

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

ESPS manuscript NO: 19918

Title: New regulations for medical devices: Rationale, advances and impact on research and patient care

Reviewer's code: 01218364

Reviewer's country: United States

Science editor: Yue-Li Tian

Date sent for review: 2015-05-27 20:09

Date reviewed: 2015-05-30 06:03

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input checked="" type="checkbox"/> Accept
<input checked="" type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good		<input type="checkbox"/> Duplicate publication	
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Minor revision
	<input type="checkbox"/> Grade D: Rejected	BPG Search:	<input type="checkbox"/> Major revision
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

Your opinions are interesting and may in fact be valid. Lacking any scientific methodology I would liken this more to an editorial and opinion paper. As such it may be of interest to the readers.

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

ESPS manuscript NO: 19918

Title: New regulations for medical devices: Rationale, advances and impact on research and patient care

Reviewer's code: 03069301

Reviewer's country: Spain

Science editor: Yue-Li Tian

Date sent for review: 2015-05-27 20:09

Date reviewed: 2015-06-08 21:30

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

The authors present a very interesting paper on a very important field as medical devices regulation is. The paper also has some interesting comments on ethical issues. I think that in general the paper is good. However, it lacks of some references according to WJO editorial style: - Page 5 "ASR" should be written in full and then in brackets; further citations can be written in acronymic. The same for "3M": it should be followed by TM. - We guess that Lit 13 means "limitations number 13", but where are the other 12? This must be explained. - In page 7 after the sentence "LI Havekin..." there should be a reference. - Some other references should be in all the following pages.

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

ESPS manuscript NO: 19918

Title: New regulations for medical devices: Rationale, advances and impact on research and patient care

Reviewer's code: 01200726

Reviewer's country: Japan

Science editor: Yue-Li Tian

Date sent for review: 2015-05-27 20:09

Date reviewed: 2015-06-09 22:32

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input checked="" type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input checked="" type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

No comments

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

ESPS manuscript NO: 19918

Title: New regulations for medical devices: Rationale, advances and impact on research and patient care

Reviewer's code: 02990871

Reviewer's country: Netherlands

Science editor: Yue-Li Tian

Date sent for review: 2015-05-27 20:09

Date reviewed: 2015-06-08 01:35

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input checked="" type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

This is a well written pleading on the current aspects of scientific review in orthopedics. The authors expect increasing importance of registrar data for orthopedic implants. Although this idea may be true, I think it is important to mention the place of registrar data in the development of new implants. In the end, register data will of course give the most information on implant survival. However, before this data is available, other (biomechanical and clinical) studies are still needed before prothesis are implanted in large groups of patients. The authors should stress this more in the article. It would be interesting if the authors could mention a paragraph on for who/when/how (etc) registerdata is available. Furthermore, there are some statements without adequate references. For instance: 'the number of incidents registered does not seem te decrease, rather the contrary is true.' and 'about half of the implants examined ... as a measure of average patient care' Reference style should be checked.

ESPS PEER-REVIEW REPORT

Name of journal: World Journal of Orthopedics

ESPS manuscript NO: 19918

Title: New regulations for medical devices: Rationale, advances and impact on research and patient care

Reviewer's code: 00505434

Reviewer's country: United States

Science editor: Yue-Li Tian

Date sent for review: 2015-05-27 20:09

Date reviewed: 2015-06-11 23:54

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input checked="" type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		BPG Search:	<input type="checkbox"/> Major revision
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input checked="" type="checkbox"/> No	

COMMENTS TO AUTHORS

Overall this is a good review article. While this is an interesting topic, I would recommend authors to rewrite the abstract to make it concise and right on the points. The authors have discussed the importance of register database, but also need to discuss about importance of prospective, randomized clinical trials for evaluation of the implants. The authors mentioned the new legislation but did not specifically describe it, do you mean guidelines? in some countris it is not possible to make it a legislative action. The guidelines for establishing a registry are indeed needed in order to obtain meaningful data.