

# Signals for Quality Assurance in Medicinal Products Regulatory Sciences

Valentina Sammut, Anthony Serracino Inglott

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

Quality, Continuous Improvement and Internal Audit Unit, Malta Medicines Authority, San Gwann, Malta

email: [valentina.tabone-borg.15@um.edu.mt](mailto:valentina.tabone-borg.15@um.edu.mt), [anthony.serracino-inglott@um.edu.mt](mailto:anthony.serracino-inglott@um.edu.mt)

## INTRODUCTION

### The Term Signal

Adopted in various contexts to outline complex environments (aviation, anaesthesiology, medical surgery, healthcare, biological signalling, pharmaceuticals, road traffic management infrastructure, natural hazards, supply chain management, and building management systems).<sup>1</sup>

### The Philosophy of Signals

Inhabitants lacking a signalling system would invent one often for survival reasons. An intuitive example of signalling is portrayed by the prominent ant pheromone trails.

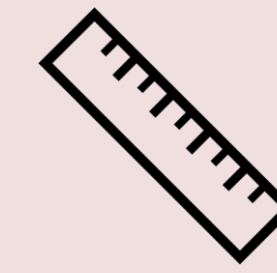
### Signals in the Context of Regulation of Medicinal Products

Contribute to safety, quality, efficacy, and further to accessibility and environment equity principles.<sup>2</sup>

## AIMS



Identify potential signals from sources within the Quality Assurance Unit



Categorise the identified signals in accordance with quantitative and qualitative factors



Develop signal minimisation action plans at the heart of the regulatory scientific field

## METHOD

### SETTING

- Pharmacy Department, University of Malta,
- Quality Assurance Unit at the Malta Medicines Authority



- Using the Standard Operating Procedures of the Quality Assurance Unit for the assessment of operations
- Opportunities for identifying signals are recorded



- Quantitative categorisation is carried out by using a Likert Scale ranging from 1 (not serious) to 5 (very serious)
- Qualitative categorisation depends on the occurrence from a range of 1 (occurring less than 10 times) to 10 (occurring more than 100 times)



Development of a checklist for the verification of carrying out instructions or procedures precisely

## RESULTS



### Opportunities for Signal Detection

- Analyses of Internal Audit Performance Reports
- Submission of Quality Improvement Forms
- Submission of Deviations and inclusion of Potential Deviations
- Corrective Actions and Preventive Actions



### Categorisation of Signals

- Training Requirements
- Quantitatively
- Qualitatively

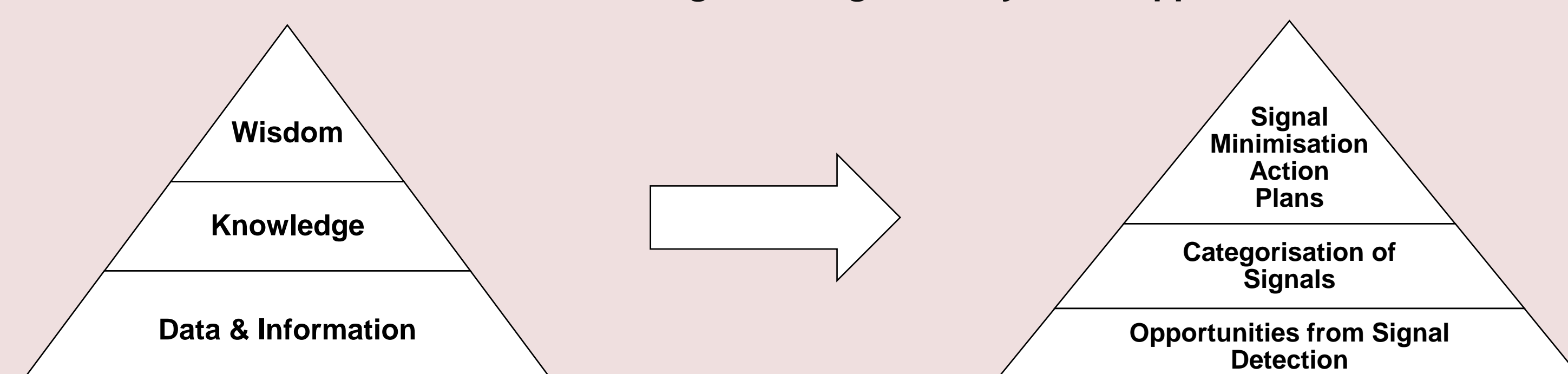


### Signals Minimisation Action Plans

- Development of Quality Assurance officers that will be attached closely to the Operating Units of the organisation

## CONCLUSION

This study reflects on the innovative science of signal management by using the assembled findings as an example on how a pharmaceutical regulator could transform scientific data into factual information, into learned knowledge, and significantly to the application of wisdom in decision-making.



## REFERENCES

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