



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Patient Health Protection

Project 00305: Implementation of the new Pharmacovigilance legislation European Medicines Agency and Member States Joint Implementation Check-list

The EMA and Member States Joint Implementation Check-list (hereafter referred to as check-list) has been updated to reflect the prioritisation applied to the current development of deliverables.

The implementation of the pharmacovigilance legislation has been prioritised due to budget and resource restrictions. Activities contributing to public health have been given the highest priority, followed by activities increasing transparency and improving communication and then activities that simplify processes.

Whereas the original checklist was divided into 2 parts dealing with operational work and IT tools, because of the prioritisation exercise, this updated checklist focuses on the operational aspects.

The checklist provides an overview on:

- The topic
- The activities to be undertaken.

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- The deliverable(s) for each activity.
- The priority which has been allocated to each deliverable. Deliverables are classified as:
 - Priority “A”: this means that it is necessary to deliver in 2012.
 - Priority “B”: this means that the final implementation beyond 2012.
- The responsible Project Team or relevant development forum. Annex I outlines the Stakeholders or fora involved in the consultation, agreement, endorsement and adoption of each type of deliverable.
- The June status as well as any relevant comments (e.g. key legal references).

1. Operational work

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
1.	Pharmacovigilance Audits	Define Pharmacovigilance Audits	Reflection paper on pharmacovigilance audits	A	Project Team 1 Audit/ Inspections	Completed
2.	Pharmacovigilance Audits	Define any common elements and collaborate to Pharmacovigilance audit methodology for the Agency and NCAs.	Good Vigilance Practice module (module IV)	A	Project Team 1 Audit/ Inspections HMA	Ongoing
			Pharmacovigilance Audit methodology and templates	A		Ongoing Reg. Art 28f, Dir. Art 101.2
3.	Pharmacovigilance Audits	Set up a process for the cooperation in the coordination of PhV Audit and sharing of information	Good Vigilance Practice module (module IV)	A	Project Team 1 Audit/ Inspections	Ongoing Reg. Art 57(1)
4.	Pharmacovigilance Audits	Ensure the conduct of independent audits of the Agency's PhV tasks and report results to its MB every 2 years	First Pharmacovigilance task audit report	B	Project Team 1 Audit/ Inspections	Ongoing (First audit 2013) Reg. Art 28f
5.	Pharmacovigilance Audits	EC to make public a report on conduct of Pharmacovigilance Tasks by the Agency	EC audit report template	B	Project Team 1 Audit/ Inspections	Ongoing Reg. Art 29a, Dir. Art 108b

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
		and by the MS (3-yearly)				NB: Both reports within 3 years after the date of application/transposition and every 3 years thereafter
6.	Inspections/ Pharmacovigilance Systems	Set up a process for cooperation in the coordination of Pharmacovigilance inspections and sharing of information	Inspections guidelines	B	Project Team 1 Audit/ Inspections	Ongoing Dir. Art 111 (1), Dir. Art 111 (8), Dir. Art 122 (2), Reg. 18(3), Reg. 19(1), Reg. 19(3)
			SOP/WIN/Templates	B		
7.	Inspections/ Pharmacovigilance Systems	Inspections and follow-up of inspections	SOP/WIN/Templates	A	Project Team 1 Audit/ Inspections	Ongoing
8.	Inspections/ Pharmacovigilance Systems	Define the content and procedures for maintenance of the PhV System Master File	Technical contribution to Commission implementing measures	A	Project Team 1 Audit/ Inspections	Completed Reg. Art 87a and Dir. Art 108
			Good Vigilance Practice module (module II)	A		
9.	Inspections/ Pharmacovigilance Systems	Define the minimum requirements of the quality system for the performance of PhV activities	Technical contribution to Commission implementing measures	A	Project Team 1 Audit/ Inspections	Completed Reg. Art 87a and Dir. Art 108
			Good Vigilance Practice module (module I)	A		
10.	Periodic Safety	Define procedure for	Good Vigilance Practice module	A	Project Team 2 PSUR	Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	Update Reports	PSUR (electronic) submission and assessment (including work sharing)	(module VII)		EMA/PSUR Work sharing Group	
			New process for the submission, assessment and agreement of PSURs for CAPs	A		Completed
11.	Periodic Safety Update Reports	Define functional specifications for the PSUR repository	Reflection paper on functional specifications	A	Project Team 2 PSUR EMA/PSUR Work sharing Group	Ongoing
12.	Periodic Safety Update Reports	Establish PSUR repository based on the functional specifications	Business Requirements	B	Project Team 2 PSUR EMA/PSUR Work sharing Group	Ongoing
			User Guide (technical guidance)	B		Reg. Art 25a
			Business Rules (technical guidance)	B		Ongoing
			Good Vigilance Practice module (module VII)	A		Completed
			Audit Plan	B		Ongoing
13.	Periodic Safety Update Reports	Define PSUR format and content	Technical contribution to Commission implementing measures	A	Project Team 2 PSUR EMA/PSUR Work sharing Group	Completed
			Good Vigilance Practice module (module VII)	A		Reg. Art 87a and Dir. Art 108
			Updated ICH E2C guideline			Completed
						Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
			HL7 standard for PSUR submission (PSUR electronic submission) (technical guidance)	B		Ongoing
			Detailed planning with ICH and HL7	B		Ongoing
			Templates	B		Ongoing
				A		
14.	Periodic Safety Update Reports	Establish, maintain and publish the list of European Union Reference Dates (EURD) and frequency of submission of PSURs	Good Vigilance Practice module (module VII)	A	Project Team 2 PSUR PSUR Work sharing Group	Completed
			List of EURD	A		Ongoing
			Reflection paper	A		Completed
15.	Periodic Safety Update Reports	Interim arrangements due to postponed EU single assessment procedure for NAPs	Communication material	A	Project Team 2 PSUR	Ongoing
16.	Periodic Safety Update Reports	Define handling of amendments to MA following PSUR assessment	Good Vigilance Practice module (module VII)	A	Project Team 2 PSUR EMA/CMD	Completed
17.	Product Information	Publication of SPCs and PILs on web-portals	Reflection paper	B	Project Team 6 Communication/Transparency	Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
18.	Product Information	Define exemption on PL, labelling exemption and translation obligation	Guidance on labelling	B	Project Team 3 ADR	Ongoing
19.	Product Information	Define format for the electronic submission of product information for the EU medicines list	Guidance on submission of product information	A	Project Team 3 ADR EMA/PhVWP	Completed Reg. Art 57(2)
			Electronic submission format	A		Completed
			Data entry tool	A		Completed
20.	Product Information	Select symbol for 'additional monitoring' and agree SmPC standard text on suspected ADR reporting	Good Vigilance Practice module (Module X)	A	Project Team 6 ADR QRD	Ongoing Reg. Art 23(5)
			Updated SmPC guideline	A		Ongoing
			Agree SmPC and PL standard text on suspected ADR reporting (updated QRD template)	A	Project Team 3 ADR	Ongoing
21.	Product Information	Establish criteria for additional monitoring	Reflection paper	A	Project Team 3 ADR	Ongoing
			Good Vigilance Practice module (Module X)	A		Ongoing
22.	Product Information	Set-up and maintain the list of products requiring additional monitoring	Good Vigilance Practice module (Module X)	A	Project Team 3 ADR	Ongoing Reg. Art. 23(1)

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
23.	Product Information	Identification and traceability of biologics	Reflection paper	A	Project Team 3	Ongoing
24.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Define ADR reporting rules and establish guidance for the application of ADR reporting requirements upto audit of EV	Good Vigilance Practice module (module VI)	A	Project Team 3 ADR EMA/EV-EWG/ PhVWP	Completed Reg. Art 24(1), Reg. Art 24(2)
	Business rules (technical guidance)	B	Completed			
	Guidance on format and content of electronic ADR reports (including Data Protection)	B	Ongoing			
	First Annual report on EV from EMA	A	Ongoing			
	Functional specifications (business requirements) and timelines	A	Completed			
	Technical contribution to Commission implementing measures	A	Completed Reg. Art 87a and Dir. Art 108			
25.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Prepare guidance on how to report suspected adverse reactions for Healthcare professionals and Patients (including using web-based	Good Vigilance Practice module (module VI)	A	Project Team 3 ADR EMA/EV-EWG/ PhVWP	Completed Reg. Art 25
	Core information on websites (technical guidance)	B	Ongoing			
	Standard (harmonised between EU and National) web-based forms	B	Ongoing			

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
		reporting forms)	Reflection paper on web-forms	A		Ongoing
			Reflection paper on medication errors	A		Ongoing
26.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Handle requests for public access to EV data, based on EV access policy	Updated EV access policy	A	Project Team 3 ADR	Completed
			EV access policy procedures	A	EMA/EV-EWG/ HMA	Ongoing
			Published aggregated ADR data for CAPs on EMA website	A		Completed
27.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Define requirements and establish submission of information and ADR reports to WHO and EMCDDA	Business requirements for EU ICT systems	B	Project Team 3 ADR EMA/EV-EWG	Ongoing Reg. Art 28c(1), Reg. Art 28c(2)
			Good Vigilance Practice module (module VI)	A		Completed
28.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Use of internationally agreed terminology, formats and standards for the performance of Pharmacovigilance activities	Technical contribution to Commission implementing measures	A	Project Team 3 ADR	Completed Reg. Art 87a and Dir. Art 108
29.	EudraVigilance/ Suspected Adverse Drug Reaction	The format and content of electronic transmission of suspected adverse	Technical contribution to Commission implementing measures	A	Project Team 3 ADR	Completed Reg. Art 87a and Dir. Art 108

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	reporting	reactions by Member States and marketing authorisation holders	Good Vigilance Practice module (module VI)	A		Completed
30.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Re-routing of ICSRs reported by MAHs to NCAs	Business requirements for EU ICT systems	B	Project Team 3 ADR	Completed Reg. Art 24(4)
31.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Ensure the quality and integrity of the information collected in the Eudravigilance database	Business requirements for EU ICT systems	A	Project Team 3 ADR	Completed Reg. Art 24(3)
			Good Vigilance Practice module (module VI)	A		Completed
32.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports	Good Vigilance Practice module (module VI)	A	Project Team 3 ADR	Completed Dir. Art 102(c)
33.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Identify clearly any biological medicinal product prescribed, dispensed, or sold in the territory of a Member State, which is the subject of a suspected adverse reaction report, with due regard to the	Business requirements for EU ICT systems	A	Project Team 3 ADR	Completed
			Good Vigilance Practice module (module VI)	A		Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
		name of the medicinal product, in accordance with Article 1(20), and the batch number (Dir 2010/84/EC Article 102(e))				
34.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	International standards for Individual Case Safety Reports	ICH Implementation Guide for Individual Case Safety Reports	A	Project Team 3 ADR	Ongoing
			ISO/HL7 standards	A		Completed
35.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Prepare EU Region specific Implementation Guide for Individual Case Safety Reports	Good Vigilance Practice module (module VI)	A	Project Team 3 ADR	Completed
			EU Region specific Implementation Guide for Individual Case Safety Reports following ISO	B		Ongoing
36.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Draft functional specifications for EV Audit	Functional Specifications EV Audit and timelines	A	Project Team 3 ADR	Completed
37.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Establish process to support PSUR assessment with analysis of EV data for CAPs	SOP/WIN/Templates	A	Project Team 3 ADR	Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
38.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Establish process to supply Member States with EV data to perform signal detection for NAPs	SOP/WIN/Templates	A	Project Team 3 ADR	Ongoing
39.	EudraVigilance/ Suspected Adverse Drug Reaction reporting	Develop data analysis support to referrals	Guidance on data analysis support to Referrals	A	Project Team 3 ADR EMA/PhVWP	Ongoing
			SOP/WIN/Templates	A		Ongoing
40.	Literature Monitoring/Signal detection	Literature monitoring: Define list requirements and establish list of defined active substances and journals to be monitored	Good Vigilance Practice module (Module VI)	A	Project Team 3 ADR EMA/EV-EWG	Completed Reg. Art 27(1)
			First list of defined active substances and journals to be monitored	B		Ongoing
			Literature Monitoring Options Paper	A		Ongoing
41.	Literature Monitoring/Signal detection	Literature monitoring: Implement requirements for literature monitoring and entering cases	Good Vigilance Practice module (Module VI)	B	Project Team 3 ADR EMA/EV-EWG	Completed Reg. Art 27(2-3)
			EV Business rules to reflect authorised senders of these reports (technical guidance)	B		Ongoing
			Guidance on entry of relevant information in EV from selected literature	B		Ongoing
			Technical specifications (including			

No.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
			copyright and translations of abstracts)	B		Ongoing
42.	Literature Monitoring/Signal detection	Signal detection: Further define and implement new responsibilities on Signal Detection	Good Vigilance Practice module (module IX)	A	Project Team 3 ADR EMA/Signal Management Sub-group	Completed Reg. Art 28a(1) Completed Reg. Art 87a and Dir. Art 108
			Technical contribution to Commission implementing measures	A		
43.	Literature Monitoring/Signal detection	Establish new process for signal detection and management by EMA for CAPs	SOP/WIN/Templates	A	Project Team 3 ADR	Completed
44.	Literature Monitoring/Signal detection	Process to collect information to publish withdrawn products	Reflection paper	A	Project Team 3 ADR	Ongoing
45.	Post Authorisation Safety and Efficacy Studies	Define requirements, formats, key elements for PASS to be reflected as conditions to the MA, procedure and criteria for requesting PASS	Good Vigilance Practice module (module V)	A	Project Team 4 RMP EMA/PhVWP	Completed Completed Completed Reg. Art 87a and Dir. Art 108
			Good Vigilance Practice module(s) (module VIII)	A		
			Technical contribution to Commission implementing measures	A		
46.	Post Authorisation Safety and Efficacy	Define requirements, key elements for PAES to be reflected	Scientific Guideline on PAES (EMA)	A	Project Team 4 RMP EMA/CHMP	Ongoing Reg. Art 10b and Dir.

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	Studies	as conditions to the MA, procedure and criteria for requesting PAES	Reflection paper on PAES (focusing on the situations when they would be required and their objectives)	A		Art 22(b) Completed
			Delegated acts (EC)	A		
			Good Vigilance Practice module (module V)	A		Ongoing Completed
47.	Post Authorisation Safety and Efficacy Studies	Establish process for the submission, assessment and agreement of protocols for non-interventional PASS for CAPS	Good Vigilance Practice module (module VIII)	A	Project Team 4 RMP	Completed
			SOP/WIN/Templates	A		Ongoing
48.	Post Authorisation Safety and Efficacy Studies	Define procedure for PASS (non-interventional) oversight	Good Vigilance Practice module (module VIII)	A	Project Team 4 RMP EMA/PhVWP SAWP	Completed
49.	Post Authorisation Safety and Efficacy Studies	Define policy and procedure for joint company PASS requirements	Good Vigilance Practice module (module VIII)	B	Project Team 4 RMP EMA/PhVWP/ ENCePP	Completed
50.	Post Authorisation Safety and Efficacy Studies	Define handling of amendments to MA following PASS	Good Vigilance Practice module (module VIII)	A	Project Team 4 RMP EMA/CMD NTA	Completed
51.	Post Authorisation	Define formats of	Technical contribution to Commission	A	Project Team 4 RMP	Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	Safety and Efficacy Studies	protocols, abstracts and final study report for the post-authorisation non-interventional safety studies	implementing measures	A		Reg. Art 87a and Dir. Art 108 Completed
			Good Vigilance Practice module (module VIII)	A		Ongoing
52.	Post Authorisation Safety and Efficacy Studies	Establish mechanism for the submission and publication of study protocols and summary results	Good Vigilance Practice module (module VIII)	A	Project Team 4 RMP	Completed
53.	Risk Management System	Define procedure and criteria for requesting RMP (new and existing products)	Good Vigilance Practice module (module V)	A	Project Team 4 RMP EMA/PhVWP/ CHMP	Completed
54.	Risk Management System	Establish new process for submission, assessment and agreement of RMPs	SOP/WIN/Templates	A	Project Team 4 RMP	Ongoing
55.	Risk Management System	Define RMP format and content (including RMP summary)	Good Vigilance Practice module (module V)	A	Project Team 4 RMP EMA/PhVWP	Completed
			Technical contribution to Commission implementing measures	A		Completed Reg. Art. 87a(f) and Dir. Art. 108(f)
56.	Risk Management	Define effectiveness	Good Vigilance Practice module	A	Project Team 4 RMP	Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	System	of risk minimisation and establish monitoring system	(module XVI)		EMA/PhVWP/ ENCePP	Reg. Art 28a(1)
57.	Risk Management System	Define effectiveness of risk minimisation and establish monitoring system	Establish monitoring system (policy paper on measurement of health outcomes)	B	Project Team 4 RMP	Ongoing
58.	Committees/ Referrals	Establish revised Coordination Group and define its tasks and interaction with PRAC	Rules of procedure	A	Project Team 5 Committees EMA/CMD/ HMA	Completed
			SOP/WIN/Templates	A		Ongoing
59.	Committees/ Referrals	Establish PRAC, set-up nomination process, EC to appoint members and elect its Chair and Vice-Chair	Rules of procedure	A	Project Team 5 Committees EMA / MSs / Commission calls	Ongoing
			Procedures for Chair election and members' nomination	A		Reg. Art. 61a
			Reflection paper on Principles (and Procedure, including templates) for MS delegation to another MS (at time of appointment/ongoing within term of mandate)	A		Completed
			Reflection paper on Nomination procedure – decision of Timelines for nomination	A		Completed
			Call for expression of interest – Relevant expertise – Clinical,	A		Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
			Pharmacoepidemiology – to be appointed by Commission			
			Call for expression of interest – Health Care professionals – to be appointed by Commission further to European Parliament consultation	A		Ongoing
			Member States shall Liaise with Management Board and Commission to ensure that final composition covers relevant scientific areas – understanding requirement and procedure	A		Completed
60.	Committees/ Referrals	Define interactions between CHMP and PRAC	CHMP Rules of Procedure	A	Project Team 5 Committees EMA/CHMP	Ongoing
61.	Committees/ Referrals	List of expertise required for PRAC	Reflection paper	A	Project Team 5 Committees	Completed
62.	Committees/ Referrals	List of tasks to be performed by PRAC	Reflection paper (incl. Overview table)	A	Project Team 5 Committees	Completed
63.	Committees/ Referrals	Current agreements with International partners	Reflection paper	A	Project Team 5 Committees	Ongoing
64.	Committees/ Referrals	Identification and justification of IT requirements for referrals	IT business requirements (including Process Map/List of requirements)	A	Project Team 5 Committees	Completed
65.	Committees/ Referrals	Define Scope and start of Article 107,	Reflection paper on Scope and start of Article 107, 107i(1) and 107i(4)	A	Project Team 5 Committees	Completed Dir. Art 107, 107i(1)

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
	Referrals	107i(1) and 107i(4)				and 107i(4)
66.	Committees/ Referrals	Define Temporary measures 107i(3)	Reflection paper on Temporary measures 107i(3)	A	Project Team 5 Committees	Completed Dir. Art 107i(3)
67.	Committees/ Referrals	Define Public announcement and Communication 107j(2)	Reflection paper on Public announcement and Communication 107j(2)	A	Project Team 6 Communication/Transparency	Completed Dir. Art 107j(2)
68.	Committees/ Referrals	Establish Process of PRAC recommendations, interactions and conclusions 107j(3)	Reflection paper on Process of PRAC recommendations, interactions and conclusions 107j(3)	A	Project Team 5 Committees	Completed Dir. Art 107j(3)
69.	Committees/ Referrals	Establish Process for adopting Opinion, timelines for implementation 107k	Reflection paper on Process for adopting Opinion, timelines for implementation 107k	A	Project Team 5 Committees	Completed Dir. Art 107k
70.	Committees/ Referrals	Establish Process of outlined in Art.31(1)	Reflection paper on Process of Art.31 31(1)	A	Project Team 5 Committees	Ongoing Dir. Art 31(1)
71.	Committees/ Referrals	Establish Process outlined in Art.20 (Regulation)	Process of Art.20 (Regulation)	A	Project Team 5 Committees	Ongoing Reg. Art 20
72.	Committees/ Referrals	Appointment of Rapporteur and collaboration within CHMP Rapporteur/RMS	Reflection paper	A	Project Team 5 Committees	Ongoing
73.	Committees/ Referrals	Agendas and Minutes-PRAC, CHMP AND Co-ordination	Reflection paper	A	Project Team 5 Committees	Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
		Group – templates, timing, level of detail				
74.	Committees/ Referrals	Publication of Agendas and Minutes	Decision on timing	A	Project Team 5 Committees	Completed
75.	Committees/ Referrals	Define roles and responsibilities and new procedure for referrals	Procedural guidance	A	Project Team 5 Committees EMA/PhVWP/CMD/CHMP	Ongoing Dir. Art 107i(1-2), Dir. Art 107k(1)
76.	Committees/ Referrals	Define outputs of PRAC and CMD(h)	Table of PRAC, CMD(h) and CHMP outputs	A	Project Team 5 Committees	Ongoing
77.	Committees/ Referrals	Create an agenda Inaugural (July) meeting of the PRAC and September PRAC meeting	Agenda	A	Project Team 5 Committees	Completed
			Agenda structure	A		
78.	Committees/ Referrals	Define support from Working Parties to Committees	Strategy document	A	Project Team 5 Committees	Ongoing
79.	Committees/ Referrals	Supply to existing patients of withdrawn medicines	Reflection paper	A	Project Team 5 Committees	Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
			GVP modules XII (Continuous pharmacovigilance, ongoing benefit-risk evaluation, regulatory action and planning of public communication) and XIV (Referral procedures for safety reasons)			Ongoing
80.	Communication/ Transparency	Define support to Member States with rapid communication and coordinate safety announcements	Good Vigilance Practice module (module XV)	A	Project Team 6 Communication EMA/PhVWP/ HMA Group of comm. profs	Ongoing Dir. 2010/84/EU Art. 106
	Reflection paper on Coordination of Safety Announcement		A	Completed		
	Mandate and Rules of Procedure of European Medical Information Network (EMIN)		A	Ongoing		
	EMA SOP(s)/WIN(s)		A	Ongoing		
81.	Communication/ Transparency	Define the strategies, the design and functional requirements, the management and maintenance of EU medicines web-portal	Reflection paper on Web Portal	B	Project Team 6 Communication EMA/HMA	Completed
	Legal notice on use of the EMA website as EU web portal in short-term		B	Reg. Art 26		
	Master project plan (Agency website, Portal)		B	Ongoing		
	Operational guidance on EU Medicines web-portal		B	Ongoing		
82.	Communication/ Transparency	Define public hearing requirements	Guideline on modalities and rules of procedure for public hearings	A	Project Team 6 Communication EMA/PhVWP	Ongoing

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
			Rules of procedure on the organisation and conduct of public hearings	A	Project Team 6 Communication	Dir. Art 107k(2)
			Guidance for criteria for public hearings	A	Project Team 5 Committees/Referrals	Ongoing
			Guidance for identification of relevant target groups	A	Project Team 6 Communication	Ongoing
			Reflection paper on Public Hearing	A	Project Team 6 Communication	Ongoing
83.	Communication/ Transparency	Define transparency requirements	Reflection paper on Transparency in the context of the new Pharmacovigilance legislation (including overview list)	A	Project Team 6 Communication	Ongoing
			Guidance document	A		Ongoing
			Guidance document outlining key elements with regards to information to be provided to Healthcare Professionals/Patients/public aiming to raise awareness on the new pharmacovigilance provisions	A		Ongoing
			Guidance documents/ templates/SOPs	A		Ongoing
84.	Others	Modify grounds for additional renewal and deadlines for	Guideline on processing of renewals	A	Project Team 2 PSUR EC	Completed

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
		submission of renewal			NTA	
85.	Others	Define impact on Variations	EC Guideline (on the details of various categories of variations)	B	Project Team 5 Committees CIAG (Classification Advisory Group) EMA/CMD/ NTA	Ongoing
86.	Others	Contribute to EC report on environmental effects to the EP and Council & assessment whether EU legislation should be amended	EC report	B	EC	Ongoing Reg. Recital 2a / Dir. Recital 5a
87.	Others	Contribute to EC assessment report on current shortcomings in Summary of Product Characteristics ('SPC') and Patient Information Leaflet ('PIL') & if appropriate proposal for improvement	EC assessment report	A	EC	Ongoing Article 59 (3) Dir NB: Within 18 months of publication of Dir in OJ

N o.	Topic	Activity	Deliverable	Priority	Project Team / Development Forum	Status and additional comment(s)
88.	Others	Re-define International liaison in the context of the new Pharmacovigilance legislation	Reflection paper	A	EMA	Ongoing
89.	Other	Define short-term workaround IT system to support business processes	Paper	A	EMA	Completed
90.	Other	Coordinate the templates development	Paper on methodology (RACI matrix)	A	EMA	Completed
91.	Other	Collection of data to review the impact of the legislation over time ('10 yearly review')	Impact measurement plan proposing a Programme (e.g. need for studies)	A	EMA	Ongoing
92.	Other	Ensure that ongoing issues in EPiTT are closed or mapped to the new processes	List of safety issues still open in July 2012	A	EMA	Ongoing
93.	Other	EMA support for NAPs and transitional issues for NAPs	Reflection paper	A	EMA	ongoing

ANNEX I – Table of Deliverables from EMA/Member States Project Teams – Pharmacovigilance Legislation Implementation

Type of deliverable from EMA/Member States Project Teams	Action				
	Consultation	Agreement	Endorsement	Adoption	
EMA Technical Contribution to Implementing Measure ¹	<ul style="list-style-type: none"> High-level presentation to Stakeholder Forum 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> N/A 	
Good Vigilance Practice Modules	<ul style="list-style-type: none"> High-level presentation to Stakeholder Forum Formal consultation process with stakeholders² 	<ul style="list-style-type: none"> ERMS-FG on draft documents prior to launch of formal consultation and on the revised documents following such formal consultation 	<ul style="list-style-type: none"> CHMP, PRAC/PhVWP, Coordination Group, applicable existing Expert Groups (where relevant) 	<ul style="list-style-type: none"> EMA – Executive Director 	
Scientific Guideline	<ul style="list-style-type: none"> High-level presentation to Stakeholder Forum Formal consultation process with stakeholders² 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> CHMP, PRAC (where relevant) 	
EMA Guidance (procedural, regulatory, technical guidance)	<ul style="list-style-type: none"> Reflection Paper 	<ul style="list-style-type: none"> High-level presentation 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> HMA, MB³ 	<ul style="list-style-type: none"> N/A

¹ Adoption process for the Implementing Measures will be undertaken by the European Commission in accordance with applicable Union legislation, on the basis of the EMA technical contribution.

² In accordance with the “Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework”.

³ Restricted to those situations where strategic choices need to be made and/or with impact on the EU Regulatory Network.

Type of deliverable from EMA/Member States Project Teams	Action			
	Consultation	Agreement	Endorsement	Adoption
<ul style="list-style-type: none"> Recommendation / Procedural Advice 	<ul style="list-style-type: none"> to Stakeholder Forum (where relevant) Formal consultation process with stakeholders² 	<ul style="list-style-type: none"> ERMS-FG on draft document prior to launch of formal consultation and on revised document following such formal consultation 	<ul style="list-style-type: none"> HMA, MB (where relevant, i.e. in case of major change in strategy or important change in resource consequences) 	<ul style="list-style-type: none"> EMA – Executive Director
Business Requirements for EU ICT systems that need to be audited (i.e. EudraVigilance, PSUR Repository)	<ul style="list-style-type: none"> EudraVigilance EWG, EudraVigilance SC, MB TC for EudraVigilance MB TC for PSUR Repository 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> HMA, MB 	<ul style="list-style-type: none"> EMA – Executive Director
Business Requirements for other EU ICT Systems (EU medicines web-portal, EPITT database, ENCePP database)	<ul style="list-style-type: none"> MB TC 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> HMA, MB (EU medicines web-portal) 	<ul style="list-style-type: none"> EMA – Executive Director
Other EMA documents, such as				
<ul style="list-style-type: none"> RoP/Mandate 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> ERMS-FG 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> CHMP, PRAC, Coordination Group (where relevant)
<ul style="list-style-type: none"> SOP/WIN/Template 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> ERMS-FG (where relevant) 	<ul style="list-style-type: none"> N/A 	<ul style="list-style-type: none"> EMA – Executive Director (delegated)