



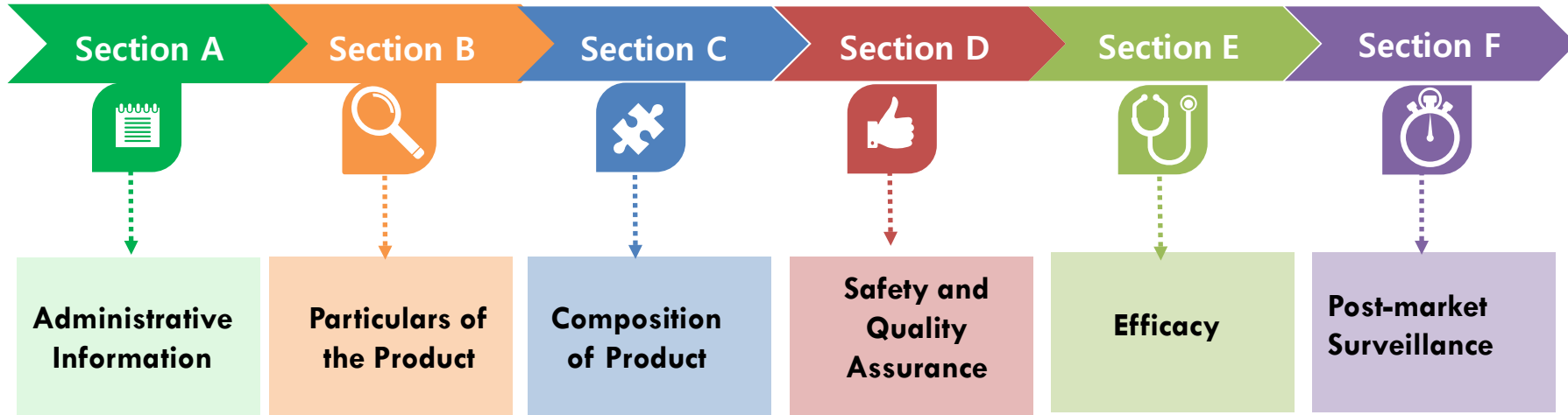
Medicines Control Authority of Zimbabwe

# COMMON DEFICIENCIES

**HYBRID COMPLEMENTARY  
MEDICINES STAKEHOLDERS  
ENGAGEMENT**

MAUD FARIRAI NYAMUKAPA

# Overview of Dossier Structure



# Section A – Administrative Information



**Cover Letter:** (Signed, dated, responsible person)



**CM 1 Application Form:** Fully completed, signed, and dated.



**Applicant Declaration:** Signed and dated



**Proof of Payment**



**Manufacturing & Marketing Authorizations:** must be valid



**Product Samples:** only two



**Labelling & Product Information:** Labels, package inserts



# Common Deficiencies

- ☐ **Structure of dossier** (some structures hard to navigate)
- ☐ **Unreadable submissions** (damaged discs, corrupted files)
- ☐ **Cover Letter:**
  - Missing full details (name, email) of responsible person
  - Not signed and dated
- ☐ **CM 1 Form:**
  - Incomplete or incorrectly filled
  - Not signed and dated
  - Must be updated
- ☐ **Samples**
- ☐ **GMP certificates:**
  - Must be provided by NRA
  - OR MCAZ inspectorate to inspect
  - FSSAI and ISO certificates do not suffice
- ☐ **Proof of registration in country of origin**
  - Free sale certificate or retention license

# Common Deficiencies

## ❑ Indications

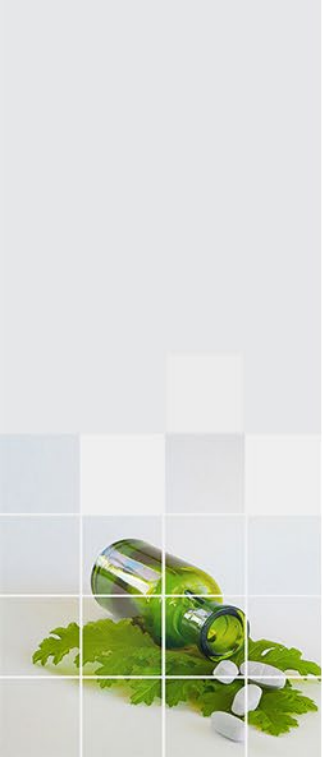
- Structural or functional claims e.g. “Supports immune health”  
“Has a role in general metabolism and protein synthesis”  
“Helps in the formation and maintenance of bones and teeth”
- Acceptable claims and indications: Annex B and Annex C

## ❑ Labelling

- Zimbabwe approval number not “Zim Reg No” or “MCAZ Reg No”
- Category for distribution (CMGS/PCM)
- **NO APPROVED THERAPEUTIC CLAIMS**
- Batch details

## ❑ Package inserts

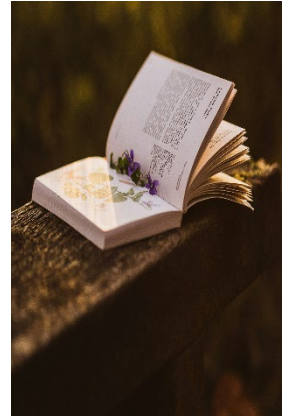
- Pharmacological actions should not suggest therapeutic activity



# Section B – Particulars of the Product



- **Product Name**
- **Dosage form of the product**
- **Strength of the product:** shall be given per unit dosage form or per specified quantity
- **Therapeutic use(s):** the intended use should be only the major indication(s).
- **Visual description of the product**
- **Type of container:** primary and secondary packaging
- **Pack size(s):** the presentation of the product to be registered  
i.e. list all pack sizes, fill volume
- **Proposed Shelf life (in months):** supported by stability studies
- **Storage conditions**
- **Status of registration of the product in the country of origin**
- **RECURRING CHALLENGES:** information should be consistent throughout dossier



# Section C – Composition of Product



- List of all active ingredient(s) and all non-active ingredient(s)
- Scientific name
- The common name/synonym/English name.
- Part of Plant used

## **Common Deficiency:**

- Reason for inclusion



# Section D – Safety and Quality Assurance



## SAFETY - Part I: Herbal Based



**Botanical  
identification/  
authentication**



**Geographical  
source of the  
plant used**



**Harvesting and  
collection of  
the plant**



**Method of  
drying**



**Storage and  
preservation of  
plant material**



**Biological  
information  
(via literature  
search/  
database)**



**Toxicity studies**



# Section D – Safety and Quality Assurance

## SAFETY - Part II: Nutritional Substances

Upper safe levels  
of vitamins and  
minerals

Recommended  
Daily Allowances



# Section D - Quality Assurance



## ACTIVE RAW MATERIALS

### Part I: Herbal Based

- Identification of plant(s): Latin name, synonyms, vernacular names
- Part of the plant used and the condition of the plant material used
- Specifications and analytical methods

### Part II: Nutritional Substances

- Identification of Substance: definition/synonyms
- Specifications and analytical methods

# Section D - Quality Assurance



## **EXCIPIENTS**

- **Specifications and analytical methods**

## **FINISHED PRODUCT**

- **Name of the Manufacturer**
- **Description of manufacturing process and process controls**
- **Finished product specifications & analytical methods**
- **Stability Studies**
- **Packaging specifications**



# Common Deficiencies - Section D

- Lack of safety and toxicology data
- Missing BSE/TSE declaration
- Missing asbestos free declaration for talc
- **Bronopol is prohibited oral liquid preparations**
- Inadequate specifications – lack critical tests
- Lack of analytical methods
- Inadequate description of manufacturing process – lack list of equipment, process controls
- Inadequate stability studies – wrong conditions, too short etc
- Packaging specifications do not include identification and material of construction
- **QMS – documents not signed, dated or version controlled**



# Common Deficiencies



Applicable to Herbal-based medicines

## SECTION F: Post-market Surveillance

- Adverse drug reaction form
- Product defect form



Medicines Control Authority of Zimbabwe

**THANK YOU!**

