Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

Pharmacist Day 25th September

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Content

Editorial

It has been noticed that the Ministry of Health and Family Welfare, Government of India is publishing advertisement seeking application for the "National Florence Nightingale Nurses Award" to recognize meritorious services of Nurses working in the State, Central, Autonomous Institutions, Private, Missionary and Voluntary organization in India. This award is being given on 12th May every year to recognize the service of a Nurse in India, which will in turn encourage other Nurses. Similar award is given to recognize doctors on 1st July every year, which will encourage doctors to serve the society better. Though two important health providers are being recognized, very unfortunately the third important health providers –"Pharnacists" are ignored till date.

A few years back Her Excellency Mrs. Prativa Patil, President of India, in a programme at New Delhi declared that similar award will be given to the Pharmacist to recognize their contribution to the health care system. Unfortunately that has not happened till date. It may be due to bureaucratic delay or may be lack of persuasion by the pharmaceutical Organizations.

It is high time that all pharmaceutical organizations be united and pursues the matter. Hope we will see a similar advertisement seeking recommendation for such an award to be conferred during ***"Pharmacist Day"***-25th September***.***

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New Drug: Ceftolozane and Tazobactam for Injection

This combination has been approved by USFDA in 2014.

INDICATIONS AND USAGE: ZERBAXA (ceftolozane/tazobactam) is a combination product consisting of a cephalosporin-class antibacterial drug and a beta-lactamase inhibitor indicated for the treatment of the following infections caused by designated susceptible microorganisms: • Complicated Intra-abdominal Infections, used in combination with metronidazole (1.1) • Complicated Urinary Tract Infections, including Pyelonephritis (1.2) To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA and other antibacterial drugs, ZERBAXA should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

DOSAGE AND ADMINISTRATION: ZERBAXA (ceftolozane/tazobactam) for Injection, 1.5 g (1 g/0.5 g) every 8 hours by intravenous infusion administered over 1 hour for patients 18 years or older with creatinine clearance (CrCl) greater than 50 mL/min. (2.1) • Dosage in patients with impaired renal function (2.2): Estimated CrCl (mL/min) Recommended Dosage Regimen for ZERBAXA 30 to 50 Ceftolozane/tazobactam 750 mg (500 mg/250 mg) intravenously every 8 hours 15 to 29 Ceftolozane/tazobactam 375 mg (250 mg/125 mg) intravenously every 8 hours End-stage renal disease (ESRD) on hemodialysis (HD) A single loading dose of ceftolozane/tazobactam 750 mg (500 mg/250 mg) followed by a 150 mg (100 mg/50 mg) maintenance dose administered intravenously every 8 hours for the remainder of the treatment period (on hemodialysis days, administer the dose at the earliest possible time following completion of dialysis) DOSAGE FORMS AND STRENGTHS ZERBAXA for Injection (ceftolozane/tazobactam) 1 g/0.5 g powder for reconstitution in single-dose vials containing 1 g ceftolozane (equivalent to 1.147 g ceftolozane sulfate) and 0.5 g tazobactam (equivalent to 0.537 g tazobactam sodium) (3)

CONTRAINDICATIONS: ZERBAXA is contraindicated in patients with known serious hypersensitivity to ceftolozane/tazobactam, piperacillin/tazobactam, or other members of the beta-lactam class. (4)

WARNINGS AND PRECAUTIONS: • Decreased efficacy in patients with baseline CrCl of 30 to ≤50 mL/min. Monitor CrCl at least daily in patients with changing renal function and adjust the dose of ZERBAXA accordingly. (5.1) • Serious hypersensitivity (anaphylactic) reactions have been reported with beta-lactam antibacterial drugs. Exercise caution in patients with known hypersensitivity to beta-lactam antibacterial drugs. (5.2) • Clostridium difficile-associated diarrhea (CDAD) has been reported with nearly all systemic antibacterial agents, including ZERBAXA. Evaluate if diarrhea occurs. (5.3)

ADVERSE REACTIONS: The most common adverse reactions (≥ 5% in either indication) are nausea, diarrhea, headache and pyrexia. (6.1)

USE IN SPECIFIC POPULATIONS • Dosage adjustment is required in patients with moderately or severely impaired renal function and in patients with end-stage renal disease on hemodialysis (HD). (2.2, 8.5, 8.6, 12.3) • Higher incidence of adverse reactions was observed in patients age 65 years and older. In complicated intra-abdominal infections, cure rates were lower in patients age 65 years and older. (8.5) • ZERBAXA has not been studied in pediatric patients.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/206829lbl.pdf

Status in India: Each single use 20 ml vial contains: Ceftolozane 1gm (equivalent to 1.147 gm of Ceftolozane sulfate) and Tazobactam 0.5gm (equivalent to 0.537 gm of Tazobactum Sodium) has been approved by CDSCO on 06.08.2018 indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:

- Complicated intra-abdominal infections (cIAI) caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus,and Streptococcus salivarius in combination with metronidazole in ICU setting only.

- Complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa in ICU setting only.

  Availability in India: ZERBAXA-Manufacturer: CUBIST PHARMS LLC

Burnout making doctors prescribe wrong medicines

Doctors with burnout are twice as likely to prescribe wrong medicines and make incorrect diagnoses, a large-scale study has found. The study, published in the journal JAMA Internal Medicine, looked at 47 research papers which together analyzed the responses of 43,000 doctors. It found that burnout in doctors has devastating consequences on the quality of care they deliver, researchers said.

Burnout also doubles the likelihood of lower professional standards, such as not following set guidelines or malpractice, they said.

It may have an impact on dropping patient satisfaction, said Maria Panagioti from the University of Manchester in the UK, who led the study. The study found that patient satisfaction is three times more likely to be lower when doctors are physically, emotionally and mentally exhausted -- core signs by which experts identify burnout. It also found that in junior doctors in particular, burnout increases the likelihood of lower professional standards by 3.5 times."This meta-analysis provides a snapshot of what happens to patients when their doctors are burnt out," Panagioti said.

Researchers noted that this is not the fault of doctors. It is caused by a combination of factors including high workload, the way teams work together and the absence of measures which improve wellbeing, they said.

"But it is also about a performance culture which in recent years has become more prevalent in the medical profession," said Panagioti.

"Doctors are increasingly being asked to be superhuman, when they are not. They need care and attention that anyone would need when under such enormous pressure and that is just not happening," she said.

Ref. https://medicaldialogues.in

Research findings of NCTR & CVM on Antimicrobial-Resistance

Impact of Tetracycline on the Human Intestinal Microbiome and Antimicrobial Resistance:

Scientists from NCTR and CVM have shown—using *in vitro* batch cultures of bacteria-laden fecal slurries derived from humans—that tetracycline, an antibiotic, at low-residue concentrations following acute and chronic exposure could affect the human intestinal-microbiome composition and the antimicrobial-resistance gene profile. There are two microbiological endpoints that are measured based on national regulatory guidelines: 1) microbial composition changes that could cause colonization barrier disruption and 2) selection/emergence of resistance after antibiotic exposure. The use of antibiotics in food-producing animals may result in residues of these drugs in meat, milk, and eggs. Dietary exposure to antimicrobial agents in food may lower the gastrointestinal-colonization barrier to allow the emergence of resistant bacteria in the human intestinal microbiome.

Plasmids from Salmonella *can* contribute to their Antimicrobial Resistance and Potential Virulence:

Scientists from NCTR, the University of Arkansas at Fayetteville, and the University of Arkansas at Pine Bluff found that many plasmids carry genes for bacterial toxins that may give bacterial strains (that carry the plasmids) a competitive advantage in shared environments. Antimicrobial resistance and virulence properties in Salmonella*can* be encoded on plasmids—non-chromosomal DNA elements that replicate independently of the bacterial chromosome—that can carry and spread antimicrobial resistance and pathogenicity-associated genes in bacteria. In this study, scientists evaluated 92 *Salmonella enterica* strains (known to carry a class of plasmids termed "incompatibility group I1 plasmids") for their susceptibility to nine different antimicrobial agents and ability to produce bacterial colicin toxins. Approximately 90 percent of the strains were resistant to at least one antimicrobial, and more than 50 percent were resistant to five or more antimicrobials. Over half of the strains also

produced colicin toxins that inhibited the growth of another bacterial strain.

For more information www.fda.gov

Course on Access to Medicines: The International People's Health University

The International People's Health University of the People's Health Movement jointly with Gonoshasthaya Kendra, PHM Bangladesh, Third World Network and SAMA Resource Group for Women and Health with Naripokkho announce "THE STRUGGLE FOR HEALTH"; a short training course for young health activists from 6 to 13 November 2018 in Savar, Bangladesh. Full details here <https://iphu.org/en/announcement/iphu-savar2018>.

The course to be held in Savar will commence as a single course, then split into two parallel streams of specialist study, dealing with 1) medicines policy, and 2) gender and health respectively, and then come together again for the final day.

This course is held in the lead up to the 4th People's Health Assembly which will be held at Gonoshasthaya Kendra from 15-19 December. It is expected that participants in the IPHU course will also be participating in PHA4. Deadline for receiving applications: 14 September2018. Applicants will be advised of the outcome of their application by 25 September. Apply here: https://www.iphu.org/en/savar2018/application.

Recommendations for Acharya P. C. Ray Memorial Gold Medal Award, 2018 invited

The Indian Pharmaceutical Association, Bengal Branch gives annually gold medal on the occasion of celebration of National Pharmacy Week during 3rd week of November of each year to perpetuate the memory of great national figure Acharya P.C.Ray, the pioneer designer of Pharmaceutical Industry in our country since 1962.

IPA, Bengal Branch Council select the awardee amongst the Pharmaceutical Scientists, Teachers, Pharma Regulators, Hospital Pharmacists, Community Pharmacist, Administrators, etc. for outstanding contribution in their respective field and for overall development of the profession of pharmacy. Any member of IPA can recommend name of the person with their detailed Bio-data & Two Page summary of the Bio data for 2018 award, which may be sent by 15th October 2018 to:

The Hony. Secretary,
Indian Pharmaceutical Association, Bengal Branch, 22 B Panchanontola Road, Kolkata – 700029
e-mail: ipabengal@gmail.com

Ref. N.B.: Biodata should include the following points-

1. Date of Birth.
2. Qualification.
3. Experiences in the selected field.
4. Achievements in advancement of sciences/Administration/relevant field.
5.
    a. Whether member of IPA? If yes, how many years?
    b. Whether member of allied pharmaceutical profession other than IPA? If yes, how many years?
6. Services rendered (in years) on the executive Council of IPA Centre or any of its Branches in the capacity as:
    a. President/Vice President / Hony. Secretary/Treasurer/Editor of Official Publication of IPA.
    b. Executive Council Member.
7. Recognition/Award received from other professional organizations including industry/trade associations.
8. Award/Recognition/Honour received from international/national Govt. authorities or prestigious institution/organization by way of award or membership of their constituted body/committee other than sl. No. 6 above.
9. Performance in growth/ improvement of any of the field of pharmacy and shown creditable leadership in the chosen field.
10. Involvement and outstanding achievements in professional development in national/international arena.
11. Notable achievements in any other field or profession excluding pharmacy for which the nominee is nominated for the award including social welfare activities with Govt. and Non Govt. organizations.