RESPONSE TO: Commission Public consultation on legislative proposals:

STRATEGY TO BETTER PROTECT PUBLIC HEALTH BY STRENGTHENING AND RATIONALISING EU PHARMACOVIGILANCE

Name: Pharmacovigilance department
Type of stakeholder: Public health institution
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SPECIFIC COMMENTS ON TEXT		
Line no. + page + paragraph no.	**PROPOSED TEXT**	**COMMENT AND RATIONALE**
Section 3 Legislative strategy and the key proposals for legislative change		
3.2.1. Page 4 3rd §	"*Impact* Adverse reactions to medicines are the 5th most common cause of death in hospital and there is abundant evidence of the major public health burden that adverse drug reactions cause. There will be a major benefit to public health by ensuring that important safety issues are rapidly and robustly dealt with across the EU."	References?
3.2.6. page 8 1st §	"*Impact* Benefit to public health by freeing up resource for both industry and regulators which can then be reinvested into efforts more closely linked to health protection and promotion (…)".	Positive response, but reinvestments into promotion must be scrupulously controlled in order to avoid the only commercial promotion.
Annex 1		
Strategy to better protect public health by strengthening and rationalising EU pharmacovigilance: detailed proposals for legislative changes		
2nd item Page 11	"Directive 2001/83/EC Article 1(13) ~~Unexpected adverse reaction: An adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics."~~	Negative response Why is this definition deleted?
3rd item Page 11	"Directive 2001/83/EC Article 1(16) ~~Abuse of medicinal products: Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects."~~	Negative response Why is this definition deleted?
1st item Page 12	"Post-authorisation safety study: A pharmacoepidemiological study or a clinical trial with an authorised medicinal product ~~in~~	Replace with : ""Post-authorisation safety study: A clinical trial, a

	~~accordance with the terms of the marketing authorisation~~, conducted with the aim of identifying, characterising or quantifying a safety hazard or confirming the safety profile of the medicinal product."	pharmacoepidemiological study or any other studies with an authorised medicinal product ~~in accordance with the terms of the marketing authorisation~~, conducted with the aim of identifying, characterising or quantifying a safety hazard or confirming the safety profile of the medicinal product."
Last item Page 12	"Directive 2001/83/EC Article 8 (3)(iaa) A detailed description of the pharmacovigilance and, where appropriate, of the risk-management system which the applicant will introduce. This risk management system shall be proportionate to the identified and potential risks taking into consideration the information available on the medicinal product."	Not enough precise.
Last item Page 17	"Directive 2001/83/EC Article 26 1. The marketing authorisation shall be refused if, after verification of the particulars and documents listed in Articles 8, 10, 10a, 10b and 10c, it is clear that: (a) the risk-benefit balance is not considered to be favourable; or ~~(b) its therapeutic efficacy is insufficiently substantiated by the applicant; or~~ (b) its qualitative and quantitative composition is not as declared."	Why is this sentence deleted? Does it mean that ineffective medical products can be marketed as long as they raise no safety concerns?
Annex 1		
Directive 2001/83/EC Title IX (Articles 101-108) 'Pharmacovigilance" to be replaced with the following text [with equivalent changes to Regulation (EC) N° 726/21004 Article 20 and 21-29]		
Article 101a 2nd § Page 20	"The Member States shall take all appropriate measures to encourage doctors and other health care professionals to report suspected adverse reactions to the marketing authorisation holder or the competent authorities. The Member States may impose specific requirements on doctors and other health -care professionals in respect of the reporting of suspected serious or unexpected adverse reactions."	The definition has been deleted on page 11.
3rd item Page 23	"The Member States shall record all adverse reactions that occur in their territory which are brought to their attention from healthcare professionals and patients. Member States shall submit electronically to Eudravigilance and to the marketing authorisation holders all of these	The quality of reports could be decreased. Ok for patient

	reports which meet the notification criteria in accordance with the guidelines referred to in Article 101b. To facilitate the reporting of suspected adverse reactions by healthcare professionals and patients each Member State shall accept reports of adverse reactions via their websites which shall be linked to the European medicines safety web - portal referred to in Article 101i."	notification but patient associations must be involved to avoid quality deterioration.
4th item Page 23	"By -/- (5-years after the entry into force of this directive), the Agency, in collaboration with the Member States shall make available web-based structured reporting forms for European healthcare professionals and patients to facilitate electronic reporting of adverse reactions and submission to Eudravigilance."	Deadline too short and obviously not realistic.
Article 101o Page 34	"Member States shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge the obligations contained in this Title is subject to effective, proportionate and dissuasive penalties."	Who will decide? Is it the Agency or the competent authority in each Member State? What measures will be taken?
2nd item Page 39	"Direction 2001/83/EC Article 116 The competent authorities shall suspend, revoke, withdraw or vary a marketing authorisation if the view is taken ~~that the product is harmful in normal conditions of use, or that it lacks therapeutic efficacy, or that~~ the risk-benefit balance is not positive ~~under normal conditions of use~~, or that its qualitative and quantitative composition is not as declared. ~~Therapeutic efficacy is lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.~~"	Negative response
1st item Page 43	"For the purposes of inspection the supervisory authority for pharmacovigilance shall be the competent authorities of the Member State in which the qualified person responsible for pharmacovigilance resides."	The risk is that QPPV could reside in a Member State which performs few inspections.