	המכון לביקורת ותקנים של חומרי רפואה			
	נושא	תאריך פרסום	חוזר מספר	

	רק אישור מכון	רק אישור מחלקת הרישום	אישור מחלקת הרישום וגם המכון	אישור מחלקת רישום ומדור בקרה רוקחית	אישור מכון , מחלקת רישום ובקרה רוקחית
A.1 Change in the name and/or address of the marketing authorisation holder				X	
A.2 Change in the (invented) name of the medicinal product					X
A.3 Change in name of the AS					X
A.4 Change in the name and/or address of a manufacturer or supplier of the AS	לתכשירים כימיים X		לתכשירים ביולוגיים X		
A.5 Change in the name and/or address of a manufacturer of the FP				X	
A.6 Change in ATC Code / ATC Vet Code		X			
A.7 Deletion of manufacturing sites	חומרים פעילים ומחלקת רישום.		ואישור מחלקת רישום בלבד לכל יתר האתרים. לתכשירים ביולוגיים: לכל האתרים אישור המכון		
A.8 Changes to date of the audit to verify GMP	X				
B.I.a.1 Change in the manufacturer of a starting material	X				

			B.I.a.2 Changes in the manufacturing
		X	process of the AS
		X	B.I.a.3 Change in batch size of AS
		X	B.I.a.4 Change to in-process tests or limits
	X		B.I.a.5 Changes of strain of vaccine
			B.I.b.1 Change in the specification
		X	parameters of an AS
		X	B.I.b.2 Change in test procedure for AS
			B.I.c.1 Change in immediate packaging of
		x	the AS
			B.I.c.2 Change in the specification
		X	packaging of the AS
			B.I.c.3 Change in test procedure for the
		X	immediate packaging of the AS
			B.I.d.1 Change in the storage period or
		X	storage conditions of the AS
			B.I.e.1 Introduction of a new design space
		X	for the AS
			B.I.e.2 Introduction of a post approval
		X	change management to the AS
			B.I.e.3 Deletion of an approved change
		X	management
			B.I.e.4 Changes to an approved change management
		X	protocol
			B.I.e.5 Implementation of changes foreseen in an approved
		X	change management protocol
		X	protocol related to the AS
	X		B.II.a.1 Change for product marking
			B.II.a.2 Change in the shape of the
	X		pharmaceutical form

	B.II.a.3 Changes in the composition of the FP
X	**B.II.a.4 Change in coating weight of capsule shells**
X	
לא ניתן להגיש כשינוי. יש להגיש כתכשיר חדש	**B.II.a.5 Change in concentration of a single-dose**
	B.II.a.6 Deletion of the solvent / diluent container
X	**B.II.b.1 Replacement or addition of a manufacturing site of the FP**
X	**B.II.b.2 Change to batch release arrangements and QC testing of the FP**
	B.II.b.3 Change in the manufacturing process of the FP
	B.II.b.4 Change in the batch size of the FP
	B.II.b.5 Change to in-process tests of the FP
	B.II.c.1 Change in the specification parameters of an excipient
	B.II.c.2 Change in test procedure for an excipient
	B.II.c.3 Change in source of an excipient with TSE risk
	B.II.c.4 Change in synthesis of a non-pharmacopoeial excipient
	B.II.d.1 Change in the specification parameters of the FP
	B.II.d.2 Change in test procedure for the FP

			B.II.d.3 Variations related to the introduction of real-time release or parametric release of the FP
		X	
X			B.II.e.1 Change in immediate packaging of the FP
			B.II.e.2 Change in the specification parameters of the packaging of the FP
		X	
			B.II.e.3 Change in test procedure for packaging of the FP
		X	
X			B.II.e.4 Change in shape or dimensions of the container or closure
X			B.II.e.5 Change in pack size of the FP
X			B.II.e.6 Change in any part of the packaging material
			B.II.e.7 Change in supplier of packaging components
		X	
X			B.II.f.1 Change in the shelf-life or storage conditions of the FP
			B.II.g.1 Introduction of a new design space for the FP
		X	
			B.II.g.2 Introduction of a post approval change management protocol related to the FP
		X	
			B.II.g.3 Deletion of an approved change management protocol related to the FP
		X	
			B.II.g.4 Changes to an approved change management protocol
		X	
			B.II.g.5 Implementation of changes foreseen in an approved change management protocol
		X	

	B.II.h.1 Update to the "Adventitious Agents Safety
X	**Evaluation**
	B.III.1a Submission of a new or updated Ph. Eur. certificate of suitability
X	
	B.III.1b Submission of a new TSE certificate of suitability
X	
X	**B.III.2 Change to comply with Ph. Eur. pharmacopoeia**
X	**B.V.a.1 Inclusion of a new PMF**
	B.V.a.2 Inclusion of a new Vaccine Antigen
X	**Master File**
	B.V.b.1 Update of the quality dossier intended to
	implement the outcome of a Union referral
X	**procedure**
	D.1 Change in the name and/or address of
X	**the VAMF**
X	**certificate holder**
X	**D.2 Change in the name and/or address of**
X	**the PMF**
	D.3 Change or transfer of the current PMF
X	**certificate**
	D.4 Change in the name and/or address of a
X	**blood**
	D.5 Replacement or addition of a
X	**blood/plasma collection**
	D.6 Deletion or change of status
X	**(operational/nonoperational)**

	D.7 Addition of a new blood establishment
X	**for the**
	D.9 Addition of a new blood establishment
X	**for testing of**
	D.10 Replacement or addition of a new
X	**blood**
	D.11 Deletion of a blood establishment or
X	**centre(s) in**
	D.12 Replacement or addition of an
X	**organisation involved**
	D.23 Change in the steps that would be
X	**taken if it is found**
X	**D.14 Addition of a CE-marked test kit**
X	**D.15 Addition of a non-CE marked test kit**
X	**D.16 Change of kit/method used to test pools**
	D.17 Introduction or extension of inventory
X	**hold procedure.**
X	**D.20 Change in storage / transport**
X	**D.21 Introduction of test for viral markers**