Outlines:

✓ Brief background
✓ Present status
✓ Impact
✓ Data analytics
✓ Way forward
Background

- Unsuccessful attempts
- Project report in Sep. 2012
- Go ahead by MoHFW in Dec. 2014
- MoU signed in Dec. 2014
- Software development initiated in Dec. 2014
- First module launched in Nov. 2015
Present status

✓ All import related processes
  • Drugs/devices/cosmetics
✓ BA/BE studies
✓ Global clinical trial
✓ Vaccine trials & marketing permissions
✓ Integration with XLN
✓ Integration of seven labs
✓ Online payment of fees
✓ Archived documents – 15,000,000 pages
Present status contd..

✓ Lot release by CDL online
✓ Databases
  • Retail/Wholesale licences
  • Manufacturing facilities
  • Formulations
Statistics-2016

Total Applications: 15917 In Year: 2016

<table>
<thead>
<tr>
<th>Month</th>
<th>Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAN</td>
<td>33</td>
</tr>
<tr>
<td>FEB</td>
<td>88</td>
</tr>
<tr>
<td>MAR</td>
<td>292</td>
</tr>
<tr>
<td>APR</td>
<td>411</td>
</tr>
<tr>
<td>MAY</td>
<td></td>
</tr>
<tr>
<td>JUN</td>
<td></td>
</tr>
<tr>
<td>JUL</td>
<td>1,670</td>
</tr>
<tr>
<td>AUG</td>
<td>2,227</td>
</tr>
<tr>
<td>SEP</td>
<td>2,379</td>
</tr>
<tr>
<td>OCT</td>
<td>2,179</td>
</tr>
<tr>
<td>NOV</td>
<td>2,396</td>
</tr>
<tr>
<td>DEC</td>
<td>2,942</td>
</tr>
<tr>
<td>Total</td>
<td>15,917</td>
</tr>
</tbody>
</table>
Statistics - 2016

Total Licences issued by SLAs: 48597

<table>
<thead>
<tr>
<th>State</th>
<th>Total Licence(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PY - PUDUCHERRY</td>
<td>172</td>
</tr>
<tr>
<td>GA - GOA</td>
<td>181</td>
</tr>
<tr>
<td>HP - HIMACHAL PRADESH</td>
<td>876</td>
</tr>
<tr>
<td>JH - JHARKHAND</td>
<td>1187</td>
</tr>
<tr>
<td>PB - PUNJAB</td>
<td>2440</td>
</tr>
<tr>
<td>CG - CHHATTISGHARH</td>
<td>2460</td>
</tr>
<tr>
<td>KL - KERALA</td>
<td>2950</td>
</tr>
<tr>
<td>DL - DELHI</td>
<td>3883</td>
</tr>
<tr>
<td>GJ - GUJARAT</td>
<td>8006</td>
</tr>
<tr>
<td>MH - MAHARASHTRA</td>
<td>26352</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>48597</strong></td>
</tr>
</tbody>
</table>
Statistics - 2016

Total Application(s) received (State Wise): 6924

<table>
<thead>
<tr>
<th>State</th>
<th>Applications</th>
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</thead>
<tbody>
<tr>
<td>Chandigarh</td>
<td>29</td>
</tr>
<tr>
<td>Maharashtra</td>
<td>3,301</td>
</tr>
<tr>
<td>Gujarat</td>
<td>808</td>
</tr>
<tr>
<td>Karnataka</td>
<td>400</td>
</tr>
</tbody>
</table>

Top 10 States with Highest number of Applications:

- Chandigarh
- Maharashtra
- Gujarat
- Telangana
- Karnataka
- Tamilnadu
Statistics - 2016

User Log In Details for Today

Logged In: 874
Logged Out: 1,199

Logged In Details

<table>
<thead>
<tr>
<th>S.No.</th>
<th>User</th>
<th>Browser</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><a href="mailto:CARVIN@LOTUSLABS.COM">CARVIN@LOTUSLABS.COM</a></td>
<td>CHROME 66</td>
</tr>
<tr>
<td>2</td>
<td><a href="mailto:VIVEK.MALHOTRA@STRYKER.COM">VIVEK.MALHOTRA@STRYKER.COM</a></td>
<td>CHROME 66</td>
</tr>
<tr>
<td>3</td>
<td><a href="mailto:VIVEK.MALHOTRA@STRYKER.COM">VIVEK.MALHOTRA@STRYKER.COM</a></td>
<td>CHROME 66</td>
</tr>
<tr>
<td>4</td>
<td><a href="mailto:SURESH.ANEKAL@BIOCON.COM">SURESH.ANEKAL@BIOCON.COM</a></td>
<td>CHROME 66</td>
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<tr>
<td>5</td>
<td><a href="mailto:AMO.INDIARA@ABBOTT.COM">AMO.INDIARA@ABBOTT.COM</a></td>
<td>CHROME 66</td>
</tr>
<tr>
<td>6</td>
<td><a href="mailto:INFO@ENEMNOSTRUM.COM">INFO@ENEMNOSTRUM.COM</a></td>
<td>CHROME 66</td>
</tr>
</tbody>
</table>
IMPACT on CDSCO and Industry
Impact on timelines

Month wise application submitted and average days taken to process an application

- Allocated Days
- Actual Days
- Total Application Received
- Approved Applications
Impact-CDSCO

- Reduced human interface
- Prescreening of applications
  - Not necessary
  - Officers utilised for other work
  - Digital licences
- Tracking of applications
- Clock showing the remaining time left for processing of each application
- Alerts to the supervising officer if timeline exceeded
- Ecofriendly
  - Millions of paper saved
Impact - Industry

- Reduced human interface with the regulator
  - Tracking
  - Digital licences/permissions/NoC’s
  - Online queries
- Relocation/reduction of the staff
- Dashboard provides the history of all the activities
- Creation of sub-logins
  - The sites can make their applications
- Approvals published on homepage
- Intelligent search option for approvals
Data Analytics

- MIS reports can be generated on all parameters
- Policy framing
- Review of functioning
- Allocate human resources according to the need
- Drugs imported for personal use
  - insights
Data analysis

Top 25 Countries for Bulk Drug Imports
Data Analysis

Top 25 Countries for Bulk Drug Imports
Way forward

1. Scanning of Barcode
2. DAVA
3. SUGAM
4. SDC
5. CDSCO zonal off
Way forward

SUGAM

All States

Samples by DI

Recall Alerts

Labs
THANK YOU