National Regulatory System in Iraq

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- To be one of the market participant you must register your product first.
- Registration is the filing of certain information about the safety , efficacy , quality and origin of products to be marketed in Iraq.
- Registration should be done by manufacturers, marketing authorization holder, contract manufacturers.

Who should be registered ?

- - Pharmaceutical companies that have one or more of a pharmaceutical factory.
- - Companies producing General products.
- -Medical appliances and disposables producing companies.
- -Laboratory diagnostic kit manufacturers .

The Products are

- Products that are required to be registered are any pharmaceutical products, vaccines and sera with a therapeutic effect.
- a- prescription only drugs (full documentation is required)
- b- OTC drugs (reduced documentation is required)
- *reduced documentation:- no bioavailability or bioequivalence study is required , however dissolution profile to be submitted

Validity

- Registration of a pharmaceutical product is valid for 5 years.
- For national pharmaceutical products is valid for 10 years.
- Re-registration will be required thereafter.

- Anew registration file for registrated Product should be submitted prior to major modifications to the formulation, manufacturing process or method of preparation.
- While upon minor modifications only notification with samples is required.
- Requirements for resubmission of a product for registration after its refusal depends on the reason of that refusal.

- Registration of a pharmaceutical product will be revoked whenever new scientific evidence proves facts contrary to the information supplied with the original registration documents.
- The Registrant is responsible for the product quality and the recalling process of the product.
- All documents submitted by a pharmaceutical company concerning registration of a product shall treated as confidential and should not be passed to any other party.

Priority of registration

- In the registration of a drugs or biological products the following priorities shall be followed :
- first priority :- new chemical entity
- second priority :- national drugs.
- third priority :- other drugs.

The Inspection

- Inspection of pharmaceutical manufacturing establishments :
- - Legal basis : drug registration system .
- - authority : Ministry of Health (MOH) / registration department registration department have the right to inspect any pharmaceutical establishment for compliance with GMP regulations.
- If an inspection is deemed necessary by the Registration Department, then it will be at the Registrant expense.

- Time required for evaluation from the date of full data submission is not more than one year for pharmaceutical products and not more than 90 days for companies.
- Arabic and English are the accepted languages for the application forms.
- Scientific data should be in English.

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