**Recommendations of the SEC (Analgesic & Rheumatology) made in its 90th meeting held on 16.11.2022 at CDSCO (HQ), New Delhi:**

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
|---|---|---|---|
| **Biological Division** | | | |
| 1. | BIO/MA/22/000084<br><br>Adalimumab | M/s. Shilpa Biologicals | The proposal was deferred for next meeting. |
| **SND Division** | | | |
| 2. | SND/MA/22/000211<br><br>Tofacitinib Oral Solution 1mg/ml | M/s. Mascot Health | The firm presented the proposal for manufacturing and marketing of Tofacitinib Oral Solution 1mg/ml for the treatment of juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older.<br><br>After detailed deliberation, the committee opined that the firm should submit safety data/PMS data in pediatric patients (2- 17 years) along with subgroup analysis of clinical trial conducted in Indian and Asian patients by innovator for further review by the committee. The proposal may be redeliberated in presence of pediatrician. |
| **FDC Division** | | | |
| 3. | FDC/MA/22/000153<br><br>Tranexamic Acid 750mg + Mefenamic acid 375mg ER tablets | M/s. Lupin Ltd | In light of earlier SEC recommendation dated 23.06.2022, the firm presented their proposal along with justification.<br><br>After detailed deliberation, the committee opined that the firm should present the safety data on proposed higher strengths as Mefenamic acid 375mg ER tablets is not yet approved by this office.<br>Gynecologist expert should also be invited in the next SEC meeting. |
| **Medical Device Division** | | | |
| 4. | IMP/MD/2021/41651<br><br>Innotere 3D Scaffold | M/s. Avana Medical Devices Pvt. Ltd. | The firm did not turn up for presentation. |
| 5. | IMP/MD/2022/59985<br><br>Adhesion control barrier gels | M/s. Leader Biomedical & Surgery India Pvt. Ltd. | The firm did not turn up for presentation. |

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| **GCT Division** | | | |
| 6. | CT/54/22 Online Submission (32557)<br><br>Ianalumab (VAY736) | M/s. Novartis | The firm presented protocol no. CVAY736A2302 version 00 dated 31-Jan-2022 for grant of permission to conduct a Phase III clinical trial before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with the condition to increase sample size proportionate to patient population in India. |
| **SND Division** | | | |
| 7. | SND/MA/22/000296<br><br>Tofacitinib Oral Solution 1mg/ml (Additional dosage form) | M/s. Akums Drugs & Pharmaceuticals Limited. | The firm presented the proposal for manufacturing and marketing of Tofacitinib Oral Solution 1mg/ml for the indication for the treatment of active polyarticular course juvenile idiopathic arthritis (pcJIA) in patients 2 years of age and older who have had an inadequate response or indolence to one or more TNF blockers".<br><br>After detailed deliberation, the committee recommended that the firm should submit safety data/PMS data in pediatric patients (2-17 years) along with subgroup analysis of clinical trial conducted by innovator in Indian and Asian patients for further review by the committee. The proposal may be redeliberated in presence of pediatrician. |
| 8. | SND/MA/22/000190<br><br>Naproxen Sodium Tablets 275mg & 550mg | M/s. RPG Life sciences Limited. | The firm presented their proposal alongwith BE report of the higher strength of the applied drug products i.e. Naproxen Sodium Tablets 550mg before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Naproxen Sodium Tablets 275mg & 550mg for the proposed indication. |

| S. No. | File Name & Drug Name, Strength | Firm Name | Recommendations |
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| 9. | SND/MA/20/000533<br><br>Paracetamol Oral Solution 250mg/5ml | M/s. Pulse Pharmaceuticals Pvt. Ltd. | The firm presented their proposal along with BE report of the higher strength of the applied drug products i.e. Paracetamol Oral Solution (Taste Masked) 250 mg/5ml before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Paracetamol Oral Solution (Taste Masked) 125mg/5ml & 250mg/5ml for proposed indication. |
| 10. | SND/MP/22/000245<br><br>Hydroxychloroquine Sulphate 100mg tablets | M/s. Laurus Labs Limited. | The firm did not turn up for presentation. |
| 11. | SND/MA/22/000273<br><br>Paracetamol Injection 1000mg/4ml IV use | M/s. Troikaa Pharmaceuticals Ltd. | The firm presented their proposal alongwith Pharmacokinetics study report and Phase III CT protocol of Paracetamol injection 1000mg/4ml before the committee.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial of the applied drug product as per the protocol presented subject to the condition that pain on injection site at the time of injection should be recorded and the same should be included as secondary endpoint of the study. |