

Pharmacy Standards and Pharmacy Inspections

Pharmacy Information Session



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Summary

- Introduction
- Conduct of inspection
- 2009 Inspection Findings
- Discussion re most common findings
- Conclusion

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Introduction

Medicines Authority (MA) took over pharmacy inspections in 2005

MA started enforcing standards in legislation for pharmacy inspections since 2005

These requirements were discussed with pharmacists during the 2005 pharmacy inspections

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Introduction

In addition MA gave presentation to pharmacists at MCPP in Jan 2006 on Regulations Pertaining to Pharmacies

Initially inspections were carried out on an annual basis

Since 2008 inspections are being carried out on a 2 year cycle

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Conduct of Inspection

Legal basis for inspections - Article 88 of
Medicines Act 2003

Inspections mainly cover requirements and
standards in Medicines Act 2003, LN 279 of 2007
(amended by LN 81 of 2008 & LN 198 of 2010)
and Conditions of Licence

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Conduct of Inspection

Focus during pharmacy inspection is on:

- general condition and upkeep of pharmacy
- pharmacist appearance (white overall/identification tag)
- daily and dangerous drug registers and locum register
- ambient and fridge temperature monitoring records
- thermometer calibration records
- pest control records
- cleaning records
- condition of fridge and dangerous drug cupboard
- pharmacy equipment
- expiry dates

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Conduct of Inspection

The unannounced inspection is conducted by 2 MA inspectors who fill in 2 copies of the inspection report

At the end of the inspection the pharmacist is given a copy of the inspection report

During the inspections held in 2008 (following the previous inspections with an educational approach) it was noted that pharmacy standards/compliance were not improving

Decision was taken by MA to start issuing warning letters following repeated inspection findings, a major finding or an aggregation of findings

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2009 Inspection findings

In Malta and Gozo there are 209 licenced community pharmacies

133 pharmacy inspections were carried out in 2009 ie 64% of licenced pharmacies were inspected

49 of the pharmacies were involved in POYC scheme

In total 56 warning letters were issued (42%):

-24 warning letters were issued for the 49 POYC pharmacies (49%)

-32 warning letters were issued for the other 84 pharmacies (38%)

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2009 Inspection findings

Warning letters were addressed to the managing pharmacist and when applicable even to the licence holder

A reply was requested with adequate corrective and preventive action (CAPA)

The managing pharmacist is warned that in case of further failures they will be reported to the Pharmacy Council and court proceedings can be initiated by the MA

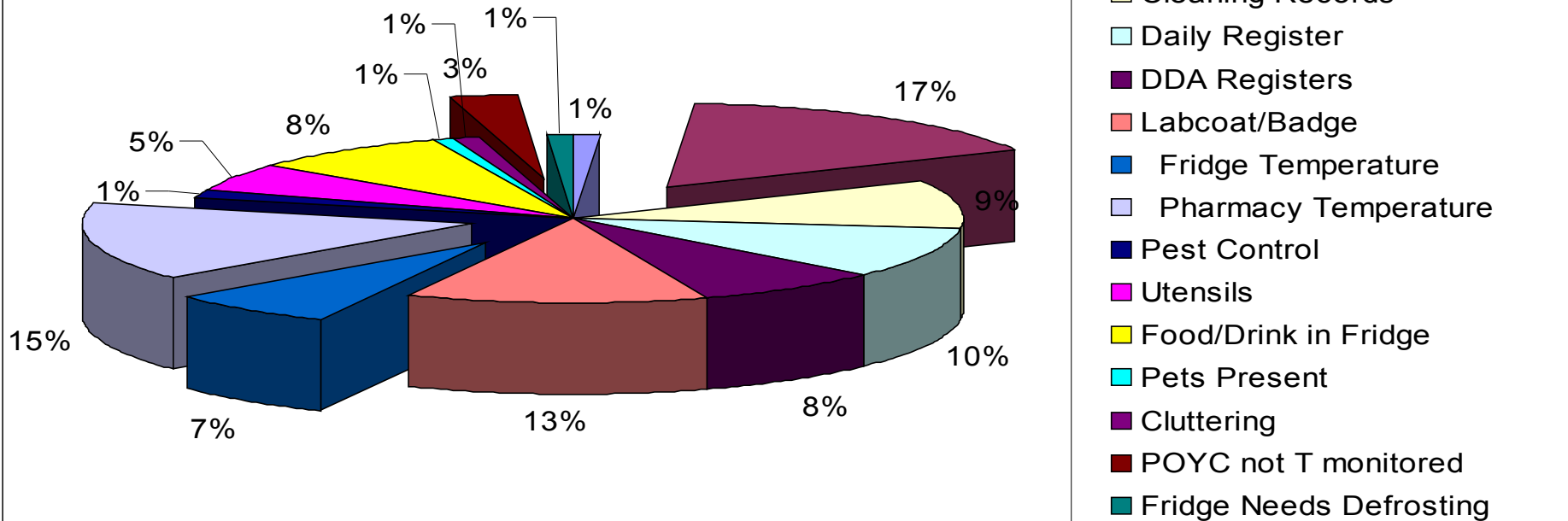
When applicable the licence holder is warned that in case of further failures, action will be taken against the pharmacy licence

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2009 Inspection findings

Percentage Distribution of Findings

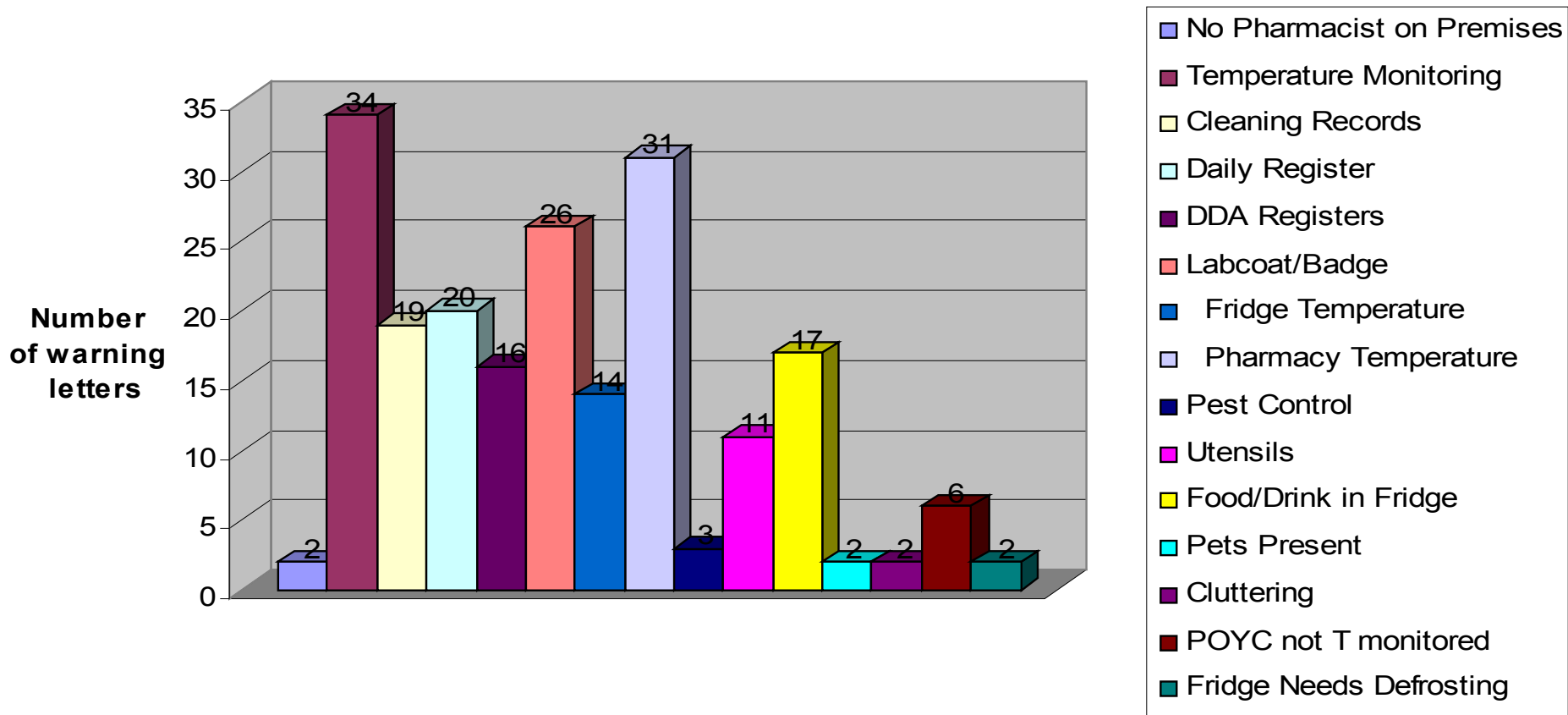


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2009 Inspection findings

Distribution of findings in the 56 warning letters



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Discussion re most common findings

It is clear that the major shortcoming in pharmacies is related to the lack of or inadequate temperature control and monitoring eg:

- no temperature records being kept
- ambient temperatures in pharmacy above 25°C (even 30°C and over)
- temperatures below 2°C and above 8°C in refrigerators (one instance during inspection temperature in refrigerator was 16°C)
- small overloaded (POYC insulins and vaccines) domestic refrigerators cannot maintain required temperature

This situation is totally unacceptable since it has direct effect on quality, safety and efficacy of medicinal products

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Discussion re most common findings

As a minimum pharmacists are required to:

- monitor all areas where medicinal products (including POYC) are stored and refrigerator with a min/max thermometer
- record the min/max temp of each thermometer daily and reset the thermometers
- calibrate thermometers at adequate intervals and keep calibration certificates as records
- take and record adequate CAPA if ambient temperature above 25°C and not within 2-8°C in refrigerator
- maintain refrigerator in adequate conditions eg defrost refrigerator as required
- buy a new larger refrigerator (pharma fridge is recommended) if size is not adequate for current stock

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Discussion re most common findings

Inspection findings concerning daily and dangerous drugs registers included:

- overdue entries
- registers not available on site

Pharmacists are required to have registers at pharmacy during opening hours and entries in registers should not be overdue

Electronic registers are allowed but these should be printed and signed by the pharmacist

Re the pharmacist appearance you are reminded that you should be wearing a white overall and identification tag whilst carrying out your duties

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Discussion re most common findings

POYC issues

Specific POYC related findings included:

- cluttering/disorganised pharmacy
- inadequate storage of POYC medicinal products (no temp control/monitoring of POYC area, medicinal products stored on the floor or on unlicensed premises, inadequate refrigerator size for POYC related increase in cold items eg insulins)

POYC products should not be treated differently from other products and same standards apply

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Conclusion

The community pharmacy is at the end of the medicinal product supply chain

However community pharmacy compliance to legislation and standards are not optimal

Before taking on POYC responsibilities the LH and MP have to ensure that the pharmacy setup is adequate to take on the new workload

For MA adequate temperature control of pharmacy area, stores and refrigerator are of great importance

Medicines Inspectors in Inspectorate & Enforcement Directorate within MA are available for any clarifications

Our and your goal should be the same: good practice within the community pharmacy setup for the patient's benefit

Thank You



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