



IX ALL-RUSSIA  
GMP CONFERENCE



MINISTRY OF INDUSTRY  
AND TRADE OF RUSSIA



# Most frequent non-conformities Experiences of different foreign inspectorates

**Wisseem ACHOUR – National agency for pharmaceutical products - Algeria**





**The National Agency for Pharmaceutical Products**

**Types of inspections**

**Recent data concerning inspections**

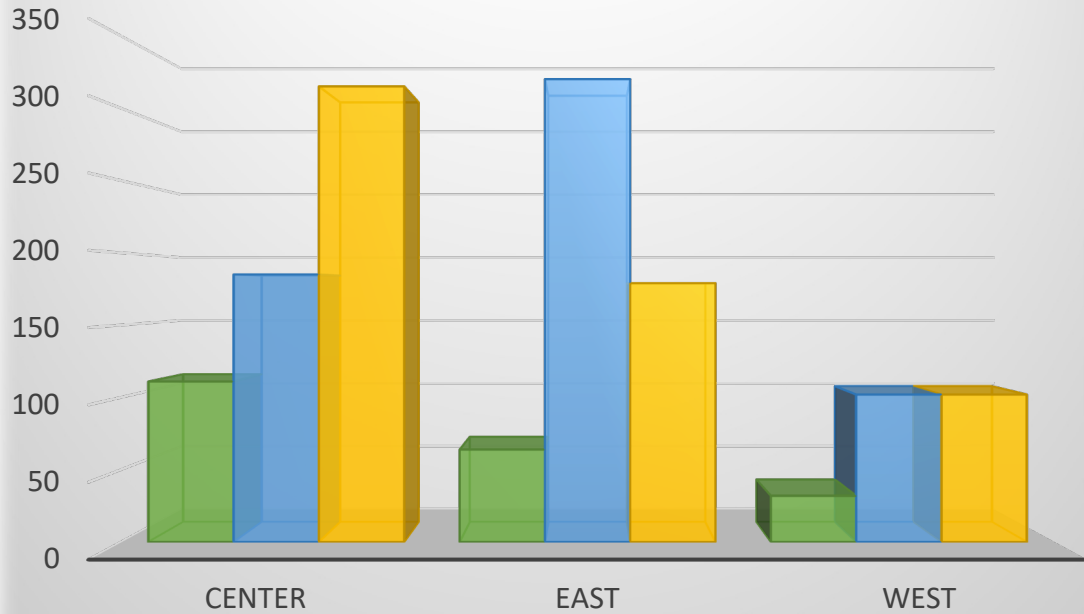
**Non-conformities most frequently noted during inspections**

**Conclusion**

# ALGERIAN NATIONAL AGENCY FOR PHARMACEUTICAL PRODUCTS (ANPP)

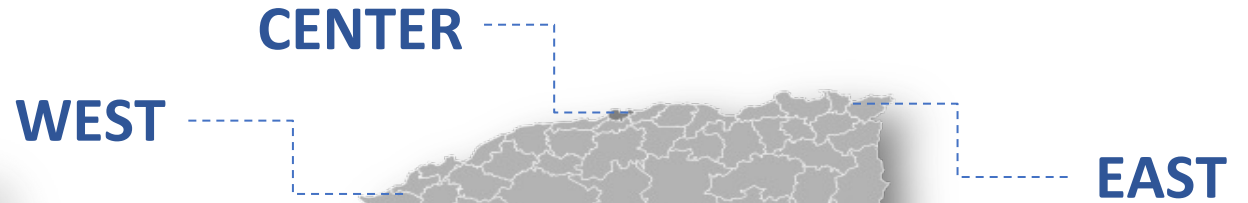


## Number of establishment / Region



	Center	East	West
Manufacturers	111	64	32
Wholesale distributor	185	320	102
Importers	315	179	102

■ Manufacturers   
 ■ Wholesale distributor   
 ■ Importers



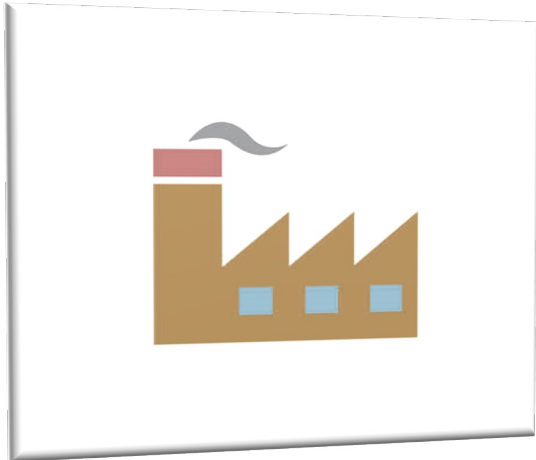
s to CARRY  
 TIONS of  
 ments on

National territory

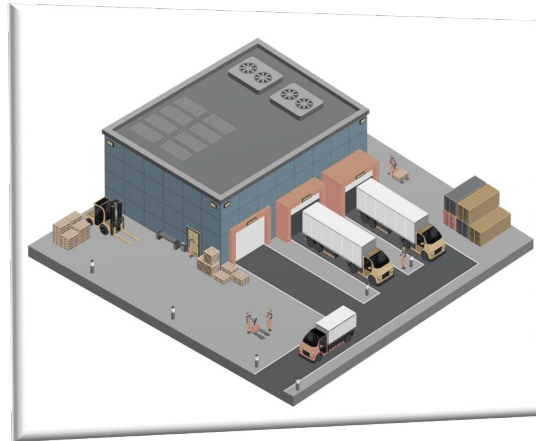
# TYPES OF INSPECTIONS



**Medicines and Medical  
Devices  
MANUFACTURING**



**Medicines and Medical  
Devices  
WHOLESALE DISTRIBUTION**



**Medicines and Medical  
Devices  
STORAGE**



**Medicines and Medical  
Devices  
QUALITY CONTROL**



**UNANNOUNCED INSPECTIONS**

**VISITS**

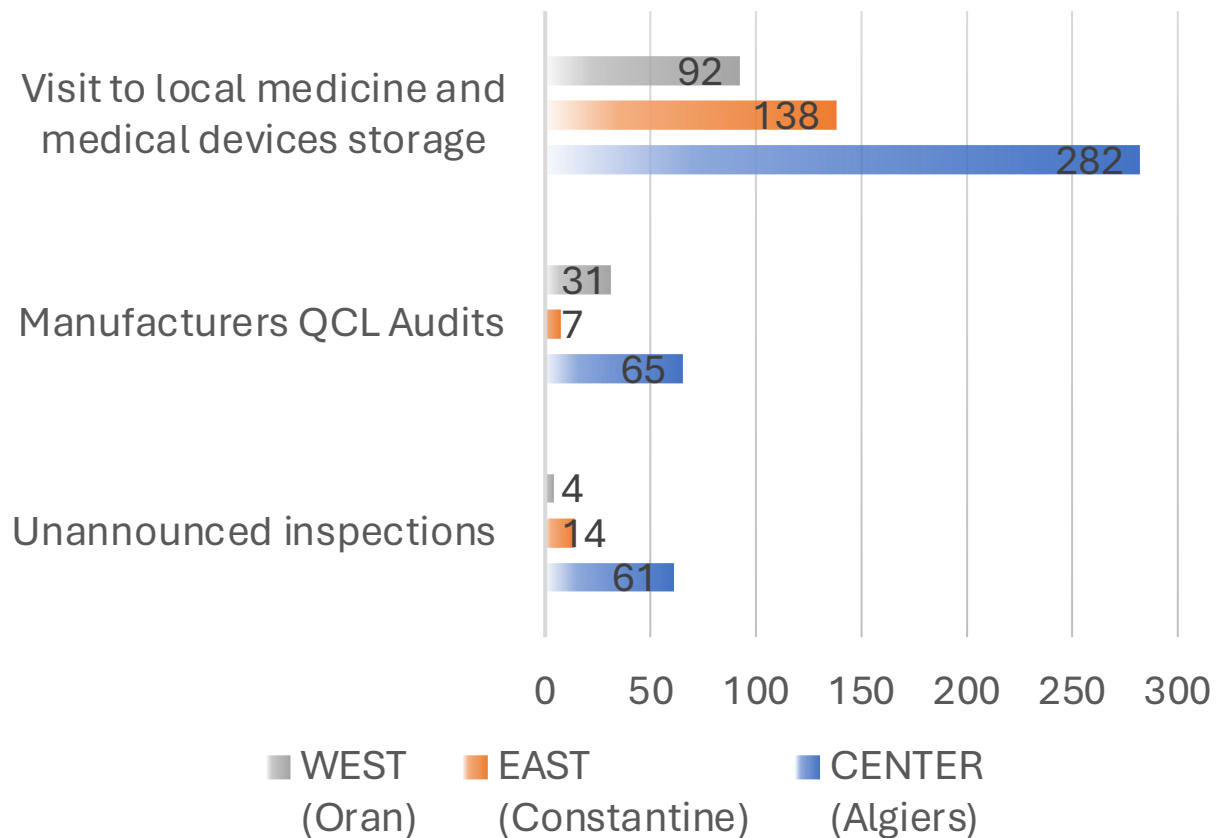
**AUDITS**

# INSPECTIONS CONDUCTED IN 2023- 1<sup>ST</sup> HALF OF 2024

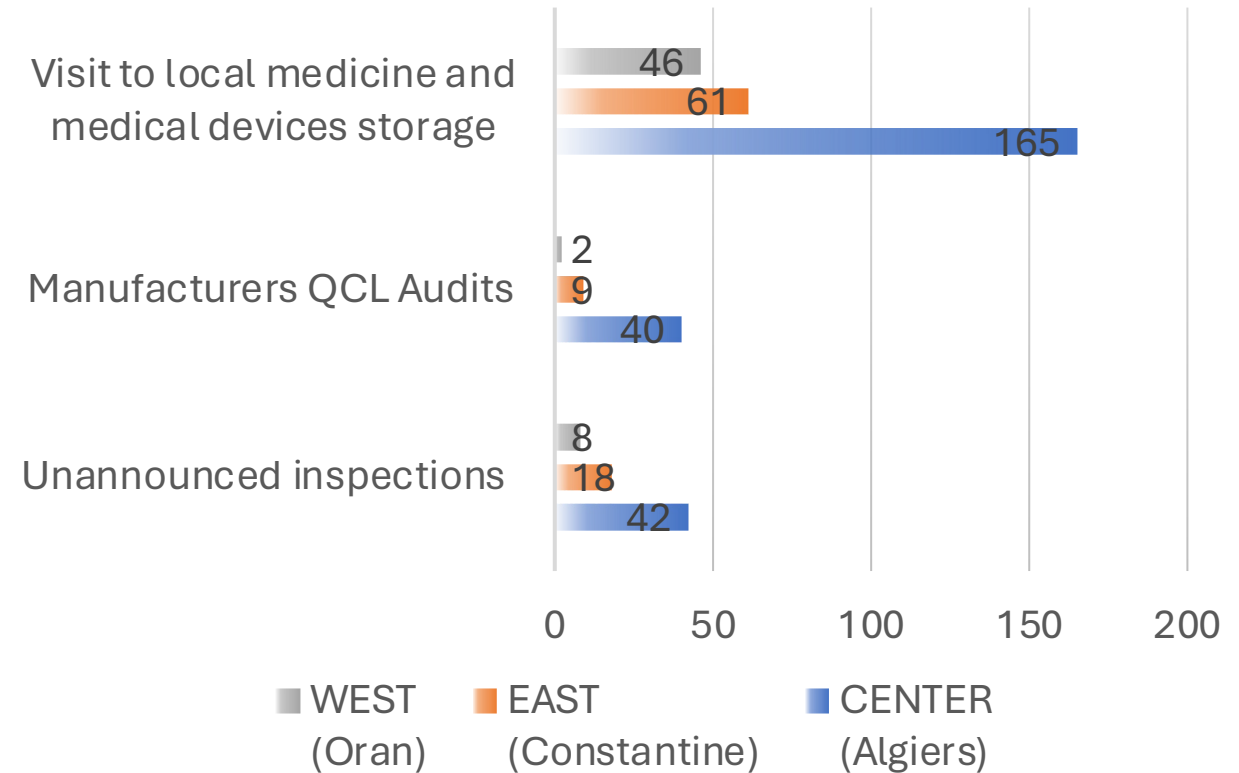


In 2023 and first half of 2024 the ANPP carried out the inspections, audits and visits as follows

## INSPECTIONS CONDUCTED 2023



## INSPECTIONS CONDUCTED 1ST HALF OF 2024



**Chapter 04**  
**Documentation**  
**4.7 / 4.8 / 4.9**

**Poorly Maintained Records**

**Chapter 06**  
**Quality control**  
**6.15**

**Test methods not validated**

**Chapter 06**  
**Quality control**  
**6.35**

**Issues with Out-of-  
Specification Test Results**

## **Chapter 03**

**Premises and  
equipment**

**3.3 - 3.19**

**Inadequate storage facilities**

## **Chapter 01**

**Pharmaceutical  
quality system**

**1.4**

**Change control issues**

## **Chapter 02**

**Staff**

**2.10**

**Staff empowerment inadequate**

# CONCLUSION



**Detailed  
Reports**

**Supervisory  
authority  
Review**

**Decision**

**Focus  
areas  
commonly  
non-  
compliant**





**Thank you for your attention**



ORGANIZERS



S GROUP

GENERAL PARTNER



STRATEGIC PARTNER



GENERAL INFORMATION  
PARTNER



GENERAL INFO AND ANALYTICAL  
PARTNER

*Фармацевтический*  
**ВЕСТНИК**

STRATEGIC INFORMATION  
PARTNER

**ФАРММЕДПРОМ**