Intricacies in the approval of radiopharmaceuticals

The article by Sharma *et al.*[1] discusses the regulatory requirements for approval of radiopharmaceuticals in USA, Europe and India, and contains useful information. There are however several observations and statements made by the authors, which are deemed inappropriate and some inaccurate too.

For example, the statement, 'particularly India, which does not have guidelines for their approval, and intensifies the concern for a harmonized regulatory platform of global acceptance', is wrong and will mislead the readers about the scenario in the country.

Further, the authors have misinterpreted the mandate and responsibilities of Board of Radiation and Isotope Technologies (BRIT). In the context of the article, the authors' citing presumed modes of BRIT and BARC operation is not deemed warranted.

Necessary clarification cum factual position, on a point-by-point basis, is provided below to respond to the erroneous observations in the article.

1. 'The premier agency governing radiopharmaceuticals and their regulations in India is the Atomic Energy Regulatory Board (AERB).'

AERB is the legally mandated national regulatory authority for (nuclear and) radiation safety matters, including those governing radiopharmaceuticals, but not for the pharmaceutical aspects.

2. 'The BRIT is an independent unit of the Department of Atomic Energy (DAE), GoI, which caters to the requirements of products and services based on radiation and isotopes in India. In conjunction with Radiopharmaceuticals Division of the Bhabha Atomic Research Center (BARC), Mumbai it carries out development, production and supply of radiopharmaceuticals to many nuclear medicine centres throughout the country.'

BRIT is Board of Radiation and Isotope Technology and it has been wrongly quoted as 'Board of Radiation and Isotopic Studies'. This has been misquoted in the caption of figure 6 also. BRIT manufactures and supplies radiopharmaceutical products, whose QC monographs and production manuals have been reviewed and approved by the DAE's Radiopharmaceutical Committee (RPC). Such supplies are made to many nuclear medicine centres throughout the country.

3. 'However, cases exist where BRIT has not been able to meet the demands of most commonly used products like I-131 capsules, solution and injection. In such cases it has been conceived that direct import can be made for such compounds without any registration requirements. Export of any BRIT product is subject to approval from DAE. BRIT has also been vested the responsibility of interaction with AERB regarding authorization and approval of transportation packages for disposal.'

The above text would imply that iodine-131 products are being imported without registration requirement. This is incorrect. All imports of radiopharmaceutical products require registration with DCGI (being pharma products). They also require NOC of AERB, being radioactive material intended to be brought into our country. BRIT also requires the approval of AERB for import of radioactive consignments, including iodine-131. Furthermore, authorized medical end-users are eligible to import such radiopharmaceutical products, even when BRIT may make available such products indigenously and not to address only short fall of BRIT supplies.

4. 'Many lacunae exist for such BRIT-approved products as quality control tests like sterility testing and LAL test are done according to "suitable method" with regard to their protocols and do not bear reference to *Indian Pharmacopoeia*, which is critical keeping in view the quality concerns of such products.'

BET is a mandatory requirement before release of the products, including for the short-lived fluorine-18 and gallium-68 based products. Sterility tests, requiring 7–10 days for completion, are carried out post-facto and with the commencement of testing time according to RPC-approved monographs. BRIT has a dedicated testing facility, where all physicochemical and biological QC are carried out on each batch of every radiopharmaceutical produced in BRIT.

5. 'Moreover some radiopharmaceuticals can also be prepared "onsite" in various hospitals and institutes for which there is no RPC approval and as such the matter pertaining to its quality remains contentious although they are produced in AERB licensed facility.'

Approval by the Radiopharmaceutical Committee (RPC) of the DAE (peer review process by an experts group) is applicable only for products made for distribution by DAE units like BRIT, BARC. Manufacture of radiopharmaceuticals in other centres like hospitals is therefore not under the purview of RPC. The statement made by the authors that, 'quality remains contentious' is therefore inappropriate and not relevant for RPC context. AERB license of a hospital Radiopharmaceutical facility is only from the radiation safety point of view.

6. 'Another cause of concern is the inconsistent and sometimes inordinate price tag for such locally produced products, indicating an indispensable need of the Drug Controller General of India (DCGI) to intervene in such matters, so that the benefits of technology are made available to all sections of society at an affordable cost.'

BRIT follows a duly instituted pricing process approved by DAE for sale of radiopharmaceutical products.

It is pertinent to point out that a system of internal controls and self-regulation, instituted by BARC–DAE, has been functioning all along, to review and approve the QC monographs and production manuals for individual radiopharmaceutical products for their regular production and supply. This has been done in terms of the peer-review process by an experts' group, called the 'Radiopharmaceutical Committee (RPC)' of the DAE. One of the authors[1] (S.J.) has been a member in the RPC since a long time. This has been an important internal mechanism (of DAE) functioning well, in view of the 1977 notification granting exemption to radiopharmaceuticals from the provisions of Chapter IV of the Drugs and Cosmetics Act.

The Indian Pharmacopoeia Commission (IPC) through an Expert Committee formed in 2010, had engaged the RPC, as well as made use of the RPC-provided, IAEA-facilitated entries of monographs of radiopharmaceuticals in the International Pharmacopoeia. This led to IPC including a general chapter and radiopharmaceutical monographs for many products, for the first time, in the *Indian*

Pharmacopoeia 2014 (*IP-2014*) version (additional entries done in subsequent editions). Incidentally, the corresponding author[1] (R.K.S.) was the Chair of the IPC Expert Committee tasked with the first-time entry of monographs of radiopharmaceuticals in the *IP*.

The above-mentioned points should serve to clarify the internal regulatory approval process of DAE units for production and supply of radiopharmaceuticals in India, as well as will respond to the authors' generic contention in the abstract ('and particularly India, which does not have guidelines for their approval, and intensifies the concern for a harmonized regulatory platform of global acceptance.').

1. Sharma, S. *et al.*, *Curr. Sci*., 2019, **116**(1), 47–55.

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Teaching English for science students

The 2005 editorial by Balaram[1] throws much light on the poor English language ability of students of science. Although it is more than a decade now, there has not been any improvement and the situation seems to be as grave as before. Raman[2] has expounded his experience on the dire need of sparing more than four hours of teaching basic English to students who registered for research under him. Most students of science and technology are under the misconception that English language learning is trivial and something that is unnecessary. It is considered petty, little forgetting that English is an international language which is widely spoken across the globe and used in all sectors. It is time pupils realize and understand the absolute significance of English in their lives and careers. Subbarao[3] opined that students of science, even at the postdoctoral level, are unable to appreciate, let alone practice, the importance of correct English.

Working as English professors in a university, we find it unpalatable to read the atrocious English in the scripts of our science students. At graduate and post-graduate levels, we do find it tricky to explain to them, the appalling errors in their scripts. English is not a language that is as simple as it seems; it has extensive vocabulary, intricate grammar and broad lexicology. In most cases, teachers of English in higher educational institutions are trapped in following a conservative and outdated system of teaching and not wary of the demands of the industry and research institutions. They are acutely bothered about completing the syllabus on time and hence the teaching is painfully robotic and monochromatic. 'Teaching' most of the time is rushed through without giving consideration to the student's ability to comprehend what is being taught. English for specific needs is the order of the day. It is vital to provide an opportunity to the students to bask on the myriad facets of language – exposing them to vocabulary-building, newspaper reading, writing of articles, scientific writing, story-telling, paraphrasing, précis writing, comprehensive listening, impromptu speaking, debating, role-playing, language-gaming, mock-interviewing, book reviewing, etc. can come a long way in developing proficient English language skills. Teaching or learning English is a never-ending process. The task of the teacher is only to give the student a blissful taste of what English language is. The unquenchable thirst by itself will awaken the student's voracity to learn and yearn for more. For 'A little learning is a dang'rous thing;/Drink deep, or taste not the Pierian spring', so quoted Alexander Pope in his poem.

1. Balaram, P., *Curr. Sci.*, 2005, **88**, 205–206.
2. Raman, A., *Curr. Sci.,* 2015, **109**, 398.
3. Subbarao, C., *Curr. Sci*., 2005, **88**, 847.

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Can peptide nucleic acid be the future substitute for antibiotics?

With the emergence of growing antibiotic resistance among microbes because of habitual use of antibiotics, there is an urgent need to develop appropriate and economical substitutes for antibiotics. Antimicrobial resistance (AMR) threatens the conventional method of treatment and prevention of a wide range of multidrug-resistant (MDR) microbes which include bacteria, parasites, fungi, etc. AMR is gradually establishing itself as a serious threat to global public health which requires immediate attention from the scientific community across the globe. According to a report of the World Health Organization (WHO), in 2016 alone, approximately 500,000 people developed MDR tuberculosis worldwide and it also expected that such growing antibiotic resistance will make the fight against HIV and malaria more complicated soon[1].

In recent times, peptide nucleic acid (PNA)-based antimicrobial products are