Guidance for Submission for registration request approval modification for Under-registration Human pharmaceutical product

Scope:

This guidance applies for any under- registration human pharmaceutical product.

Objective:

This guidance aims to provide companies with the documents required for registration request approval modification for under- registration Human pharmaceutical product.

Items	الأوراق المطلوبة	Original	Copy	Original to review
1- Covering letter signed and stamped showing that the company asking for approving registration request approval modification and showing the modification needed. (With the company's undertaking that the file submitted includes all approvals issued for the product to date)	١- خطاب من الشركة معتمد ومختوم موضحاً به طلب الشركة في الموافقة على تعديل موافقة طلب التسجيل مع ذكر التعديل المطلوب. (مع تعهد الشركة بأن الملف المقدم يشمل كافة الموافقات الصادرة للمستحضر حتى تاريخه)	√		
2- Registration request Approval	٢- موافقة طلب التسجيل		√	
3- Documents showing that the product is still valid: ▪ Scientific Committees approval or submission (for non-referenced products) ▪ Naming Approval or Submission ▪ Pricing Approval or Submission ▪ Pharmacovigilance Approval or Submission (if found) ▪ Any other documents….	٣- مايفيد أن المستحضر مازال سارياً في اجراءات التسجيل: ▪ موافقة اللجان العلمية المتخصصة او مايفيد التقدم في المهلة المحددة (للمستحضرات الغير مرجعية) ▪ موافقة الإسم التجاري للمستحضر أو مايفيد التقدم في المهلة المحددة ▪ موافقة التسعيرة للمستحضر أو مايفيد التقدم في المهلة المحددة ▪ موافقة اليقظة للمستحضر أو مايفيد التقدم في المهلة المحددة(ان وجد). ▪ أي مستندات أخرى....		√ √ √ √ √	
4- Approved scientific Reference for modification needed.(if found)	٤- المرجع العلمي المعتمد للتعديل المطلوب.(ان وجد)		√	
5- Receipt of 1000 L.E stamped from stamped from Financial department, General Administration of Drug Policy & Planning & Central Administration of Pharmaceutical Products written on it: (product name & purpose)	٥- ايصال قيمته ألف جنيهاً مختوم من الادارة المالية و مركز التخطيط و السياسات الدوائية و الادارة المركزية للمستحضرات الصيدلية ومدون عليه اسم المستحضروالغرض من السداد.		√	
6- Receipt of 5000 L.E stamped from stamped from Financial department, General Administration of Drug Policy & Planning & Central Administration of Pharmaceutical Products written on it: (product name & purpose) in case of changing License Holder.	٦- ايصال قيمته خمسة الاف جنيهاً مختوم من الادارة المالية و مركز التخطيط و السياسات الدوائية و الادارة المركزية للمستحضرات الصيدلية ومدون عليه اسم المستحضروالغرض من السداد في حالة تغيير الشركة المالكة للمستحضر.		√	

Items	الأوراق المطلوبة	Original	Copy	Original to review
(In case of imported or under-license products) (في حالة المستحضرات المستوردة او المصنعة محلياً بترخيص من شركة أجنبية)				
7- Valid & legalized new CPP with modification needed Or Valid Electronic Certificate of Pharmaceutical Product (eCPP) (*).	٧- شهادة CPP جديدة (سارية وموثقة) للمستحضر مذكور بها التعديل المطلوب أو شهادة الكترونية لتداول مستحضر صيدلي eCPP (سارية) للمستحضر.(*)		√	√
8- Valid GMP for the new manufacturing site (in case of changing manufacturer for imported products)	٨- شهادة GMP للمصنع الجديد في حالة تغيير المصنع للمستحضرات المستوردة		√	

Note:

In case of the required registration request approval modification is in dosage form:

- It will be accepted in case the modification is within the same row and same box (Attached Box Distribution table).
- Otherwise, the company must submit a new registration request inquiry as a line extension.

(*) In case of the required registration request approval is imported:

- The company is allowed to submit with Electronic Certificate of Pharmaceutical Product (eCPP) without the need of legalization only under the condition that the company submit a method to make sure the data in the submitted eCPP is correct.

١

جدول دمج الأشكال الصيدلية فى صندوق المثائل
وفقا لقرار اللجنة الفنية بجلستها فى ٢٠١٦/٠٣/١٣

1	**Box I**	Solid unit dosage form (traditional (Conventional) immediate release)	Tablets (Sugar - Film Coated)	Hard Gelatin capsules	Dragees (Tablet in French)	Caplets	Lactabs	Pilules (Pills / Capsule)	Spansules (Sugar coated Pills /Capsule)			
			Lozenges									
			Gums									
			Soft Gelatin capsules									
2	**Box II**	Solid Unit Dosage Form (Fast Immediate Release)	Quick Tablets	Flash Tablets (DISOLVE IN MOUTH only)	Oro-disintegrating	Melt tablets	Oro-Dispersible Tablets					
			Chewable Tablets									
			sublingual Tablets									
			Buccal Mucoadhesive Tablets (Buccal Mucoadhesive Tablets(prolonged only in mouth for local effect or systemic effect)									
			effervescent Tablets	Disintegrating Tablets	Dispersible Tablets							
			Effervescent Granules/Powders	Powder in Bottle (each dose will be reconstituted at time of use	Powder / Sachets							
3	**Box III**	Solid unit Dosage Form (Modified release)	SR, CR, MR, XR Capsules / Tablet	Depotabs	Retard Capsules / Tablet	Enteric Coated tablets						
			Modified Release Powder/Granules in Sachets	Modified Release Powder/Granules in Bottle (each dose will be reconstituted at time of use								
4	**Box IV**	Oral Preparation (Liquid-	Solutions	Syrup	Oral	Elixirs	Drinking	Powders /oral	Powders/ (Emulsion /	Emuls	Suspensio	Oral	Oral

		semisolid-Powder/ Granules for Reconstitution)		s	drops		ampoules	(Solution)	Susp.)	ion	n	Gels	Jellys
			Modified Release Oral Preparations										
5	**Box V**	Buccal Preparation	Oral Paste										
			Oromucosal Gels										
			Oromucosal Sprays										
			Gargles						Mouth washes				
6	**Box VI**	Sterile Preparation (injections)	Solutions					Suspensions			Emulsions		
			Irrigation Solutions (LVP)										
			Modified release Injections						oily injections				
7	**Box VII**	Implants											
8	**Box VIII**	Sterile Preparation (sterile Prefilled Injections)	Prefilled Syringes										
			Pen Filled Preparations										
			cartridges										
9	**Box IX**	Traditional topical Preparation	Topical Cream										
			Topical gels/Emulgel										
			Topical ointments										
			Topical solutions					Topical lotions (if solution)					
			Topical Emulsions					Topical lotions (if Emulsion)					
			Topical Pastes					Poultices (Cataplasm)					
			Topical Nail Preparation										
			Topical Paints										
			Topical Shampoos										
			Topical Plaster										

			Topical Liniments				
			Roll on (Pack)				
10	**Box X**	Non Traditional Topical Preparations	Topical Sprays (Pressurized)				
			Topical Foams				
			Bag on valve (BOV)				
11	**Box XI**	Transdermal Systems	Transdermal Patches (Transdermal Plaster)				
			Medicated dressings				
			Transdermal Semisolids				
12	**Box XII**	Vaginal & IUD Preparations	Vaginal Creams				
			Vaginal ointments				
			Vaginal Foams				
			Vaginal Ovules/Pessaries	Vaginal Capsules	Vaginal Tablet		
			Medicated IUD				
			Vaginal Rings (Diaphragm)				
			Vaginal Sponges				
			Vaginal Douches				
13	**Box XIII**	Rectal Preparations	Rectal suppositories	Rectal Tablets	Rectal Capsules		
			Rectal Creams				
			Rectal ointments				
			Enemas				
			Rectal Foam				
14	**Box XIV**	Eye/ear Preparations	Solutions	Viscous Liquids (Soln)	Drops	Suspensions	Viscous Liquids (Susp)
			Gels				

			Ointments		
			Ocular Injections		
			Ocuserts		
			Creams (Not Found)		
			Sprays (Not Found)		
15	**Box XV**	Nasal Preparations	Nasal Drops	Nasal Solutions	
			Nasal Sprays		
			Nasal Viscous Liquids	Nasal Gels	
			Nasal Ointments		
			Nasal Creams (Not Found)		
			Nasal Powder		
16	**Box XVI**	Inhaler	Rota Tabs		
			Capsules		
			Solutions		
			Powders		
			aerosols		
17	**Box XVII**	Nebules	Respules		
18	**Box XVIII**	Oral Soluble Films	Thin Film	Wafer	Sublingual Wafer