

## Medicinal Cannabis

### **EUMCA (EU Medicinal Cannabis Association)**

#### **Guiding Principles**

1. The product contains known amounts of specified active ingredient(s) confirmed by validated analytical methodology, compliant with the monograph of the nation in which products are sold. The inactive ingredients, excipients, (e.g. oils, preservatives, diluents, flavouring agents) are GRAS listed and/or recognised by Regulatory Agencies /Pharmacopoeias, compliant with the monograph of the nation in which products are sold.
2. Each batch of product has been QC tested and complies with established QA specifications (including traceability of the source and quality of the active and inactive ingredients) compliant with the monograph of the nation in which products are sold.
3. The product has been compounded/manufactured in facilities that are compliant with accepted GMP standards.
4. The quality of the product has been shown to be reproducible batch to batch, compliant with the monograph of the nation in which products are sold.
5. The shelf life (and hence the stability) of the product under storage conditions specified on the label/packaging has been estimated/confirmed using validated analytical methodology, compliant with the monograph of the nation in which products are sold.
6. The label/packaging accurately reflects 1, 2 and 6 above, compliant with the monograph of the nation in which products are sold.
7. Any therapeutic claims for the efficacy of the product are supported by adequate clinical evidence and are compliant with national legal requirements relating to Medicines or Herbal Products or Food Supplements. (Ideally, claims for therapeutic use are approved by national Medicines Regulatory Agencies).
8. Advertising literature /copy should truly reflect the current state of knowledge of any suggested therapeutic use of the product.
9. The bioavailability of the active ingredient(s) has been established either in healthy volunteers and/or patients.
10. A mechanism should be established for Pharmacovigilance of the product to assess any concerns relating to the safety of the product in each EU national regulatory authority.