[Medical Product Alert]

“Colicraft Lyophilized Powder for Injection & Infusion.”

M/s Biolabs (Pvt) Ltd.,
Plot No.145 Kahuta Triangle Industrial Estate Islamabad,

Subject: DRUG RECALL OF SUBSTANDARD COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407, BATCH NO. L-279, MFG. DATE 02-2020, EXP. DATE 01-2022 MANUFACTURED BY M/S BIOLABS (PVT.) LTD., ISLAMABAD.

I am directed to refer to the subject cited above and CDL, Karachi report vide No.R.KQ.209/2020 dated 26th August, 2020 wherein your product “COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407, BATCH NO. L-279, MFG. DATE 02-2020, EXP. DATE 01-2022 has been declared of Substandard quality. Details of CDL reports are as under;

<table>
<thead>
<tr>
<th>S. No.</th>
<th>test</th>
<th>Specifications</th>
<th>Result</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Identification</td>
<td>Colistimethate Sodium identified.</td>
<td>Complies.</td>
<td>USP 43</td>
</tr>
<tr>
<td>3</td>
<td>Bacterial Sterility</td>
<td>Must be sterile.</td>
<td>Does not comply.</td>
<td>USP 43</td>
</tr>
<tr>
<td>4</td>
<td>Endotoxin test</td>
<td>Not more than 2.0 EU per mg</td>
<td>Complies.</td>
<td>USP 43</td>
</tr>
<tr>
<td>5</td>
<td>Assay Colistin</td>
<td>90.0% - 110.0%</td>
<td>109.4%</td>
<td>USP 43</td>
</tr>
</tbody>
</table>

You are therefore directed to recall all the stock of above-mentioned batch of product “COLICRAFT LYOPHILIZED POWDER FOR INJECTION & INFUSION., REG. NO. 082407” from market, alert your sales officers/suppliers/distributors to issue instructions to the pharmacies/hospitals, point of sales/purchase/use for the return of suspected stocks of product in question. Furthermore, you are directed to submit a compliance report of recall to this division within seven (07) days positively.
Copy for information and necessary action – with request to issue necessary directions to points of use/sale (Hospitals Pharmacies, Medical stores, Distributors, Whole sellers, etc) under administrative control/ fall under area of jurisdiction, please.

1. The Secretary (SHC&ME) Health Department (Government of Punjab).
2. The Secretary Primary and Secondary Health Department (Government of Punjab).
3. The Secretary Health Department (Government of Sindh).
4. The Secretary (SHC&ME) Health Department (Government of KPK).
5. The Secretary (SHC&ME) Health Department (Government of Baluchistan).
6. The Secretary (SHC&ME) Health Department (Government of AJ&K).
7. The Director General Health, M/o NHSR&C, Islamabad.
8. The Director General Health, Government of Punjab.
10. The Director General Health, Government of KPK.
11. The Director General Health, Government of Baluchistan.
12. The Director General Health, Government of AJ&K.

Copy to:-

i. The Director, QA&LT, DRAP, Islamabad.
ii. The Additional Director MIS with request to upload it on official website in the larger interest of public.
iii. FID-V, DRAP, Karachi for information record and necessary action, if any, please.
iv. PS to CEO, DRAP, Islamabad.
v. Office copy.