aptar

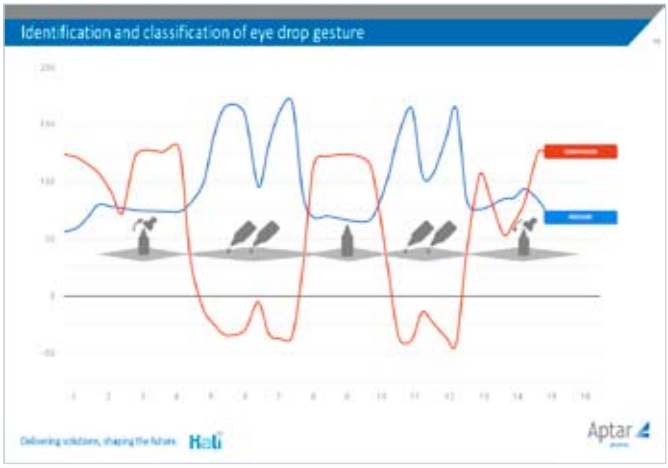

Conclusions from this Study
01
The microbial contamination identical with the TSIT 2.0 procedure resulted as expected in a massive initial contamination of the dosing orifice and thus the next delivered drops.
02
The microbial load of the delivered doses decreased over time on all dropper types.
03
24 hours after the massive microbial tip contamination, still a high number of microbes could be detected in the delivered drops of all dropper types.
04
No higher risk for microbial eye infections are reported for any of the tested systems.
In this study, the Hy-Opti system using the Ophthalmic Squeeze dispenser had the fastest decrease in the microbial load of the next dispensed doses.
Aptar


Recommendations for additional studies
Some additional studies with the product (formulation + OSD + container) should be considered to ensure a safe product:
• How growth promoting is the formulation?
• Perform tests with different type of germs according USP <51> or Ph. Eur. 5.1.3 with formulation for risk assessment
• Transport simulation/rough handling/dropping
• Is the system still tight after rough handling as there are just mechanical barriers?
• Does the formulation have an impact on the function of the air filter?
• Tip seal integrity test with formulation at the end of the intended shelf life
• Establish a deterministic integrity test (e.g., vacuum tightness or vacuum decay test)
Aptar

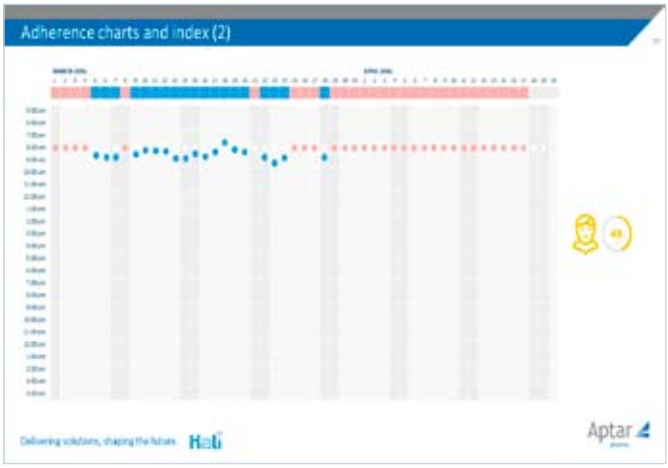

Aptar Pharma
Connected devices in eye care – an outlook
Matthias Birkhoff
5 November 2021
Delivering solutions, shaping the future.
Aptar

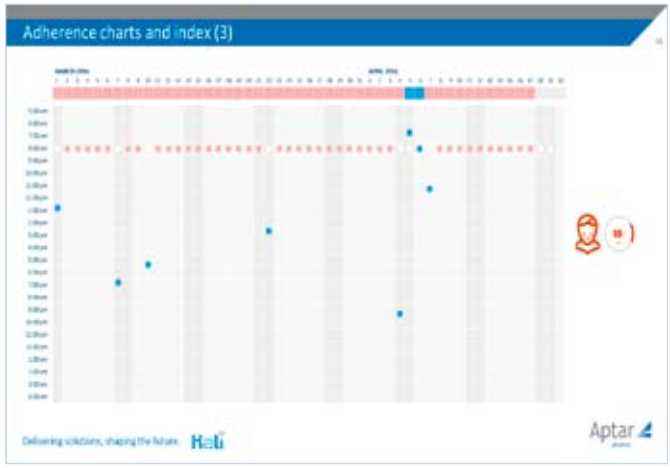

Aptar-Kali Collaboration
Digital monitoring system for ophthalmic medications will help reducing the costs and complexity of ophthalmic clinical trials.
Revolutionary sensor technology allows clinicians to replace adherence assumptions in clinical trials with collected real-time patient data.
Kali
Aptar


Identification and classification of eye drop gesture
Kali
Aptar


Identification and classification of eye drop gesture
Aptar


Adherence charts and index (1)
Aptar


Adherence charts and index (2)
Aptar


Adherence charts and index (3)
Aptar


These days are over...
Aptar


Delivering solutions,
shaping the future.
Aptar

EU seeks to bypass patents to boost drugs access in crises amid Covid pandemic

The European Union is planning bold measures to boost its access to drugs, from side-stepping Patent Rights in emergencies to offering incentives for companies to shift production to Europe, according to EU documents published on Wednesday, 25.11.2020. The possible moves are meant to tackle the chronic shortages of medicines that have dogged the bloc for years and have become more serious since the COVID-19 pandemic and its associated trade disruptions and drug export bans.

The European Union Commission wants faster procedures during crises to produce generic versions of drugs in EU states without the consent of patent holders, an EU document says. So-called Compulsory Licensing is allowed under World Trade Organization (WTO) Rules in emergencies as a waiver of normal regulations and could be applied during the COVID-19 pandemic. "The Commission sees the need to ensure that effective systems for issuing Compulsory Licences are in place, to be used as a means of last resort and a safety net, when all other efforts to make IP (Intellectual Property) available have failed," the first of Wednesday's (25.11.2020) documents said. Ironically, the proposal is part of an EU action plan on Intellectual Property that is mostly aimed at strengthening the protection of EU companies' patents against foreign actors.

In the first months of the COVID-19 pandemic, lawmakers and activists had urged the EU to use the WTO waiver to gain access to potential vaccines and drugs against the new Coronavirus, which have mostly been developed outside the 27-nation bloc.

The EU initially struggled to order large volumes of antiviral drug Remdesivir, which some studies have shown to be effective against COVID-19, because nearly all stocks of the drug produced by Gilead had been ordered by the United States. Though the EU executive has so far refused to invoke the WTO waiver and has struck multibillion-euro deals with drug makers to secure COVID-19 shots and therapeutics, the pandemic has led to a reconsideration of existing procedures that largely fall under the remit of national Governments in the bloc.

'Fast-Track Procedures':

"The Commission calls on member states to ensure that the tools they have are as effective as possible; for instance, by putting in place fast-track procedures for issuing Compulsory Licences in emergency situations," the document says.

To avoid distortions to trade and innovation, the Commission is also considering creating an emergency co-ordination mechanism that would be triggered at short notice when an EU Government wants to issue a Compulsory Licence. The move differs from proposals from South Africa and India to pre-emptively waive WTO Intellectual Property Rules during the pandemic - proposals the EU has said are too drastic.

The Commission said in a second document that, after a consultation process with Pharmaceuticals companies next year, it will make proposals aimed at addressing vulnerabilities in Global Supply Chains. That could lead to incentives, or other less benign measures, to persuade manufacturers to move production of medicines to Europe from China and India, on which the EU relies heavily for medical imports.

The Commission said it was important "to assess whether manufacturing capacity for certain critical medicines may be required in the EU", adding that any action would be in line with WTO Rules. "We need to be able to rely on ourselves, not on others," the Commission's Vice-President, Margaritis Schinas, told a news conference, emphasising the bloc's need for "strategic autonomy" on drugs. To avoid disruptions, drugmakers will also be subjected to stricter requirements on supply obligations and disclosure of stock levels under proposals due in 2022.The possible measures are part of a wider EU strategy published on Wednesday, 25.11.2020. The plans aim to increase access to cheap medicines and boost competition, including through broader use of generics that could hit revenues of large drugmakers, in line with a *Reuters* report earlier this week.

Source: Francesco Guarascio, Reuters/LiveMint, 26.11.2020

Suspension of Manufacture, sale and distribution of Ulipristal Tablets 5mg until definitive conclusion is arrived - reg.

DCG(I) Circular Ref.F.No.SND/MA/18/000009, dated 12th November 2020

To
All State/UT Drugs Controllers;

Ulipristal Acetate Tablets 5mg was approved by CDSCO on 14.03.2018 indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age and intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

There are reports from EMA regarding the liver failure associated with the use of Ulipristal acetate tablets 5mg.

In May 2018, Pharmacovigilance Risk Assessment Committee (PRAC) in European Medicines Agency finalised a review of the benefit-risk balance of Ulipristal Tablets 5mg initiated due to three cases of serious liver injury leading to liver transplantation. During the review, an additional case was reported regarding an acute liver failure associated with the use of ulipristal acetate 5 mg. As outcome of the review and taking all data available into consideration, the PRAC recommended measures to minimise the risk of serious liver injury associated with ulipristal acetate 5 mg.

Further, the PRAC reviewed the new case (the 5th case) of serious liver injury leading to liver transplantation reported with ulipristal acetate 5 mg and concluded on a probable causal association with the use of ulipristal acetate 5 mg. The PRAC also noted that a progression in the development of hepatic failure leading to liver transplantation could not be prevented despite the risk minimisation measures implemented previously were followed.

The PRAC therefore recommended that the use of ulipristal acetate 5 mg is suspended while a thorough assessment of all available data related to the benefit-risk of ulipristal acetate 5 mg and effectiveness of the risk minimisation measures is performed.

Based on the above recommendations of EMA the following countries have directed voluntary product recall of Esmya tablet 5mg (Ulipristal acetate) were, Philippines, Thailand, Malaysia, Singapore, Ireland and Dubai.

In light of report of serious liver injury in EU and recommendation of PRAC in EMA for suspension of the drug, the safety issue of the drug was deliberated in Subject Expert Committee. After detailed deliberation the committee recommended for suspension of Ulipristal Tablets 5mg until definitive conclusion is arrived.

In view of above you are requested to direct the manufacturer of Ulipristal tablets 5mg under your jurisdiction to suspend the manufacturing, sale or distribution of Ulipristal Acetate Tablets 5mg.

You are also requested to take necessary action to recall the stock in respect of subject product from the market. Action taken in the matter may be communicated to this Directorate at the earliest.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, Subsequent New Drugs Division, Directorate General of Health Services, New Delhi.

● ● ●

CBIC notifies New Exchange Rates w.e.f. 06th November 2020 - reg.

Notification No.105/2020-Customs (N.T.), dated 05th November, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.99/2020-Customs(N.T.), dated 15th October, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes andCustoms hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 6th November, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	54.50	52.20
2.	Bahraini Dinar	203.40	190.95
3.	Canadian Dollar	57.55	55.55
4.	Chinese Yuan	11.35	11.00
5.	Danish Kroner	11.90	11.50
6.	EURO	88.80	85.65
7.	Hong Kong Dollar	9.75	9.40
8.	Kuwaiti Dinar	250.70	235.10
9.	New Zealand Dollar	51.15	48.85
10.	Norwegian Kroner	8.10	7.85
11.	Pound Sterling	97.95	94.60
12.	Qatari Riyal	21.05	19.75
13.	Saudi Arabian Riyal	20.45	19.20
14.	Singapore Dollar	55.65	53.80
15.	South African Rand	4.85	4.55
16.	Swedish Kroner	8.60	8.30
17.	Swiss Franc	83.20	79.85
18.	Turkish Lira	9.05	8.50
19.	UAE Dirham	20.90	19.60
20.	US Dollar	75.15	73.45

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	72.60	68.40
2.	Korean Won	6.75	6.20

F.No.468/01/2020-Cus.V

Bullo Mamu, Under Secretary , Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Environment Impact Assessment Notification

Lok Sabha Unstarred Question No: 1143

Prof Sougata Ray:

Q. Will the Minister of **ENVIRONMENT, FORESTS AND CLIMATE CHANGE** be pleased to state;

(a): whether a group of Special Rapporteurs to the United Nations have expressed their concerns over the proposed Environment Impact Assessment draft Notification 2020;

(b): if so, the details thereof;

(c): whether the notification is in contravention with India's "Obligations under International Law"; and

(d): if so, the details thereof?

Answered on 18th September 2020

A. (a) & (b): Yes Sir. The Ministry is aware that Special Rapporteurs to the United Nations had expressed their views on the draft EIA Notification 2020. However, as against the views expressed by the Special Rapporteurs, the draft EIA Notification, 2020, inter alia, does not (a) give any exemptions from public consultation for large industries and projects; (b) no change in the provisions with respect of public consultation in respect of projects or activities involving other strategic considerations; (c) there is no provision for ex-post facto clearance of violation cases. Such cases shall be liable for punitive action under Environment (Protection) Act, 1986 and in addition shall be liable for damage cost, etc.

(c) & (d): No Sir. The draft EIA is not in contravention to the stand taken by India as a party to international law (conventions). As envisaged in these conventions, the draft EIA Notification 2020, inter alia, promotes the environmental cause and sustainable development; removes redundancies; encourages modernization and less polluting options; brings defaulters into environmental regime with requisite action, penalty and remediation; and introduces standardization and a technology driven process

Minister of State in the Ministry of Environment, Forest and Climate Change (Shri Babul Supriyo)

In Rajya Sabha

Pharmasceutical Park in Karnataka

Rajya Sabha Unstarred Question No.701

Shri K C Ramamurthy:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether Government has received a proposal from Government of Karnataka to set up a pharmaceutical park in Kadechur in Yadagiri district;

(b): whether it is a fact that Yadagiri district in Karnataka has been identified as aspirational district;

(c): whether it is also a fact that in the light of COVID-19, the importance of setting up of Pharma parks has gone up; and

(d): if so, whether Government proposes a separate scheme for setting up of Pharma parks in the country?

Answered on 18th September 2020

A. (a): Yes Sir. A proposal dated 14.01.2020 was received from Government of Karnataka for setting up a Bulk Drug Pharma Park in Kadechur Industrial Area, Yadagiri seeking financial assistance under the sub-scheme viz Assistance to Bulk Drug Park for Common Facility Centre. However, at that time the sub-scheme was under revision which was intimated to the Government of Karnataka on 13.03.2020. The revised scheme i.e. "Promotion of Bulk Drug Parks" was approved by the union Cabinet on 20.03.2020.

(b): Yes Sir.

(c) & (d): Yes Sir, the importance of setting up of Bulk Drug Parks has definitely gone up in the light of COVID-19 pandemic. The Department of Pharmaceuticals has prepared a scheme called "Promotion of Bulk Drug Parks". The detailed guidelines of the scheme were released on 27th July, 2020. The Guidelines of the scheme are available on the website of the Department under the tab titled 'schemes'.

Minister in the Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

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Scientists have Developed "Ultrapotent" COVID-19 Vaccine Candidate: Study

Scientists have developed a vaccine candidate for COVID-19 that produces "extremely high levels" of protective antibodies in animal models, an advance that may lead to a novel therapeutic to curb the pandemic.

According to the researchers, including those from the University of Washington (UW) School of Medicine in the US, the nanoparticle vaccine produces virus-neutralising antibodies in mice at levels much greater than is seen in people who have recovered from the disease.

The study, published in the *journal Cell,* noted that it generates ten times more neutralising antibodies in mice, even at a six-fold lower vaccine dose, and also shows a strong B-cell immune response after administration, which can be critical for a durable vaccine effect.

When a single nonhuman primate was immunised with the vaccine, the scientists said the candidate therapeutic produced neutralising antibodies targeting multiple different sites on the spike protein of the Coronavirus, which it uses to enter human cells.

They said this may ensure protection against mutated strains of the virus, should they arise. According to the study, the molecular structure of the vaccine roughly mimics that of a virus, which may account for its enhanced ability to provoke an immune response.

"We hope that our nanoparticle platform may help fight this pandemic that is causing so much damage to our world," said Neil King, a co-author of the study from UW Medicine.

"The potency, stability, and manufacturability of this vaccine candidate differentiate it from many others under investigation," Mr King said.

(Except for the headline, this story has not been edited by NDTV staff and is published from a syndicated feed.)

Source: PTI, ndtv.com, 04.11.2020 (Excerpts)

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Ayurveda drugs can be effective in mild to moderate cases of Covid-19: AIIA

A team of doctors from the Delhi-based All India Institute of Ayurveda (AIIA) under the Ayush Ministry has found that Ayurveda interventions like Ayush Kwatha and Fifatrol tablets can be effective in mild to moderate cases of Covid-19 infection in a "very short period" with "complete regression of symptoms". Use of four Ayurveda interventions -- Ayush Kwatha, Sanshamanivati, Fifatrol tablets and Laxmivilasa rasa not only improved the condition of Covid-19 patient but also turned therapid antigen test negative within six days of treatment, according to a case report published in the *journal of AIIA -- 'Ayurveda Case Report'* in October.

Presently, there is no specific cure for the disease that has infected over 44.7 million people and claimed 1.17 million lives world over. Citing the case of a 30-year-old male health worker infected with Coronavirus, the report said his infection was managed with Samshamana therapy that included oral administration of Ayush kwatha, Sanshamani vati, Fifatrol tablets, and Laxmivilasa rasa. The patient after testing positive for Covid-19 was advised home quarantine.

"The mentioned treatment plan was effective in the symptomatic relief (fever, dyspnea, anorexia, fatigue, anosmia, and dysgeusia) as well as in the resolution of viral load, as the patient tested negative in the RAD for Covid-19 within six days of intervention and RT-PCR test was also done on day 16, which was reported negative," the study said.

Herbal drug Fifatrol developed by AIMIL Pharmaceutical helps fight infection, flu and cold. It has immunity strengthening herbs like guduchi, sanjeevini ghanvati, daruharidra, apamarga, chirayata, karanja, kutaki, tulsi, godanti (bhasam), mrityunjayarasa, tribhuvana kriti rasa and sanjivani vati.

Ayush Kwatha is a combination of four medicinal herbs commonly used in every Indian kitchen - basil leaves (tulsi), cinnamon bark (dalchini), Zingiber officinale (sunthi), and krishna marich (Piper nigrum).

Sanshamani Vati (also called guduchi ghana vati) is an ayurvedic herbal formulation used for all types of fevers. Laxmivilas Ras is a traditional herbomineral medicine that mainly contains Abhrak Bhasma and cures cough, cold and rhinitis. It soothes the throat and sinuses. The report has been authored by Dr Sisir Kumar Mandal, Dr Meenakshi Sharma, Dr Charu Sharma, Dr Shalini Rai and Dr Anand More from the AIIA.

"The present case study proved the efficacy of Ayurveda interventions in mild-to-moderate case of Covid-19 infection in a very short period with complete regression of symptoms," the report said. "The treatment was personalised, holistic, and purely based on Ayurvedic principles, and no conventional medicines were used. With this case study, it can be inferred that Ayurveda has vast potential to address Covid-19 and such other pandemics; a large sample-sized, multi-center randomized and controlled Clinical studies are the need of the hour," the report said.

Source: PTI, ET-Health World, 02.11.2020

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Chronic exposure to Air Pollution can hurt people diagnosed with Covid

A new analysis of more than 3,000 counties in the US has found that people with long-term exposure to fine-particle pollutants may be more likely to die from COVID-19, findings which may make policymakers reexamine the harms of air pollution and help reduce deaths during the pandemic.

The research, published in the journal Science Advances, investigated the impact of long-term exposure to PM 2.5 pollutants - tiny particles in the air that are two and one half microns or less in width - on COVID-19 mortality rates in 3089 counties in the US," covering 98 percent of the population."

'It found that "higher historical exposure" to these particulate pollutants is associated with greater county-level COVID-19 mortality rates after accounting for several area-level risk factors. While the study could not provide insights into the mechanism underlying the relationship, the scientists, including those from Harvard University in the US, believe chronic exposure to PM 2.5 may cause over production of the ACE-2 receptor in the lungs, which the Novel Coronavirus uses to enter host cells.

They believe the prolonged exposure to air pollution may also impair people's immune system.

"Chronic exposure to PM 2.5 causes alveolar ACE-2 receptor over expression and impairs host defences. This could cause a more severe form of COVID-19 in ACE-2-depleted lungs, increasing the likelihood of poor outcomes, including death," the scientists wrote in the study. Citing the limitations of the study, the scientists said they were unable to adjust for individual-level risk factors such as age, race, and smoking status as such data were unavailable.

"This approach leaves us unable to make conclusions regarding individual-level associations," the scientists said. However, the researchers said the analyses provide strong justification for follow-up investigations as more and higher-quality COVID-19 data become available. "Research on how modifiable factors may exacerbate COVID-19 symptoms and increase mortality risk is essential to guide policies and behaviours to minimise fatality related to the pandemic," they noted in the research.

Source: PTI, The Economic Times, 06.11.2020 (Excerpts)

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IIT develops low-cost tech to produce Psychoactive drugs, anti-ageing compounds from agri resources

Researchers at the Indian Institute of Technology (IIT), Guwahati, have developed a low-cost membrane technology to produce Psychoactive drugs and anti-ageing compounds from wide range of agricultural resources like citrus fruits and peels especially orange peels, berries, parsley, pulses, tea, sea buckthorn and onions.

The technology which has been patented and developed by Mihir Kumar Purkait, Head, Centre for the Environment and Professor, Department of Chemical Engineering, IIT Guwahati along with his M Tech student V L Dhadge, does not use any organic solvents.

"The health-related benefits of psychoactive drugs (caffeine) and anti-ageing compounds (flavonoids) attributed to stimulating detoxification of enzyme activity and inhibition of cell invasion and angiogenesis. Because of medicinal applications, flavonoid components have gained popularity as ingredients in pharmaceutical industry. These are also found in smaller amount in bamboo leaves, grapes, apples, and other natural sources," said Purkait. "The developed technology is exclusively pore and particle size based pressure driven membrane separation process. The water extracts of the plants, fruits or leaves at optimum operating conditions are passed through a specially made cascade membrane units of fabricated with appropriate Molecular Weight Cut Off (MWCO) membranes capable of separating targeted flavonoids selectively," he added.

The permeate and retentive part from appropriate membrane unit is then fridge dried to get the powdered product. "We have synthesized stimuli responsive smart membrane for the selective separation and purification of

targeted compound from the mixture of plants or leaves or fruits extract in simple water," he further said.

The Professor explained that the commercially available techniques are using various costly organic solvents like Chloroform, Acetone, Acetonitrile, among others and as a result the price of these important pharmaceutical raw materials are quite high that ultimately increases the price of the antioxidant. "Since organic solvents are used, the technology suffers various disadvantages like low product quality and yield, high operating and product cost, more time consuming and high energy intensive process for solvent recovery and has limitation to run continuation mode in industrial scale.

"The technology developed by us doesn't require any costly organic solvents and uses only water. Hence, the cost of the process and price of pharmaceuticals thereon is much cheaper than that of existing solvent based separation technique. The patented membrane based green technology has enormous scope to replace existing costly organic solvent based techniques and can be used for continuation mode of operation in industrial scale," he said.

(Disclaimer:- This story has not been edited by Outlook staff and is auto-generated from news agency feeds).

Source: PTI, outlookindia.com, 27.10.2020

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New therapy for flu may help in fight against COVID-19

A new therapy for influenza virus infections that may also prove effective against many other pathogenic virus infections, including HIV and COVID-19, has been developed by Purdue University scientists.

In an average year, more than 2 million people in the United States are hospitalized with the flu, and 30,000 to 80,000 of them die from the flu or related complications.

The Purdue team's work is detailed in Nature Communications and uses a targeted therapy approach against the virus infections.

"We target all of the antiviral drugs we develop specifically to virus-infected cells," said Philip S. Low, the Purdue Ralph C. Corley Distinguished Professor of Chemistry. "That way, we treat the diseased cells without harming healthy cells. We use this capability to deliver immune-activating drugs selectively into flu-infected cells. There is also the potential that this therapy will prove efficacious in people infected with COVID-19."

The flu virus, like many other pathogenic viruses, exports its proteins into its host cell surface and then buds off nascent viruses in the process of spreading to adjacent host cells. Because these exported viral proteins are not present in the membranes of healthy host cells, the Purdue team has exploited the presence of viral proteins in infected cells by designing homing molecules that target drugs specifically to virus-infected cells, thereby avoiding the collateral toxicity that occurs when antiviral drugs are taken up by uninfected cells.

"We chose to start our tests with influenza virus because the results can often be applied to other enveloped viruses," Low said. "Our lab tests show that our process works in influenza infected mice that are inoculated with 100 times the lethal dose of virus."

Low said the new therapy may prove effective against other pathogenic virus infections such as hepatitis B, HIV and respiratory syncytial virus (RSV).

Source: World Pharma News, 24.11.2020 (Excerpts)

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IPC issues LoI for prospective AMCs for voluntary reporting of ADRs due to COVID-19 drugs by healthcare professionals

In order to enroll new Adverse Drug Reactions (ADRs) monitoring centres (AMCs) in the country, the Ghaziabad-based Indian Pharmacopoeia Commission (IPC) has issued Letter of Intent (LoI) for prospective AMCs for voluntary reporting of ADRs due to COVID-19 drugs by healthcare professionals. This is very much required as many drugs have been repurposed around treatment, prevention and management of COVID-19 pandemic. Therefore, more AMCs are enrolled for effective and comprehensive reporting of ADRs.

"As of today, there are 311 AMCs under Pharmacovigilance Programme of India (PvPI) and around 50 under the Materiovigilance Programme of India (MvPI). There is a need to integrate both the flagship programmes of the Centre to optimally utilize the current capacity of AMCs in the interest of patient safety," according to a senior official associated with the development.

As per the AMCs Guidelines, a Pharmacovigilance Associate is supposed to report ADRs under the supervision of the coordinator of the respective AMCs, the official further informed. IPC last month had also rolled out a suspected ADR reporting form for voluntary reporting of ADRs by healthcare professionals to report ADRs for drugs used in prophylaxis for treatment of COVID-19.

The Ghaziabad-based IPC, which is the National Coordination Centre (NCC) for PvPI, has also rolled out medicine side effect reporting form to report ADR for consumers and patients. As a part of the roll out, a Toll Free PvPI Helpline -1800-180-3024 has been launched for public from Monday to Friday between 9:00 am to 5:30 pm.

Confidentiality is maintained to protect the patient's identity. Submission of an ADR report does not have any legal implication on the reporter. It has been recommended that all non-serious, known or unknown, frequent or rare ADRs need to be reported. A reaction is serious when the outcome is death, life-threatening, hospitalization (initial or prolonged). All Clinicians, Dentists, Pharmacists and Nurses etc can report ADRs.

Duly filled in Suspected ADR Reporting Form can be sent to the nearest ADR Monitoring Centre (AMC) or directly to NCC for PvPI through helpline or mailed at **pvpi.ipc@gov.in** or **pvpi.ipcindia@gmail.com**. The causality assessment is then carried out at AMCs by using WHO-UMC scale. The analyzed forms are forwarded to the NCC-PvPI through ADR database.

Finally, the data is analyzed and forwarded to the global Pharmacovigilance database managed by WHO Uppsala Monitoring Centre (UMC) in Sweden. The reports are periodically reviewed by the NCC-PvPI. The information generated on the basis of these reports helps in continuous assessment of the benefit-risk ratio of medicines. The signal review panel of PvPI reviews the data and suggests any interventions that may be required.

Mandatory fields to be filled for ADR Reporting Form includes patient name with initials, age at onset of reaction, reaction term(s), date of onset of reaction, suspected medication(s) and reporter information. NCC-PvPI has also developed an advanced version of the android mobile app which empowers all the healthcare professionals and consumers for ADR reporting. "Through this application, related images of ADR and lab investigation reports can be attached in a user-friendly manner for clinical assessment and signal detection," said an official associated with the development.

The mobile application by the name "ADR PvPI" Android mobile app for ADR reporting has been developed to have administrative control of data with IPC, NCC-PvPI. This will empower all the healthcare professionals and consumers for ADR reporting with features like support source document and image attachment, healthcare professionals as well as consumer reporting, XML generation and auto filling of report details to save time.

CDSCO under the Union Health Ministry had initiated a nation-wide PvPI in July 2010. To strengthen ADR monitoring, IPC had also come out with Guidelines focused on targeted drugs and events as a part of intensive ADR monitoring exercise under PvPI so that action could be taken on specific drugs involving adverse reactions.

Source: Shardul Nautiyal, Pharmabiz, 18.11.2020

NIMS launches 3rd phase Clinical Trials on humans for Covaxin

The Nizam's Institute of Medical Sciences (NIMS), Hyderabad has officially launched the 3rd Phase Clinical Trials for the COVID-19 vaccine, Covaxin, here in Hyderabad. Announcing the launch of 3rd phase Clinical Trials for their newly Covaxin vaccine, Dr Krishna Ella, Chairman and Managing Director (CMD) of Bharat Biotech International said that they have commenced the 3rd phase of Clinical Trials for Covaxin at NIMS in Hyderabad and the same will be carried out in 24 other centers across India.

"With the success of first and second phase trials, we have embarked on the 3rd phase Clinical Trials. For this we have already selected 25 centers across India and had obtained ethical committee approvals from 8 centers so far. As many as 26,000 thousand subjects will be injected with the vaccine in two phases to study the safety, efficacy and effectiveness of the vaccine on the large section of population in India," said Dr Ella.

With Bharat Biotech and Indian Institute of Medical Sciences and National Institute of Virology at Pune successfully conducted and evaluated the data in the first two phases of Clinical Trials for Covaxin and found out that the vaccine is successful on over 1,000 subjects in the first and second phase trials has cleared all the safety, immunogenicity and efficacy parameters.

After the success of 1st and 2nd trials, now, for finding out the Vaccine's effectiveness on the larger section of population, Bharat Biotech, along with ICMR and NIV have officially launched the 3rd phase Clinical Trials for Covaxin at NIMS Clinical Trial center in Hyderabad, Dr Ella said.

It is learnt that as many as 800 volunteers have already been selected and approved by the ethical committee to carry out the Clinical Trials at NIMS. The investigators have already divided the volunteers into two groups and administered with the Covaxin, however among these selected groups, the subjects from one group will be given a placebo, wherein there will be no vaccine, while the subjects in another group will be given with Covaxin of 6 microgram (mcg) injection.

The subjects are divided into two groups to make sure that the trial is double blinded, such that the investigators, the participants and the company will not be aware of who is assigned to which group. However the data will be known only to the researchers and the key company authorities involved in the investigation.

It is learnt that the volunteers will be given two intramuscular injections approximately 28 days apart. Both the groups will be tracked for the next one year, wherein they will be undergoing regular health check-ups and tests to gather data of their health condition to find out the impact of the vaccine and its effects on their health.

Apart from commencement of 3rd phase of Clinical Trials, Bharat Biotech has also announced that it is also working on nasal drop vaccine for COVID-19, so as to reduce the cost and complications of administering the vaccine to large scale population.

Source: A Raju, Pharmabiz, 18.11.2020

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Indian Pharma exports may cross $25 billion this fiscal

Pharmexil Director General lauds sector's manufacturing abilities

During the first six months, Pharma exports were $11.38 billion, nearly 15 per cent more than last year's figure - Iuchschen

Indian Pharmaceutical industry is expected to export medicines and other goods worth over $25 billion in the current financial year, up from $20.5 billion in 2019-20, said Ravi Uday Bhaskar, Director General of Pharmaceutical Export Promotion Council of India (Pharmexil) , on Monday, 23.11.2020.

Bhaskar, who participated in a virtual meet in connection with Global Virtual Healthcare & Hygiene Expo 2020 organised by FICCI, said Indian Gharmaceutical exports during the first six months were $11.38 billion, nearly 15 percent more than that in the same period last year. "This is significant considering that 55 percent of Indian Pharma exports is to highly regulated markets," he added.

"During these difficult times Indian pharmaceutical industry is doing very well. The world is looking at India for two reasons. One is for generic medicine front, where we are capable of producing quality medicines at affordable prices. Secondly on Covid-19 vaccine front, most of Indian vaccine companies are working closely with academic institutions and industry outside India," Pharmexil DG said.

Covid vaccines:

Another advantage is that India is the only country that can produce Covid-19 vaccines in large volumes. Indian medical devices industry too rose up to the occasion. "At the beginning of Covid-19, Indian industry was not capable of producing N95 masks, PPE kits and other devices required for fighting the pandemic. But now Indian industry is capable of manufacturing all these in adequate quantities," Bhaskar said.

Similarly syringes for Covid-19 vaccines. Both the AstraZeneca-Oxford University vaccine produced by Serum Institute of India and Covaxin by Bharat Biotech India Ltd being two-dose vaccines, Indian industry would have to produce 260 crore syringes if the entire Indian population is to be covered. Bhaskar said he was confident that the industry would be able to meet the challenge.

Earlier talking at the webinar, Pradeep Multani, Co-Chair of FICCI Ayush Committee and Chairman of Multani Pharmaceuticals, said India's Ayurveda product exports, which are at $3 billion currently, are expected to grow by 16-18 percent per annum over the next five years.

Source: The Hindu Business Line, 24.11.2020

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Health Ministry to amend Schedule V of D&C Rules to allow vitamins up to one RDA to be regulated under FSS Act

The Union Health Ministry is planning to amend provisions of Schedule V of the Drugs and Cosmetics (D&C) Rules, 1945 to ensure vitamins with doses up to one Recommended Dietary Allowance (RDA) to be regulated under Food Safety and Standards (FSS) Regulations. This is following the Drugs Technical Advisory Board (DTAB) having recently examined the Indian Council of Medical Research (ICMR) recommendations. Based on the same, it has been suggested that vitamins with doses of up to one RDA should be regulated under FSS Act.

Other vitamin preparations having prophylactic and therapeutic claims should be regulated under the D&C Act, 1940 and Rules, 1945 including Schedule V of the D&C Rules.

DTAB proposed that necessary review of doses specified under Schedule V may be undertaken subsequently. Board was apprised that a proposal has been received from Food Safety and Standards Authority of India (FSSAI) proposing that D&C Rules, 1945 may be amended to delete the preparations containing the prophylactic doses under Schedule V considering the provisions of doses under Section 22 of FSS Act, 2006 especially products formulated in tablets, capsules, liquids, etc meant for oral administration.

As per Section 22 of FSS Act, 2006, it is evident that the products in drug type matrix (i.e. tablets, capsules etc) covered under FSS Act which are containing vitamins below RDA also fall under prophylactic and some of the therapeutic doses prescribed in Schedule V of the D&C Rules, 1945. FSSAI has also proposed amending the Schedule K (10) for revising the scope of substances which are used both as articles of food as well as drugs so that same are exempted from the provisions of Chapter IV of the D&C Act and Rules made there under.

Accordingly, DCC in its 52nd Drugs Consultative Committee (DCC) meeting held on September 18, 2017 deliberated the proposal and recommended that a provision may be incorporated in D&C Rules, 1945 especially in Schedule V and Schedule K to exclude multivitamin preparations containing vitamins in a strength which is lower than RDA for Indians as recommended by ICMR and FSSAI, from the provisions of D&C Rules, 1945.

The DTAB further deliberated the matter in its 78th meeting held on February 12, 2018 and opined that the matter may be referred to Director-General (DG), ICMR for their recommendations. The said matter was then referred to DG, ICMR and a reply in the form of letter dated June 10, 2019 addressed to the DCGI was received along with comments from DG, ICMR. Further, ICMR had made another communication vide letter dated October 14, 2019 to the FSSAI on the same matter.

Source: Shardul Nautiyal, Pharmabiz, 25.11.2020

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DoP organises meeting with industry associations to discuss implementation of Phase II PLI scheme

The Secretary of Department of Pharmaceuticals (DoP) organised a meeting with the representatives of key industry associations and discussed identifying effective ways to implement the recently announced Production Linked Incentive (PLI) scheme of Rs. 15000 crores. A source close to the development informed that the industry association representatives have jointly submitted their suggestions to the department.

The industry expects that for the success of the phase II PLI scheme, the concerned authorities should also allow Brownfield investments, use of existing unutilised capacity and second-hand machines. Besides, the industry is also looking forward to relaxations in environmental clearance.

Likewise, the industry feels that the country's MSMEs are capable of producing most items listed in the category 1 and 3 of the PLI scheme, namely repurposed drugs, autoimmune drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs, and ARVs, *in vitro* diagnostic devices, phytopharmaceuticals, other drugs not manufactured in India, other drugs as approved etc.

Yogin Mazumdar, Chairman of Bulk Drug Committee, IDMA said, "We are seeking business security from the Government, which have been repeatedly suggested by the Pharma stakeholders as it is one of the major apprehension faced by the prospective investors of PLI scheme, particularly for the higher value investments, which required for the fermentation-based products." He added, "Instead of looking forward creating employment through the PLI scheme with the minimum investment criteria, our submission to the Government is to consider and formulate Guidelines which help in creating value addition and the industry becoming self-reliant."

Source: Usha Sharma, Express Pharma, 21.11.2020

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Indian Pharma companies take Coronavirus ride; production of anti-malarial drugs shoot up 334%

The Coronavirus pandemic has devastated almost all corners of the economy; however, the Pharma industry has used it as a launch pad. The production of anti-malarial drugs rose by a record 334.3 percent from Rs.5.4 crore in H1 FY20 to Rs.21.9 crore in H1 FY21, said a report by Care Ratings. The surge in production was led by the recommendation of the 'National task force for Covid-19'.

However, as the patients refrained from visiting doctors amid the lockdown, the production of other medicines had a fall, but not as much to offset the surge in the anti-malarial drugs. Prime Minister Narendra Modi said that India will soon have a safe Corona Vaccine and urged the state Governments to start working on cold storage.

In an effort to boost the Indian Pharma industry, Chemicals and Fertilizers Minister D V Sadananda Gowda apprised that the Government is proactively looking to provide industrial park facilities to grow Active Pharmaceutical Ingredient (API), pharmaceutical, and nutraceutical industry. He added that the Indian Pharma industry will continue to play a prominent role as the Pharmacy of the World. We are also encouraging innovation in pharmaceuticals and medical devices, he further said.

Meanwhile, in the recent SCO summit, PM Modi said that India's Pharma industry sent essential medicines to over 150 nations in this difficult time of an unprecedented epidemic. The Prime Minister had added that the world's largest vaccine producing country, India will use its capacity to help entire humanity in fighting the crisis. Earlier, he had also said that vaccines made in India are responsible for two-thirds of the vaccine needs of the world's children and India's companies are active in international efforts for the development and production of the Covid-19 vaccine.

Source: Samrat Sharma, The Financial Express, 24.11.2020 (Excerpts)

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Alternative medicine can be used as immunity booster, not as cure for COVID-19: SC

The Supreme Court (SC) has recently said that alternative medicine can be used as an immunity booster but not as a cure for COVID-19. The apex court made the remarks while hearing an appeal against a Kerala High Court order which had asked the state Government to use alternative medicine only as an immunity booster. The court has, however, allowed qualified medical Ayush practitioners to prescribe immunity booster mixture or tablets, as suggested by the Union Ministry of Ayush.

The three-judge bench comprising Justices Ashok Bhushan, R Subhash Reddy and M R Shah was hearing an appeal against the order of the Kerala High Court directing doctors practicing Ayush medicines not to prescribe any medicines, stating that it is curative for COVID-19 disease.

The High Court had passed the order on a plea which had sought a direction to the state authority to ensure that homoeopathic practitioners are immediately allowed to perform in accordance with the March 6 Notification of the Ministry of Ayush, which had said that state Government shall take steps to adopt homoeopathic system among other systems of medicines in the fight against the menace of Coronavirus.

The high court had further noted that as per the medical protocol of the Government, doctors practicing in Ayush medicines are not supposed to prescribe any medicines stating that it is curative for COVID-19 disease.

Advisory of the Union Ministry of Ayush is being followed by the Government and tablets are given free of cost to those persons as immunity boosters. As per the state medical protocol, COVID-19 affected persons should not be treated by anybody other than the Government and those authorised by the Government, the High Court noted.

When the Central as well as State Governments has approved prescription of certain mixtures and tablets, as immunity boosters, qualified medical practitioners in Ayush can also prescribe the same, but only as immunity boosters, it further stated.

Source: Neethikrishna, Pharmabiz, 21.11.2020

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India's overall spending on health sector 'low', says Niti Aayog member V K Paul

India's overall spending on the health sector is "low" and the situation must be "corrected", Niti Aayog Member (Health) V K Paul said on Thursday, 19.11.2020. Emphasising that there is a need to request both the Union and State Governments to enhance spending on health, he said the Covid-19 experience will justify an increase in expenditure on health sector.

"India's overall spending on the health sector is low. It has been coming from constrained resources... many many competing priorities. It is low and must be corrected," he said while addressing a virtual event organised by industry body CII.

In 2018-19, India's spending on health sector was 1.5 percent of GDP, somewhat an improvement over the last decade, Paul said. While noting that "definitely expenditure of 1.5 percent of GDP on health is not acceptable, not good", he pointed out that in European countries, spending on the health sector is 7-8 percent of GDP.

Citing the National Health Mission (NHM) document, Paul said India's expenditure on the health sector should be to the tune of 3 percent by 2025. "We all need to request both the Union and State Governments' to enhance the expenditure on health," he said, adding that post Covid-19, there will be a way to increase healthcare sector infrastructure.

Paul is also a key official in coordinating the central Government's efforts to deal with the Coronavirus pandemic. Further, Paul said that the Government may target the primary healthcare sector and the private sector should focus on the secondary and tertiary healthcare sector. "In secondary and tertiary healthcare, there is a huge scope for expansion," he noted. In the last six years, Paul said there was a 45 percent increase in the number of medical colleges., a 48 percent increase in the number of under graduate medical seats and a 79 percent increase in post graduate medical seats. As many as 114 new Government hospitals will come up in the next three years, he added.

Source: PTI, ET-Health World, 20.11.2020

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India's first animal study on COVID-19 by Ayush Ministry and DBT moves into final stages

The first animal study in India on SARS-CoV-2 virus, which is a collaborative effort between the Union Ministry of Ayush and the Department of Biotechnology (DBT), has moved to its final stages. This concerns pre-clinical studies on four oral interventions that have already been taken up for clinical studies, said the Union Ministry of Ayush. The clinical studies are being pursued through another collaboration of the Ministry of Ayush, the partner in this one being the Council for Scientific and Industrial Research (CSIR).

In a statement, it describes the study as one of the most sophisticated research projects in the country in the COVID-19 context. The collaboration relating to the animal study (*in vivo* study) was signed between the National Medicinal Plants Board (NMPB) of the Ministry

of Ayush and the DBT. It is based on the concept of reverse pharmacology (PH) which explores the scientific reasoning behind established medical practice like those of Ayurveda.

"This study is being held at the Translational Health Science and Technology Institute (THSTI), an autonomous institute of DBT located in Faridabad. The sophisticated BSL-3 level laboratories of THSTI are housing these studies, which are held on hamsters," said the release.

Through this study, the country has registered a landmark in SARS-CoV-2 virus (COVID-19) research, this being India's first *in vivo* anti-SARS-CoV-2 virus study using oral interventions. The first round of experiments has just been completed and the results are awaited. In the meanwhile, the *in vitro anti-viral* studies have been initiated at Regional Centre for Biotechnology (RCB), Faridabad (a statutory institute of DBT). These studies are expected to complete by January 31, 2021, it further stated.

The phase-1 of the *in vivo* study at THSTI has been completed. Out of the said four interventions, analysis with respect to anti-viral activity of Aswagandha has been completed. The analysis in respect of other three interventions is in progress and the study results are expected to be announced shortly. The National Medicinal Plants Board and The Central Council for Research in Ayurvedic Sciences with the help of industry partners have developed the trial interventions.

Source: Shardul Nautiyal, Pharmabiz, 24.11.2020

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UN report cites ISRO efforts in assisting Indian Government to contain Covid-19 pandemic

A report by the United Nations has cited efforts by Indian Space Research Organisation (ISRO) to leverage its geospatial tools in assisting the central and state Governments towards containing the Covid-19 pandemic and supporting sustainable development projects in the country.

Practices for Sustainable Development in Asia and the Pacific 2020' cites the role being played by 'BHUVAN', the national geo-portal developed and hosted by ISRO comprising of geo spatial data, services and tools for analysis, in combating Covid-19. "The Government of India and its state Governments have taken several steps to contain the Covid-19 pandemic. ISRO has assisted in this by providing and leveraging geospatial tools, in particular BHUVAN - the Indian Geo-Platform," the report said. It added that the geospatial information platform provided service in six aspects: tracking, identifying hotspots, vegetable markets, food needed, home isolation and pollution.

"Additionally, as India needed a dashboard to better understand the current circumstances in the country, ISRO customised the Geo-portal and developed 'Bhuvan-Covid-19' at a national level to track the pandemic and update the public on the current situation, " the report said. The report, released on Wednesday, 18.11.2020 by the UN Economic and Social Commission for Asia and the Pacific (ESCAP), showcases examples from the region's countries employing applications of space technology to advance sustainable development.

It said that Asian and Pacific nations are increasingly leveraging space technology and geospatial information to respond to challenges on the ground, including in their efforts to contain the spread and mitigate the impact of the Coronavirus pandemic. The report also said that India has been making significant progress in responding to the demands of today's cities by incorporating robust space technologies and GIS (Geographic Information System) into the urban planning, transport management and traffic navigation techniques.

It said the development of Road Asset Management system for National Highways (NHs) is a flagship project by the National Highways Authority of India in association with the Indian Space Research Organisation and the World Bank. "Bringing both public and private funded roads under one umbrella, the main objective of this project is to assist in accurate and scientific maintenance planning, enhance road safety measures and plan the development of the NH network in India," the report said.

The report also noted that ESCAP, with the support of India, regularly facilitates young professional officials from developing countries in the region to join a nine month post-graduate course on remote sensing and the Global Navigation Satellite Systems at the Centre for Space Science and Technology Education in Asia Pacific, in Dehradun. Some of the other practices undertaken by countries in the region and cited in the report include 'Night-light' satellite images monitoring the impact of lockdowns, 'heatmaps' to chart out communities vulnerable to the pandemic and its socioeconomic consequences, real-time situational analysis, and dashboards integrating

a wide gamut of critical information to support decisions are some of the practices cited.

The examples, according to the report, show how space applications and geospatial data have played an important role in providing essential location based and temporal data to make an "overall data map" and snapshots on the Covid-19 pandemic for policymakers and the public. In addition, combining spatial data from contact tracing, quarantining, and social distancing with digital solutions and Artificial Intelligence (AI)-driven risk analytics can help enhance community resilience.

Such applications can also help in the recovery phase to build back better, by providing an evidence base for decisions on the easing of lockdown and the resumption of economic and social activities, the report added. "The effective integration of geospatial data, with existing statistics and ground based information, will be key to delivering the timely data needed for Governments, businesses, communities and citizens to make evidenced-based decisions," Executive Secretary of ESCAP Armida Salsiah Alisjahjabana said.

The report, issued two years after Asian and Pacific countries endorsed an ambitious plan of action on use of space technologies to support sustainable development also provides a baseline for assessing future progress in the region. In addition to presenting an overview of the status along thematic areas such as disaster risk, natural resource management, connectivity, social development, energy, and climate change, the report also highlights the importance of multi-stakeholder partnerships.

"Many regional and country-based efforts are sparking innovations that attract both public and private capital, supporting start-ups and spinoffs from space applications research and pilots," said ESCAP. The report outlined seven key recommendations for policymakers to integrate applications of geospatial information into their planning and actions towards achieving the Sustainable Development Goals (SDGs).

Source: PTI, ET-Health World, 20.11.2020

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Health Ministry to amend D&C Rules to specify batch number on final container label of trade pack for vaccines

Union Health Ministry is planning to amend Drugs and Cosmetics (D&C) Rules to specify batch number on separate final container label of trade pack (final packed unit) for vaccines containing multi-components.

The amendment is based on the premise of Central Drugs Standard Control Organisation (CDSCO) apprising the Drugs Technical Advisory Board (DTAB) about clarification to GSK Pharmaceutical Limited that in case of multi component vaccines, the outer carton of vaccine should contain combined batch number and expiry date of component of shortest expiry date.

However, the primary label of individual components may contain their respective batch number and expiry date. Also, the firm is needed to have proper record and traceability for said combined batch number.

DTAB was apprised by CDSCO that GSK Pharmaceutical Limited, GSK House, Dr Annie Besant Road, Worli, Mumbai vide their application number July 25, 2018 requested clarification regarding batch numbers to be declared on trade packs for vaccines containing two components in a separate final container based upon observation raised by the Central Drug Laboratory (CDL), Kasauli during the testing of Hexavalent vaccine of GSK Pharmaceutical Limited (Trade name-InfanrixHexa) (DTaP-HBV-IPV+Hib) vaccine.

The CDL had stated that the company had not mentioned the combination batch number on the product pack even though the same was mentioned on the summary lot protocol submitted to them with samples for lot release. InfanrixHexa comprises DTaP+HBV-IPV Pentavalent liquid suspension in Prefilled Syringe (PFS) and freeze dried Hib component in vial.

The GSK in its letter clarified following points that for packs containing two components, e.g. freeze dried vaccine in vial + diluent in PFS or freeze dried vaccine in vial + liquid suspension of second vaccine in PFS, firm is declaring the batch number, manufacturing date and expiry date of both the component on the carton and the individual label of vial/PFS.

For such vaccines which contain two components, the firm additionally maintains a combination batch number i.e. the batch number assigned to the final packaged unit of the freeze dried vaccine + liquid vaccine or freeze dried vaccine + diluents combo pack. This packaged lot number (combined batch number) is not declared on the label but mentioned on the company's batch release certificate and summary lot protocol. Global practice followed by the firm for marketing of the said product in countries like EU, Australia, Canada, etc, for the declaration of

batch number is as follows - In the inner label of vial of Hib component, batch number of the Hib component is declared, in the inner label of PFS of DTaP+HBV+IPV component, batch number of the DTaP+HBV+IPV component is declared. In the outer carton, batch number of the combined DTaP+HBV_IPV/Hib vaccine is declared. There is no specific international Guideline on declaring batch number on trade packs of vaccines containing two components. Submission was made to the DTAB that there is no specific rule in D&C Rules 1945 or Guidelines for declaration of batch number on label of the trade pack (final packed unit) for vaccine containing multi-component in separate final container. DTAB after deliberation agreed to the proposal for appropriate amendment in the D&C Rules, 1945.

Source: Shardul Nautiyal, Pharmabiz, 24.11.2020

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INTERNATIONAL NEWS

WHO soon to set up Global Centre for Traditional Medicine in India

The World Health Organisaton (WHO) will soon set up a Global Centre for Traditional Medicine in India. An announcement in this regard came from the WHO Director General Tedros Adhanom Ghebreyesus in a video message at an event in which Prime Minsiter Narendra Modi was addressing at future-ready Ayurveda institutions in western India. The intent of the WHO is to set up a Global Centre for Traditional Medicine in India, with Prime Minister Narendra Modi expressing confidence that just like the country has emerged as the 'pharmacy of the world', the WHO institution will become the centre for global wellness.

Ghebreyesus made the announcement in a video message at an event in which Prime Minister Modi dedicated two future-ready Ayurveda institutions in Jaipur and Jamnagar to the nation via video conferencing on the occasion of the National Ayurveda Day. The Institute of Teaching and Research in Ayurveda (ITRA), Jamnagar in Gujarat and the National Institute of Ayurveda (NIA), Jaipur in Rajasthan are both premier institutions of the Indian systems of medicine in the country.

Speaking to Pharmabiz, experts from the Foundation of Revitalisation of Local Health Traditions which have Institute of Ayurveda and Integrative Medicine (I-AIM) and the University of Trans Disciplinary Health Sciences and Technology said that this was the step in the right direction. In July this year, the Mahamana Declarations on Ayush, an independent initiative, was formed to give a fillip to Ayurveda, Unani, Siddha and Homoeopathy systems of medicine. Promoted by the Faculty of Ayurveda Institute of Medical Sciences (IMS) at the Banarus Hindu University (BHU), Quality Council of India (QCI), FICCI and Patient Safety and Access Initiative, its effort is to expand the reach and use of this Indian traditional medicine. The whole idea was conceptualised by Prof Bejon Kumar Misra, Adviser-Consultant, IMS, BHU who also leads the patient groups of the country with the formation of nine Special Interest Groups (SIGs).

In the wake of this we see India has been making several efforts to bring this traditional system of medicine to the fore. The gesture by WHO is laudable and now Ayush needs to strengthen its regulatory authority with suitable Act/Rules with proper implementation to keep country's to be able to manufacture 100% quality & efficacious medicines. It is here we see that the Mahamana Declaration members are working hard to submit a report to Minsitry of Ayush with suitable suggestions to make it achievable, said BnR Jagashetty, former National Adviser (Drugs Control) to MoHFW & CDSCO.

D B A Narayana, Chief Scientific Officer, Ayurvidye Trust, and a Pharma Scientist who has researched in Ayurveda for decades, notes that the long overdue action is happening now with this announcement. It is a welcome step and there is a need to work in a time bound manner to promote wellness delivery to consumers and patients. Indian knowledge systems of health care needs to be globally accessible. The WHO centre should consider to integrate it with current drug and device based health care.

From an industry perspective was Chintan Gandhi, Managing Director, Millennium Herbal Care who said that this was an excellent development for the Ayush industry. It will give further validation from a modern medical science perspective to Ayush treatments. A long-term collaboration with WHO can multiply the international market for Ayush products, possibly enabling them to make health claims as mentioned in the shastras.

Source: Nandita Vijay, Pharmabiz, 25.11.2020

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Twin challenges for Indian Pharma – Boosting drug discovery and localizing API Production

*by **Nikkhil Masurkar,** Executive Director, ENTOD Pharmaceuticals*

India is often referred to as the *'Pharmacy of the World'*; not without reason. The third largest Pharmaceutical market in the world by volume, India supplies a bulk of generic drugs globally not just to under-developed countries but also to the US and UK. Notably, India supplies almost 40% of the total American generic drug demand and addresses as much as 25% of the total drug demand in the UK. India's Pharmaceutical Sector also fulfils over half of the total global demand for vaccines.

However, despite having a robust network of Pharma companies and drug manufacturing facilities along with a large pool of scientists and researchers, India remains a laggard in the area of discovery of new drug molecules. A research paper published in the *CHEMMEDCHEM* journal in 2017 estimated that since the 1990s when Indian Pharma companies started their own R&D efforts, they had been able to zero in on over 200 pre-clinical and clinical-stage development compounds.

However, just a handful of these could make it to the market. This tells us that despite a large pool of scientists and biotechnologists, India's Pharma sector has been unable to crack the drug discovery puzzle. Drug discovery is a long term commitment and Indian companies have traditionally been low investors in R&D due to the high risk and high costs involved. At the same time, paucity of strong industry academia ties also acts as a hurdle to the realization of India's true scientific potential in drug discovery.

A bulk of new drugs in the global market emanate from the US and European countries. In recent years, neighbouring China too has marked the beginning of a new phase of Pharma innovation. In 2018, China is estimated to have contributed to over 10% of the new drug launches in the world along with 7.8% of the drug innovation pipeline.

India's Pharma sector needs to reinvent itself and move forward from its long standing dependence on export of generics towards enabling the industry become an end-to-end drug manufacturer. This includes a parallel thrust on localising a bulk of API manufacturing.

Boosting new drug discovery requires multi-dimensional efforts on the part of both the Government and the industry. What we need is a comprehensive infrastructure and regulatory framework that supports innovation and aligns our practices with international standards.

Government's latest R&D thrust:

The Government has in recent times has shown the inclination to address this glaring gap by launching a dedicated policy plan to address the R&D deficit in Pharma sector. A series of reports last year had suggested that the Department of Pharmaceuticals was planning to create a separate department for R&D and was looking at having a dedicated R&D head in place to push for discovery of commercially viable new molecules.

This policy push when comes to fruition will definitely help channelize the scattered innovation efforts and give them better direction. Unfortunately, the COVID-19 outbreak seem to have relegated this agenda to the back burner for the time being, as India's Pharma sector works overtime to address the needs arising out of the pandemic.

Covid-19 and API shortage:

The Covid outbreak in China and the resultant disruption of trade supplies from that country threw light on our excessive dependence on Beijing for Active Pharmaceutical Ingredients (API) and Key Starting Materials (KSMs). With up to two thirds of the total imports of bulk drugs or drug intermediaries being imported from China, any supply shock can literally put a halt on drug production in India and create huge shortages.

The Government's Production Linked Incentive (PLI) scheme focusing on APIs and the API Parks scheme to boost competitiveness of India's indigenous manufacturing are a step in the right direction. However, the industry faces the challenge of escalating costs if it tries to scale up the local production of APIs, KSMs and solvents.

Escalating costs are a challenge to profitable production and private sector might not be wholesomely game for it. It is important therefore that the Government helps finance of subsidize production for the next few years either through public laboratories or through Public Private Partnerships.

Challenges to indigenous drug discovery and way ahead:

Inadequate Intellectual Property Protection, long delays in getting approvals for Clinical Trials and low venture capital interest in biotech firms makes the business environment challenging for Indian Pharma companies and startups. At the same time challenges of low R&D investment and skill shortage are glaring enough.

The Indian Patents Act of 1970 which enabled Indian Pharma sector acquire process patents helped create one of the world's largest generic manufacturing industry. However, it also in a way failed to incentivise new molecule discovery and led to a gap in Research and Innovation skills in the Indian industry.

At the same time, India's education system which its minimal focus on applied science has failed to create enough skilled manpower to feed the growing innovation needs of the industry. High cost of development of new drugs is another factor that makes investing big drug discovery a risky proposition.

In 2018, an analytical report by Deloitte found that since 2010 the cost of developing a new drug had almost doubled and average return on R&D fallen significantly. According to the report, the average cost of bringing a new drug to market stood at USD 2.18 billion in 2018 as compared to USD 1.19 billion in 2010. Evidently, India's investment on R&D remains abysmally low as compared to western countries which account for a bulk of new molecule discoveries.

We do not just need to scale up investments in R&D but also need to incentivise entrepreneurship in biotechnology. Untrained human resource and lack of industry readiness among Science Graduates needs to be bridged by creating close industry academia ties, making pedagogy more relevant to the industry and boosting the system of academic research for students.

The Pharma industry itself needs to diversify its research focus to cover a wide variety of diseases including neglected tropical diseases and Non-Communicable Diseases.

(Disclaimer: The views expressed are solely of the author and ETHealthworld.com does not necessarily subscribe to it. ETHealthworld.com shall not be responsible for any damage caused to any person/organisation directly or indirectly.)

Source: ET-Health World, 16.11.2020

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Indian Pharma Industry: Backbone of Indian economy in the current pandemic

***Taruna Sondarva,** Principal Consultant, IKON Marketing Consultants, outlines how the Indian Pharma industry is contributing towards the health of our economy during the pandemic and opines that it will continue to be a growth driver in times to come*

In the current pandemic (COVID-19) where India's GDP has shrunk by 23.9 percent in Q1 of the current fiscal, some of the sectors keeping the country alive is healthcare and Pharma besides agriculture. The Indian Pharma industry is known as 'the Pharmacy of the World' as it is a leading supplier in generics with one of the highest numbers of US FDA approved plants. According to IKON Marketing Consultants's estimates, in the current fiscal, 2020-21 the Indian Pharma industry is estimated to be worth $43 billion. Let's have a look at how it is contributing during the current pandemic towards the health of our economy and check its pulse on different parameters.

The contribution to GDP and FDI inflow:

In the last fiscal itself, the sector contributed around 1.72 percent to the country's GDP, making a significant mark. It was around one percent a decade ago. A lot of Research & Development, Government initiatives and FDI inflows opened newer avenues for the industry to grow further.

There were around $ 16.5 billion FDI inflows during April 2000-June 2020, as 100 percent FDI is allowed in Greenfield projects under automatic route and 74 percent FDI is allowed for Brownfield projects under the automatic route. Still, there is an investment opportunity of $366.31 million in the Pharma segment alone for almost 18 projects of different nature in different states await investors.

The major pillar: Exports

In the case of exports, drugs and Pharma products have recorded positive growth of 24.89 percent during September 2020 *vis-à-vis* September 2019 amongst a few other commodity groups. The export of Pharma stood at $ 7,595 million and it remains the second-highest contributor with 7.79 percent of total exports during April – August 2020, the first being minerals with 8.94 percent.

Tackling the current pandemic:

The efforts of Pharma companies to combat the current crisis with the help of the Government shows the robustness of the industry itself. India is a hub and the largest manufacturer of vaccines in the world, the fight against COVID-19 cannot succeed without Indian vaccine manufacturers.

India is also pioneering the discovery of COVID-19 vaccines and currently, a few of them are undergoing human trials. The times ahead would witness India at the forefront of the immunization drive against COVID-19.

The path towards becoming *aatmanirbhar:*

To reduce the industry's dependency on raw materials import, in March itself, the Indian Government made a significant announcement of a package of Rs.14,000 cr to boost the domestic production of Active Pharma Ingredients (APIs) and various medical devices. GoI is planning to set up mega bulk drug parks and also aims to make India a major hub for end-to-end drug discovery.

The road ahead:

The current industry trends suggest that post-crisis, the Indian Pharma industry will have improved storage and supply chain infrastructure and witness increased usage of digital media to market the drugs as well as to reach out to the prescribers and patients. Not just the urban markets, but Pharma companies will increase their spending to develop better medical infrastructure to tap the rural markets as well.

It is also expected that in the next decade, approx $200 billion will be spent on the medical infrastructure of the country. With the NCD component in India set to match international ratios, Indian companies are poised to bring down the cost of chronic therapy treatments worldwide. The Indian Pharma industry will be one of the key drivers of growth in the country's attempt to reach a five trillion dollar economy by 2024.

By all these means, not just during the current crisis, but in future too, the Indian Pharma industry will prove to be the backbone of our economy and will work towards making India healthy and an 'Aatmanirbhar' country in the true sense.

Source: EP News Bureau, Express Pharma, 22.11.2020

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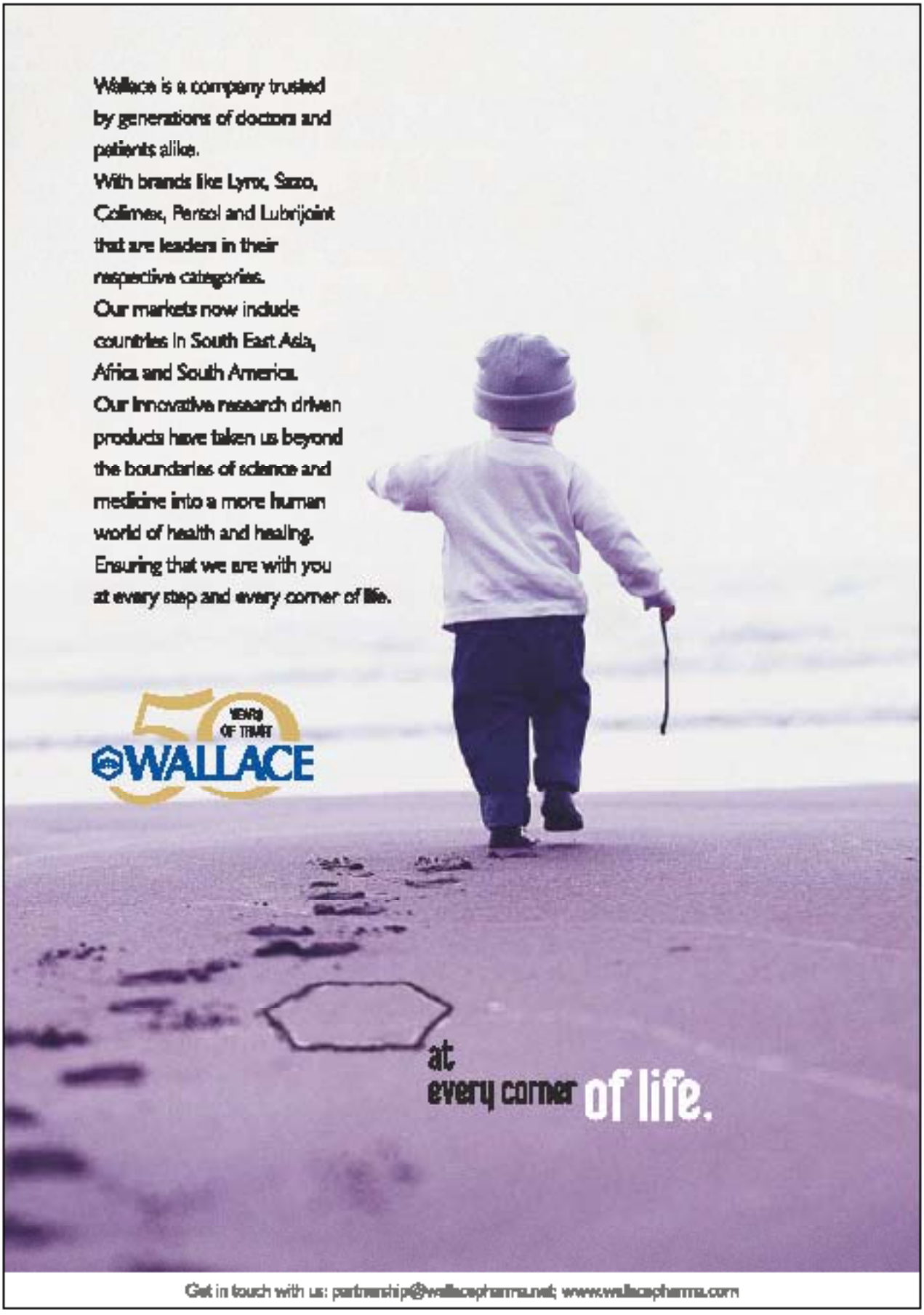
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