Guidance to applicant for Administrative Requirements For Variation Submission

General Administrative Variation Requirements:

1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped.
2. Registration license (copy)
3. Variation Application form for each variation describing the variation submitted with cleared & detailed scope as in covering letter.
4. Approval on the variation from the Health authority in the country of origin (Legalized), or other relevant documents (CPP, ……). For imported products.
5. C.D containing all content of the dossier.
6. A declaration on applicant head letter that all data in the file is true, accurate and identical to the CD.
7. Payment receipt.

Requirements for Some Variations Not Mentioned in WHO Guidelines:

Imported Biological Products	Local Biological Products
Requirements for Insert update Either Smpc or PIL or IPI	
1. Original Legalized Declaration Letter from Market Authorization Holder or License Holder **attached with Proposed SMPC or PIL or IPI** State that "This insert version no… is most updated one and marketed in country of origin." 2. The Scientific data related to the scope of variation Submitted (if needed). 3. Most updated **PSUR** or **PBRER** (if needed). 4. **2** copies from proposed insert. 5. **1** copy from current approved insert. 6. Tracking between the proposed and current inserts.	1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped. 2. The Scientific data related to the scope of variation Submitted. 3. **2** copies from proposed insert. 4. **1** copy from current approved insert. 5. Tracking between the proposed and current inserts.
Requirements for pack update: • Design • colour • No. of units/pack**.**	
1. Original Legalized Declaration Letter from Market Authorization Holder or Licenses Holder attached with new pack State that "This pack is most updated one and marketed in country of origin." 2. **7** copies from colored art work of proposed pack (outer pack &inner Pack) 3. **1** copy from the current approved pack. *If there is no current approved pack the company will submit the marketed original pack.	1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped. 2. **7** copies from colored art work of proposed pack (outer pack &inner Pack) 3. **1** copy from the current approved pack. *If there is no current pproved pack the company will submit the marketed original pack.
Requirements for Market Authorization Holder / License Holder Change: • The variation Change In MAH / License Holder. • The variation either Change in Name or Address.	
1. Original Legalized CPP mentioned in it the new market authorization holder.	1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped by the registration general manager**.**
Requirements for Applicant Change:	
1. Original Legalized authorization letter mentioned	1. Original authorization letter mentioned the name and

the name and the duties of the proposed applicant. 2. Termination letter for the previous applicant. 3. Translation into Arabic for all submitted documents.	the duties of the proposed applicant. 2. Termination letter for the previous applicant. 3. Translation into Arabic for all submitted documents.
Requirements for Manufacturing Facility Change: • If the variation either Change in Name or Address	
1. Original Legalized CPP mentioned in it The Name and address of the proposed facility. 2. Copy Legalized of Valid GMP form Health authority for proposed facility. 3. Copy Legalized of valid Manufacturing license for proposed facility.	1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped by the registration general manager. 2. Manufacturing license for proposed facility.
Requirements for Product Name Change:	
1. Original Legalized CPP mentioned in it the New Product Name.	1. Covering letter with cleared & detailed scope on applicant head letter dated, signed, stamped by the registration general manager.
Requirements for Annual Strain	
1. WHO Recommendation 2. EMA Recommendation 3. Original Legalized Composition 4. 1 copy of current Insert 5. 7 copies of pack 6. Stability Studies for the previous approved strains 7. Original Signed Stability commitment Letter for the proposed strain. 8. Batch Analysis 9. All data support the update 10. Tracking insert 11. CD for PV and another one for variation.	

Time line for Issuing Notifications/ Approvals:

- **In case of Minor / Non – reportable Variations:**
  BRS issues assessment report within five working days, notification letters within 1 week from receiving a complete variation file.

- **In case of Administrative Changes/ Pack update & Insert Editorial Changes:**
  BRS issues assessment report within five working days, the final approvals/ disapprovals within 1 week from receiving a complete variation file.

- **In case of Moderate/ Major Variations/ Scientific & Safety Insert Update:**
  - BRS issues assessment report within five working days,
  - The expected time for evaluation varies from one week (in case of safety labelling update) to 8 weeks (in case of major quality variations),
  - The final approvals/ disapprovals are issued within 1 week from receiving the last reply from internal and/or external evaluation par