Preamble

Application form is an essential administrative document of all the marketing authorization applications. An application form encompasses all the key information essential for the product registration, life-cycle initiation and management.However, in addition to essential information required for administration of product registration and life cycle management, application form contains technical and legal information which is also part of the dossier sections. This duplication of information and redundancy indicates the need for the optimization of the contents of application form. Vaccination is part of global healthcare drivefor many leading institutions and organizations. The uniform harmonized application form will help to achieve operational efficiency in product registration and compliance.

An application form essentially covers three (3) partscontaining Information about the applicant and the legal representative in the country, Information about the product and Regulatory status respectively. In the present concept paper, the application forms of various countries were compared and standardized model application form has been developed. An attempt has been made to build a standard template for a harmonised application form which covers all the administrative and regulatory aspects of finished product which will enable applicants/MAHs to avoid redundant information to be filled and also facilitate faster more accurate review for the respective NRAs.

Content

A harmonised application form consists of three main headings

1) Information about the applicant and the legal representative in the country,
2) Information about the product and
3) Regulatory status

The said application form is presented here along with brief description of every sub-heading which will enable the end-user to fill in the correct details.

1. **Information about the applicant and the legal representative in the country**

1.1. Name of pharmaceutical company:

This presents the name of the pharmaceutical entity which is concerned with the finished product registration.

1.2. Name and Address of manufacturer of drug substance(s):

This presents the name and address of the manufacturer(s) of the drug substance(s) used in the manufacturing of the finished product.

1.3. Name and Address of manufacturer of the finished product:

This presents the name and address of the manufacturer(s) of the finished product.

1.4. Name and Address of applicant/legal representative/marketing authorization holder:

This presents the name and address of the MAHof the finished product. This may be a pharmaceutical company, a legal representative of any local consultation firm, any authorized and designated person thereof OR any person authorized to place the product on the market.

1.5. Name and address of other manufacturer(s) involved in the manufacturingprocess:

This presents the name and address of all the manufacturer(s) which are involved in a part of the manufacturing process of finished product

1.6. Contact person for Quality and Pharmacovigilance:

This presents the name and address of the authorized representative(s) on behalf of the applicant/MAH. Contact person for quality is responsible for the overall quality of the finished product intended for marketing and contact person for Pharmacovigilance is responsible for the overall health and safety of the intended patient population and also responsible for any returns and recalls related finished products due to safety concerns.

1.7. Person/company authorized for communication between the MAH and NRA & Official(s) responsible for batch testing and batch release of finished product:

This presents the name and address of the authorized representative(s) on behalf of the applicant/MAH. Any communication regarding the intended products/applications should be forwarded from NRAs only to the person/company authorized for communication between the MAH and NRA. For all the product batches destined to be marketed in the proposed NRAs wherein the requirement of batch release exists should have a provision of a designatedperson/company responsible for the releasing of the batches of finished product.

2. Information about the product

2.1. Name of the medicinal product including non-proprietary name or common name of vaccine:

This presents the non-proprietary/generic/invented name of the finished product or common name of thevaccine for which the registration application is applied.

2.2. Pharmaceutical form:

This presents the dosage form in which finished product is intended to be marketed for use.

2.3. Physical description of pharmaceutical form:

This presents complete physical appearance throughout shelf life of the finished product being applied for the registration.

2.4. Commercial presentation(s):

This presents the amount/quantity of unit dose of finished product per pack intended to be marketed.

2.5. Indication(s):

This presents the therapeutic indication(s) for which the finished product is intended to be approved for.

2.6. List of excipients, product shelf-life, storage condition, packaging configuration(s):

This represents the list of excipients used in the manufacturing of finished product, proposedproduct shelf-life and/or in-use shelf-life of product; storage condition during shelf-life and primary packaging of the finished product intended for the marketing.

2.7. Dosage and Administration:

This presents the posology of the finished productand method of administration.

2.8. Qualitative and Quantitative Composition:

This presents full details of drug substance(s) and excipients. Quantity of drug substance(s) and excipients should be expressed per dosage unit/per unit volume/per unit of weight, as per internationally recognized standard terms.

2.9. Name of drug substance(s):

This presents name of drug substance(s) present in finished product.

3. Regulatory status

3.1. Date and number of registration in origin country:

This presents the date of first authorization in country of origin and registration number assigned to that approval as per the prevalent regulations of NRA(s).

3.2. List of countries in which finished product is registered:

This presents the list of countries where the intended finished product is registered.

3.3. List of countries where the product is marketed:

This presents thelist of countries where the intended finished product is marketed.

3.4. Did you apply for scientific advice before submission:

Any scientific advice sought before submission from the respective NRA(s) should be outlined here.

3.5. Type of application:

This presents the type of application to be registered as per the regulatory guideline(s) of the respective NRA(s).

3.6. Annexed documents:

This presents any additional information provided as separate documents.

Abbreviations:

MAH : Marketing Authorization Holder

NRA : National Regulatory Authority