Suggested CDSCO to incorporate Interpersonal Induced
Suspected drug being marketed in India.
CDSCO is incorporating into the package inserts of this
treatment with possible IC50 value 0.75 and suggested
potential signal as it was supported by histopathological
examination and findings (AGEP) combination to be a
combination of respiratory and pulmonary induced
Acute Generalized
SRP considered Ceftriaxone induced Acute Generalized
Respiratory distress syndrome
Malignant Dune.
- Programmatic (NDDCP) for the monitoring of Anti-
Pneumonitis (NDDCP) for the monitorying of Anti-
Infections with the National Vector borne Disease
Control
- SRP needed PPI to issue drift alert for Amebiasis
SRP considered PPI to keep a watch on
Pneumocystis/Infections Induced DRESS Syndrome
The outcome of the meeting is as follows:
SRP agreed to issue 8th SRP meeting of PPI at CDSCO.

IPCC Organised its 8th SRP meeting of PPI at CDSCO.

The reports of quality/Incomplete reports will be reverted back to
Inadequate/Poor review.
The reported cases are under the assessment for
completeness, integrity and clinical relevance.

During the index period NCC received 5741 ISRS
Data collection and processing

No. Description
1

Major Outcome/Action Taken

PPI Monthly Progress Report - July 2016
National Co-ordination Centre (NCC) - Pharmacovigilance Programme of India (PPI)
Indian Pharmacopoeia Commission

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Recommended PPI to communicate the same to CDSCO. PPI to incorporate the following adverse drug reactions of suspected drug marketed domestically & recommended PPI:
- Hypersensitivity syndrome
- Stevens-Johnson syndrome
- Toxic epidermal necrolysis
- Abnormalities induced by exposure

In package inserts of this suspected drug marketed in India, the following information should be taken into account:

- Incorporation of the above adverse drug reactions into the package inserts of this suspected drug marketed in India
The outcome of the workshop is as follows:

- Specifications for the forthcoming NRA assessment
- Joint strategic cooperation plan was prepared for
  - Self-assessment
  - On-site visits
- Implementation of the Global Benchmarking Tool to document and
  - Strengthen the regulation of medicinal products and Good Regulation Practices in India and
  - Participate in the forthcoming CDSCO/WHO joint workshop on Good Regulatory Practices for National Regulatory Authorities

**WHO - CDSCO International Workshop on Good Regulatory Practices for National Regulatory Authorities in India**

A joint workshop was held in New Delhi, India, from 20-21 July 2016.

The workshop was attended by representatives from various regulatory authorities, including those from India, and focused on strengthening the implementation of the Global Benchmarking Tool to document and strengthen the regulation of medicinal products and Good Regulation Practices in India and the region.

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**WHO - CDSCO International Workshop on Good Regulatory Practices for National Regulatory Authorities in India**

The workshop was attended by representatives from various regulatory authorities, including those from India, and focused on strengthening the implementation of the Global Benchmarking Tool to document and strengthen the regulation of medicinal products and Good Regulation Practices in India and the region.
The role of the National Pesticide Policy was discussed.

- The need for increased vigilance and monitoring of single-microbial drug resistance linked with the QM of MOH.

The outcome of the training workshops are as follows:

- WHO - CDSCO International Dissemination and Training Workshop on Drug Safety: Programme.

22nd July 2016 at Hotel I-Tara, New Delhi

Medical Products

- Sponsors, Facility, Logistics, and other necessary arrangements

FOR DISSEMINATION AND TRAINING

- Introduction to the WHO - CDSCO International Dissemination and Training Workshop on Drug Safety: Programme.
To send a clarificatory letter to the Article Health
suggested by the Secretary Health may be discussed
essential and interesting the active participation is
The coordinators suggested the following during the

<table>
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<tr>
<th>Recognized AMC's under PYP</th>
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</table>
| 26th & 27th July at ICE, Ghaziabad | Program on Program on
| Pharmacovigilance for Coordinators of Newy |

1. Since clinicians in the Programme is very

- Communication on training programme to DGH
- Induction training

- Each AMC, UP to be held at least twice in a year
- Communication meeting of the PYP members of
  State
- Provided an available mobile App for general
- The WTP, GoI
- National Pharmacovigilance Day to be declared by
  the locale
- The AMC identified by the AMC
  - As per
  - Time
  - The AMC can conduct the training programme
  - Doctor, etc.
- convince about the benefits of reporting and alerting
  - Through a seminar by inviting learned speakers to
  - In major hospitals/colleges and other health
    workers
- The PYP practice medicine pharmacists and other health
  field
- SHAT’s RUAH, College of

- Effective functioning of the system

- Identified PYP, Eastern UP, Coordinating centre, for
I. National Institute of Epidemiology (NIE), Chunabhatti

Baseline pharmacovigilance in the field expanded below:

ICMR institutions as PPI collaboration centres for research
DC, ICMR in conjunction with the following scenario:

The outcome of the meeting is as follows:

July 2016 at ICMR, HQ. ANMCS Campus, New Delhi

<table>
<thead>
<tr>
<th>Coordinating Centres</th>
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<tbody>
<tr>
<td>ICMR Institutions as PPI</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
</tr>
<tr>
<td>through Research based Pharmacovigilance</td>
</tr>
<tr>
<td>ICMR</td>
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<tr>
<td>Through collaboration research</td>
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</tbody>
</table>

6. Every AMC should have one PPI program:

- ambassador for the success of the PPI program
- professional besides a pharmacovigilance

5. More number of experts need to be identified for the year:

- be assigned against the overall amount sanctioned for the activities at their respective centres. This shall
- be given in an advance so that they can kick start
- departmental budget. However, the co-
- of every financial year. However, the co-
- 6000/00/year (maximum) is reimbursed at the end
- of AMC's, the annual compensatory amount of Rs.
- 4. in the current system of PPI, for the functioning
- function and monitoring the data collected.
- 3. PPI to coordinate with clinicians of professional
- current guidelines and action plan
- co-ordination of AMC's of PPI to discuss the
- guideline and other healthcare professionals be
- sections stating that ADRs reporting by the

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PPfP database & to make prevention plans for the
PPfP recommends NDDTC to monitor the drugs
causing the dependence or ADRs. NDDTC on 13th September 2016,
NCR, New Delhi, has been established. KEM, Mumbra; RIMS, Imphal & GMC, Imphal at
PPEMR, Chandigarh, NIMHANS, Bengaluru,
and PPEMR, Chandigarh, NIMHANS, Bengaluru;
NDDTC recommended PPfP to organize orientation
training centres under NDDTC.

The outcome of this meeting:

- NCR-PfP & NDDTC centre agreed to bridge the gap
- NCR-PfP & NDDTC centre agreed to bridge the gap

Professor, NDDTC, Chazhibad 29th July 2016 at IpC.

NCR-PfP organized meeting with Dr. Akhil Amerka,
NCCR-PfP organized meeting with Secretary-cum-Scientific Director-IpC,
Interdepartmental Meeting with

NIRF, Centre for Research in Tuberculosis
National Institute of Communicable Diseases
C-KCIVD, Kochi - for safety monitoring of vaccines
National Institute of Cholera & Diarrhoeal Diseases
Health (NIRM), Mumbra - for safety monitoring of
National Institute for Research in Reproductive
National AIDS Research Institute (NARI), Pune - for
National Institute of Nutrition (NIN), Hyderabad - for
National Institute for Nutrition (NIN), Hyderabad - for
National Institute for Nutrition (NIN), Hyderabad - for
Pharmacovigilance and data management

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