

PHARMA ZONE

AT IGI AIRPORT

A Unique initiative taken up by CDSCO



Presented by:

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PHARMA ZONE OVERVIEW:

- ❑ **WHAT IS PHARMA ZONE ?**
- ❑ **WHAT PHARMA ZONE SHOULD HAVE ?**
- ❑ **WHY PHARMA ZONE AT DELHI ?**
- ❑ **CURRENT CARGO AREA LAYOUT**
- ❑ **PHARMA ZONE BRIEF PROPOSALS**

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What is Pharma Zone ?

BASIC DEFINATION:

A separate dedicated temperature and atmosphere controlled area to maintain the safety, efficacy, and quality of Imported and Export Drugs / Pharma products in line with the product requirements and GMP compliance within the cargo premises of ports.

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What Pharma Zone should have ?

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→ Cold Room Facility to maintain varied temperature (-20, +2-8 Degrees Centigrade)

→ Comfort zone having temperature below 25° C (22-25° C) for examination, storage in bonded area

→ Humidity Control to prevent moisture damage in summer and freeze in winter

→ Sampling, Dispensing area and basic testing facility

→ Office of the ADC(I) and Other Regulatory authorities

→ Palletisation area to ensure preparation of pallets In the cool chain facility

→ Fixed Location system for different dose forms

→ Provision to keep narcotic and allied, separately

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WHY PHARMA ZONE IS REQUIRED AT IGIA ?

- 1) Delhi is a major pharmaceutical hub for exports /Imports.
- 2) Increase in Exports and Imports in last 4 years based on the statistics of shipments handled by ADC office at IGIA.
- 3) Industry estimates on future projections in terms of volumes show a very high growth.
- 4) Constraints.

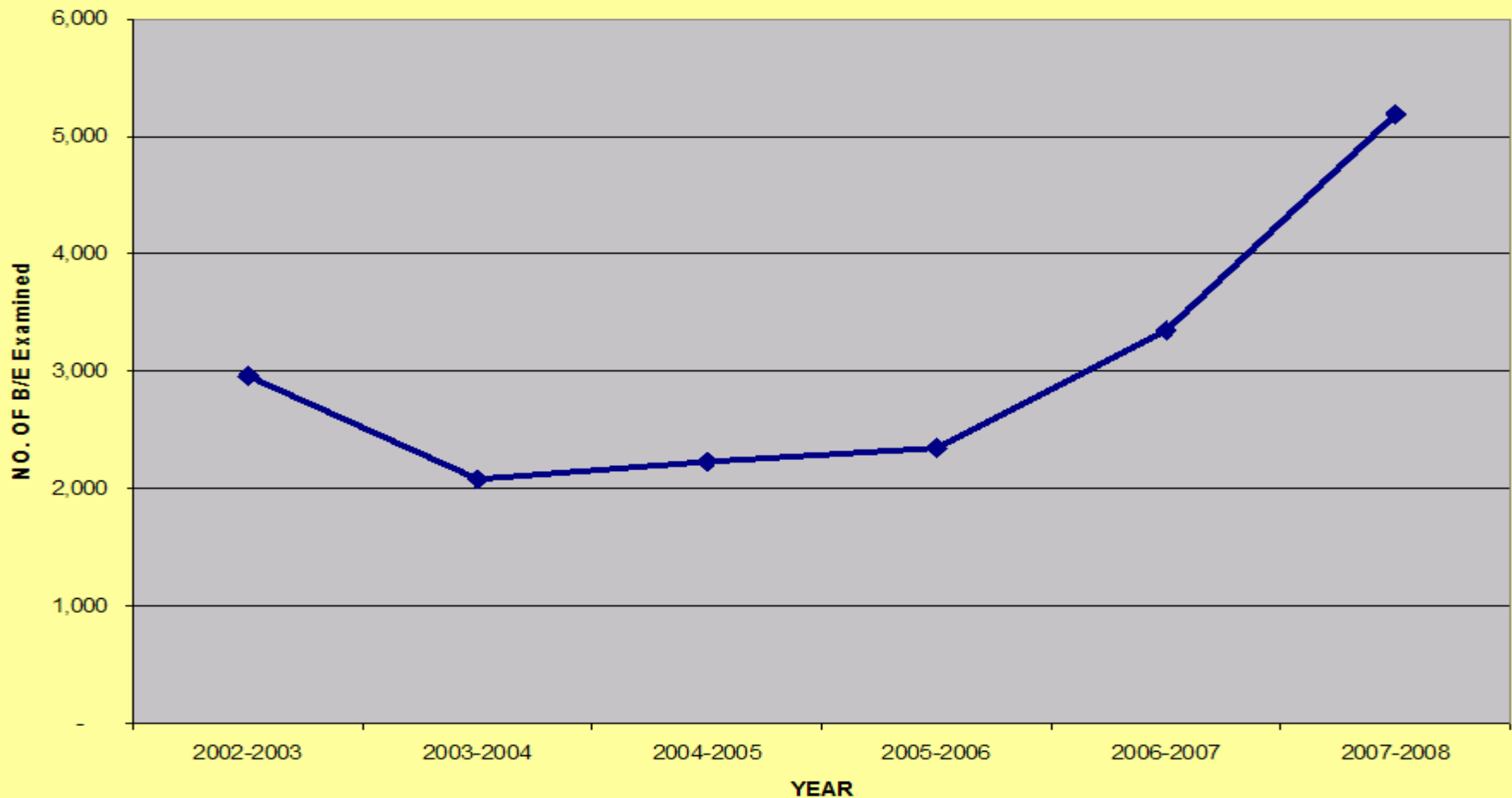
DELHI – HUB FOR PHARMACEUTICALS

- **Establishment of new pharmaceutical companies in North India under Govt. Policy excise/ income tax incentives.**
- **Outsourced contract manufacturing (Adv. Licence/ 100% EOU).**
- **CRAMS and CRO'S new trends in North India (e.g. Quintiles, Kendle, Neeman, Jubilant, etc.)**
- **Industry poised to grow as major patented blockbuster drugs going off patent from 2010 onwards, worth billions. (e.g LIPITOR – PFIZER in 2010, ADAVIR – GSK in 2010, ZYPREXA – LILLY in 2011, SEROQUEL , CRESTOR – AZN in 2011 and 2012 etc.)**

Bill of Entry – Examined at DEL Airport

B/E handled increased from 2229 to 5189

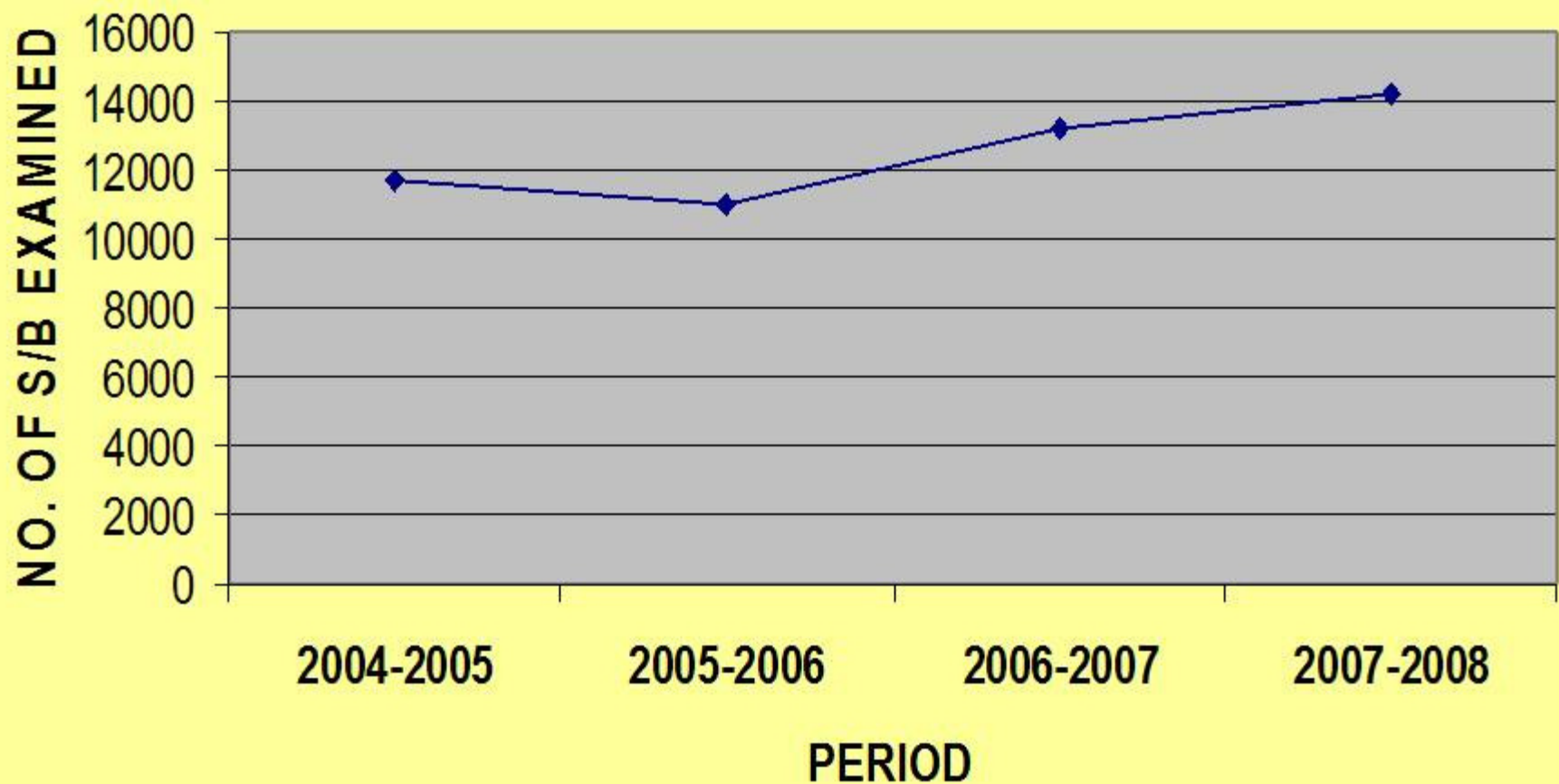
TREND (B/E EXAMINED)



Shipping Bills- Examined at DEL Airport

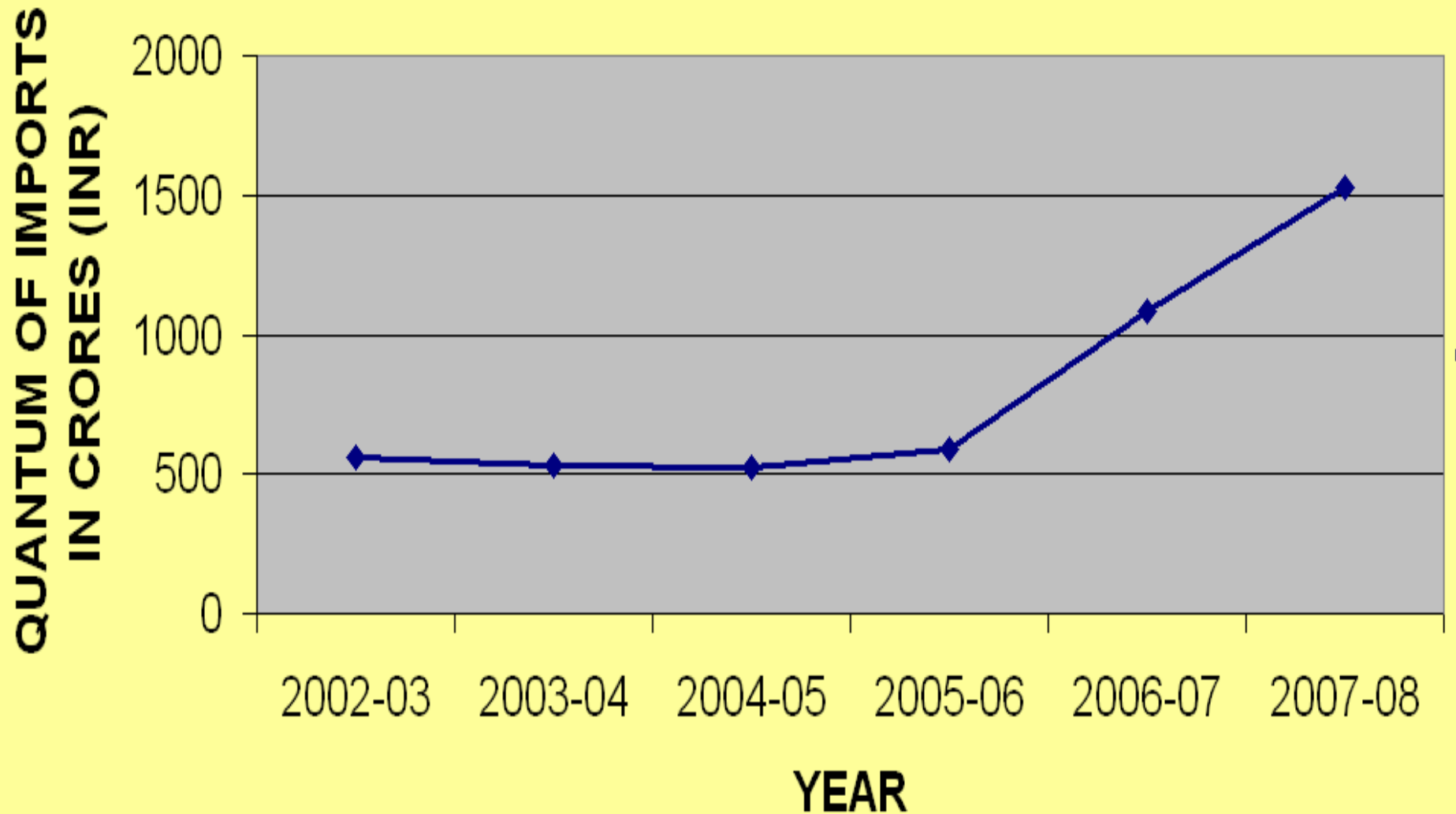
S/B handled increased from 11671 to 14500

TREND (QUANTUM OF S/B EXAMINED)



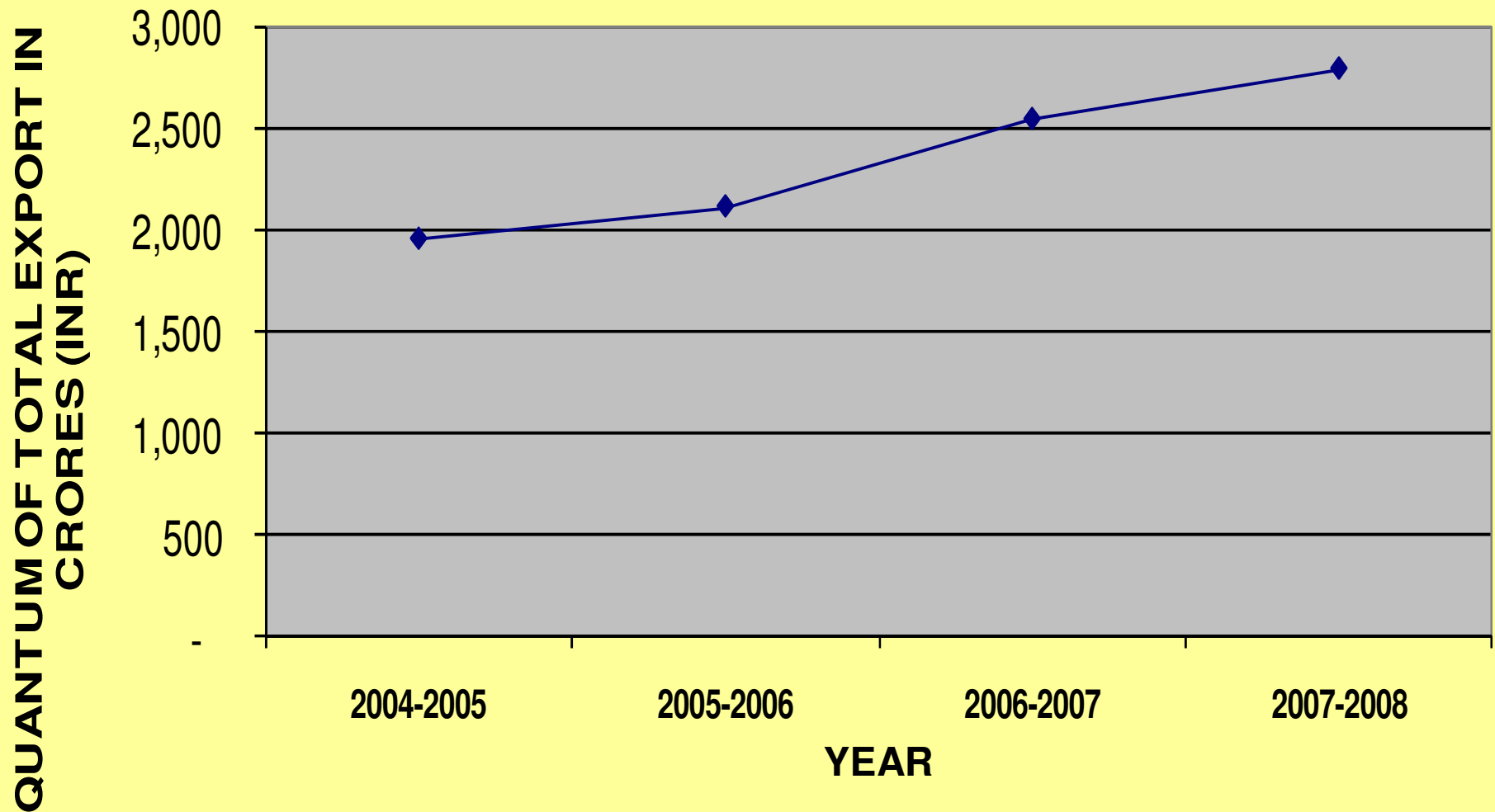
300 % INCREASE IN IMPORTS IN VALUE TERMS

TREND (QUANTUM OF IMPORTS)



50% INCREASE IN EXPORTS IN VALUE TERMS

TREND (QUANTUM OF EXPORT)



Volume requirement – Based on 5 year projection provided by various Pharmaceutical Organizations

IMPORTS

Volume from January 2008 – December 2008				Expected Volume after Five Years			
To be store at 2 to 8 C (Tons)	Comfort Zone		To be store at or Below -20 C (Tons)	To be store at 2 to 8 C (Tons)	Comfort Zone		To be store at or Below -20 C (Tons)
	To be store at 8 to 25 C (Tons)	Room Temperature (Tons)			To be store at 8 to 25 C (Tons)	Room Temperature (Tons)	
A	B	C	D	A	B	C	D
831.86	642.17	2137.25	38.59	1850	1400	3900	60
	Total B+C = 2779.42						
Total Imports of Drugs : A+B+C+D = 3649.87				Expected Imports of Drugs ~ 7250			

EXPORTS

Volume from January 2008 – December 2008				Expected Volume after Five Years			
To be store at 2 to 8 C (Tons)	Comfort Zone		To be store at or Below -20 C (Tons)	To be store at 2 to 8 C (Tons)	Comfort Zone		To be store at or Below -20 C (Tons)
	To be store at 8 to 25 C (Tons)	Room Temperature (Tons)			To be store at 8 to 25 C (Tons)	Room Temperature (Tons)	
A	B	C	D	A	B	C	D
249.82	8372.00	2617.18	164.74	1150	48500	5310	275
	Total B+C = 10989.18						14
Total Exports of Drugs : A+B+C+D = 11403.75				Expected Exports of Drugs ~ 55000			

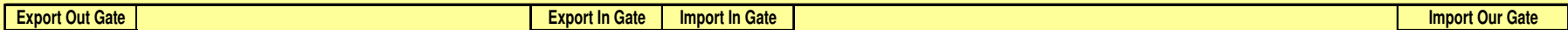
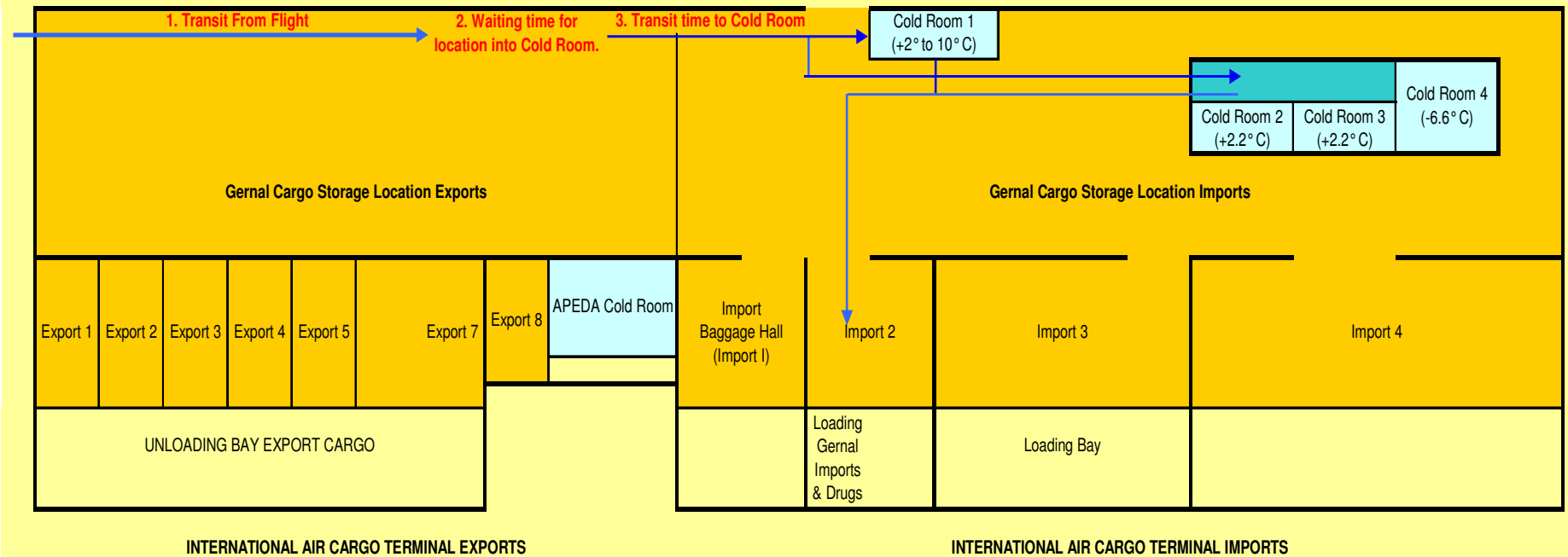
CONSTRAINTS

- a. No facility with specific temperature and atmospheric controls.
- b. Infrastructure bottlenecks and no new development in recent past for handling pharma at cargo premises at IGI Airport .
- c. There is no temperature controlled area for life saving drugs and vaccines. (e.g. no cold chamber for storage at -20 ° C and 10 to 25° C).
- d. Non drug and drug items stored together which is a big hazard and may compromise the integrity of the product specially in respect to its degradation and contamination and same may affect the quality and safety which is a prime motto for us.
- e. No competent handling staff understanding proper pharma handling.
- f. Handling of Pharma in general area does not give the requisite priority for Pharmaceuticals and allied products.

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PRESENT AVAILABLE FACILITY AT THE INTERNATIONAL CARGO TERMINAL



Colour Representation

- Custom Bonded Uncontrolled atmospheric storage and examination area (Gernal for all cargo and no temperature control).
- Custom Bonded Cold Room with different temperature zones.

1. Most of the Perishable Cargo comes in Passenger Aircraft, unloading and transit time of cargo to Cargo Terminal is 2 to 4 hours. During this period the goods are in non temperature controlled environment.
2. Due to various requirement of the authority/customs another 2 to 3 hours waiting in Gernal location for transfer to cold room.
3. Incase of unavailability of space in cold room drugs are stored in non temperature controlled environment with Gernal Cargo.
4. For the examination purpose of the Drugs, the same are to be moved to the Examination Hall again a non temperature controlled environment.
5. After examination the drugs are again sent back to original location (this takes around 2 hours).
6. Finally after the release of the goods the drug consignments are also unloaded with Gernal Cargo, it takes 1 to 2 hours depending on the volume of the Cargo.
7. The entire Air Cargo complex is covered by tin sheets and except the area advised in blue all other area is uncontrolled atmospheric area.

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Pharma Zone Brief Proposals

1. Draft proposal is based on the Existing Trends and Data collected and compiled from major exporters and Importers in the region in volume terms for previous year and for next 5 years as per the growth trends (approximate figs.)
2. Should cater to meet the requirements for requisite transit storage and handling, so that the safety, efficacy and quality of product is well maintained.
3. Separate area for storage, customs processing etc so that there is no contamination from other potential hazardous substances like meat, vegetables, food stuff (which is the case at present).
4. Dedicated area so that proper trained competent handling staff can be stationed. Will help meet international acceptable standards.

Pharma Zone Brief Proposals

5. Volume Projections vis-à-vis Possible Area Requirement

CURRENT EXPORTS AREA REQUIREMENT : 458 Sq. Mtr.

CURRENT IMPORTS AREA REQUIREMENT : 193 Sq. Mtr.

TOTAL CURRENT REQUIREMENT : 651 Sq. Mtr.

PROJECTED EXPORTS AREA REQUIREMENT: 1907 Sq. Mtr.

PROJECTED IMPORTS AREA REQUIREMENT : 327 Sq. Mtr.

TOTAL PROJECTED REQUIREMENT : 2234 Sq. Mtr.

**Addition of the proposed area to cover additional requirements : 1400 Sq.
Mtr.**

**Total Area requirement required for meeting the future projected .
requirements: Aprox 3700 Sq. Mtr.**

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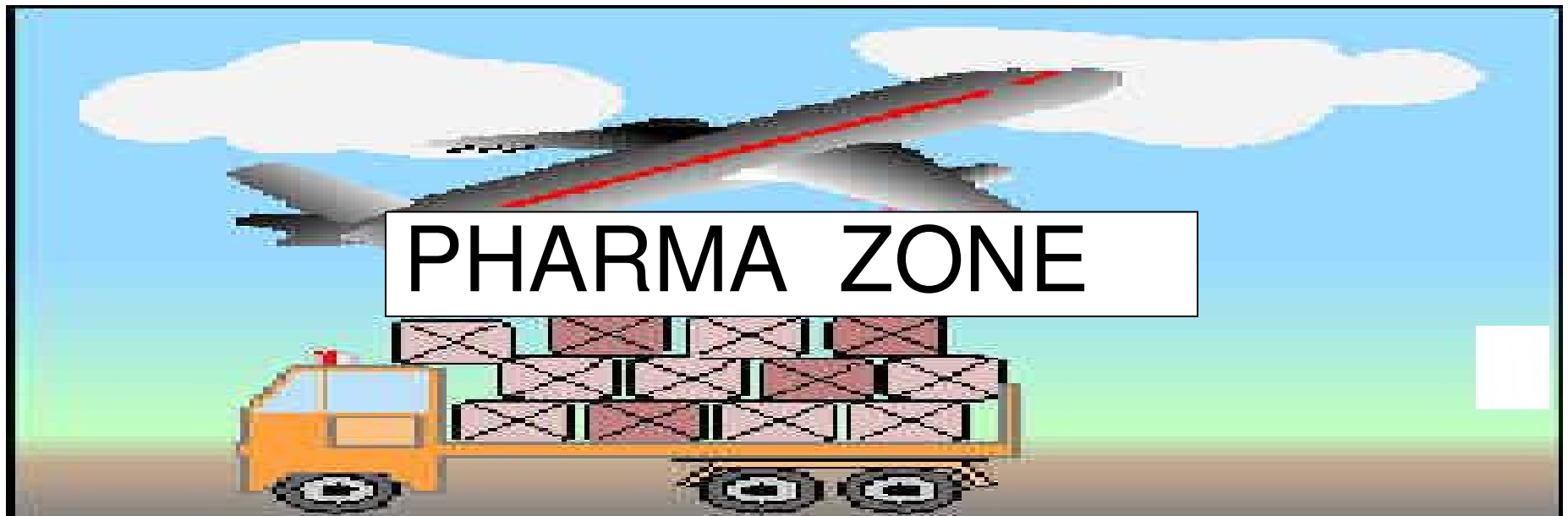
Tentative infrastructure cost will be approx. 7 crores (excluding land cost)

Pharma Zone Brief Proposals

UNIQUE



INITIATIVE TAKEN UP BY CDSCO



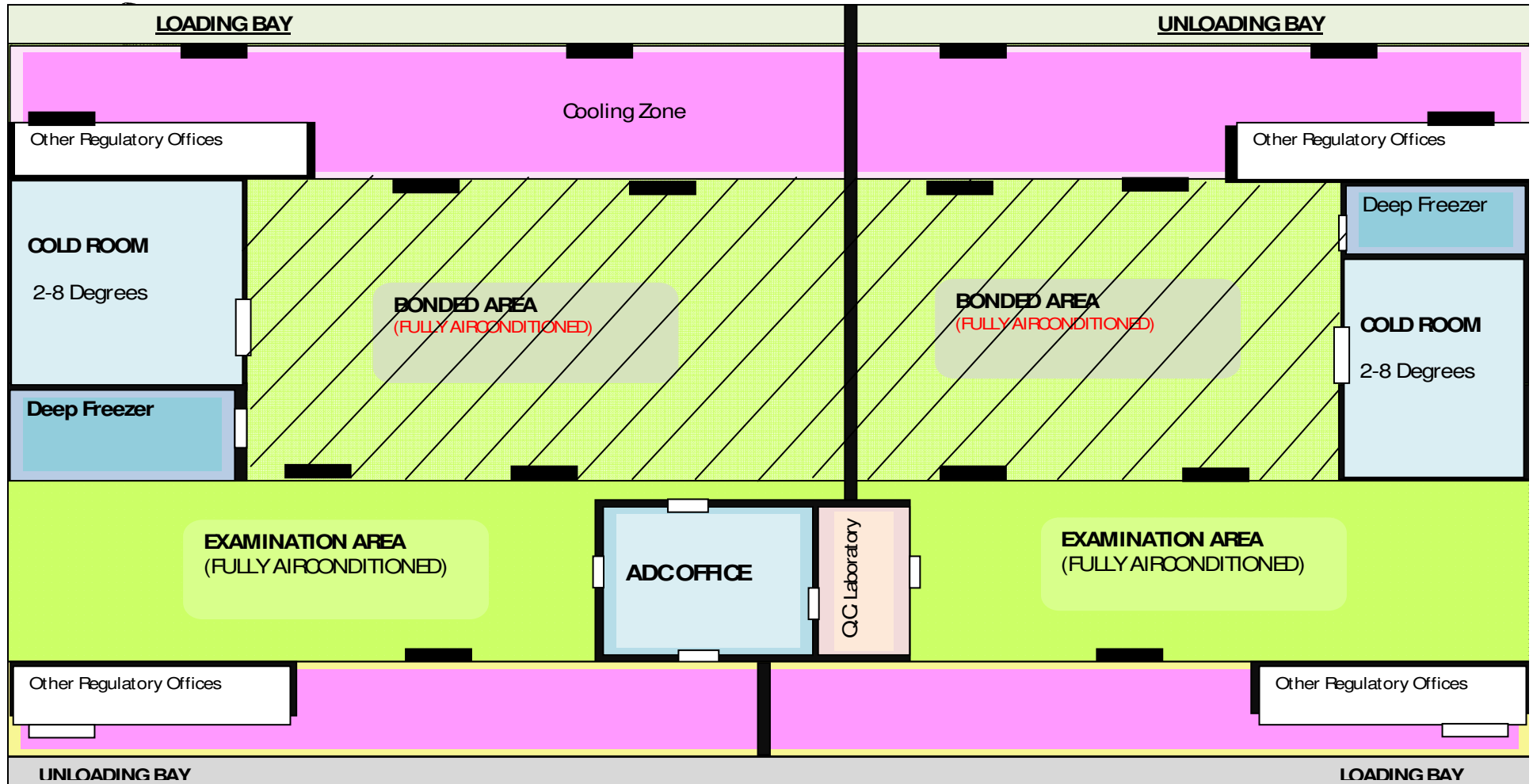
Proposed Layout



2.

AIRCRAFT – LOADING BAY

AIRCRAFT UNLOADING BAY



EXPORT

PHARMAZONE – NEW DELHI

IMPORT

Pharma Zone

OPEN FLOOR DISCUSSIONS

THANK YOU