

GUIDELINES FOR QUALITY CONTROL OF MEDICAL CANNABIS

Julian Mifsud, Janis Vella Szijj, Lilian M. Azzopardi

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

email: julian.mifsud.18@um.edu.mt

INTRODUCTION

Medicinal cannabis is used for management of cancer and visceral pain, neuroinflammatory and neurodegenerative disorders, epilepsy, spasms and inflammatory bowel disease. Quality Control (QC) of medicinal cannabis is required for patient safety.¹

AIMS

To compare QC tests related to the analysis of medicinal cannabis in different countries. Focus is placed on tests required to determine cannabinoids, terpenes, mycotoxins, pesticides and heavy metals in cannabis.

METHOD

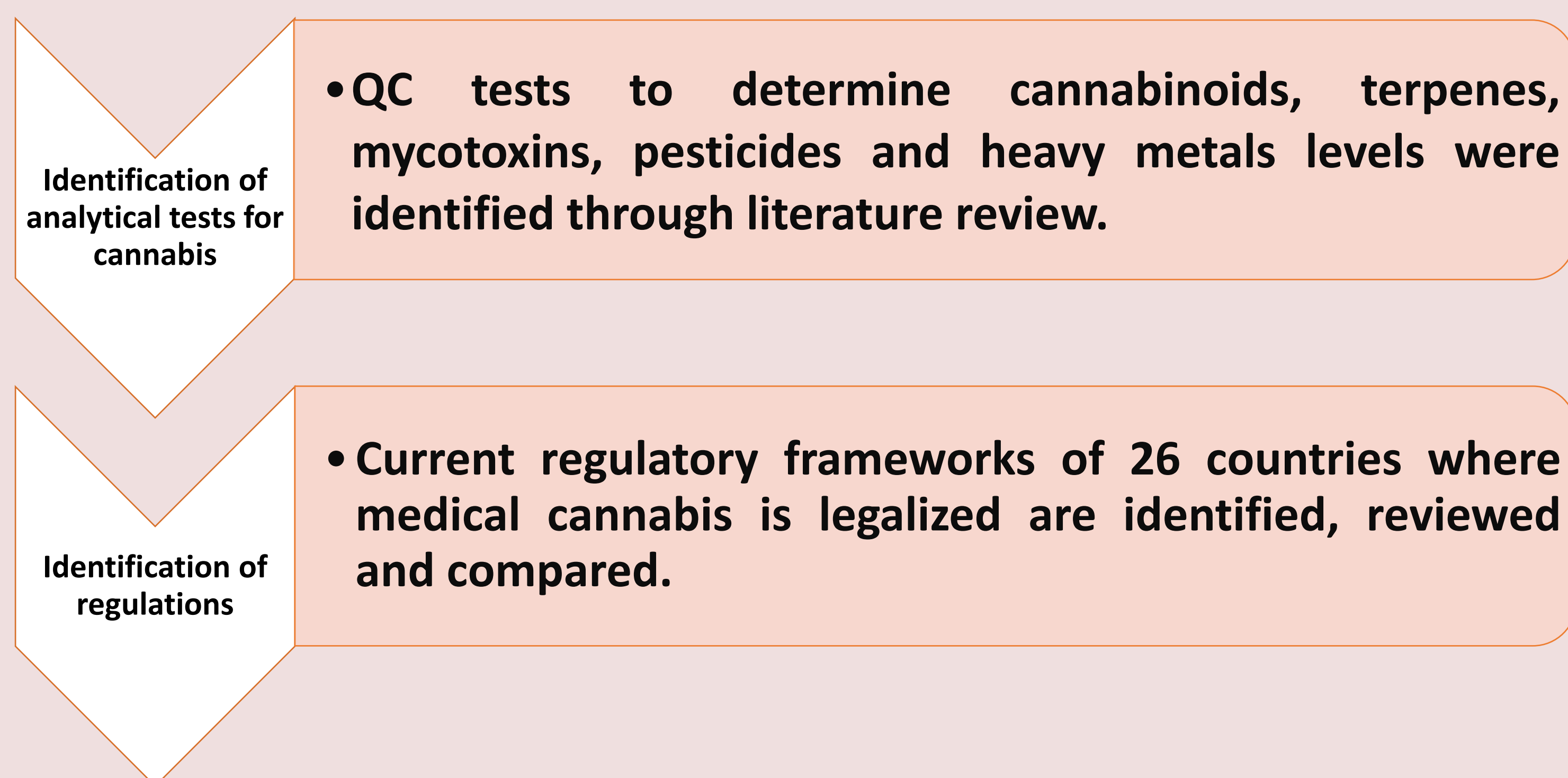


Figure 1: Method overview

RESULTS

Out of the 26 countries identified, 23 follow the Herbal Monograph of the European Pharmacopoeia for contaminant limits. Table 1 shows the findings from 4 of the reviewed countries for the allowed concentrations of cannabinoids, heavy metals, pesticides and mycotoxins in Germany, Malta, Australia and the United States.

Table 1: QC parameters of tests for medical cannabis in Germany, Malta, Australia and the United States.

Tested parameters	Germany	Malta	Australia	United States
Delta -9- Tetrahydrocannabinol (THC) conc.	Minimum: 1.0% Maximum : 25.0%	Approved products range from 6.0% - 22.0%	Products on the market may range from 0.4% - 55.0%	Varies according to state
Cannabidiol (CBD) conc.	N/A	Approved products range from <1.0% - 8.0%	Products on the market may range from 0.04% - 99.9%	Varies according to state
Heavy Metals conc.	As per Ph. Eur. requirements maximum concentrations: Cadmium: 1.0ppm Lead: 5.0ppm Mercury: 0.1ppm	As per Ph. Eur. requirements maximum concentrations: Cadmium: 1.0 ppm Lead: 5.0 ppm Mercury: 0.1 ppm	Maximum allowed concentrations: Cadmium: 0.5 ppm Lead: 5.0 ppm Mercury: 0.5 ppm Arsenic: 3.0 ppm	Maximum allowed concentrations: Cadmium: 0.3 ppm Lead: 0.5 ppm Mercury: 0.1 ppm Arsenic: 0.2 ppm
Pesticides conc.	As per Ph. Eur. requirements Eg. Diazinon: 0.5mg/kg Permethrin 1mg/kg	As per Ph. Eur. requirements	As per Ph. Eur. requirements	Varies according to state
Aflatoxins conc.	As per Ph. Eur. requirements Aflatoxin B ₁ : 2mcg/kg Sum of B ₁ , B ₂ , G ₁ & G ₂ 4mcg/kg	As per Ph. Eur. requirements Aflatoxin B ₁ : 2mcg/kg Sum of B ₁ , B ₂ , G ₁ & G ₂ 4mcg/kg	As per Ph. Eur. requirements Aflatoxin B ₁ : 2mcg/kg Sum of B ₁ , B ₂ , G ₁ & G ₂ 4mcg/kg	Maximum allowed concentrations: Aflatoxin B ₁ : 5 mcg/kg Sum of B ₁ , B ₂ , G ₁ & G ₂ : 20 mcg/kg
Mycotoxin conc.	Ochratoxin (Conc. not specified)	Ochratoxin (Conc. not specified)	Ochratoxin A 20mcg/kg	Varies according to state

CONCLUSION

Harmonisation between countries is present with regards to QC parameters of mycotoxins, pesticides and heavy metals, but not for allowed cannabinoid concentrations. Proposal of updated guidelines on QC tests related to the analysis of cannabinoids, terpenes, mycotoxins, pesticides and heavy metals will help contribute to harmonisation towards establishing safety, quality and efficacy of medicinal cannabis products.

REFERENCE

1. Levinsohn E, Hill K. Clinical uses of cannabis and cannabinoids in the United States. Journal of the Neurological Sciences. 2020;411:116717.