30 May 2016

Submission of comments on module V of the good pharmacovigilance practices (GVP) on risk management systems (EMA/838713/2011 Rev. 2)

Comments from:

Name of organisation or individual
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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	To improve patient safety: the priority should be the patients, not the companies In late February 2016 the European Medicines Agency released for public consultation a revised module on good pharmacovigilance practices on risk management systems. Over the years Prescrire has advocated for strong and independent pharmacovigilance systems in the European Union and for the European Medicines Agency to play a proactive role in defending patient safety and protecting the population from avoidable drug-induced harm. Citizens should not be exposed to the adverse effects of drugs that have been released onto the market prematurely. The very high human and financial costs of adverse drug reactions end up being borne by the patients who experience them and by society at large. Yet, instead of strengthening pharmacovigilance in Europe, the EMA proposal falls short in three fundamental	

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	aspects: 1. It sustains weak marketing authorisation practices; 2. It tightens marketing authorisation holders' stranglehold on pharmacovigilance; 3. It maintains a lack of transparency. 1. The proposal sustains weak marketing authorisation practices. Under the misleading reassurance of post-authorisation safety studies and risk management programmes, inadequately evaluated medicines are allowed to reach the market and to be prescribed, dispensed and administered to some patients. Risk management systems (RMPs) should be used to complement pharmacovigilance as an add-on to standard pharmacovigilance practices and not to substitute a thorough pre-marketing evaluation of potential harms. They are to be applied to any medicine where doubts about adverse effects exist or emerge, even for those medicines which have been in use for a longer time or even are available as	

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	generics. Risk management systems must be designed by and conducted under the close supervision of health authorities (national and regional pharmacovigilance systems in particular), with complete independence. The RMP objectives must be to identify all the adverse reactions of the drug in question, to clarify their frequency and seriousness, both short-term and long-term, and above all, to prevent their recurrence by helping the regulatory authorities to reach a timely decision. Clear timelines for completion of the RMP by the marketing authorisation holder need to be established and, when necessary, coercive measures and/or sanctions for non-compliance must be applied. It is also essential to define the milestones at which the agency will be evaluating the RMP.	

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	2. The proposal tightens marketing authorisation holders' stranglehold on pharmacovigilance By delegating the collection, analysis and interpretation of data in RMPs to the pharmaceutical industry, the EMA is outsourcing key functions in pharmacovigilance to the party which has a vested interest in delaying pharmacovigilance decisions. Such an arrangement provides an opportunity for pharmaceutical companies to withhold and manipulate the data. Many examples serve as reminders that the pharmaceutical companies' sense of responsibility is often overcome by the enticement to withhold data or delay its disclosure, so as to delay decisions that would adversely affect sales. A recent example is Roche's mismanagement of pharmacovigilance data whereby the company had a cache of approximately 80,000 potential adverse event reports which had not been submitted to the EMA. Decisions about the measures to be taken are reached slowly and after much avoidance,	

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	mostly due to the fact that the preparatory phase of the decision-making process, i.e. data interpretation, is entrusted to the pharmaceutical companies. Indeed, it is up to the pharmaceutical companies – who play the roles of judge and party - to produce the "scientific evaluation of the risk-benefit balance" of their drug within the framework of the periodic benefit-risk evaluation reports (former periodic safety update reports (PSURs)). Evidence has shown that the burden of proof required by agencies to withdraw a drug is much higher than that which is demanded when authorising it on to the market: clearly, this is not placing the patients' interest above those of pharmaceutical companies. 3. The proposal maintains a lack of transparency. Data about the adverse effects experienced by patients are not commercial data to be collected by pharmaceutical companies as part of their marketing services. These are public scientific data. They are to be analysed and interpreted to prevent recurrence and to help	

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	independent decision-making. Similarly, results of RMPs should be publicly accessible, based on EC regulation No 1049/2001. However, in the EMA proposed module there is no clarification about how these studies and their results are to be made available. We encourage the EMA in its policy to support public health by: • proactively providing public access to useful qualitative data such as anonymised summaries of cases; • ensure that information to patients about the harmful effects of approved medicines is up-to-date and made promptly available; • granting public access to consumption data of drugs in the EU. This information is available from the periodic safety update reports and is necessary to estimate the incidence of a given adverse drug reaction associated with a drug; • providing access to all drug regulatory authorities' assessment reports of MAH's periodic benefit-risk evaluation reports (former PSURs); • providing access to the protocol and	

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	results of post-marketing authorisation studies and risk management programmes, particularly those which are required within the framework on conditional marketing authorisations, or that stem during a review due to safety concerns.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.