

## FAQ'S

### Question 13

Pre-licence activity - Advertisement and promotion are subject to domestic legislation, i.e. if a product is not registered in South Africa, it cannot be promoted, even if the congress is international in nature, unless exemption has been granted in terms of applicable legislation. Who grants that exemption?

*Bernice Grusd replies*

- PART A CLAUSE 4
- Promotion of a medicine must be in accordance with the registration & consistent with the PI
- A medicine must not be advertised or promoted:
  - Prior to registration
  - Exception - application has been submitted in terms of Section 14(3) of the Medicines Act (“old medicine”), which permits its sale, supply and use in South Africa.
- The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that this does not constitute promotion.
- The MCC grants that exemption