**Recommendations of the SEC (Neurology & Psychiatry) made in its 39th meeting held on 12.09.2018 at CDSCO HQ New Delhi:**

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **Introductory remarks** | | | |
| **Biological Division** | | | |
| 1 | PAC/BP-2/J&J/Evicel/III/17-BD EVICEL-Fibrin sealant kit as for suture line sealing in dura matter closure | M/s Johnson & Johnson Private Limited, Maharashtra | The firm did not turn up for the presentation. |
| 2 | 6-5/BP-19/17-BD (P-1) Mouse Nerve Growth Factor 20µg/ml | M/s Synergy Diagnostics, Pvt. Ltd. Maharashtra | The firm requested for indication of promoting nervous system damage repair like cerebral palsy. However, the firm did not present any data with reference to cerebral palsy. The committee also noted that the published literature presented by the firm did not meet current standards of scientific evidence for regulatory approval. Hence, the committee did not recommend. |
| **Fixed Dose Combination Division** | | | |
| 3 | 4-26/2008-DC (Pt. Sun) Paroxetine HCl eq. to Paroxetine (as extended release) 12.5mg/25mg+Clonazepam IP 0.5mg/0.5mg tablets | M/s. Sun Pharmaceuticals | The firm presented the BE study report before the committee. The committee noted that the FDC of Clonazepam IP 0.5mg/0.5mg + Paroxetine CR 12.5mg/25mg capsule form is already approved for same indication. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Paroxetine Hcl eq. to Paroxetine (as extended release) 12.5/25mg+Clonazepam IP 0.5mg/0.5mg tablets for the proposed indication. |
| 4 | 04-81/2017-DC Part A: Each Film coated sustained release tablet contains: Betahistine HCL IP 48mg & Part B: Each film coated tablet contains:Cholecalciferol IP 400IU (as stabilized form) combipack (Film coated tablet) | M/s Madras Pharma | The firm presented their proposal for Combipack of Betahistine Hcl IP 48mg & Cholecalciferol IP 400IU (as stabilized form) before the committee. After detailed deliberation, the committee recommended that the firm should submit the documentary evidence in support of co-administration of Betahistine HCL IP 48mg & Cholecalciferol IP 400IU for review by the committee. |
| **Subsequent New Drugs Division** | | | |

| Agenda No | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| 5 | 12-06/2017-DC (Pt-Abbott-SND)<br>Clonazepam mouth dissolving tablet 0.25/0.5/1.0/2.0mg | M/s Abbott India Ltd. | As per recommendation of SEC made in its meeting held on 17.03.2017, the firm has conducted the BE study and report of the study was presented before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the Clonazepam mouth dissolving tablet 0.25/0.5/1.0/2.0mg for the proposed indications.<br>The drug should be sold by retail on the prescription of Neurologist or Psychiatrist. |
| 6 | 12-08/2018-DC (Pt-Intas-SND)<br>Clobazam oral suspension 2.5mg/ml (add. Dosage form) | M/s Intas Pharma Ltd. | As per the recommendation of the SEC made in its meeting held on 11.07.2018, the firm presented the BE report along with graphical representation of Conc. Vs Time profile and frequency of adverse events.<br>The committee noted that the Clobazam oral suspension 2.5mg/ml is approved in many countries including UK, USA.<br>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the Clobazam oral suspension 2.5mg/ml for the indication already approved for tablet. |
| **New Drugs Division** | | | |
| 7 | 12-01/18-DC (Pt-206)<br>Pregabalin | JIPMER, Puducherry | The applicant presented the protocol for academic clinical trial before the committee.<br>After detailed deliberation, the committee recommended for grant of permission to conduct the trial. |