

DEVELOPMENT OF A VALIDATED TOOL TO IDENTIFY COMPETENCES RELEVANT FOR RESPONSIBLE PERSON POSITION IN GOOD DISTRIBUTION PRACTICE

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INTRODUCTION

Pharmaceutical wholesale distribution forms an integral part of pharmaceutical supply chain and bears a strong socio-economic impact on multi-faceted healthcare systems¹.

Defined competences or educational frameworks are not established within the EU to define educational development for the Responsible Person (RP) position in wholesale distribution of pharmaceuticals.

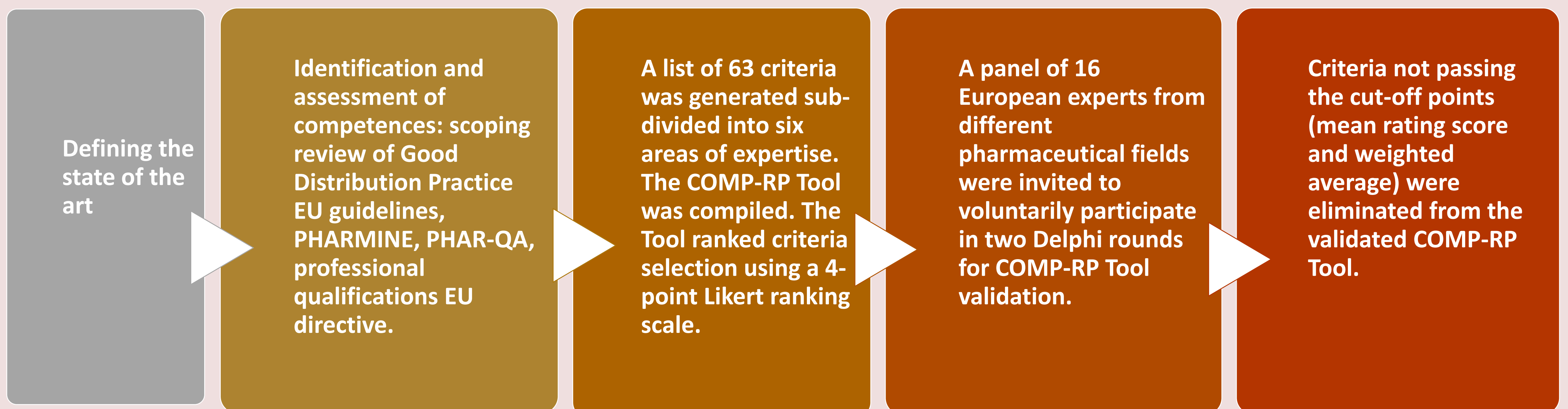
The educational approach for current educational development for the accession to the RP position is topic-driven and not competency-based.

AIMS

To establish competences required for the RP position by:

- Identifying and assessing knowledge, skills and competences required in pharmaceutical wholesale distribution;
- Proposing a validated COMP-RP Tool; a Tool to identify Competences Relevant for the Role of the Responsible Person.

METHOD



RESULTS

❖ 63 criteria were generated for assessment subdivided into six areas of expertise as shown in Table 1.

❖ Demographic data for the panel of experts indicates that a total of N=15 experts participated in the two Delphi rounds of which 13 were either RPs or regulatory affairs specialists and all participants had over 10 years of working experience.

❑ First Delphi Round Validation Results:

❖ Four of the N=63 criteria did not pass the cut off point (pertaining to leadership and documentation practices).

❑ Second Delphi Round Results:

❖ 58 of the N=59 criteria passed the eliminated cut-off points in Delphi round 2, resulted to be valid and were included in the final COMP-RP Tool. The n=1 criterion eliminated pertained to Documentation practices.

The final COMP-RP Tool was deemed final and validated (Figure 1).

Table 1 - Six areas of Expertise Identified for RP Role

1. Quality Management in relation to a Quality System
2. Management of 'outsourced activities'
3. Reviewing and monitoring
4. Leadership
5. Wholesale distribution premises and activities related to medicinal products
6. Documentation

Figure 1 – Extract from the final, validated COMP-RP Tool

5 Wholesale distribution premises and activities related to Medicinal Products
Quality mind-set to ensure the integrity of the medicinal product
Conduction of self-inspections for all GDP practices and engage in audits. These should be recorded and any CAPAs implemented within stipulated timeframes
Management of issues with medicinal products to ensure patient safety
Risk assessment, management and mitigation

CONCLUSION

The consideration of the implementation of a competency-based approach in this research is supported by other studies^{2,3,4} which highlight the importance of having a competency-based pharmacy education centric approach.

The developed COMP-RP Tool contributes to the identification of competences that are relevant to the RP position and facilitates the harmonisation in GDP educational requirements to support patient-centric and safe wholesale distribution practices.

In conclusion, through this research, the COMP-RP Tool has identified general competences which are relevant and can be implemented and applied to all pharmacy education programs.

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