

Licensing: Manufacturers, Importers, Exporters

Dr Joey Gouws
Department of Health
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Introduction

- Globally
 - Evident that CAMs Industry has shown immense growth in recent years and this growth has led to its extensive commercialization worldwide.
- Sudden public awareness
 - Public access to world-wide information through www
 - Widespread news coverage
 - Commercial advertisements
 - Lay press ranging from tabloid publications to magazine
 - Cost of modern allopathic medical care
 - Mistaken impression that natural products are always safe

Introduction cont....

- National Medicine Regulatory Authorities are faced with an urgent need to implement a systematic regulatory approach to ensure the safety of CAMs with GMP, safety and quality issues taking centre stage

Introduction cont....

- Recognised MRA calling for quality control over manufacturing of CAMs
 - USA, FDA: June 2010 all dietary supplements in a GMP compliance facility
 - Australia, TGA all listing products in a GMP compliance facility
 - Canada all Herbal products in a GMP compliance facility
 - UK, MHRA, all Herbal products in a GMP compliance facility
 - Singapore, all traditional medicines in a GMP compliance facility

Introduction cont....

- RSA
 - MCC: November 2013 all complementary medicines be imported by a licensed entity
 - November 2013 all complementary medicines be manufactured in a licensed facility
 - Licensed facility  GMP compliance facility

Legislation

- Pharmacy Act (Act 53 of 1974)
- Medicine Act (Act 101 of 1965)

Legislation cont....

- Pharmacy Act (Act 53 of 1974)
 - Section 22
 - Apply to DG for premises licence
 - Activities conducted by Pharmacist
 - Pharmacist responsible to SAPC
 - Acts performed by pharmacy
 - Notify SAPC for recording premises

Legislation cont....

- Medicine Act (Act 101 of 1965)
 - Section 22C
 - Apply to the MCC
 - Pay a fee
 - Comply with GMP / GDP
 - Regulation 19
 - How to apply
 - Appoint a pharmacist (manufacturing / distribution)
 - Appoint a natural person (compliance with the Act)

Who must apply

“manufacture” means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls” and

“wholesaler” means a dealer or trader who acquires any medicine or medical device from a manufacturer and sells or distributes it to the retail sector.

Who must apply cont....

- Manufacturers (South Africa)
- Applicants:
 - Import
 - Release
 - Export
- Wholesalers/Distributors
- Over-labeling = packaging
- Contract Laboratory

How to apply

- Application form
 - www.mccza.com
- Fee
 - Manufacturer: R20 000
 - Importer: R12 000
 - Wholesaler: R12 000
- List of Products

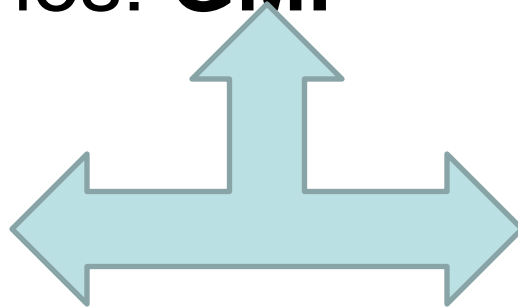
GMP compliance

- Manufacturers of CAMz must comply with the SA guidance on Good Manufacturing Practice for Medicinal Products
- 9 basic chapters and 17 specialised Annexes
- Annexure 7 deals specifically with Herbal manufacturing and GACP

GMP compliance: Manufacturer

- GMP - No magic word
 - working in a **Clean**
 - **Reliable**
 - **Orderly** manner
 - leaving behind a **Documentation** trail
- Herbal medicines: **GMP**

GACP: Crude herb



GMP: Finished

GCAP compliance

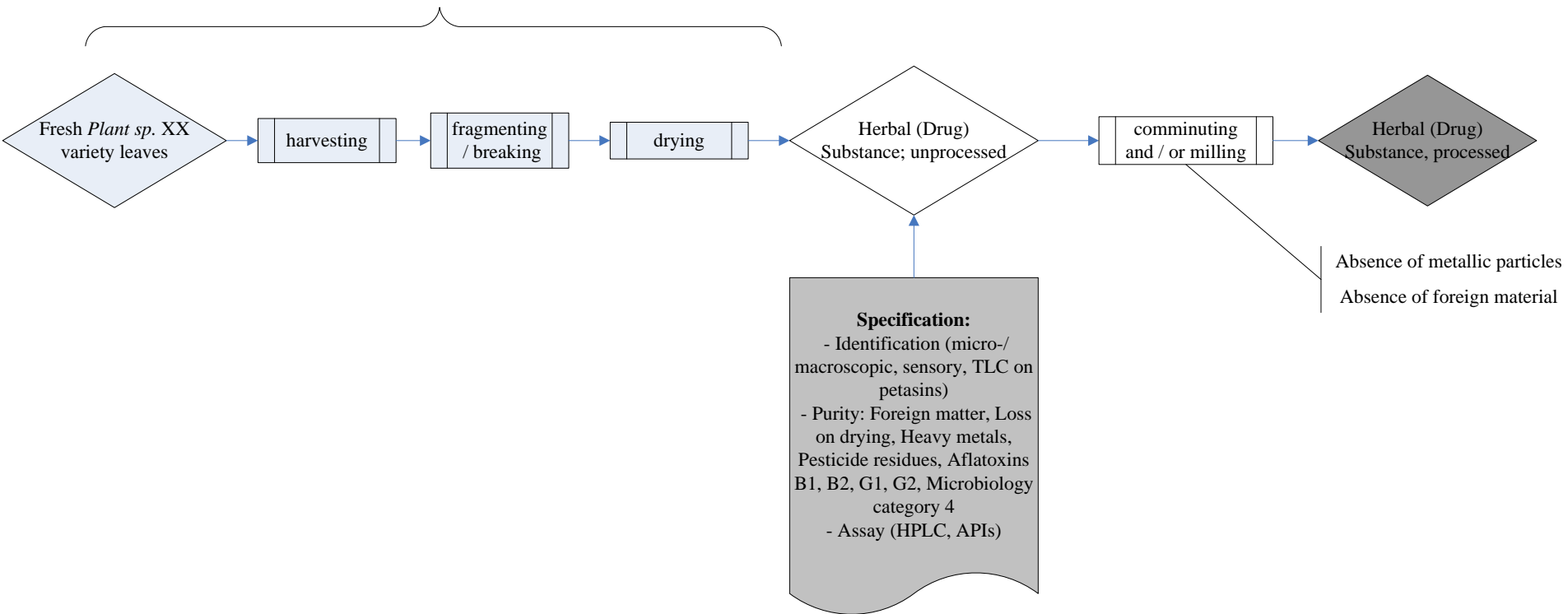
Herbal Specific Requirements [Annex 7]:

- Premises
- Documentation
- Sampling
- Quality Control

Annex 7 emphasises the importance of control of starting materials [including correct identification], storage and processing

Manufacturing of Herbal Product: Harvesting and comminuting

GACP



GACP compliance

- Hygienic production/growth of herbal substances to reduce microbial and contamination with other foreign matter
- Careful handling of herbal substances so that the material is not adversely affected by collection, cultivation, processing or storage
- Avoidance of misidentification/cross-contamination
- Includes both wild crafting and cultivation

GACP compliance cont....

What is covered by it:

- Personnel & Education
- Building & Facilities
- Equipment
- Documentation
- Seeds
- Cultivation

GACP compliance cont....

What is covered by it

- Collection
- Harvest
- Primary Processing
- Packaging
- Storage & Distribution
- Also includes:
 - Adherence to local/regional guidance:
 - collection, environmental damage etc
 - endangered species

GMP compliance: Finished Product site

What is covered by it:

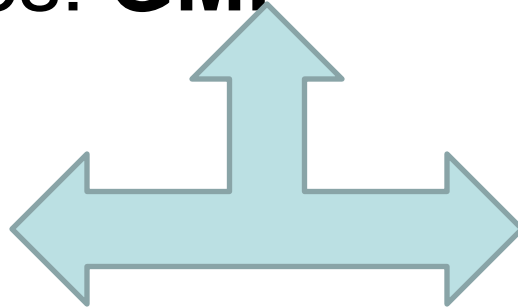
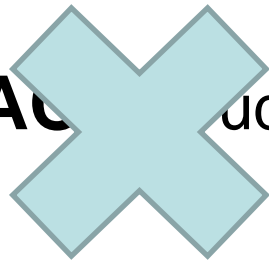
- Quality Management
- Personnel
- Premises & Equipment
- Documentation
- Production
- Quality Control
- Contract Manufacture and Analysis
- Complaints & Product Recall
- Self-inspection

GMP compliance: Importer

- GMP - No magic word
 - working in a
 - **Reliable**
 - **Orderly** manner
 - leaving behind a **Documentation** trail
- CAM medicines: **GMP**

GAC

ude herb



GMP: Finished

GMP compliance Importer

cont....

What is covered by it:

- Quality Management
- Personnel
- Contract Manufacture and Analysis
- Documentation
 - Production: Batch Records
 - Premises and Equipment
- Quality Control
- Complaints & Product Recall
- Self-inspection
- Herbal specific requirements
 - control of starting materials [correct identification]
 - storage and processing

Licence issued

- Import or manufacture medicine
- Import: Ports of Entry (4)
 - OR Tambo airport
 - Durban airport / harbour
 - Port Elizabeth airport / harbour
 - Cape Town airport / harbour

Wholesale licence

- Who to apply?
 - Wholesaler that wholesale medicines bought from various Manufacturers / Importers
- Application
 - Form available on MCC website
 - Fee: R12 000
 - Compliance with Good Wholesaling Practises

GWP compliance

What is covered by it:

- Quality Management
- Personnel
- Premises & Equipment
- Documentation
- Picking and packaging
- Complaints & Product Recall
- Self-inspection

Closure

- Manufacturing of CAMs has been regarded a day-to-day, easy, straight forward and cheap activity in relation to other aspects involved in the complementary pharmaceutical cost structure
- Marketing has been regarded difficult, requiring imagination, genius, luck and money.
- Future the manufacturing and wholesaling role will have to be more recognised as a competitive and combating weapon in the pharmaceutical business success of complementary medicines due to the community, customer and stakeholders demand for high quality, cost effectiveness and acceptable medicine.

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Dr J Gouws
Gouwsj@health.gov.za