

## Review Form 1.6

Journal Name:	<a href="#">Journal of Pharmaceutical Research International</a>
Manuscript Number:	Ms_JPRI_93400
Title of the Manuscript:	Challenges in the research and development of Orphan drugs: A comprehensive review
Type of the 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:

<https://www.journalpri.com/index.php/JPRI/editorial-policy>

### 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)
<b>Compulsory</b> REVISION comments	<p>Orphan drugs research and development remains an area of research that is highly under-emphasised, due to its peculiarities. Firstly it has low market profile and fewer incentives. It is highly commendable that the authors have chosen to write on the challenges of orphan research and development. In Table 1. Correlation of the regulation of rare diseases and orphan drugs between different countries; most of the regulations were enacted more than 20 years ago. Does it mean that there are no recent regulations on orphan drugs in these countries? Again, Taiwan's regulation has no year it was enacted. Also, the tables on the currently available orphan drugs and those currently in clinical trials, do not have the countries mentioned and how long has the clinical trials been going on.</p> <p>Although, this research is on orphan drugs, the authors should have compared the research and development of orphan drugs with that of conventional drugs, to give more depth to the work and enable the scientific audience and readers to better appreciate the magnitude of the challenges faced in the development of orphan drugs.</p> <p>Again, there should have been an attempt to present the economic implication of orphan drug challenges; i.e. mortality statistics from rare diseases in the countries/continents, estimated cost of developing orphan drugs and which countries have developed the most orphan drugs, try to establish if there is a link between the number of orphan drugs and reduction in rare disease mortality, if any.</p>	
<b>Minor</b> REVISION comments	The abstract is poorly written, less informative and too short.	
<b>Optional/General</b> comments	The grammar needs some editing.	

### PART 2:

	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)
Are there ethical issues in this manuscript?	<i>(If yes, Kindly please write down the ethical issues here in details)</i>	

### Reviewer Details:

Name:	Johnson-Ajinwo, Okiemute Rosa
Department, University & Country	University of Port Harcourt, Nigeria