Controlled Copy

Directorate General of Drug Administration (DGDA)
Mohakhali Dhaka.
(www.dgdagov.info)

Document No.:
Date of Approval
Effective Date:
Date of Revision:

Guide Line for Medical Information on Packaging Material

Prepared by (Name & designation)	Approved by (Name & Designation)	Authorized by (Name & Designation)
1. Md. Salahuddin Deputy Director 2. Md. Aziulla Asst. Director 3. Dr. Fahim Nowsheen Medical Officer	Mohammad Mozammel Hossain Deputy Director Date:	Major General Md Mahbubur Rahman Director General Directorate General of Drug Administration Date:

Guideline for Medical Information on Packaging Materials:

Contents-

10. Pharmacological properties
    - 10-1- Pharmacodynamics properties
    - 10-2 Pharmacokinetic properties
    - 10-3- Pre-clinical safety data
11. Pharmaceutical particulars
    - 11-1- List of excipients
    - 11 2- Incompatibilities
    - 11-3- Shelf life
    - 11-4- Special precaution for storage
    - 11-5- Nature & contents of container
    - 11-6- Special precaution for disposal of a used medicinal product or waste materials derived from such medical product.
12. Marketing Authorization Holder (Registration)
13. Marketing Authorization Numbers
14. Date of first authorization/Renewal of the Authorization
15. Date of Revision of the text.
16. Dosimeter (Exclusive for Radio pharmaceuticals)
17. Instruction for preparation of Radio pharmaceuticals (lf applicable)
18. Distribution of information Packaging material
    1. Primary Packaging
    2. Secondary Packaging
    3. Tertiary Packaging
19. Annexure-1: Summary Product Characteristics (SmPC)

MM

Draft Guideline for Product Information on packaging materials:

Introduction:

The name of manufacturer on label of product with its full address including dose and indication is very important and useful for the patient/users. The name of active ingredient or composition, batch no, manufacturing and date of expiry is very essential for users of all labels. Considering this matter Directorate General of Drug Administration take initiative to prepare a draft Guide Line on for medical information on packaging material. Approved packing material carrying the Indication of Marketing authorization that make the consumers to use medicine confidently. It is not only technical information but also country's legal requirements.

(A) Reference used for preparing of Product I information on Packaging Material
(UK MHRA)

(B) Legal basis for Product Information on Packaging Material
The Drug Rules, 1945

- Section 44-52
- Section 94-106
- Schedule F(A) 6 for labeling of Bacterial Vaccine
- Schedule F(R) 6, Vaccine
- Schedule F(C) 7, Vaccine
- Schedule F(E) 2, Tetanus Toxin
- Schedule F(F) 5, Tetanus Toxin
- Schedule F(B) 2, Diphtheria Prophylactic
- Schedule F(O) 2, Staphylococcus Toxoid
- Schedule F (Part IV) (A) 3, Particular Sera and Toxin
- Schedule F (Part IV) (R) 6, Anti Dysentery Serum
- Schedule F (C) 7, Diphtheria Antitoxin
- Schedule F (D) 7, Tetanus Anti Toxin
- Schedule F (F) 6, Gas Gangrene Antitoxin
- Schedule F (I) I, J and K, Anti Pneumococcal Serum
- Schedule F (L) 5, Anti venom Serum
- Schedule F (D) VI 8, Insulin and VII 7 Insulin
- Schedule F (Part X) 4(f) Surgical ligature and Suture
- Schedule F (Part XI) D 2 Preparation or drug Containing Vitamin

The Drug Rules 1946 Part VI Section 55-65 and Part VII 68

- Schedule E-6-Bacterial Vaccine
- Schedule F: (D)-7- Anti Rabbis Vaccine
- Schedule F: (E) 2 Tetanus Toxoid
- Schedule F. (D) 2 Tubercle Vaccine
- Schedule F: Part IV (A) Sera and Anti Toxin
- Schedule F: Part VI-8, Insulin
- Schedule E Part VIII 05 Surgical Ligature and Suture
- Schedule F: Part X (B) Fish Liver oil
- Schedule E Part X (D) vitamin

2. Packaging and labeling

Packaging is the science, art and technology of enclosing or protecting products for distribution, storage, sale, and use. Packaging also refers to the process of design, evaluation and production of packages. Packaging can be described as a coordinated system of preparing products for transport, warehousing,

logistics, sale, and end use. Packaging contains, protects, preserves, transports, informs, and sells, Package labeling or labeling is any written, electronic, or graphic communications on the packaging or on a separate but associated label.

3. The purposes of packaging and package labels

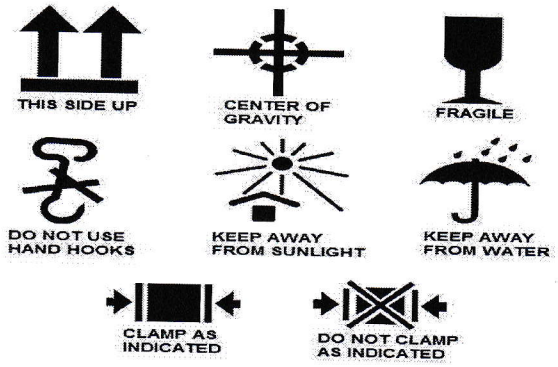
Packaging and package labeling have several objective [7]

- **Physical protection** - The objects enclosed in the package may require protection from. among other things,
mechanical shock, vibration, electrostatic discharge,
compression, temperature, [8] etc.
- **Barrier protection** - A barrier from oxygen, water vapor, dust, etc., is often required. Permeation is a critical factor in design. Some packages contain desiccants or Oxygen absorbers to help extend shelf life.
- **Information transmission** - Packages and labels communicate how to use, transport, recycle, or dispose of the package or product.
- **Marketing** - The packaging and labels can be used by marketers to encourage potential buyers to purchase the product. Package graphic design and physical design have been important. Marketing communications and graphic design are applied to the surface of the package and (in many cases) the point of sale display.
- **Security**-Packaging can play an important role in reducing the security risks of shipment. Packages can be made with improved tamper resistance to deter tampering and also can have tamper-evident [11] features to help indicate tampering.
- **Anti-counterfeiting Packaging** - Packages can be engineered to help reduce the risks of package pilferage or the theft and resale of products: Some package constructions are more resistant to pilferage and some have pilfer indicating seals. Counterfeit consumer goods, unauthorized sales (diversion), material substitution and tampering can all be prevented with these anti-counterfeiting technologies. Packages may include authentication seals and use security printing to help indicate that the package and contents are not counterfeit. Packages also can include anti-theft devices, such as dye-packs, RFID tags (Radio frequency identification), or electronic article surveillance [12] can be activated or detected by devices at exit points and require specialized tools to deactivate. Using packaging in this way is a means of loss prevention.
- **Convenience** - Packages can have features that add convenience in distribution, handling, stacking, display, sale, opening, reclosing, use, dispensing, reuse, recycling, and ease of disposal.

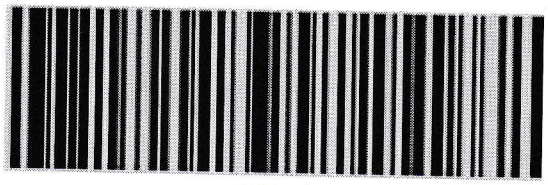
4. Packaging types

- Primary packaging is the material that first envelops the product and holds it. This usually is the smallest unit of distribution or use and is the package which is in direct contact with the contents.
- Secondary packaging is outside the primary packaging, perhaps used to group primary packages together.
- Tertiary packaging is used for bulk handling, warehouse storage and transport shipping. The most common form is a palletized unit load that packs tightly into containers.

5. a. Symbols used on packages and labels



"Print & Apply" corner wrap UCC (GS1-128) label application to a pallet load



Wikipedia

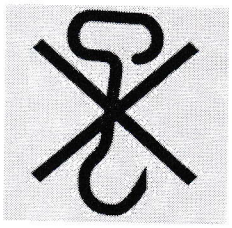
A bar code encoding the word "Wikipedia" in Code 128

Shipping container labeling

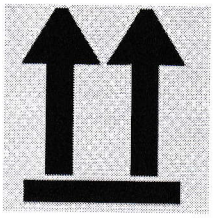
Technologies related to shipping containers are identification codes, bar codes, and electronic data interchange (EDI). These three core technologies serve to enable the business functions in the process of shipping containers throughout the distribution channel. Each has an essential function: identification codes either relate product information or serve as keys to other data, bar codes allow for the automated input of identification codes and other data, and EDI moves data between trading partners within the distribution channel.

Shipments of hazardous materials or dangerous goods have special information and symbols (labels, placards, etc.). Two examples are below:

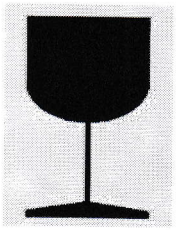
With transport packages, standardized symbols are also used to communicate handling needs. Examples are below:



Do not use hand hooks

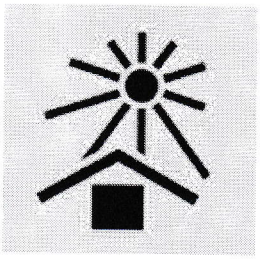


This way up:

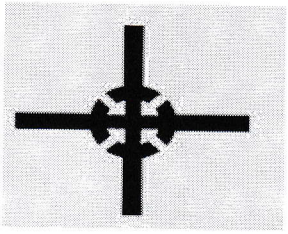


Fragile material

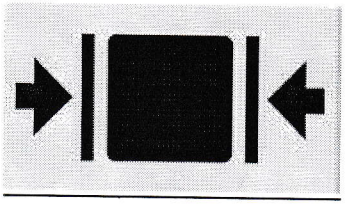
Keep away from water



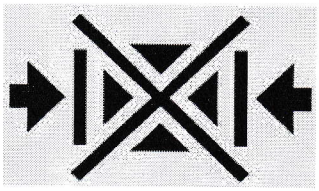
Keep away from sunlight



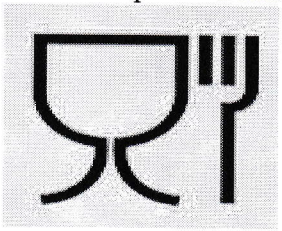
Centre of gravity



Clamp as indicated



Do not clamp as indicated



Food contact material

Attention for this material

5.b. User of picture/organ picture in Packages and Labels

DGDA has authority to approve or disapprove use of human body or it's any orgán which could facilate the correct use or misuse of medicine upon through evaluation of picture.

6. Summary of product characteristics

6.1. NAME OF THE MEDICINAL PRODUCT

The name should be followed by both the strength and the pharmaceutical form. The International Non-proprietary Name (INN) or the usual common name of the active substance should be used when referring to properties of the active substance(s) rather than those of the product. The use of pronouns (e.g. "it") is encouraged whenever possible.

6.1.1 Strength

The strength should be the relevant quantity for identification and use of the product and should be consistent with the quantity stated in the quantitative composition and in the posology. Different strengths of the same medicinal product should be stated in the same way, e.g. 250 mg, 500 mg, 750 mg. The use of decimal points should be avoided where these can be easily removed (e.g. 250 microgram, not 0.25 mg). However, where a range of medicinal products of the same pharmaceutical form includes strengths of more than one unit (e.g. 250 microgram, I mg and 6 mg), it may be more appropriate in certain cases to state the strengths in the same unit for the purpose of comparability (e.g. 0.25 mg, 1 mg and 6 mg). For safety reasons, micrograms and millions (e.g. for-units) should always be spelled out in full rather than be abbreviated.

6.1.2 Pharmaceutical form (Dosage form)

The pharmaceutical form of a medicinal product should be described by a single full Standard Term of the Pharmacopoeia using the plural form if appropriate (e.g. tablets).

7. QUALITATIVEAND QUANTITATIVE COMPOSITION

Full details of the qualitative and quantitative composition in terms of the active substance(s) and excipients.
If diluent is part of the medicinal product, information should be included.

7.1. Qualitative declaration

The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant, or the Pharmacopoeial name. If no INN exists, the Pharmacopoeia name should be used or if the substance is not in the pharmacopoeia, the usual common name should be used. In the absence of a common name, the exact scientific designation should be given. Substances not having an exact scientific designation should be described by a statement on how and from what they were prepared. References to the pharmacopoeial quality should not be included.
When the medicinal product is a radiopharmaceutical kit, the qualitative declaration should clearly indicate that the radioisotope is not part of the kit.

7.2. Quantitative declaration

The quantity of the active substance should be expressed per dosage unit (for metered dose inhalation products, per delivered dose and/or per metered dose), per unit volume, or per unit of weight and should be related to the declaration of strength.
Quantity should be expressed in internationally recognized standard term which could be complemented with another term if more meaningful to healthcare professionals.

7.3. Salts and hydrates

Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the mass (or biological activity in International (or other) units where appropriate) of the active moiety (base, acid or anhydrous material), e.g. '60 mg toremifene (as citrate) or toremifene citrate equivalent to 60 ing foremifene".
Where a salt is formed in situ during the preparation of the finished product (i.e. formed during the mixture of a solvent and powder), the quantity of the active moiety should be stated, with a reference to the in situ formation of the salt.
In the case of established active substances in medicinal products where the strength has traditionally been expressed in the form of a salt or hydrate, the quantitative composition may be declared in terms of the salt or hydrate, e.g. '60 mg diltiazem hydrochloride'. This may also apply when the salt is formed *in situ.*

7.4. Esters and pro-drugs

If the active substance is an ester or pro-drug, the quantitative composition should be stated in terms of the quantity of the ester or pro-drug. When the active moiety is an active substance of an already approved medicinal product, the quantitative composition should also be stated in terms of the quantity of this active moiety (e.g. 75 mg of fosphenytoin is equivalent to 50 mg of phenytoin).

7.5. Oral powders for solution or suspension

The quantity of active substance should be stated per unit dose if the product is a single-dose preparation or otherwise per unit dose volume after reconstitution; a reference to the molar concentration may also be appropriate in some cases.

7.6. Parenterals excluding powders for reconstitution

For single-dose parenterals, where the total contents of the container are given in a single dose (total use), the quantity of active substance(s) should be stated per presentation (e.g. 20 mg etc.) not including any overages or overfill. The quantity per ml and the total labelled volume should also be given.

For multi-dose and large volume parenterals, the quantity of active substance(s) should be stated per ml. per 1000 mil, per 1000 ml, etc. as appropriate, except for multidose vaccines containing 'n' doses of the same dose. In this case, the strength should be ex pressed per dose volume. Overages or overfills should 1iot be included.

7.7. Powders for reconstitution prior to parenteral administration

When the product is a powder to be reconstituted prior to administration, the total quantity of active *substance in the container should be stated not including* overages or overfills, as well as the quantity per ml when reconstituted, unless there are several means of reconstituting, or different quantities used, which result in different final concentrations.

7.8. Concentrates

The quantity should be stated as the content per ml in the concentrate and as the total content of the active substance. The content per ml when diluted as recommended should also be included unless the concentrate is to be diluted to within a range of different final concentrations.

7.9. Transdermal patches

The following quantitative details should be given: the content of active substance(s) per patch, the mean dose delivered per unit time, and the area of the releasing surface, e.g. Each patch contains 750 micrograms of estradiol in a patch size of 10 cm^2, releasing a nominal 25 micrograms of estradiol per 24 hours.

7.10. Multidose solid or semi-solid products

Quantity of active substance should be stated, where possible, per unit dose, otherwise per gram, per 100 g or percentage, as appropriate.

7.11 Biological Medicinal

Products

7.11.1 Expression of strength.

The quantity of biological medicinal products should be expressed in terms of mass units, units of biological activity, or International Units as appropriate for the particular product, and reflecting *Pharmacopoela* usage where relevant.

7.11.2 The biological origin of the active substance.

The origin of the active substance should be defined briefly. Thus, the nature of any cellular system(s) used for production and, if relevant, the use of recombinant DNA technology should be specified. The entry should take the form: "produced in XXX cells <by recombinant DNA technology>". The following are examples of the application of this principle:

*produced in human diploid (MRC-5) cells",

"produced in Escherichia coli cells by recombinant DNA technology",

"produced in chick-embryo cells",

"produced from the plasma of human donors",

"produced from human urine",

"produced from <animal>blood",

"produced from porcine pancreatic tissue",

"produced from porcine intestinal mucosa".

7.11.3 Special provisions for normal immunoglobulins.

In the case of normal immunoglobulins, the IgG subclass distribution should be stated in terms of percent of total IgG present. The upper limit of the IgA content should follow.

7.11.4 Special provisions for vaccines.

In the case of vaccines, the content of active substance per dose unit (e.g. per 0.5 ml) should be stated. Adjuvants, if present, should be stated qualitatively and quantitatively.
Residues that are of special relevance (e.g. ovalbumin in egg derived vaccines) should be specified.

A guideline need to be prepared on biotechnological medicinal products on the Pharmaceutical Aspects of the Product Information for Human Vaccines. (Need translation to Bangla).

8. PHARMACEUTICAL FORM

The pharmaceutical form should be described by a full standard term of the official Pharmacopoeia using the singular form. For example, a visual description of the appearance of the product (colour, markings, etc.) should be given, in a separate paragraph to the standard term. including information on the actual size of a solid oral formulation, e.g.

Tablet, White, circular flat hevelled-edge tablets of 5 mm marked '100' on one side.

In case of tablets designed with a score line, information should be given on whether or not reproducible dividing of the tablets has been shown. e.g. the scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses', 'the tablet can be divided into equal halves".
Information on pH and osmolarity should be provided, as appropriate,
In case of products to be reconstituted before use, the appearance before reconstitution should be stated. Appearance of the product after reconstitution should be stated.

9. CLINICAL PARTICULARS

9.1 Therapeutic indications (Reference must be followed from authorized reference)

The indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indication. When appropriate it should define the target population especially when restrictions to the patient populations apply.

It should be stated in which age groups the product is indicated, specifying the age limits, c.g. X is indicated in *<adults><neonates><infants><children> <adolescents> <aged x to y <years, months>>*.

If the product's indication depends on a particular genotype or the expression of a gene or a particular phenotype, this should be stated in the indication.

9.2 Posology and method of administration

In case of restricted medical prescription, this section should be started by specifying the conditions. In case of specific safety need, any recommended restriction to a particular setting should also be stated *(e.g. "restricted to hospital use only" or "appropriate resuscitation equipment should be available").*

Posology

The dosage should be clearly specified for each method/route of administration and for each indication, as appropriate.
Where appropriate, a reference to official recommendations should be made (e.g. for primary vaccination and antibiotics as well as for booster dose).

Dose recommendations (c.g. mg, mg/kg. mg/m') should be specified per dose interval for each category where appropriate (specify age/weight/body surface area of subsets of the population as appropriate), Frequency of dosing should be expressed using time units (eg. once or twice daily or every 6 hour) and, to avoid confusion, abbreviations e.g. OD or BID should not be used.

Where appropriate, the following points should be addressed:

- the maximum recommended single, daily and/or total dose,
- the need for dose titration,
- the normal duration of use and any restrictions on duration and, if relevant, the need for tapering off, or advice on discontinuation,
- advice on action to be taken if one or more dose(s) is (are) missed, or e.g. in case of vomiting (the advice should be as specific as possible, taking into considerstion the recommended frequency of dosing and relevant pharmacokinetic data)
- advice on preventive measures to avoid certain adverse drug reactions. e.g. administration of antiemetics.
- the intake of the product in relation to drink and food intake.
- advice regarding repeat use, with any information on intervals to be observed between courses of treatment, as appropriate,
- interactions requiring specific dose adjustment.

Where relevant to the particular product, the following should appear The potency of this medicinal product is expressed in <invented name> units. These units are not interchangeable with the units used to express the potency of other active substance name preparations.

9.3 Special populations

Dosage adjustments or other posology related information in specific patient groups should be stated where necessary, in well-defined sub-sections ordered by importance, e.g. regarding:

- elderly population; it should be made clear whether or not any dosage adjustment is necessary in any subsets of the elderly population.

- renal impairment; the dose recommendation should relate as precisely as possible to the cut-off values for biochemical markers of renal Impairment in clinical studies and to the results of these studies;
- hepatic impairment, specified according to the patients included in studies, for instance 'alcohol-related cirrhosis' and the definitions used in the studies, for instance Child-Pugh score/grade of the patients;
- patients with a particular genotype. other relevant special population (e.g. patients with other concomitant disease or overweight patients).

9.4 Paediatric population

The specific 'paediatric population should always be included and the information given should cover all subsets of the paediatric population, using a combination of the possible situations presented below as appropriate.

If the product is indicated in the paediatric population, posology recommendations should be given for each of the relevant subsets. The age limits should reflect the benefit-risk assessment of the available documentation for each subset.

If the posology is the same in adults and children, then a statement to this effect is sufficient; the posology does not need to be repeated.

Dose recommendations (e.g. mg, mg/kg. mg/m2) should be specified per dose interval for the paediatric subsets where the product is indicated. Different subsets may require different dosing information. If necessary, recommendations in preterm newborns should be presented taking into account the more appropriate age e.g. gestational age or the post-menstrual age.

Depending on the subset, the clinical data and available formulations, the dose will be expressed according to weight or body surface area, e.g. *"children aged 2-4 years, I mg/kg bodyweight twice u day".*

When appropriate, information on timing of intake of the product should consider children's daily life. c.g. school or sleep.

Where a product is indicated in children and no adequate paediatric formulation can be developed. detailed instructions on how to obtain an extemporaneous preparation shall be included.

Doses and method of administration in the various subsets may be presented in a tabulated format.

If there is no indication for the product in some or all subsets of the paediatric population, no posology recommendation can be made, but available information should be summarised using the following standard statements (one or combination of several as appropriate):

- The <safety> <and> <efficacy of X in children aged x to y <months, years> <or any other relevant subsets e.g. weight, pubertal age, gender> <has><have not <yel> been established. One of the following statements should be added:
  - <No data are available>.
- X should not be used in children aged x to y <years, months><or any other relevant subsets e.g. weight, pubertal age, gender> because of <safety> <efficacy> concern(<concern(s) to be stated.
- There is no relevant use of X in <the paediatric population><in children aged x to y><years, months>><or any other relevant subsets eg weight, pubertal age, gender in the indication(s) <specify indication(s)>.
- X is contraindicated in children aged x to y <years, months> <or any other relevant subsets eg. weight, pubertal age, gender> <in the indication ...>.

If there are more appropriate strength(s) and/or pharmaceutical form(s) for administration in some or all subsets of the paediatric population (e.g. oral solution for infants).

E.g. Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

9.5 Method of administration

Any special precautions related to the manipulation or administration of the product (e.g. cytotoxic products) by healthcare professionals (including pregnant healthcare professionals), the patient or carers should be mentioned.

The route of administration and concise relevant instruction for correct administration and use should be given.

6.6 'Special precautions for disposal of a used medicinal product and other handling of the product'.

When supportive data are available, information on alternative method(s) to facilitate administration or acceptability should be given as explicitly as possible (e.g. possibility of crushing tablet, cutting tablet or transdermal patch, pulverising tablet, opening capsules, mixing with food, dissolution in 1 drinks - specifying if a proportion of the dose can be given) particularly for administration via feeding tubes.

Any specific recommendation for use related to the pharmaceutical form should be explained,e.g.:

-"the coated tablet should not be chewed because of <bad taste>,

-the enteric-coated tablet should not be crushed because coating prevents <pH sensitive degradation><irritant effects on the gut",

-"the coated tablet should not be broken because the coating is intended to ensure a prolonged release".

For parenteral formulations, information on the rate or speed of injection or infusion should be provided.

For parenteral formulations in children, especially newborns in whom quite often fluids have to be restricted it would be useful to have information on maximal concentration that can be safely administered *(e.g. "no more than X mg of Y/ml of solution").*

9.6 Contraindications

Situations where the medicinal product must not be given for safety reasons. Such circumstances could include a particular clinical diagnosis, concomitant diseases, demographic factors (eg. gender, age) or predispositions (e.g. metabolic or immunological factors, a particular genotype and prior adverse reactions to the medicine or class of medicines). The situations should be unambiguously. comprehensively and clearly outlined.
Other medicines or classes of medicine, which must not be used concomitantly or consecutively should be stated, based on either data or strong theoretical reasons. If applicable a reference should be made.
Only if pregnancy or breastfeeding is contraindicated, should it be mentioned here.

Hypersensitivity to the active substance or to any of the excipients or residues from the manufacturing process should be included, as well as any contraindication arising from the presence of certain excipients.

9.7 Special warnings and precautions for use

The order of warnings and precautions should in principle be determined by the importance of the safety information provided.

The following should be described:

- The conditions, in which the use of the medicinal product could be acceptable, provided that special conditions for use are fulfilled. In particular, specific risk minimisation measures requested as part of a Risk Management Plan to ensure safe and effective use should be described in this section. *(For example, "Liver function should be monitored before initiation of treatment and monthly thereafter, "Patients should be advised to immediately report any symptoms of depression and/or suicidal ideation, "Women of childbearing potential should use contraception'...)*
- Special patient groups that are at increased risk or are the only groups at risk of experiencing product or product class-related adverse reactions (usually serious or common), e.g. elderly, children, patients with renal or hepatic impairment (including the degree of impairment, e.g. mild, moderate or severe), patients having an anaesthesic or patients with cardiac failure.
- Serious adverse reactions to which healthcare professionals need to be alerted, the situations in which these may occur and the action that may be required, e.g. emergency resuscitation.
- If there are particular risks associated with starting the medicinal product (e.g. first dose effects) or stopping it (e.g. rebound, withdrawal effects), these should be mentioned in this section, together with the action required for prevention.
- Any measures which can be taken to identify patients at risk and prevent the occurrence, or detect early the onset or worsening of noxious conditions. If there is a need for awareness of symptori1s or signs representing early warning of a serious adverse reaction, a staten1ent should be included.
- Any need for specific clinical or laboratory monitoring should be stated. Recon1mendatio;1 for monitoring should address why, when and how the 1nonitoring should be conducted in clinical practice. If dose reduction or other posology is recommended in such circumstances or conditions, this should be included.
- Any warnings necessary for excipients or residues from the manufactu1ring process.
- Any warnings 11ecessary with respect to transmissible agents (e.g. Warning of Transmissible Agents in product character and Package Leaflets for Plasma-Derived Medicinal Products
- Subjects or patients with a specific genotype or phenotype might either not respond to the treatment or be at risk of a pronounced pharmacodynamic effect or adverse reaction. These may arise because or non-functioning enzyme alleles, alternative metabolic pathways (governed byspecific alleles), or transporter deficiencies. Such situations should be clearly described if known.
- Any particular risk associated with an incorrect route of administration (e.g. necrosis risk with extravasatio1i of intravenous formulation, or neurological consequences of intravenous use instead of intramuscular use), should be presented, with advice on management if possible.

Important safety information may be included in bold type within a box.

In general, descriptions of warnings and precautions regarding pregnancy and breast feeding, ability to drive and use machines, and other aspects of interactions should be dealt. However, in specific case of major clinical importance it might be more appropriated describe specific precautionary nieasi1res e.g. contraception measure; or when concomitant use of another medicine is not recommended.

9.8 Interaction with other medicinal products and other forms of interaction

This section should provide information on the potential for clinically relevant interactions based on the pharmacodynamic properties and in vivo pharmacokinetic studies of the medicinal product, with a particular emphasis on the interactions, which result in a recommendation regarding the use of this medicinal product. This includes in vivo interaction results which are important for extrapolating an effect on a marker ('probe') substance to other medicinal products having the same pharmacokinetic property as the marker.
Interactions affecting the use of this medicinal product should be given first, followed by those interactions resulting in clinically relevant changes on the use of others.
The following information should be given for each clinically relevant interaction:

a. Recommendations: these might be
   - contraindications of concomitant use
   - concomitant use not recommended
   - precautions including dose adjustment mentioning specific situations where these may be required.

b. Any clinical manifestations and effects on plasma levels and AUC (Area under curve) of parent compounds or active metabolites and/or on laboratory parameters.
Interactions not studied in vivo but predicted from in vitro studies or deducible from other situations or studies should be described if they result in a change in the use of the medicinal product.
If no interaction studies have been performed, this should be clearly stated.

Paediatric population
Information specific to a subset of the paediatric population should be given here if there is an indication for the particular age group.

The resulting exposure and clinical consequences of a pharmacokinetic interaction can differ between adults and children, or between older and younger children. Therefore,

- Any identified treatment recommendations should be given in relation to concomitant use in the paediatric subset(s) (e.g. dose adjustment, extra-monitoring of clinical effect marker/adverse reactions, therapeutic drug monitoring).
- If the interaction studies have been performed in adults, the statement Interaction studies have only been performed in adult' should be included.
- If the extent of an interaction is known to be similar in a paediatric age group to that in adults, this should be stated.
- If this is not known, this should also be stated.

The same applies to pharmacodynamic drug interactions.

In cases of food interaction leading to a recommendation on co-administration with a meal or specific food, it should be specified whether this is relevant for paediatric use (especially newborns and infants) whose diet is different (100 % milk in newborns).

9.9 Fertility, pregnancy and lactation

Pregnancy

In general, clinical and non-clinical data should be followed by recommendations.

With respect to non-clinical data,

- only conclusions of the reproductive toxicity studies should be included in this section. Further details should be provided.

With respect to clinical data,

- the section should include comprehensive information on relevant adverse events reported in the embryo, the fetus, neonates and pregnant women, when appropriate. The frequency of such events (for example the frequency of birth defects) should be specified when available.

- the section should specify the extent of the human experience if no adverse events have been reported in pregnancy.

With respect to the recommendations:

a) Recommendations on the use of the medicinal product during the different periods of gestation, including the reason(s) for these recommendations, should be given.

b) Recommendations for the management of exposure during pregnancy when appropriate (including relevant specific monitoring such as fetal ultrasound, specific biological or clinical surveillance of the fetus or the neonate) should be given.

Breastfeeding

If available, clinical data should be mentioned (exposed breastfed infants) as the conclusions of kinetic studies (plasma concentrations in breastfed infants, transfer of the active substance and/or its metabolite(s) into human milk...). Information on adverse reactions in nursing neonates should be included if available.

Conclusions from non-clinical studies on the transfer of the active substance and/or its metabolite(s) into milk should be given only if no human data are available.

Recommendations should be given to stop or continue breastfeeding and/or to stop or continue the treatment in cases where treatment or breastfeeding discontinuation is recommended, and the reason should be provided.

Fertility

The main information on the possible effects of the medicinal product on male and female fertility should be considered.

This section should include-

a) Clinical data if available.

b) Relevant conclusions from non-clinical toxicity studies, if available.

c) Recommendations for the use of the medicinal product when pregnancy is planned but fertility might be affected by treatment.

If there are no fertility data at all, then this should be clearly stated.

9.10 Effects on ability to drive and use machines

On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has a) no or negligible influence b) minor influence, c) moderate influence or d) major influence on these abilities. Other important factors that affect the ability to drive and use machines should be considered if known, e.g. duration of the impairing effect and the development of tolerance or adverse reactions with continued use.

9.11 Undesirable effects

This section should include all adverse reactions from clinical trials, post-authorisation safety studies and spontaneous reporting for which, after thorough assessment, a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility, based for example, on their comparative incidence in clinical trials, or on findings from epidemiological studies and/or on an evaluation of causality from individual case reports. Adverse events, without at least a suspected causal relationship. should not be listed.

In order to provide clear and readily accessible information, it should be structured according to the following recommendations.

a. Summary of the safety profile.
b. Tabulated summary of adverse reactions
c. Description of selected adverse reactions
d. < Paediatric population >
E<Other special population >

9.12 Overdose

Describe acute symptoms and signs and potential sequelae of different dose levels of the medicinal product based on all available information including accidental intake, mistakes and suicide attempts by patients.

Taking into account all relevant evidence, describe management of overdose in man, e.g. in relation to monitoring or use of specific agonists/antagonists, antidotes or methods to increase elimination

of the medicinal product such as dialysis. However, there should not be any dosage recommendation of other medicinal products (e.g. antidotes).

Additional information on special populations

Paediatric population

10. PHARMACOLOGICAL PROPER

It should be updated regularly when new in. the paediatric population.

10.1 Pharmacodynamic properties Describe:

Pharmacotherapeutic group and ATC code:

Inclusion of the therapeutic subgroup (2nd level of WHO classification) with the 3rd (pharmacological subgroup) or 4th (chemical subgroup) level is recommended.

If an ATC code is not yet available, this should be mentioned as not yet assigned".

In case of medicinal product authorised as similar biological medicinal product, the following statement will be included:

<< (Invented) Name> of biosimilar medicinal product. Detailed information is required.

- Mechanism of action (if known)
- Pharmacodynamic effects.
- Clinical efficacy and safety

10.2 Pharmacokinetic properties

Pharmacokinetic properties of the active substance(s) relevant for the advised dose, strength and the pharmaceutical formulation marketed should be given. If these are not available, results obtained with other administration routes, other pharmaceutical forms or doses can be given as alternative.

Basic primary pharmacokinetic parameters, for instance bioavailability, clearance and half-life, should be given as mean values with a measure of variability.

Pharmacokinetics items, which could be included when relevant, are given below.

a. General introduction, information about whether the medicinal product is a pro-drug or whether there are active metabolites, chirality, solubility, information on the population in which general pharmacokinetic data were obtained, etc.
b. General characteristics of the active substance(s) after administration of the medicinal product formulation to be marketed.
    - **Absorption**: complete or incomplete absorption; absolute and/or relative bioavailability; first pass effect; Tmax; the influence of food; in case of locally applied medicinal product the systemic bioavailability; involvement of transport proteins. If available, information on the site of absorption in the gastro-intestinal tract should be stated (as it may be l important for administration by enteral feeding tubes)

- **Distribution:** plasma protein binding: apparent volume of distribution per kilogram body weight (l/kg), tissue and/or plasma concentrations; pronounced multi-compartment behaviour, involvement of transport proteins.
- Biotransformation: degree of metabolism; which metabolites; activity of metabolites and contribution to effect and toxicity; enzymes involved in metabolism; site of metabolism; results from in vitro interaction studies that indicate whether the new compound can induce/inhibit metabolic enzymes.
- Elimination: elimination half-lives, total clearance; inter and/or intra-subject variability in total clearance; excretion routes of the unchanged substance and the metabolites including the relative portion of the hepatic and renal eliminated fraction, involvement of transport proteins.
- Linearity/non-linearity: linearity/non-linearity of the pharmacokinetics of the active substance with respect to dose and/or time; if the pharmacokinetics are nonlinear with respect to dose and/or time, the underlying reason for the non-linearity should be presented.

Additional relevant information should be included here.

c. Characteristics in specific groups of subjects or patients

- Variations with respect to factors such as age, weight, gender, smoking status. polymorphic metabolism and concomitant pathological situations such as renal failure, hepatic disease, including degree of impairment. If the influence on pharmacokinetics is considered to be clinically relevant, it should be described here in quantitative terms.

d. Pharmacokinetic/pharmacodynamic relationship(s)

- Relationship between dose/concentration/pharmacokinetic parameter and effect (either true endpoint, validated surrogate endpoint or side effect).
- The population studied should be described.

Paediatric population

Results of pharmacokinetic studies in the different paediatric age groups should be summarised, with a comparison to adults if available. If appropriate, the dose producing similar product exposure as in adults could be given. The pharmaceutical form(s) used for pharmacokinetic studies in children should be stated. Uncertainties due to limited experience should be stated.

10.3 Precinical safety data

Information should be given on any findings in the non-clinical testing which could be of relevance for the prescriber. in recognising the safety profile of the medicinal product used for the authorised indication(s), and which is not already included in other relevant sections.

If the results of the non-clinical studies do not add to the information needed by the prescriber, then the results (either positive or negative) need not be repeated.

11. PHARMACEUTICAL PARTICULARS

11.1 List of excipients

A list should be given of the excipients, expressed qualitatively only. All excipients, which are present in the product, should be included, even those present in small amounts, such as printing inks. Further details on the excipients to be declared may be found in the section on definitions and examples in the Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use. For transdermal patches, all ingredients of the patch (including the adhesive, release liner and backing film) should be mentioned.

The active substance itself, residues of substances used during manufacture of the finished product (for example, solvents, head-space gases or antibiotics in vaccine manufacture). lubricants for pre filled syringes and constituents of capsule shells for inhalation powders not intended to be taken should not be included.

However, certain residues such as residues of antibiotic or other antimicrobial agents used in production that are known allergens with a potential for inducing undesirable effects should be. mentioned in section 4.3 or 4.4 as appropriate.

Excipients should be referred to by their recommended INN if existing, accompanied by the salt or hydrate form if relevant or by their European Pharmacopoeia name. If an excipient has neither an INN nor European Pharmacopoeia name, it should be described by its usual common name. References to the pharmacopoeial quality should not be included. E numbers should be given along with the common name of the excipient where they exist and when necessary for proper use, e.g. when the excipient is listed in the Guideline on the excipients in the label and package leaflet of medicinal products for human use (as having recognised action or effect).

The ingredients in excipient mixtures should be listed individually. In cases where the full composition of a flavour or fragrance is not known to the applicant or is too complex, it may be declared in general terms (e.g. 'orange flavour", "citrus perfume). However, any of the components, which are known to have a recognised action or effect, should be included.

Ingredients that may or may not be added for the pH adjustment should be followed by the parenthesis (for pH-adjustment).

Invented names or general descriptive names such as 'printing ink should not be used in place of the common name of an ingredient or of a mixture of ingredients but may be used in conjunction with the name(s) of the ingredient(s), so long as it is clear which ingredients are described by the name.

Chemically modified excipients should be declared in such a way as to avoid confusion with the unmodified excipients, e.g. 'pregelatinised starch'.

In the case of a product containing a covert marker for the purpose of tracking, tracing and authentication, a general term such as authentication factor" should be included in the list of excipients instead of the name of the excipient, unless the excipient is one that is known to have a recognised action or effect.

For clarity, it is recommended that each excipient be listed on a separate line. It can be useful to list excipients according to the different parts of the product, e.g. tablet core/coat, capsule contents/shells, etc. For products that are presented in more than one container or in dual-chamber containers, the excipients should be listed per container or per chamber.

Abbreviations for excipients should not be used. However, where justified for space considerations. abbreviations for excipient names may appear on the labelling, on condition that these abbreviations are designated.

11.2 Incompatibilities

Information on physical and chemical incompatibilities of the medicinal product with other products with which it is likely to be mixed or co-administered should be stated. This is particularly important for medicinal products to be reconstituted and/or diluted before parenteral administration. Significant interaction problems, e.g. sorption of products or product components to syringes, large volume parenteral containers, tubing, in-line filters, administration sets, etc. should be stated.

Statements concerning compatibility of the product with other medicinal products or devices should not be included. Statements concerning pharmacological and chemical/physical incompatibilities with food should be included. If appropriate, the standard statement. "Not applicable', should be included.

For certain pharmaceutical forms, e.g. parenterals, either of the following standard statements should be included as appropriate:

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

11.3 Shelf life

The shelf life should be given for the medicinal product as packaged for sale and, if appropriate, after dilution or reconstitution or after first opening.

A clear statement of the shelf life should be given, in an appropriate unit of time.

For statements to be included regarding in-use shelf lives of sterile products, consult the Note for Guidance on maximum shelf life for sterile products for human use after first opening or following reconstitution. An in-use shelf life may need to be stated for other medicinal products if development studies have found it to be necessary.

Additionally, if different concentrations need to be prepared, e.g. for use in children, the physicochemical stability throughout the entire concentration range should be stated; e.g. "The stability has been demonstrated between x mg/ml and y mg/ml for t hours/days at 25 °C and 2-8 °C.

In case of a paediatric indication, if no age appropriate formulation is available for children but an extemporaneous formulation could be prepared from an existing formulation, relevant physicochemical data on storage and stability should be included here.

In case of specific temporary storage conditions need to be provided to healthcare professionals or patients, e.g. for the purpose of ambulatory use (e.g. shelf-life 24 months at 2-8°C of which 3 months could be below 25°C). specific additional guidance should be provided as appropriate. Such information should always be based on stability data. In particular, the recommended temperature range and maximum duration of temporary storage should be specified. This guidance may also include the action to be taken after the product has been stored under the temporary storage conditions (e.g. discard immediately).

Statements such as "These data are not recommendations for storage" should not be used.

No reference should be made to the container unless there are different shelf lives for different

containers. Storage conditions should not included, except for the storage conditions after opening (see corresponding guideline). Statements such as 'Do use after the expiry date should not be included.

When device supplied together with medicinal product, the in-use shelf-life of the device should be given applicable.

11.4 Special precautions storage

Storage warnings should use one or more of standard statements from the note for guidance on declaration of storage conditions in the product information of medicinal products. When such a standard statement is used, an explanation specifying whether the product is sensitive to light and/or moisture should be added.

*A guidance need to prepared declaration of storage conditions in the product information of medicinal product.

For storage of sterile products that have been opened, diluted or reconstituted, storage condition should be made.

If a specific storage warning is required, the warning should be made from the guidance to be prepared.

A warning to keep the product out of the reach and sight of children.

11.5 Nature and contents of container

Reference should be made to the immediate container using the European Pharmacopoeia standard term; the material of construction of the immediate container should be stated (glass vials. 'PVC/Aluminium blisters', 'HDPE bottles'); and any other component of the product should be listed. e.g. needles, swabs, measuring spoons, syringes inhaler devices, desiccant. The graduation on measuring devices should be explained. The container of any solvent provided with the medicinal product should also be described. Excessive detail, e.g., concerning the colour of the stopper, the nature of the heat-seal lacquer, should usually not be included. For parenteral preparations, when enclosure colour is used to differentiate between the presentations of a product, this should be stated here.

If appropriate, it should be indicated if the container closure is child-resistant.

Examples on the text in this section:

<Volume> ml suspension in a pre-filled syringe (glass) with plunger stopper (chlorobutyl rubber) with or without needle in pack sizes of 5 or 10.'

HDPE bottle with a child-resistant closure and a silica gel desiccant. Pack-sizes of 30, 60 or 90 film-coated tablets:

All pack sizes should be listed. Pack sizes mentioned should include the number of units, number of doses (for e.g. multi-dose vaccines, inhalers, etc.), total weight or volume of the immediate container, as appropriate, and the number of containers present in any outer carton. If appropriate, a standard statement, 'Not all pack sizes may be marketed, should be included, in order to alert health professionals to the fact that not all listed pack sizes may be available for prescribing or dispensing.

Multiple unit packs for distribution purposes only do not constitute new pack sizes for marketing of the product and should therefore not be included in this section.

11.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product[2]

Instructions for disposal should be included here, if appropriate for the product.

Where special precautions for the handling and disposal of certain products such as cytotoxics and some biological products or waste material derived from it are advised, e.g. in the case of products containing live organisms, these should be stated in this section, as should, where relevant, the disposal of items which come into contact with the product, such as nappies, or spoons used to administer oral vaccines.

If applicable, e.g. for cytotoxics, the following standard statement should be included, 'Any unused product or waste material should be disposed of in accordance with local requirements."

If there are no special use or handling instructions for the pharmacist or other healthcare professionals. the standard statement, 'No special requirements.' should be included.

Any directions necessary for the accurate preparation of certain products such as cytotoxics and some biological products and/or necessary for the protection of persons including parents or carers preparing or handling the product should be stated.

Instructions on handling of the product by the doctor, other health personnel, or patient should be included, as well as general information concerning the administration of the product (whether administered by the patient or the health personnel). If instructions for use/handling are needed where the medicinal product has to be prepared before use, e.g. where it must be suspended or diluted, this information has to be given here.

It is recommend that only information necessary for the pharmacist or other health personnel to prepare the product for administration to the patient should be included here.

Statements concerning compatibility of the product with other medicinal products or devices can be given here provided the data have been provided in the dossier.

In the exceptional cases where a product is indicated in children and where no adequate paediatric formulation can be developed (based on duly justified scientific grounds). information on extemporaneous formulation should appear under a sub-heading "Use in the paediatric population. Detailed instructions for the preparation of the extemporaneous formulation from the appropriate "adult" or other "older children" dosage form and additional information on extemporaneous formulations for use in younger children shall be provided and, where appropriate, the maximum storage time during which such preparation will conform to its specifications. When necessary, the required packaging material and storage conditions should be stated here.

Any specific warnings for the handling of the product should be mentioned.

Information on risks due to occupational exposure should be included in this section.

12. MARKETING AUTHORISATION HOLDER

Name and permanent address or registered place of business of the Marketing Authorisation Holder. Telephone, fax numbers or e-mail addresses may be included (not websites or emails linking to websites).

813. MARKETING AUTHORISATION NUMBER(S)

Item to be completed by the competent authority or by the Marketing Authorisation Holder once the Marketing Authorisation has been granted. For medicinal products for which the Directorate General of

Drug Administration is the Competent Authority to provide marketing authorization number (registration) as per guideline.

14 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

For medicinal products for which the Directorate General of Drug Administration is the Competent Authority to provide authorization/renewal of the authorization as per guideline.

15. DATE OF REVISION OF THE TEXT

Leave blank in case of a first Marketing Authorization.

For medicinal products for which the European Commission is the Competent Authority: date of approval of latest variation or transfer, e.g. the latest Commission Decision amending the SmPC, implementation date of the Urgent Safety Restriction or date of (EMEA) notification amending the annexes to the Marketing Authorisation.

For products for which Member States are the Competent Authorities: date of approval of latest variation or implementation date of the Urgent Safety Restriction resulting in a revision of the SmPC.

Item to be completed by the competent authority or by the Marketing Authorisation Holder at time of printing the SmPC.

16. DOSIMETRY (IF APPLICABLE)

Full details of internal radiation dosimetry should be included in this section for radiopharmaceuticals. For all other products, this section should be excluded.

17. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications.

Special instructions relating to the disposal of containers and unused contents should also be included

18. Distribution of product information on different tier of packaging material

18.1 Primary Packing
Information Bottle (Glass, Plastic) Ampoule (Glass, Plastic) Vial (Glass, Plastic), Strip, Blister and Sachet should contain the following information.

18.1.1 Brand Name: Generic name should be placed just below the brand name. The size of Generic name should be 1/2 of brand name.
18.1.2 Generic name with strength: The Pharmacopeial/Non-Pharmacopeial name of active ingredient should be placed.
18.1.3 Batch No.
18.1.4 Date of Manufacturing
18.1.5 Date of Expiry
18.1.6 Registration number of product 18.1.7 Manufacturing License number
18.1.8 Name and address of the manufacturer units with or without monogram
N.B: The date of use of contraceptive pill must be mentioned
18.2.1 In case of Ampoule and Vial.
The following information should be provided on ampoule and vial by ceramic printing

1. Brand Name
2. Generic name with strengths
3. Batch No. and Date of Expiry

In this case, the other information mentioned should be wrapped on ampoule/vial surface.

18.2.2 In the primary packaging of sterile product "Sterile and Pyrogen Free"; suitable for parenteral injection and in case of Insulin "It is to be used under medical supervision" must be printed.

On the primary packaging of IV-Fluid if the solution changes the color or precipitate the content it must be rejected

On the primary packaging of eye drops "Sterile and pyrogen free" must be printed and in case eye drops "Pyrogen free" should be printed.

18.3 Secondary Packing

18.3.1 Commercial Name: Generic name should be placed just below the commercial name and its font size should be of the commercial name.

18.3.2 Generic name
18.3.3 Pack size
18.3.4 Batch No.
18.3.5 Date of manufacturing
18.3.6 Date of expiry
18.3.7 Registration number
18.3.8 Name of manufacturer/Monogram with full address
18.3.9 Manufacturing License No.
18.3.10 Maximum retail price/Indicative price
18.3.11 Following information should be included in insert/inner leaflet
18.3.11.1 Introduction
18.3.11.2 Active ingredient
18.3.11.3 Pharmacodynamics and Pharmacokinetics
18.3.11.4 Therapeutic indication
18.3.11.5 Dosage and administration
18.3.11.6 Side effects
18.3.11.7 Adverse reaction
18.3.11.8 Contraindication
18.3.11.9 Precaution
18.3.11.10 Use in pregnancy and Lactation
18.3.11.11 Drug Interaction
18.3.11.12 Over dose and treatment
18.3.11.13 Storage
18.3.11.14 Pack Size
18.3.11.15 Name of Manufacturer and address

Administration procedure of Aerosol/Inhale, Eye drop, Infusion and relevant set should be described in detail. Figurative instruction could be given, if appropriate language could be Bengali and English for insert and leaflet

N.B: Information of 18.3.1 and 18.3.2- is in Bengali and in addition in English, other information could be in English or Bengali. In case of imported product, in addition, name of representative and its address, information on inner lifleaflet/insert should in Bengali in addition in English. Other that the unit container presentation, the pack size should mentioned on secondary.

- Only for Veterinary use should be placed on the secondary packing of product and if appropriate, withdrawal should be placed, 'Vet' should be in printed with the commercial name

- Storage condition of vaccine, Insulin. Sera, Antitoxin of all doses in a container and precaution must be printed.
- In case of combipack (Combiproduct) the name of active ingradients must be printed with registration number
- Only for external use should be printed in case lilimeat, lotion and liquid antiseptic.
- Narcotic, Psychotropic. Anesthetic (General and Local). Antineoplastic, Anti-infective and Drug must not be used by prescription, should be printed on Secondary packing
- 'Shake well before use' in all type of suspention.
- Directive of Drug control committee' and Licensing authority should be strictly followed in this regard.
- If the commercial name and packaging material is found similar with another, then only earlier approval commercial name and packaging will be material treated as valid.
- For getting the Marketing authorization registration/applicant must get final approval of submitted packaging material

19. Following information should be included in insert/inner leaflet
19.1. Introduction
19.2 Active ingredient
19.3 Pharmacodynamics and Pharmacokinetics
19.4 Therapeutic indication
19.5 Dosage and administration
19.6 Side effects
19.7 Adverse reaction
19.8 Contraindication
19.9 Precaution
19.10 Use in pregnancy and Lactation
19.11 Drug Interaction 19.12 Over dose and treatment
19.13 Storage
19.14 Pack Size
19.15 Name of Manufacturer and address

Administration procedure of Aerosol/Inhaler, Eye drop, Infusion and relevant set should be described in detail. Figurative instruction could be given if appropriate language could be Bengali and English for insert/leaflet 20. Information of Tertiary packing

- Commercial name
- Date of manufacturer and expiry
- Batch no.
- Precautions directives and appropriate symbols in case of shipment as per the directives in the guide lines

Annexure-1		
	FORM Title: Summary Product Characteristics (SmPC)	

1. **NAME OF THE MEDICINAL PRODUCT AND STRENGTH**
   1.1 {(Invented) name strength pharmaceutical form}

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**
   2.1 Excipient(s)
   2.2 A full list of excipients

3. **PHARMACEUTICAL FORM**
   3.1 The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.
   3.2 The tablet can be divided into equal halves.
   3.3 The tablet should not be divided.

4. **Clinical particulars**
   4.1 **Therapeutic indications:**
   {X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>

   4.2 **Posology and method of administration**

   4.2.1 **Posology**

   4.2.2 ***Paediatric population***

   4.2.2.1 <The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>

   4.2.2.2 <No data are available.> <Currently available data are described in Section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

   4.2.2.3 <{X} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

   4.2.2.4 <There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years>, <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...>

   4.2.2.5 <{X} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication> (see Section 4.3).

4.2.3 **Method of administration**

4.3 **Contraindications**

4.3.1 Hypersensitivity to the active substance(s) or to any of the excipients <or {name of the residue(s)}.

4.4 **Special warnings and precautions for use**

4.5 **Interaction with other medicinal products and other forms of interaction**

4.5.1 No interaction studies have been performed.

4.5.2 Interaction studies have only been performed in adults.

4.6 **Pregnancy and lactation**

4.6.1 Women of childbearing potential

4.6.2 Contraception in males and females

4.6.3 Pregnancy

4.6.4 Breastfeeding

4.6.5 Fertility

4.7 **Effects on ability to drive and use machines**

4.7.1 {Invented name} has <no <or negligible> influence> <minor influence>, <moderate influence> <major influence> on the ability to drive and use machines.

4.7.2 No studies on the effects on the ability to drive and use machines have been performed.

4.7.3 Not relevant.

4.8 **Undesirable effects**

4.9 **Overdose**

4.9.1 No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 **Pharmacodynamic properties**

5.1.1 Pharmacotherapeutic group

5.1.2 Mechanism of action

5.1.3 Pharmacodynamic effects

5.1.4 Clinical efficacy and safety

5.1.5 Paediatric population

5.2 **Pharmacokinetic properties**

5.3 **Preclinical safety data**

5.3.1 Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

5.3.2 Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

5.3.3 Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:

MY

6. **PHARMACEUTICAL PARTICULARS**
   - 6.1 **List of excipients**
   - 6.2 **Incompatibilities**
     - 6.2.1 Not applicable.
     - 6.2.2 In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.
     - 6.2.3 This medicinal product must not be mixed with other medicinal products.
   - 6.3 **Shelf life**
   - 6.4 **Special precautions for storage**
   - 6.5 **Nature and contents of container**
   - 6.6 **Special precuations for disposal and other handling**
7. **Marketing Authorization holder name and address**
8. **Drug Authorization number**
9. **Date of first authorization**
10. **Date of revision of the text**