Pharmacovigilance
Programme of India (PvPI)
Newsletter

Call for Submission of 'Letter of Intent'

A 'Letter of Intent' is invited from the Heads of the Institutions (Medical Colleges/Hospitals) for consideration as ADR Monitoring Centre. So far 43 ADR Monitoring Centres have been enrolled. An additional 60 centers are expected to be enrolled by the end of the year 2011. Further addition of 100 centres each in the year 2012 and 2013 is expected. By the year 2014 – 15 it is expected that all medical colleges will have ADR Monitoring Centres.

Address for Communication

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Pharmacovigilance
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Inside this issue:

Secretary cum Scientific Directors Message

Dear colleague,

It gives me immense pleasure to bring to the notice of you all that the National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI) at IPC; Ghaziabad has initiated the publication of PvPI newsletter. This is the first issue of the Newsletter from this Centre. As the range of newer drugs is increase day-by-day, therefore it becomes important that the Adverse Drug Reaction (ADRs) of all drugs are monitored by the all ADR Monitoring Centres (AMCs) of the country and reported to the NCC continuously. For this the integrated and dedicated efforts of all the healthcare professionals including clinicians, pharmacists, nurse, drug manufacturers and others need to be put so that high quality data is generated indigenously and this will make the sound of spontaneous reporting/voluntary reporting will further strengthen this programme.

I am delighted to share with you that the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services under the aegis of Ministry of Health & Family Welfare, Government of India in collaboration with Indian Pharmacopeia Commission, is taking keen interest in supporting the cause and in taking various strategic decisions for successful running of this programme. The programme is in the expansion mode to meet its objectives.

I am confident that with the support and active involvement of everyone this programme will become one of the most vibrant healthcare programmes of the country and will play a vital role in safety monitoring of drugs at global level.

Dr. G. N. Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission

Introduction to Pharmacovigilance Programme of India

Introduction

Pharmacovigilance is a highly specialized branch of medical science dealing with activities relating to the detection, assessment, understanding and prevention and control of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include monitoring of ADRs associated with

- Herbal products
- Biolologics including blood and blood related products, recombinant DNA derived therapeutic products, vaccines
- Medical devices etc.

There are differences among countries (and even regions within countries) in the occurrence of ADRs and other drug related problems. The reasons could be multiple such as differences in diseases and prescribing practices, genetics, diet, traditions of the people, drug manufacturing processes which influence pharmaceutical quality, composition, drug distribution and use including their dose and availability etc. Therefore, Pharmacovigilance is needed for detecting ADRs and specifically tomeet the requirements so that the drugs 'not of standard quality' do not find place in the Indian market. ADR monitoring ensures that patients obtain safe and efficacious products.

Structure of PvPI

The structure of PvPI is:

I. Steering Committee

Steering Committee consists of 10 members with DCG(I) as the Chairman.

II. Working Group

The Working Group consists of 11 members with Secretary-cum-Scientific Director, Indian harmacopoeia Commission as the Chairman.

The following committees will provide technical support to the programme

- Signal Review Panel
- Core Training Panel
- Quality Review Panel

Mission of PvPI

To ensure that the benefits of medicine outweigh the risks and thus safeguard the health of the population.

Objectives of PvPI

To monitor Adverse Drug Reactions (ADRs) in Indian population

- To create awareness amongst health care professionals about the importance of ADR reporting in India
- To monitor benefit-risk profile of medicine to generate independent, evidence based recommendations on the safety
- Support the CDSCO for formulating safety related regulatory decisions for medicines
- Create a National Centre of Excellence at par with global drug safety monitoring standards.

NCC-UMC Uplinking

WHO's UMC provides technical support to more than 100 countries worldwide on matters pertaining to drug safety which includes Pharmacovigilance Programme in India.

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VigiFlow & VigiBase

VigiFlow is a web-based Individual Case Safety Report (ICSR) management system that is specially designed for use by national centres in the WHO Programme for International Drug Monitoring. It can also be used by pharmaceutical companies or clinical research organizations for monitoring of their ICSR. VigiFlow is based on and compliant with the ICH E2B standard and is a trademark of the UMC and maintained by the UMC in Uppsala, Sweden. ICSR data can be manually entered into VigiFlow with support from the latest versions of terminologies such as the WHO Drug Dictionary and WHO-ART. Some fields are mandatory, and this, together with built-in error checks, helps users to add data correctly. It is also possible to import ICSR data as XML files in the E2B format. If a country has regional Pharmacovigilance centres, the manual entry of ICSRs can be done at this level.

Handling of ICSRs

It is easy to communicate within VigiFlow by adding a digital 'post-it' note to the ICSR. This note will stay with the report when it is sent from a regional centre to the national centre or while different people at the national centre work on the report. Once a report is complete and committed the first version of the ICSR is considered to be finalized. It is easy to retrieve reports to amend the contents or add follow-up information. An audit trail on each report will keep copies of earlier versions and show which user added new information.

It is easy to access information about potential safety hazards of medicines (worldwide data)

Analysis

A search and statistics module is part of VigiFlow; both line listings and statistical tools are among the profiles available. The results can be exported in different output formats, either as PDF files or in spreadsheet format compatible with Microsoft Excel.

Communication with External Organizations

ICSR data can be sent to external contacts such as companies or other regulatory agencies either as PDF files (as computer files or hardcopy printouts) or in E2B

formatted XML files. The submission manager in VigiFlow will keep track of which ICSRs should be sent to an external contact and which have already been sent. All imported E2B files are also tracked. ICSRs will automatically be flagged for being copied to VigiBase, the WHO Global ICSR database when they are committed; however, national centres can easily remove this and thereby keep a specific report private.

Technical Information

Since VigiFlow works over the Internet, no local installations, back-ups or maintenance are necessary. The only requirements are a web browser, preferably Mozilla Firefox or Internet Explorer and an Internet connection.

The Internet access is encrypted and any information stored in VigiFlow is only accessible by users within the same country/organization identified by their individual user name and password. VigiBase is the name of the WHO global ICSR database; it consists of reports of ADRs received from member countries since 1968. VigiBase is updated with incoming ICSRs on a continuous basis. The VigiBase data resource is the largest and most comprehensive in the world, and it is developed and maintained by the UMC on behalf of the World Health Organization. VigiBase is a computerized Pharmacovigilance system, in which information is recorded in a structured, hierarchical form to allow for easy and flexible retrieval and analysis of the data. The case reports in the WHO database do not identify the patient or reporter. Its purpose is to provide the evidence from which potential medicine safety hazards may be detected. The VigiBase database system includes linked databases containing medical and drug classifications.

WHO-ART and WHO DD

These classifications enable structured data entry, retrieval, and analysis at different levels of precision and aggregation. License agreement has been signed between NCC for PvPI and UMC for using vigiflow-vigibase to upload the ADRs. National Coordination Centre for PvPI established links with Uppsala Monitoring Centre (UMC), Sweden in the last week of May, 2011 for issuing user ID and password for uploading the ADRs generated by PvPI. Within this short span of time 22 new centres have been added and 11 nonfunctional centres have been activated.

Workshops Organized By NCC, PvPI

• On 18hMay, 2011 an interactive workshop on PvPI was organized.

• Thereafter another inductionumraining workshop was organized on 20hand 21tJuly, 2011 to train the 22 existed centres as only 11 centres were active and 11 nonunctional before organizing this workshop. Experts in Pharmacovigilance from academia and industry participated in the workshop. The participants across the country attended workshop. In this handsnraining workshop the Coordinators and Technical Associates were given practical training on igiFlow Experts from academia and industry acted as trainers.he workshop was partially funded by WHOountry Office (India).

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During this workshop FOUR Training and Technical support centres at regional level were identified. These include:

1. Post Graduate Institute of Medical Education and Research (PGIMER), Sector-12, Chandigarh, Pin- 160 012, India.

2. Institute of Postgraduate Medical Education and Research (IPGMER), 244 A.J.C Bose Road, Kolkata - 700 020, India.

3. JSS Medical College, Sri Shivarathreeshwara Nagara, Mysore - 570 015, Karnataka, India.

4. Seth GS Medical College and KEM Hospital Acharya Donde Marg, Parel Mumbai - 400012, India.

• To further increase the awareness of PvPI at the global level, NCC exhibited its PvPI activity at the 71tInternational Pharmaceutical Federation (FIP) Conference at Hyderabad International Conventional Centre, Hyderabad from 3dto

8thSeptember, 2011. An overwhelming response was received from the national and international participants.

List of ADR Monitoring Centers (AMCs)

1. All India Institute of Medical Sciences, New Delhi.

2. Bangalore Medical College and Research Institute, Bangalore.

3. BJ Medical College, Ahmadabad.

4. BJ Medical College & Sassoon General Hospital, Pune.

5. Burdwan Medical College, Burdwan, West Bengal.

6. Calcutta National Medical College, Kolkata.

7. Christian Medical College, Vellore, Tamil Nadu.

8. Dayanand Medical College and Hospital, Ludhiana, Punjab.

9. Goa Medical College & Hospital, Bambolim, Goa.

10. Government Medical College, Bhavnagar, Gujarat.

11. Govt. Medical College, Bakshi Nagar, Jammu.

12. Guwahati Medical College and Hospital (GMCH), Guwahati, Assam.

13. Grant Medical College & Sir JJ Group of Hospital, Mumbai.

14. GSVM Medical College, Swaroop Nagar, Kanpur, U.P.

15. Himalayan Institute of Medical Sciences, Dehradun, Uttrakhand.

16. Indira Gandhi Government Medical College, Nagpur, Maharastra.

17. Institute of Postgraduate Medical Education & Research, Kolkata.

18. JIPMER, Puducherry.

19. JSS Medical College Hospital, Mysore, Karnataka.

20. Kasturba Medical College, Manipal, Karnataka.

21. Lady Hardinge Medical College, New Delhi.

22. Lokmanya Tilak Municipal Medical College & General Hospital, Mumbai.

23. M.K.C.G Medical College, Berhampur, Odisha.

24. Madras Medical College, Chennai.

25. Mahatma Gandhi Institute of Medical Sciences, Nagpur, Maharastra.

26. Nizam Institute of Medical Sciences and Hospital, Hyderabad.

27. Pandit Bhagwat Dayal Sharma, Post Graduate Institute of Medical Sciences, Rohtak, Haryana.

28. PGIMER, Chandigarh.

29. PSG Institute of Medical Sciences & Research, Coimbatore, Tamil Nadu.

30. R.G. Kar Medical College, Kolkata.

31. Rajendra Institute of Medical Sciences (RIMS), Ranchi, Jharkhand.

32. SAIMS Medical College, Indore-Ujjain.

33. Santosh Medical College, Ghaziabad, U.P.

34. SCB Medical College and Hospital Cuttack, Odisha.

35. School of Tropical Medicine, Kolkata.

36. Seth GS Medical College & KEM Hospital, Mumbai.

37. Sher-i-Kashmir Institute of Medical Sciences, Srinagar, J&K.

38. SMS Medical College, Jaipur, Rajasthan.

39. SMT NHL Municipal Medical College, Ahmadabad.

40. SRM Medical College Hospital & Research Centre, Chennai.

41. UPMCJ, Jalgaon, Maharastra.

42. VSS Medical College Burla, Odisha.

43. Vydehi Institute of Medical Sciences and Research Centre, Bangalore.

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