their argument that gift authorship is widely prevalent is valid, and is likely to have been one of the reasons for the Medical Council of India (MCI) recommendations. They however contradict themselves by stating that "it's hard to believe that he/she will easily give away his/her precious research and first authorship to his seniors, at least for two papers", suggesting that juniors in a department can refuse 'gift' authorship to their senior colleagues. If they can decline 'gift' authorship to a senior colleague, one would think that they would also be likely to refuse gift authorship to other colleagues, who are competitors, if all the authors listed on a publication were to get equal credit at the time of promotion. Limiting credit to two authors may paradoxically also increase the risk of gift authorship, if the primary author recognizes that the persons listed at 3rd or 4th position or beyond would not benefit from such authorship in promotions.

Whether research and publications should indeed be criteria for promotion is a wider issue. Most academic medical centers aim for excellence in three areas, namely patient-care, teaching and research. Though contribution in significant measure by faculty members in each of these may be desirable, most are unable to do so and end up contributing to only one or two of the areas [3]. Our medical teaching institutions and regulatory bodies need to engage in a debate on this subject. However, this issue was beyond the scope of our editorial, which, given our affiliation to the Indian Association of Medical Journal Editors, dealt primarily with issues that concern biomedical journals and their editors.

Overall, we accept that what constitutes 'creditable research' that should count towards academic promotions is not easy to define, and the suggestions in our editorial are certainly not infallible. The objective of our editorial was to highlight this very problem. The letters received are heartening, and we hope that these will keep this issue in focus and engender debate that will make the process of academic promotions in our medical colleges more robust.

RAKESH AGGARWAL AND PEUSH SAHNI
india.editors@gmail.com

REFERENCES

1. Aggarwal R, Gogtay N, Kumar R, Sahni P, for the Indian Association of Medical Journal Editors. The revised guidelines of the Medical Council of India for academic promotions: need for a rethink. Indian Pediatr. 2016;53:23-6.
2. Principles of Transparency and Best Practice in Scholarly Publishing. *http://publicationethics.org/files/Principles of Transparency and Best Practice in Scholarly Publishing.pdf.* Accessed June 10, 2016.
3. Fleming VM, Schindler N, Martin GJ, DaRosa DA. Separate and equitable promotion tracks for clinician-educators. JAMA. 2005;294:1101-4.

The Academy Should take-up the Issue of Off-label Prescriptions

The recent event involving the off-label use of avastin (bivacizumab injection, 100 mg/4mL) should serve as an eye-opener to pediatricians. In an unfortunate incident, a few patients lost vision after an ophthalmological procedure [1]. The regulator, Central Drugs Standard Control Organization (CDSCO) chose to issue a warning pointing out that avastin used in these patients is not approved for use in ophthalmology, and directed that such use be desisted from [1]. The warning was later withdrawn [2], once it was noted that although off-label, its use as an anti-vascular endothelial growth factor (VEGF) for the treatment of age-related macular degeneration (AMD) is endorsed by the WHO [3], International Council of Ophthalmology, National Institutes of Health, and regulatory agencies of France and Italy [2]. However, the event brought the issue of off-label drugs into a sharp focus.

Off-label drug-use is a reality and needs to be resorted to, as the discoveries made after market authorization compel medical practitioners to use the drug for new indications, in new populations using better dosage regimens. As children are usually not enrolled in clinical trials, many drugs continue to be marketed without appropriate pediatric labeling. Pediatricians prescribe drugs on the basis of available evidence (as they should), textbook-material, guidelines or consensus statements. This ensures that children are treated with better therapies as per new evidence. But, if it is used for indications not listed in the license or is administered in a manner (dose, dose regimen, route of administration, *etc*.) not described in the license; the use constitutes off-label drug use. Off-label drug use is highly prevalent in neonates and children [4,5], and while prescribing these drugs, the treating pediatricians have a greater responsibility. If any

controversy arises, they are required to prove that they acted in good faith and that their actions are supported by available evidence.

As the parents and media may misconstrue off-label use as experimental or unapproved use, the pediatrician can face rough weather. In addition, the accelerated reaction of the regulator might put an additional stress. It is imperative that the Indian Academy of Pediatrics (IAP) comes out with a guidance statement for its members regarding off-label use of drugs, detailing the legal position, role of the regulator, therapeutic decision-making process and prescriber responsibilities. As off-label use is highly prevalent among pregnant women, cancer patients and psychiatric patients as well; the Academy should collaborate with professional organizations of these specialties to plead with the regulator and policy makers for facilitating change in labels in case of older drugs, where a considerable body of evidence is available. This will help assure parents, media and the society at large that the drug therapy is safe and efficacious. IAP should also come out with evidence-based updated guidelines for management of pediatric conditions. This will act as support and a ready-reference when a pediatrician is required to employ off-label drug.

SANDEEP B BAVDEKAR
Department of Pediatrics
TN Medical College and BYL Nair Charitable Hospital, Mumbai, India.
sandeep.bavdekar@gmail.com

REFERENCES

1. Directorate General of Health Services. Office of the Drugs Controller General of India (DCGI). Notice. F No. 12-52/ 2004-DC (Part I). Available from: *http://www.dfda.goa.gov.in/images/uploads/ale_not.pdf*. Accessed May 16, 2016.
2. Directorate General of Health Services. Office of the Drugs Controller General of India (DCGI). Notice. F No. 12-52/ 2004-DC (Part I). Available from: *http://www.cdsco.nic.in/writereaddata/ AVASTIN.pdf*. Accessed May 15, 2016.
3. World Health Organization. WHO Model List of Essential Medicines. 19th list (April 2015) (Amended June 2015). Available from: *http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_JUN2015.pdf?ua=1*. Accessed May 15, 2016.
4. Jain S, Saini SS, Chawla D, Kumar P, Dhir S. Off-label use of drugs in neonatal intensive care units. Indian Pediatr. 2014;51:644-6.
5. Jobanputra N, Save SU, Bavdekar SB. Off-label and unlicensed drug use in children admitted to Pediatric Intensive Care Units (PICU). Int J Risk Saf Med. 2015;27:113-21.

Non-availability of Cloxacillin – A Deterrent for Rational Antimicrobial Practice

Indiscriminate use of antibiotics is one of the factors responsible for the rising antibiotic resistance in India [1]. The World Health Assembly in 2005 sent a call for rational use of antimicrobial agents to curb the problem of rising antimicrobial resistance [2]. Many strategies have been advocated to counter the ever increasing threat of antimicrobial resistance. One such strategy is antimicrobial stewardship [3]. One other important aspect that is a major determinant of appropriate use of antibiotics is the availability of antibiotics.

The overall prevalence of Methicillin-resistant *Staphylococcus aureus* (MRSA) among hospitalized patients in India is about 40-50% [4,5]. Although MRSA prevalence is on the rise, Methicillin-sensitive *S. aureus* (MSSA) continues to be the more common type of *Staphylococcus*. For MSSA bacteremia, early administration of beta-lactams is crucial as empirical Vancomycin therapy for MSSA bacteremia is associated with increased risk of morbidity and mortality compared to an anti-staphylococcal penicillin (oxacillin and nafcillin) or first-generation cephalosporin (cefazolin) [6]. Waiting for culture reports also would be deleterious as delays in initiation of antibiotics for staphylococcal bacteremia have also been associated with an increased odds of infection related mortality [7]. Given this background, the non-availability of Cloxacillin, especially in the private sector hospitals, makes it difficult to treat a patient with MSSA (especially the strains resistant to penicillin but sensitive to oxacillin). Treating doctors are forced to use combinations as ampicillin-cloxacillin or costlier drugs like amoxycillin-clavulanate despite knowing that these are not ideal. Moreover, at times, they are forced to use therapeutically inferior drugs such as Vancomycin [8] or drugs reserved for resistant organisms like Linezolid. Thus, non-availability of antibiotics also paves way for irrational use and hence may defeat the antimicrobial stewardship efforts. Through this letter, we would like to forward our plea to the policy-makers to take into account this