



Drug Information Bulletin

Drug Information Centre (DIC)

Indian Pharmaceutical Association

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Regulatory Affairs Division (RAD), IPA

Pharmacists Day
25th September
2019

Theme: Safe and
Effective
Medicines for all

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Editorial

Wishing you all a happy "Pharmacists Day" in advance!

Pharmacists through the world are gearing up for celebration of World Pharmacists Day on 25th September with a theme "Safe and efficacious medicines for all".

The theme for this year aims to promote pharmacists crucial role in safeguarding patient safety throughout improving medicines use and reducing medication errors. "Studies show that a significant number of patients are harmed during health care, resulting in permanent injury, increased length of stay in healthcare facilities, or even death. Medication errors are a contributing factor to this and pharmacists have a vital role in reducing this global health challenge.

Pharmacists having in depth knowledge and expertise in medicine ensure best outcome from their medicines. They are also tried to ensure access to medicines and their appropriate use, improve adherence and more. Access to medicines is a global problem especially in resource poor countries where pharmacists have an important role to play.

Indian Pharmaceutical Association through its Divisions, Branches are going to celebrate this occasion in a grand manner.



Smandal

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Study shows low-cost arthritis drug's efficacy in blood cancers

A small British study evaluated data from 11 patients with polycythemia vera and essential thrombocythemia using the rheumatoid arthritis drug methotrexate and found that the drug improved their disease symptoms and also lowered raised blood counts, according to the British Journal of Haematology. "Given the very low cost of MTX, this research could offer an effective therapy on a budget accessible to healthcare systems throughout the world -- marking a potentially substantial clinical and health economic benefit," said study co-author Dr. Martin Zeidler of the UK's University of Sheffield.

Reference: [Breaking News \(Ireland\)/Press Association \(UK\)](#)

NIH awards \$4.6M grant for Inovio's antimicrobial resistance research

Inovio Pharmaceuticals is the recipient of a \$4.6M grant from the NIH that it will use to advance research on antimicrobial resistance with the use of its DNA-encoded monoclonal antibodies scaffold. The funding will support preclinical studies to be launched as clinical trials to assess dMAbs for infections resistant to antimicrobials.

Ref.: [Seeking Alpha](#)

UK to lead joint research on infectious diseases

The UK has partnered with US, Israeli and Chinese experts to conduct research on infectious diseases' evolution and transmission and will donate \$10.2 million for the joint research project. The project will be led by the UK Research and Innovation's Biotechnology and Biological Sciences Research Council and will look at interactions between infectious diseases and humans, wildlife and domesticated plants and animals.

Ref.: [The Jerusalem Post](#)

2.0 Per Cent CSR fund can now be tapped for Research and Development

In a bid to boost research and technology, corporate houses can now fund state-backed incubators which specialise in science,

technology, engineering and medicine, Union Finance Minister Nirmala Sitharaman said on Friday.

She said, that the expansion of the scope of the two per cent Corporate Social Responsibility (CSR) fund would open a new window for large investment in research and development in the country.

"The government has also decided to expand the scope of 2 per cent CSR spending. Now CSR 2 per cent fund can be spent on incubators funded by Central or state government or any agency or public sector undertaking of Central or state government," Sitharaman told a press conference at a starred-resort near Panaji.

The CSR contributions can be made to public funded universities, IITs, National Laboratories and autonomous bodies (established under the auspices of ICAR, ICMR, CSIR, DAE, DRDO, DST, Ministry of Electronics and Information Technology) engaged in conducting research in science, technology, engineering and medicine aimed at promoting sustainable development goals, she also said.

She also said that the government will "increasingly fund" more research, but added that there was a need for large investment for research and development in India.

"Because there is need for large investment for RD we are opening up CSR window also," she said.

Citing an example of how the expansion of the scope of CSR could help the corporate sector, Union Revenue Secretary Ajay Kumar Pandey, who was also present at the media briefing with Sitharaman, said that pharma companies could now outsource their research to the National Centre for Microbial Resource or IITs.

Source: ET Health World

Nanocurcumin Enhances BCG Vaccine Efficacy

A study carried out on mice models has found that curcumin in nanoparticle form has the potential to enhance the efficacy of BCG vaccine such that it confers protection against adult pulmonary TB. The researchers found that injecting curcumin nanoparticles soon after vaccinating the mice with BCG produced an

appreciable enhancement of immune memory cells (T central memory cells) responsible for long-term protection against TB infection.

BCG vaccine is effective against disseminated and meningeal TB in young children. But the protection does not last for long as the host-protective immune responses that the vaccine induces diminishes over time. Thus the vaccine is not protective in adults.

Enhanced efficacy

The team led by Gobardhan Das and Anand Ranganathan from the Special Centre for Molecular Medicine at the Jawaharlal Nehru University (JNU) demonstrated in mice models that curcumin nanoparticles enhance vaccine efficacy in two important ways. The work was done in collaboration with KIIT University, Bhubaneswar. The [results were published](#) in the journal *Infection and Immunity*.

In children, the vaccine induces two types of immune cells — effector memory T cells and central memory T cells. While the effector memory T cells play a crucial role in mounting an immediate immune response against virulent TB bacteria and kill them, the central memory T cells help in long-term protection in children from childhood TB. After persisting for some time, the central memory cells ultimately diminish. As a result, the protection does not last beyond childhood and adults become vulnerable to TB infection despite BCG vaccination.

One way of enhancing the efficacy of the BCG vaccine is by increasing the number of central memory cells so they last longer and confer protection for longer duration. In nature, dynamic balance exists between the two types of immune T cells — central memory cells and effector memory cells. Altering the ratio to increase the number of central memory cells will help in enhancing the efficacy of the BCG vaccine. “We were able to enhance the ratio of these two cell types by using curcumin nanoparticles,” says Prof. Das.

More memory cells

Increasing the number of central memory cells with respect to the effector memory cells was

achieved through a simple process. The potassium ion channel (Kv1.3) is required for the differentiation of central memory cells into effector memory T cells. “In mice, the nanocurcumin blocks this channel and as a result the conversion of central memory cells into effector memory cells is under check. So the number of central memory cells increases leading to better vaccine efficacy,” says Shaheer Ahmad from JNU, the first author of the paper.

Curcumin also helps in the activation of innate immune cells known as macrophages and dendritic cells. TB bacteria reside and grow inside the macrophages. But once activated by curcumin nanoparticles, the macrophages and dendritic cells clear the bacteria and also enhance the level of TB-specific acquired immune cells (Th1 and Th17 cells).

Multipronged effect

“Curcumin nanoparticles not only increase the level of TB-specific acquired immune cells Th1 and Th17 but also simultaneously reduce the level of certain other cells (Th2 and Tregs) thus improving the efficacy of the BCG vaccine,” says Prof. Das. After TB infection, the levels of Th2 and Tregs cells increase and they inhibit the host-protective effect of Th1 and Th17 responses. So blocking or reducing the level of Th2 and Tregs cells enhances the vaccine efficacy.

The capacity of curcumin nanoparticles to modulate vaccine efficacy was tested in mice model. Following vaccination, the mice were treated with curcumin nanoparticles and then infected with TB bacteria. “We measured the bacterial burden in the lungs and spleen several times and observed that mice treated with curcumin nanoparticles had much less bacterial load than the controls,” says Ahmad.

“We are quite excited by this result and are hopeful further studies would take it to a stage where its application becomes a reality,” says Prof. Ranganathan.

Source: Hindu

Your turn:

Question: CDSCO clarifies manufacturing of new drug by a manufacturer in their own multiple manufacturing sites: Is this type of ruling accepted by Regulatory Authorities in High Income Countries?

Response:

Dear Sir,

I have gone through the document issued by the WHO in this regard

(WHO Technical Report Series, No. 961, 2011, Annex 7, WHO guidelines on transfer of technology)

I have no interest to go against that document as it is very clear to National Authority to handle the situations like another plant of existing manufacturer (existing product manufacturing in a new plant).

I would like quote following paragraphs:

“in pharmaceutical manufacturing for the transfer to be successful, the following general principles and requirements should be met:

- the project plan should encompass the quality aspects of the project and be based upon the principles of quality risk management;
- the capabilities of the SU (sending unit) and at the RU (receiving unit) should be similar, but not necessarily identical, and facilities and equipment should operate according to similar operating principles;
- a comprehensive technical gap analysis between the SU and RU including technical risk assessment and potential regulatory gaps, should be performed as needed;
- adequately trained staff should be available or should be trained at the RU: — regulatory requirements in the countries of the SU and the RU, and in any countries where the product is intended to be supplied, should be taken into account and interpreted consistently throughout any transfer programme project; and — there should be effective process and product knowledge transfer.

Technology transfer can be considered successful if there is documented evidence that the RU can routinely reproduce the transferred product, process or method against a predefined set of specifications as agreed with the SU. “

Dear Sir in addition to that when applying Quality Risk Management (QRM) principles as declared by the WHO Technical Report Series No. 981, 2013 (WHO Expert Committee on specifications for Pharmaceutical Preparations Forty-seventh report)

Manufacturer of the product, in this case new manufacturer, has to focus on following -

The application of QRM procedures evolves through the various stages in the development of a product.

The first QRM exercise should be performed once the preformulation work on the candidate medicine is complete. therefore both manufacturers can work together as per the technology transfer agreement

Quoting

“QRM application during validation and qualification In keeping with the principles of QRM, these guidelines recommend that process validation embraces the product life-cycle concept already mentioned. Accordingly, process validation activities should involve the generation and evaluation of data throughout the process, from development to full-scale production, which will provide a science-based assurance of consistent delivery of quality product in the production operation”.

No doubt SU and RU together can perform validation

Manufacturer (RU) should have sufficient knowledge of the process and product to ensure that by the time the product is commercialized, processes are optimized and risks are minimized.

Quoting

“new facility and changes to existing facility, e.g. start-ups, new commercial manufacturing processes, technology transfers and product discontinuation. After completion of the risk assessment and risk control activities, the outcomes should be summarized and appropriately communicated. The results may be documented in a new or existing report or they may be included as part of another document approved by appropriate decision-makers (e.g. site or functional management, system owner, or quality unit). A risk review is important if new risks or changes to existing risk levels are identified as a result of planned or unplanned events such as routine operation, changes,

complaints, product returns, discrepancies or deviations, data monitoring, trends, inspections or audits, or changes in regulatory environment. Risk review may also include evaluation of, for example: ■ effectiveness of risk control activities and actions; ■ changes in observed risk levels or existing controls. In principal, areas of focus when implementing QRM in commercial manufacturing include a system focus, a process focus and a product focus"

At last I would like to make a note that NMRA Sri Lanka will entertain applications to register a medicine from a contract manufacturer if the applicant registered both the manufacturing sites of contract giver and contract receiver in advanced.

K.P.H. Sandaruwan

Current Event:



President IPA: Dr. T.V. Narayana and President CPA: Dr. V.S.V.Vadlamudi Rao with other participants at 79th FIP World Congress of Pharmacy and Pharmaceutical Sciences at Abu Dhabi

Forthcoming Event:

Pharmacists Day Celebration

by
IPA, Bengal Branch

25th September 2019

*Distribution of get well soon card to the patients at different Hospitals of West Bengal.

*Wearing of badges specially designed for this occasion by the Pharmacists in their respective work place.

25.09.2019:

6.30 pm: Speech by Dr. Tulsi Chakrabarti, Former President, IPA, Bengal Branch on theme.

7.00 pm: Training programme on "First aid" by St. John Ambulance (India).

DISCLAIMER:

The Newsletter intends to provide updated and reliable information on medicines and other related issues in an attempt to equip healthcare professionals to take informed decision in recommending medicines to the patients. However, they are encouraged to validate the contents. None of the people associated with the publication of the Newsletter nor the organization shall be responsible for any liability for any damage incurred as a result of use of contents of this publication. The brand names of medicines, if mentioned, are for illustration only and the Newsletter does not endorse them.