CLAUSE BY CLAUSE ANALYSIS OF THE BILL (3)

- Clause 14 prohibits bonusing on the supply of products.
- Clause 15 prohibits the sampling of products.
- Clause 16 provides for the Minister to make regulation relating to the marketing of products.
- Clause 17 prohibits the sale of products which do not comply with the prescribed requirements.
- Clause 18 prohibits publications or distribution of false advertisements concerning products.
- Clause 19 provides for the authority to authorise the sale of uncertified or unregistered products for certain purposes.
- Clause 20 provides for the Chief Executive Officer to cause certain information to be furnished.

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CLAUSE BY CLAUSE ANALYSIS OF THE BILL (4)

- Clause 21 prescribes the control of products and scheduled substances.
- Clause 22 deals with publication of information relating to products or scheduled substances.
- Clause 23 deals with the licensing of substances.
- Clause 24 deals with validity and renewal of licenses.
- Clause 25 deals with the suspension and cancellation of licenses.
- Clause 26 deals with generic substitution of products.
- Clause 27 deals with the purchase and sale of products by wholesalers.
- Clause28 deals with the procedure on disposal of undesirable products.

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CLAUSE BY CLAUSE ANALYSIS OF THE BILL (5)

- Clause 29 deals with the appeal procedure against decisions of the Director General.
- Clause 30 deals with appeals against decisions of the Authority.
- Clause 31 deals with the privileges of the Authority and committees.
- Clause 32 provides for the Chief Executive Officer to appoint inspectors.
- Clause 33 provides for the Chief Executive Officer to appoint analysts, pharmacologists and pathologists for the proper enforcement of the Act.
- Clause 34 deals with the powers of inspectors.
- Clause 35 deals with offences in relation to the products

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CLAUSE BY CLAUSE ANALYSIS OF THE BILL (6)

- Clause 36 deals with penalties in relation to the Act.
- Clause 37 deals with procedure and evidence in criminal proceedings under this Act.
- Clause 38 deals with funds of the authority.
- Clause 39 deals with the delegation of power.
- Clause 40 deals with the powers of the Minister to make regulations in consultation with the authority.
- Clause 41 provides for the exclusion of any drug from operation of the Act.
- Clause 42 provides for the amendments of schedules by the authority.
- Clause 43 deals with transitional measures.

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COMMENTS ON THE MEDICINES BILL(1)

- 32 submissions were received and have been studied.
- Support Creation of an Authority.
- Comment of the two stage process of certification and registration
- The details of the submissions will be covered in the regulations.
- Request that timeframes for registration be in the Act. The regulation will incorporate this as the Act is enabling.
- Seeks clarity on particular definitions "product" vs. "health product". This will be done.

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COMMENTS ON THE MEDICINES BILL(2)

- Controlling Board for the Authority. There will be a panel of experts and/or experts that will be consulted and/or their expert opinion sought.
- Conflict of interest for those in employ of Authority. This will be in the regulations but the fact that all staff will be fulltime will reduce this issue.
- Skills of the CEO. The CEO that is appointed will have the requisite skills
- General comment of greater detail. This will be covered by the regulations.
- Pricing comments. The pricing of health products is a separate issue.

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COMMENTS ON THE MEDICINES BILL(3)

- Details of the submission will be considered in the regulations.
- The variance between pharmaceuticals and medical devices will be considered in the regulations as the structure of the authority does portray this.
- Cross reference with other prescripts is considered by the Bill where it applies.

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RECOMMENDATIONS

- That the Health Portfolio Committee consider the Bill and proceed with the legislative process

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THANK YOU

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