Orygen
The National Centre of Excellence in Youth Mental Health

Submission

Consultation: Boxed Warning guidance

31 August 2018

Orygen, The National Centre of Excellence in Youth Mental Health (Orygen) welcomes the opportunity to provide a submission to the consultation on Boxed Warning guidance.

About Orygen

Orygen, The National Centre of Excellence in Youth Mental Health is the world's leading research and knowledge translation organisation focusing on mental ill-health in young people. At Orygen, our leadership and staff work to deliver cutting-edge research, policy development, innovative clinical services, and evidence-based training and education to ensure that there is continuous improvement in the treatments and care provided to young people experiencing mental ill-health.

Please note: Orygen is not a sponsor in the context of being a holder for marketing authorisation purposes, and therefore limited this submission to applicable components only.

Support for Boxed Warning guidance

In principle, Orygen supports the Boxed Warning guidance. However, consultative processes with young people will be essential in ensuring that young people with mental ill-health are best supported in decisions relating to prescription medication.

Orygen commends the focus on drawing clear attention to 'non-actionable' risks due to the importance of informed consent discussions, for both clinical services and clinical research purposes. Young people with mental ill-health consider information provision about risks to be an important factor in decision making, ensuring that they feel comfortable in their decision[1].

Young people have unique preferences and needs, and their participation, collaboration and input is essential in developing supportive processes[2]. It is not currently clear as to which adverse reactions or risks would be included on a Boxed Warning. Particularly for mental-health related prescription medication, Orygen suggests that young people are consulted on the proposed circumstances for the inclusion of Boxed Warnings to ensure that they are supported with information that would allow them to make informed decisions about their own care. This consultation could be implemented as a required process by the market authorisation sponsor. A greater understanding of the needs and preferences of young people will continue to be essential in the Boxed Warning content, format and inclusion on promotional material.

35 Poplar Road
Parkville VIC 3052
1300 679 436

ABN 85 098 918 686
orygen.org.au

An initiative of The Colonial Foundation,
The University of Melbourne
and Melbourne Health

Orygen supports that the Consumer Medicine Information (CMI) is clearly legible, in language that is easily understood, consistent with the statement in the product information, and is of suitable presentation and format. Again, Orygen would suggest that consultation with consumers, including young people, could be required by the proposed marketing authorisation holder of the medication as part of the regulatory submission package to the TGA to demonstrate that the information presented is understandable and accessible. Additionally, Orygen suggests that culturally and linguistically diverse young people may be better supported if information is available or able to be accessed in other languages.

One potential unintended consequence could be that some Boxed Warnings increase the risk of poor compliance to prescription medication for young people, and Orygen would recommend that this is explored during consultative processes.

Given the potential impact to the adherence and uptake of prescription medication, and the opportunity to ensure that young people are supported with access to clear information, a greater understanding of the needs and preferences of young people is essential to establishing Boxed Warning guidelines for prescription medication.

An assessment of the impact

A benefit-risk assessment is a central part of decision making in any treatment plan. The proposed Boxed Warnings on medications assist in better informing clinical and patient decisions. As Orygen is not a sponsor for the purposes of marketing authorisation, any impact of the proposed changes will relate primarily to patient management in psychiatric primary and specialist care (non-financial).

In the main, the proposed Boxed Warning is supported. Orygen conducts a large number of Investigator-initiated trials with marketed products as part of clinical translation studies. There would be updates required to the Patient Information and Consent Forms (PICFs) to include the explanation of such warnings for potential clinical trial participants. Some guidance from the Human Research Ethics Committees would be beneficial in this instance. Orygen would not want PICFs to be more extensive than is current best practice.

Orygen would suggest that TGA consult with NHMRC, AHEC and other ethics and governance stakeholders to streamline communication as part of the informed consent process as per the current NHMRC National Statement[3] and ICH GCP[4]. In addition, the National Statement may require updating in this regard as it is the applicable regulatory guidance for ICH GCP (R2) purposes (Section 3). We suggest provision of a half to one page summary explaining Boxed Warnings accompany any ethics submission to fully inform potential research participants succinctly.

Contact details

For further information and follow-up relating to this submission, please contact:
Vivienne Browne
Principal Adviser, Government Relations and Policy
Orygen, The National Centre of Excellence in Youth Mental Health
[redacted]
0413 370 581

References

1. Simmons MB, Hetrick SE and Jorm AF 2011. Experiences of treatment decision making for young people diagnosed with depressive disorders: a qualitative study in primary care and specialist mental health settings. *BMC psychiatry,* 11**,** 194.

2. James AM 2007. Principles of youth participation in mental health services. *Medical Journal of Australia,* 187**,** S57.

3. National Health Medical Research Council 2007 (Updated 2018). National statement on ethical conduct in human research. The National Health and Medical Research Council, the Australian Research Council and Universities Australia. Commonwealth of Australia, Canberra.

4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) 2016. Integrated addendum to ICH E6(R1): guideline for good clinical practice E6(R2). *Step 5,* ICH Harmonised Guideline.