Article 96

Article 96 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.	Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities ***including the pharmacovigilance of the post-authorisation safety and efficacy long-term studies in children, including where relevant data from the off-label use of the product.***

Recital 9

Text proposed by the Commission	*Amendment*
(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive.	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive. ***Effort should be made to address encountered problems of medicinal products for children, such as failure to timely accomplish the paediatric clinical studies and obtain data required for marketing authorization, which results in significant delay of approval in children compared to adults.***

Recital 58 a (new) ADOPTED

Text proposed by the Commission	*Amendment*
	(58a) Cross-border healthcare is an important pathway for patients to access medicinal products that might otherwise not be available to them. To support access to medicinal products, in particular in the case of small patient populations such as for paediatric or rare diseases which are often disadvantaged when it comes to access to medicines, or where the administration of a medicine requires special competences or infrastructure, the full implementation of Directive 2011/24/EU of the European Parliament and of the Council[1a] should be supported. It is important to consider in that regard all alternative paths of making available medicinal products to patients. Competent authorities of the Member States should therefore utilise the NCAPR to exchange and share best practice regarding the implementation of cross-border access agreements and negotiations.

Proposal for a directive
Article 6 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In the absence of a paediatric investigation plan according to point (a), or where in this regard a comparative study was not carried out, a justification shall be submitted and where relevant also evidence obtained from post-marketing long-term studies.