Advancing a 21st Century Approach to Global Drug Inspections

U.S. Food and Drug Administration

Why do FDA and EU need to do this?

In the beginning...

EU's legal and regulatory framework for GMP oversight

EU's Conflict of Interest policy for drug investigators

EU's management of its inventory

Competence and Comparison of Inspectorates

In the beginning...

Competence of FDA investigators

Consistency across FDA district offices

Current roles and responsibility within FDA

Current FDA efforts to define quality metrics

Need for unredacted inspection reports


Trade Talks
Congress
Protection of
Public Health
Direct Inspectorate
Observation

How We Organized Facts

- Relevant vs. Nice or Interesting to Know
- Comparison of EU to FDA and not EU versus perfect state
- Minimize Risk of the Move to Mutual Reliance
- Maximize Benefits
- Metrics to Ensure Success

Course Defining Facts

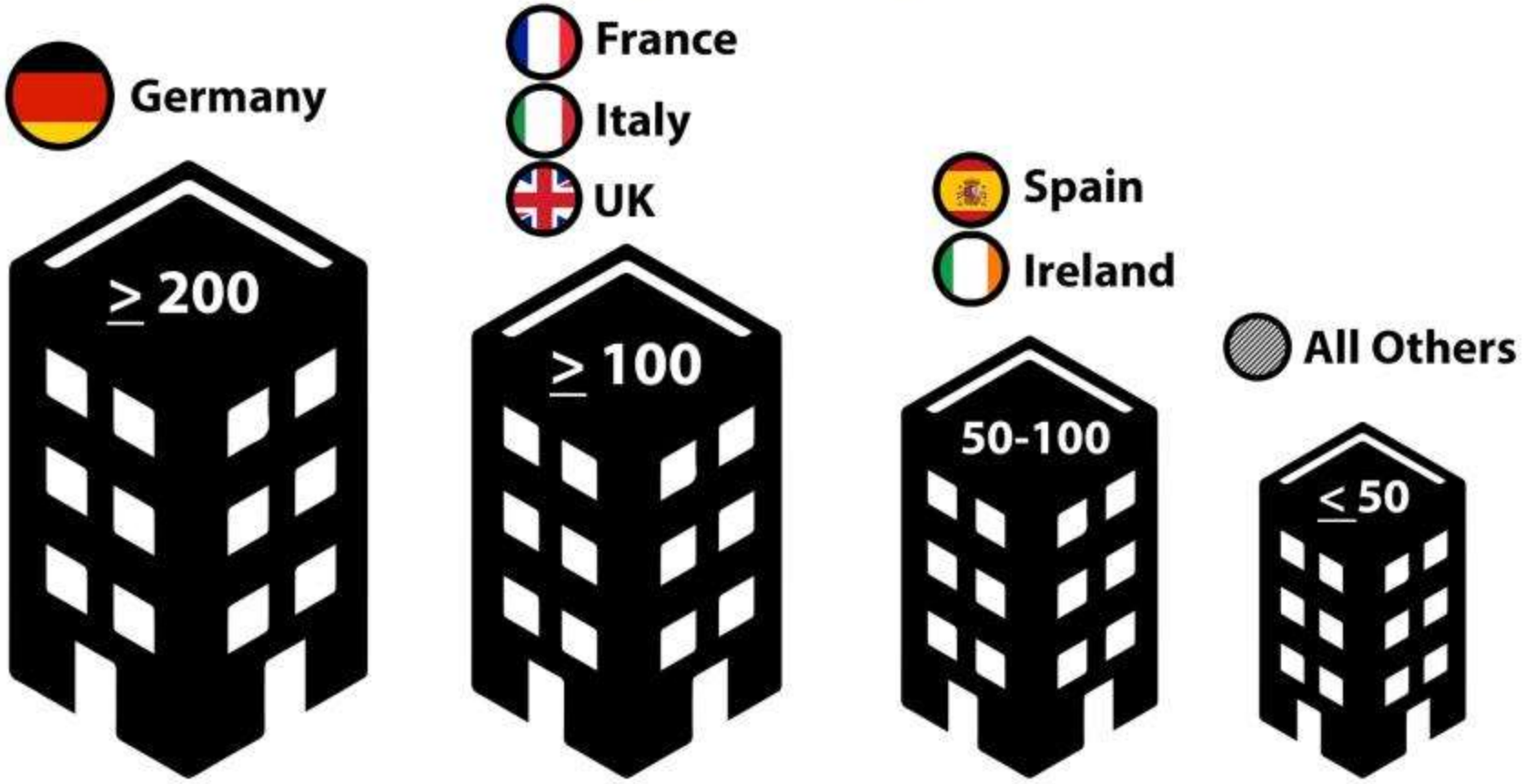
Where is our inventory in the EU?

What is the monetary value of this inventory?

How much of the inventory is inspected by the FDA?

Do any Member States stand out?

Registered Facilities in European Member States (FY 2014)



Reported Value of Imports (FY 2014)

≥ $5 billion

Germany, France,
United Kingdom, Ireland

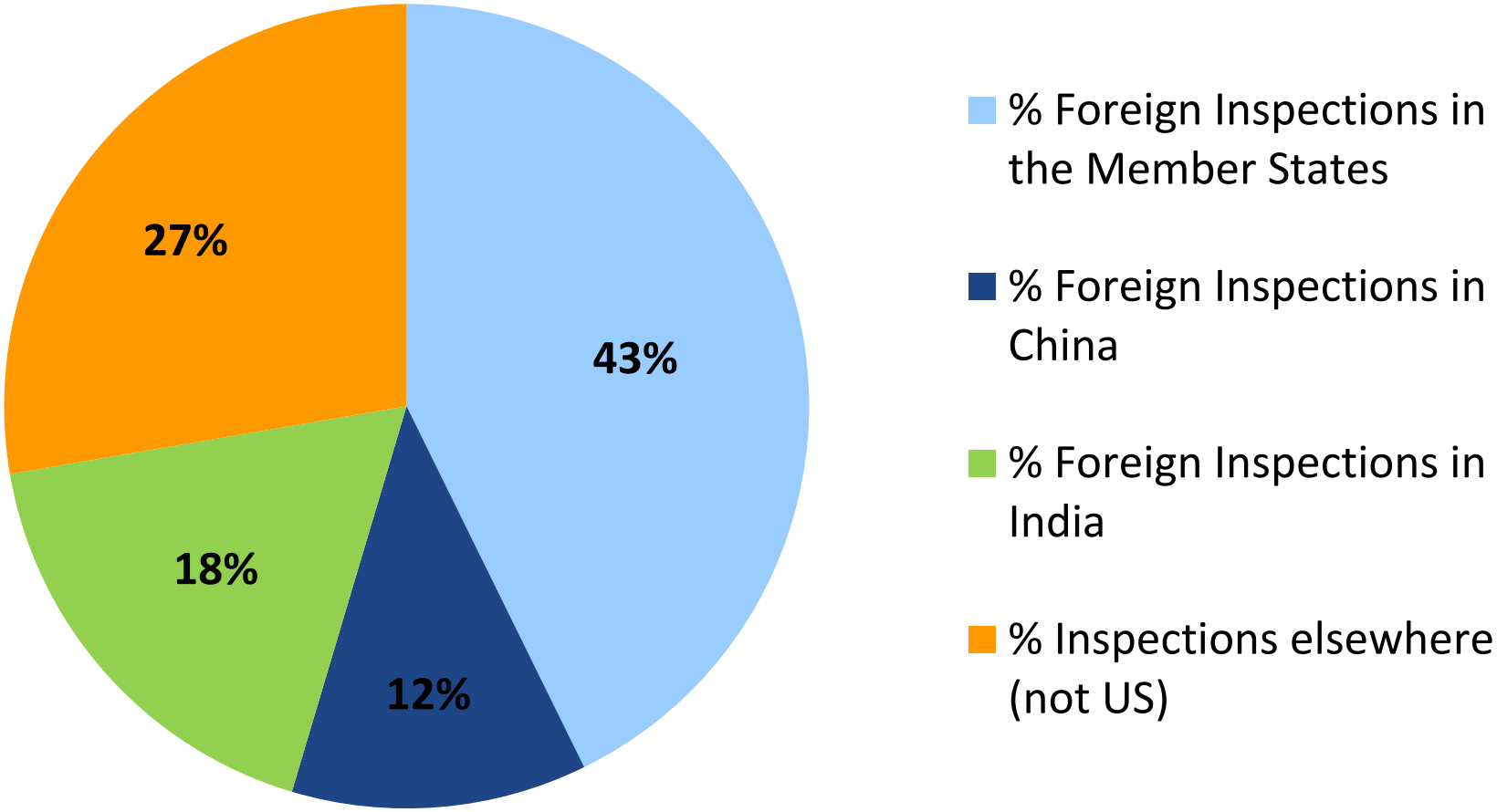
$1-5 billion

Italy, Spain, Belgium,
Netherlands, Denmark, Austria

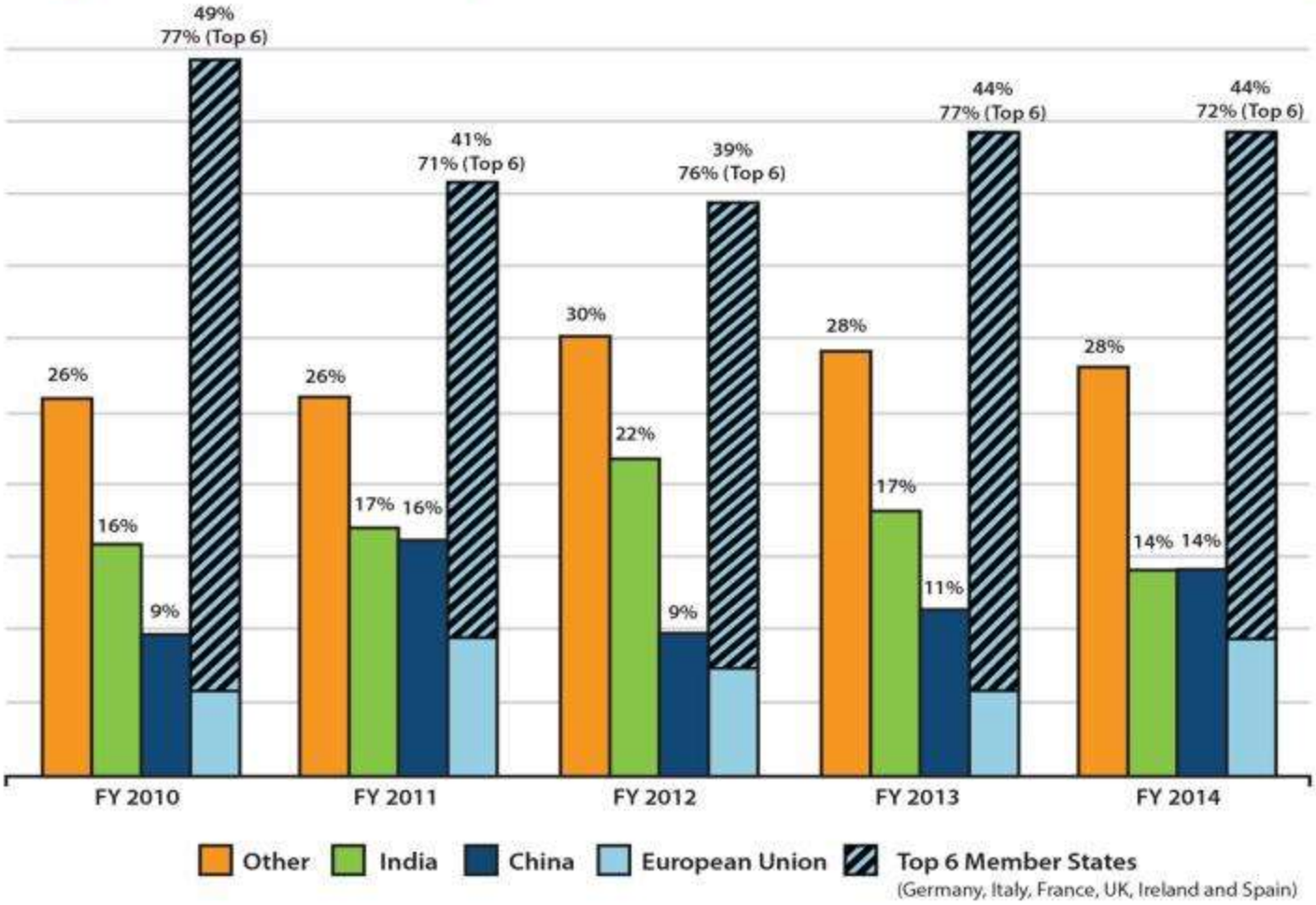
≤ $1 billion

All other member states

Average % of Foreign GMP Inspections Conducted for CDER Drugs from FY2010-14 by Location



Foreign GMP Inspections of Human Drugs



European Member States

(FY 2014 Data)

Member State*	# of Registered Human Drug Facilities	% Inventory Inspected by FDA	Reported Value of Imports
Germany	219	33%	$22,658,333,929
France	180	24%	$6,059,346,685
Italy	152	33%	$3,382,405,843
United Kingdom	150	23%	$6,583,712,510
Spain	92	22%	$1,270,596,495
Ireland	58	40%	$16,304,747,761
Belgium	42	38%	$2,195,039,066
Netherlands	38	29%	$3,156,351,665
Sweden	30	57%	$811,334,039

**Organized by highest number of registered human drug facilities*

Summary

Six European member states represent the vast majority of FDA's CDER drug inventory. Specifically,

Germany	France	Ireland
Italy	Spain	United Kingdom

These six European member states represent:

- 77% of the registered human drug facilities (as of FY14) in the EU.
- 75% of the GMP inspections from FY10-14 of CDER drugs within the EU.
- 82% of the reported value of imports from the EU in FY14.

Path Forward

Overall Agreement with the European Union

Path Forward

Criteria:

- Assessing variability of European Member State inspectorates
- Comparable Conflict of Interest Provisions
- Expert Review of Inspection Reports

Path Forward

Major Commitments:

- Relying upon inspection data from European Member State inspectorates
- Reducing number of inspections in the European Member States
- Reallocating and leveraging limited resources to increase oversight in areas of greater risk

For Additional Questions

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