

Health Products Association (HPA)
of South Africa

THE SOUTH AFRICAN CAMS & DIETARY SUPPLEMENTS CLIMATE 2016

presented by
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“SERVING SOUTH AFRICA’S HEALTH INTERESTS”

SOUTH AFRICAN MARKET



- Annual GDP growth
 - South Africa’s economy grew by 1,3% in 2015
 - In 2015 South Africa’s GDP was almost R4 trillion
- RSA population
 - 55 million people (+1.51% increase)
- Size of CAMS Market
 - R8 billion (USD 540 million)
- Overview of vitamins and dietary supplements
 - Value of market R3.8billion
 - Growth +13.5%

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REGULATORY CLIMATE



In 2013, Legislation concerning Complementary Medicines (CAMS) was published

1. The regulations that were published primarily fitted CAMS / health supplements into the current **Allopathic Medicines Framework** using the same systems and requirements (with slight modifications)
2. Our issue is not the need for regulation but the costs, appropriateness and in some instances feasibility of compliance which is creating a high level of uncertainty within Industry

AREAS OF CONCERN:

1. Definition of CAMS and Health Supplements
2. Permits and Licences
3. Responsible Person
4. Registration Process being CTD ONLY
5. Claims

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AREA OF CONCERN



- DEFINITION OF CAMS
 - The definition has been updated twice since publishing
 - The definition of CAMS includes all Traditional Complementary Medicines and more recently Health Supplements
 - It is still unclear what falls within the definition of a Health Supplements (The term has not been defined in full yet - we are still waiting for the full scope of what it covers, however it does include all vitamins, minerals, probiotics, prebiotics, amino acids, fatty acids, carotenoids, bioflavonoids, enzymes, animal extracts, aminosaccharides, saccharides and others that are in pharmaceutical dose formats)
 - We await the revised regulations and guidelines
- Solution would be to exclude “nutritional supplements” from the overall definition (provided they are within certain active levels and without specific claims) and treat them as foodstuffs

AREA OF CONCERN



- LICENCES
 - All Companies within the entire supply chain need to get a **License to manufacture, act as a wholesaler or distribute medicines**
- RESPONSIBLE PERSON
 - The RESPONSIBLE PERSON has to be a Registration Pharmacist even though there are not nearly enough Registration Pharmacists in South Africa
- SOLUTION:
 - Provide for appropriate licence requirements for CAMS (different to those for Medicines)
 - To ensure that reasonable time frames are provided for the licences
 - To expand on who a Responsible Person can be (as has been done around the world) and to allow them to include consultants (i.e. not to be in the full time employ)

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AREA OF CONCERN



- CTD : REGISTRATION OF MEDICINES
 - All products need to register via the CTD format, which is almost impossible to complete for multi-substance CAMS
 - Current time taken to register other Medicines can be up to 5 years
 - Currently companies are unable to import or innovate in regard to new products without a registration number
- SOLUTION
 - Provide for a fast track registration system for low risk products
 - Provide for a simplified and appropriate criteria within the e-CTD registration system for the balance of products
 - Provide for an interim measure as to how to deal with new products

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IMPACT



- Gridlock
- No registrations have taken place
- No new products are being imported into RSA
- No R&D is taking place
- No new products have been launched onto the market for 2 years
- An increase in “illegal” products coming onto the marketplace

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WAY FORWARD



PRIORITIES

- Get clarity on the definition of CAMS - in particular health supplements
- To get the DOH to;
 - To simplify the requirements for QSE on both Traditional Complementary Medicines, an in particular Health Supplements
 - To provide for a simplified screening / registration system for low risk CAMS / health supplement products
 - To include other people into the definition of a responsible person when dealing with CAMS / health supplements
 - To provide for a separate requirement for licences for CAMS / health supplements
 - To provide for a simpler marketing code
- To set up a separate directorate

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Are there any questions?

THANK YOU

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