



SDI Review Form 1.6

Journal Name:	Asian Journal of Research in Medical and Pharmaceutical Sciences
Manuscript Number:	Ms_AJRIMPS_40776
Title of the Manuscript:	Questionable International Pediatric Studies in the United States and Russia Triggered by Regulatory Authorities
Type of the Article	Original Research Article

General guideline for Peer Review process:

This journal's peer review policy states that **NO** manuscript should be rejected only on the basis of '**lack of Novelty**', provided the manuscript is scientifically robust and technically sound.

To know the complete guideline for Peer Review process, reviewers are requested to visit this link:

(<http://www.sciencedomain.org/page.php?id=sdi-general-editorial-policy#Peer-Review-Guideline>)

PART 1: Review Comments

	Reviewer's comment	Author's comment (if agreed with reviewer, correct the manuscript and highlight that part in the manuscript. It is mandatory that authors should write his/her feedback here)
Compulsory REVISION comments	<p>This is a study conducted to provide scientific evidence to challenge the rational for some clinical trials in the paediatric population. A few but important observations outlined below should be addressed by the authors.</p> <ol style="list-style-type: none"> Study Method (lines 52-64) should be preceded by background to study (lines 66-93). This was not the case in this manuscript. Lines 57-59 need further clarification to avoid apparent contradictions: While disregarding studies involving "children, adolescents and adults", they included studies that recruited "children and young adults up to 18-30 years" and "birth to 17 years". Table 1 has no explanatory text except for the footnote. This should be provided. Tables 4 and 5 are sandwiched within the discussion section; they should be appropriately relocated. The referencing system is inconsistent and not in conformity with any standard referencing style. This should be revised in line with this Journal's recommendation. This flaw is illustrated below: <ul style="list-style-type: none"> ➤ Shirkey H. Therapeutic Orphans. <i>J Pediatr</i> 72, 119-120 (1968) X ➤ Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations. 242 Committee on Drugs. American Academy of Pediatrics. <i>Pediatrics</i> 1995, 95, 286-94 X 	<p>Thank you for your review, and for your suggestions to correct/modify our manuscript.</p> <ol style="list-style-type: none"> Following the reviewers suggestion, we have moved the background to before the methods section To clarify out methods in a better way, we expanded the methods sections by adding (added words in red): however, we included studies recruiting children and young adults up to 18/19/20/21/24/30 years of age because both FDA and EMA often request participation of underage and young adult patients into "pediatric" studies (new lines 100-103). Thank you for noting this. We added explanatory text before table 1. Thank you for noting this We have added the sub-headings "Oncology", "Rheumatology" and "General Discussion" into the discussion session, and have added an explanatory text before table 4. Thus, we hope that now it is better visible that we discuss first oncology studies, then rheumatology/ JIA studies, followed by a general discussion. Thank you for noting this, and apologies. We adapted the referencing system consistantly to the quotations in PubMed
Minor REVISION comments	<p>Lines 32/33: PIP is repeated.</p> <p>Line 209: daily basis</p>	<p>Thanks for noting. We removed the repetition</p> <p>Thanks for noting. We corrected .</p>
Optional/General comments	<p>The Authors may consider toning down the language in the following expression to make it less offensive " Parts of pediatric academia are sullied by industry funds channeled by regulatory 20 decisions into medically superfluous studies". Lines20-21</p>	<p>Agreed. We replaced "sullied" by "misled" and "superfluous" by "questionable"</p>