F. No. 12-01/18-DC (Pt-337)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road, New Delhi
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Cefotaxime – Angioedema Adverse Reaction - Reg.

****

Cefotaxime is approved by CDSCO and marketed in the country in injectable dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Cefotaxime which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Cefotaxime-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Angioedema as an adverse drug reaction** in to the prescribing information leaflet (PIL) of the drug Cefotaxime marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 16.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that angioedema should be incorporated in the package insert of the drug Cefotaxime as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Cefotaxime formulations under your jurisdiction to mention angioedema as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

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

1. Copy for information & follow-up: -
   All Zonal / Sub Zonal Offices of CDSCO.

2. Copy for information to: -
   JS(R), Nirman Bhawan, MoHFW, New Delhi-110002.

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FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Ofloxacin – Stevens Johnson syndrome (SJS) / Toxic epidermal necrolysis (TEN) Adverse Reaction - Reg.

* * * * * * * *

Ofloxacin is approved by CDSCO and marketed in the country in the in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Ofloxacin which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Ofloxacin-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Stevens Johnson syndrome (SJS) / Toxic epidermal necrolysis (TEN) as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Ofloxacin marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 16.01.2019

at CDSCO HQR, New Delhi. After detailed deliberation the Committee has recommended that Stevens Johnson syndrome (SJS) / Toxic epidermal necrolysis (TEN) should be incorporated in the package insert of the drug Ofloxacin as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Ofloxacin formulations under your jurisdiction to mention Stevens Johnson syndrome (SJS) / Toxic epidermal necrolysis (TEN) as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

Dr. S. Eswara Reddy
Drugs Controller General of India

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FDA Bhawan, Kotla Road,
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Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Tranexamic acid – Seizure/Convulsion Adverse Reaction - Reg.

* * * * * * * *

Tranexamic acid is approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Tranexamic acid which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Tranexamic acid-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate seizure/convulsion as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Tranexamic acid marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Oncology & Hematology) meeting held on 18.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that seizure/convulsion should be incorporated in the package insert of the drug Tranexamic acid as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Tranexamic acid formulations under your jurisdiction to mention seizure/convulsion as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

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

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FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Quetiapine – Urinary Incontinence Adverse Reaction - Reg.

****

Quetiapine is approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Quetiapine which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Quetiapine-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Urinary Incontinence as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Quetiapine marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Neurology & Psychiatry) meeting held on 09.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that Urinary Incontinence should be incorporated in the package insert of the drug Quetiapine as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Quetiapine formulations under your jurisdiction to mention Urinary Incontinence as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

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

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FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Sulfasalazine – DRESS Syndrome Adverse Reaction - Reg.

* * * * * * * *

Sulfasalazine is approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Sulfasalazine which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Sulfasalazine-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) Syndrome as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Sulfasalazine marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Analgesic & Rheumatology) meeting held on 17.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the

Committee has recommended that Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) Syndrome should be incorporated in the package insert of the drug Sulfasalazine as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Sulfasalazine formulations under your jurisdiction to mention Drug Rash with Eosinophilia and Systemic Symptoms (DRESS) Syndrome as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

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

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FDA Bhawan, Kotla Road,
New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Sodium Valproate – Gum Hyperplasia Adverse Reaction - Reg.

****

Sodium Valproate is approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Sodium Valproate which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Sodium Valproate -ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate Gum Hyperplasia as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Sodium Valproate marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Neurology & Psychiatry) meeting held on 09.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that Gum Hyperplasia should be incorporated in the package insert of the drug Sodium Valproate as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Sodium Valproate formulations under your jurisdiction to mention Gum Hyperplasia as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

Dr. S. Eswara Reddy
Drugs Controller General of India

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New Delhi.
Dated: 09.04.19

To,

All State/UT Drugs Controllers,

Sir,

Sub: Cefixime – Acute generalized Exanthematous Pustulosis (AGEP) Adverse Reaction - Reg.

****

Cefixime is approved by CDSCO and marketed in the country in various dosage forms.

The National Co-ordination Centre for Pharmacovigilance Programme of India (NCC-PvPI), functioning at IPC Ghaziabad has forwarded their recommendation based on ADR reports on certain medicinal products including Cefixime which were discussed by them in the 13th Signal Review Panel (SRP) under the programme meeting held on 21st August, 2018 with an objective to detect Signal/Prescribing Information Leaflet change from Indian database and promote patient safety.

In the meeting, the PvPI has evaluated the drug Cefixime-ADR on the basis of Individual Case Study Reports (ICSR) and recommended CDSCO to take necessary steps to **incorporate acute generalized exanthematous pustulosis (AGEP) as an adverse drug reaction** in to the Prescribing information leaflet (PIL) of the drug Cefixime marketed in the country.

Subsequently, the PvPI recommendations was deliberated in the Subject Expert Committee (SEC-Antimicrobial & Antiviral) meeting held on 16.01.2019 at CDSCO HQR, New Delhi. After detailed deliberation the Committee has

recommended that acute generalized exanthematous pustulosis should be incorporated in the package insert of the drug Cefixime as suggested by PvPI.

The recommendation of the SEC has been considered by this office. Accordingly, you are requested to direct the manufacturers of Cefixime formulations under your jurisdiction to mention acute generalized exanthematous pustulosis as an adverse drug reaction in the package insert/promotional literature of the drug.

Action taken in this regard may be intimated to this office.

Yours faithfully,

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

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