

## **Drug Information Bulletin**

Drug Information Centre (DIC)

Indian Pharmaceutical Association

Bengal Branch

Tele fax: 033 24612776, E-mail: ipabengal.dic@gmail.com

Web Site: http://www.ipabengal.org

Contact: 09830136291

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## Regulatory Affairs Division (RAD), IPA

Volume: 12 Number: 07 1<sup>st</sup> July 2018

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#### **Editorial**

Antimicrobial resistance is a serious global health problem specially in resource poor countries and India is not an exception. World Health Organization (WHO) as well as Government of India has made strategies for containment of Antimicrobial resistance (AMR). Antimicrobial Resistance is the result of environmental and behavioral factors. Indiscriminate use of antimicrobials, laxity in enforcement of existing laws and lack of awareness are the main causes of AMR in India. Indian Government has taken several steps to improve pattern of use and stringent enforcement of existing regulations. Indian Pharmaceutical Association (IPA) and Commonwealth Pharmacists' Association (CPA) have taken up the issue of generating awareness on containment of AMR during last few years. Recently CPA and IPA has presented their activities in Antibiotic Guardian Conference and Awards 2018 organized by Public Health England, UK at London, where the poster of CPA was recognized as "highly commended poster" and the IPA Poster was shortlisted for presenting at the final round. Several health care agencies and associations from UK and other Commonwealth countries have presented posters in this conference. Both the posters are published in this issue of the Drug Information Bulletin as per the request of Dr. Rao Vadlamudi, President, and Commonwealth Pharmacists' Association.

Dr. Subhash C. Mandal

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**Editor** 

E mail: subhash.mandaldr@gmail.com Mob. 9830136291







### RAISING AMR AWARENESS IN THE COMMONWEALTH

#### WHO ARE THE CPA?

The CPA is a UK-based charity whose membership base consists of National Pharmacy Associations of the Commonwealth. As an affiliated organisation of the Commonwealth, the CPA has a key advocacy role for the profession at government level. The mission of the CPA is to help support the better use of medicines throughout the Commonwealth with a vision of improving the health and well being of the people of the Commonwealth.



#### AMR AND THE COMMONWEALTH

The Commonwealth encompasses % of the world's land mass and % of the global population, including many lower middle income countries (LMICs) (Figure 1). Deaths attributed to AMR are particularly marked in LMICs, making this issue an important focus for health in the Commonwealth.

A global action plan on antimicrobial resistance (AMR) was endorsed at the World Health Assembly (WHA) in May 2015, reflecting the global agreement on 3. Send a short video message around the theme of WAAW 2017 'Seek' the profound threat AMR poses to human health. In response to this, all 52 Commonwealth countries signed the UN declaration in 2016.

Analysis of published responses by Commonwealth countries in the WHO first open self assessment survey (2016-17) revealed that:

- -44% had developed an AMR action plan
- -27% had an action plan under development

Of these, more than 80% of high income and lower-middle income countries had an action plan or were the in the process of developing one, compared to 60% of upper-middle and low income countries.

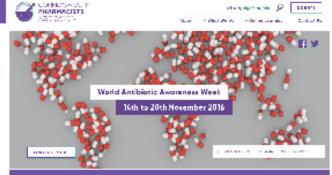
The Commonwealth provides the ideal network to share good practice and support the development of action plans in less resources rich settings. The Commonwealth Health and Education Unit has developed a Policy Brief on AMR to help support member nations in tackling this global threat https://www.thecommonwealth-healthhub.net).

#### WAAW 2016 CAMPAIGN WORK

For World Antiblotic Awareness week (WAAW) 2016 the CPA engaged with members to raise awareness of AMR, and asked them to complete a survey to investigate the situation regarding regulation and enforcement of regulation around supply of antibiotics in the Commonwealth. Amongst other things, this revealed that although 92% had legislations preventing sale of antibiotics without a prescription; only 57% of the responding organizations stated that the legislation was abided by in their country.

The survey also showed that 76% of respondents were aware of WAAW, however only 38% of the national organizations had plans for WAAW 2016, so It was suggested that one of their planned activities could be to become an Antibiotic Guardian and for Individuals or groups to send in photos with their certificates for display on the CPA website and social media channels (Figure 2). The CPA also created: an Antiblotic Guardian flyer, letter to member organizations, sample press release and a portal of resources on the CPA website to support members in raising awareness and developing their own campaigns. During this week the CPA were also able to co-host a discussion of the challenges of tackling AMR in the Commonwealth on the Commonwealth's Health Hub.

Correspondence to: victoria.rutter@commonweaithpharmacy.org



#### WAAW 2017 CAMPAIGN WORK

In the run up to WAAW 2017 the CPA held 2 webinars

- (1) To raise awareness of the role of the pharmacist in tackling AMR
- (2) To give individuals and organizations ideas of how to run their own campalons.

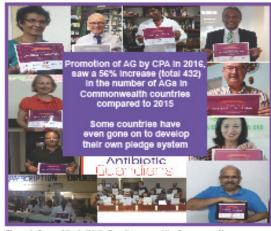
Members organizations around the Commonwealth were also requested to:

- Register activities they had planned on the Antibiotic Guardian website
   Complete and distribute a vaccines survey (in collaboration with the International Pharmaceutical Federation - FIP)
- advice from your healthcare professional before taking antibiotics'. These can be viewed on our website: www.commonwealthpharmacv.org
- 4. Send on a Malichimp to all their members containing 3 calls to actions:
  - I. Complete a survey on perceptions of AMR and share with networks
  - Become an Antibiotic Guardian
  - Consider running own campaign using tool kit/webinar on our website for ideas/resources

We actively tweeted/retweeted appropriate WAAW posts during this week.

#### FUTURE AMR WORK

The work that the CPA have carried out since 2016 has led to submission of abstracts and articles to raise awareness of AMR, as well as enabling the use of data to strengthen advocacy efforts at government level. A significant project to support pharmacist-led antimicrobial stewardship initiatives in 4 African nations in collaboration with another UK charity is currently being worked up. The CPA's WAAW 2018 Campaign is also under development.



are 2: Some of the Antibiotic Guardians around the Comm

#### IPA poster at Antibiotic Guardian Conference and Awards 2018 organized by Public Health England, UK at London



#### IPA Initiatives in the area of Antimicrobial Resistance

Dr. Rao V.S.V. Vadlamudi, Mrs. Manjiri Gharat, Dr. Subhash Mandal, Ms. Anusha Bompelli Indian Pharmaceutical Association

Kalina, Santacruz (East), Mumbai - 400 098, Maharashtra, India.



#### Introduction

Antimicrobial resistance (AMR) is a major problem faced by India as well as the world and it received a very high priority under the Global Health Security Agenda (GHSA). The Ministry of Health & Family Welfare (MoHFW), Govt. of India listed AMR among the top 10 priorities for collaborative work with WHO.

MoHFW released a national action Plan on antimicrobial Resistance (NAP-AMR) with 6 strategic priority areas. Improving awareness and understanding of AMR through effective communication, education and training was identified as the core objective among the 6.

The National Health Policy 2017 recognised AMR as a problem and urges for an effective action to address it.

#### The Indian Pharmaceutical Association's work

Indian Pharmaceutical Association (IPA), the largest national professional body of pharmacists in India is working to prevent AMR through increasing awareness among all stakeholders and improving rational use of antibiotics. This poster represents a list of activities that IPA performed through its community pharmacy division and various state and local branches spread all over the

India has participated in the AMR cartoon competition of FAPA in Oct 2015. A write up on the activities of IPA against AMR along with photographs have been sent Commonwealth Pharmaceutical Association for display in the Science Museum London.

#### Voice through media against AMR

#### Community pharmacists' role in fight against antimicrobial resistance

nation". The aim was to discourage pa





#### Activities to raise awareness on Antimicrobial resistance

The theme of 54th National Pharmacy Week (NPW) 2015 was 'Responsible Use of Antibiotics Saves Lives'. Posters/leaflets and PowerPoint presentation were developed and were used by most IPA branches, pharmacy colleges, pharmacists and others to create public awareness on AMR. New initiative taken up was a competition on the theme for practising pharmacists, students and academicians.



A colourful mobile tabloid was arranged with posters and promotional materials against "Antimicrobial Resistance", to raise awareness among the public which has travelled to different parts of Kolkata for 10 days. The entire programme was covered by a number of daily newspapers and a half hour talk show was telecasted on "Combating Antimicrobial Resistance" by Doordarshan Television Channel of India).





Several seminars were conducted to reach 1000 retail pharmacists and pharmacy owners. The seminars emphasized that pharmacies must insist on proper prescription for dispensing antibiotics, provide patient counselling for medication adherence, and discourage self-medication and Schedule H1 protocols.

Knowledge appreciation and perception survey was conducted at 5 big hospitals of Kolkata in collaboration with IPA Bengal Pharma and Healthcare Trust during the NPW week covering about 2300 patients and carers.





#### Campaign for Awareness on Responsible Use of Medicines (CARUM)

Designed posters and a handbook in 6 languages to educate the patients and their care takers on correct use of medicines with emphasis on antibiotic medication adherence.







#### **DOTS TB Pharmacist Project**

It's a public private partnership model developed by IPA with the support of Govt TB authorities where community pharmacists are engaged in the National TB Programmes which use the strategy DOTS (Directly Observed Treatment Short course). This model ensures that patients take their prescribed treatment for full duration and do not leave it halfway. Default in treatment is one of the main reasons for the emergence of MDR TB. More than 5000 pharmacists in different parts of the country are trained by IPA, Govt TB Cells and other NGOs.

#### IPA - Students' Forum (IPA-SF) Activities

IPA's Students' Forum has student chapters operating at various pharmacy institutions in India and the students chapters have taken an initiative to train school children on awareness of TB and precautions to be taken to prevent spread of the disease and also to improve adherence to treatment with in their families and neighbourhood. This initiative is being scaled up to have a profound influence on arresting development of AMR.

#### Other significant activities

Projects sponsored by Pharma Industry: Upcoming project is focused on AMR sponsored by MNC where in IPA will develop video, posters for public education and training modules for pharmacists.

Media: Interviews of IPA office bearers on AMR were telecasted in various Television Channels during Antibiotic Awareness Week 2015. Several articles on AMR were written in regional languages as well.

These are a few of the major contributions from organizations like IPA to prevent antimicrobial resistance.

#### **Contact Information**

Dr. Rao V.S.V. Vadlamudi Email: rao.vadlamudi@gmail.com Phone: +91 9866559321

Public notice issued by CDSCO for comments on proposed inclusion of all implantable medical devices and other high end equipment under the purview of sec. 3(b) (iv) of the D & C Act

# F No. 18-13/2018-DC (Part-1) Directorate General of Health Services Central Drugs Standard Control Organization FDA Bhawan, Kotla Road, New Delhi (O/o DCG (I))

Dared: 2 2 JUN 2018

#### PUBLIC NOTICE FOR COMMENTS ON PROPOSED NOTIFICATION

Subject: Proposal to include all implantable medical devices and other high end equipment under the purview of Section 3 (b) (iv) of the Drugs and Cosmetics Act, 1940 as Medical Devices-regarding.

In pursuance of sub-clause (iv) of clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), Drugs Technical Advisory Board (DTAB) in its 79th meeting held on 16.05.2018, deliberated and recommended for the proposal to specify the following medical devices under the definition of drug.

- 1) All implantable medical devices
- 2) CT sean equipment
- 3) MRI equipment
- 1) Defibrillators
- 5) Dialysis machine
- 6) PET equipment
- 7) X-Ray machine
- 8) Bono marrow cell separator

This will be notified in the official Gazette of India and it will come into force after a period of twelve months from the date of its publication. All the stakeholders are requested to forward their comments/suggestions within 21 days of Issue of this notice prior to finalization of the notification, through email at <u>designicin</u> and deedtab@edsco.nic,in or in hard copies to the O/o DCG(I), CDSCO, FDA Bhawar, Kotla Road, New Delhi-110002.

(Dr. S. Eswara Reddy) Drugs Controller General (India)

cc: ppsto IscR)

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