An audit of the approval letters issued by Drugs Controller General of India to Ethics Committees in India

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Aim: The present study is an audit of the communiqués issued by the Drugs Controller General of India [DCGI] to Ethics Committees [ECs] for content and directives after the mandatory notification of registration of Ethics Committees issued on 8th February 2013. Methods: All letters were downloaded from the website of the Central Drugs Standard Control Organization [CDSCO] and evaluated for the date of issue, number of directives, domains covered by the directives [general instructions, administrative requirements and quorum requirements], median time to approval for registration and time elapsed between date of application and issue of the approval letter. Results: There were a total of 1036 EC letters listed on the website, from which 854 [82.4%] could be downloaded. A working denominator of 841 was arrived at after discarding repeat letters and those that had an incorrect address. The state of Maharashtra had the highest number of ECs registered (209/841, 24.9%) followed by Gujarat [97/841, 11.5%] and Karnataka [96/841, 11.4%]. The number of directives within each letter ranged from 8-22. The overall time to approval was 77.5 [24-919] days and the time to approval between Institutional and Independent Ethics Committees was significantly different. Conclusions: The office of the DCGI had a very wide time range for approving registration of Ethics Committees that ranged from less than a month to more than two years. The quality and nature of the directives improved with time. As the country moves towards accreditation, letters issued by the DCGI should have uniformity. The large number of ECs in a single state and lack of even a single one in several others is something that needs to be addressed by policy makers.

Key words: Approval, audit, Ethics Committees

INTRODUCTION

On the February 8, 2013, the Drugs Controller General of India (DCGI) mandated the registration of Ethics Committees [ECs] in the country that oversaw regulatory clinical trials. At the point of writing this report, these

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registered ECs are up for renewal of registration as the validity of registration issued by the Central Drugs Standard Control Organization [CDSCO] was for 3 years. This study is an audit of the communiqués issued by the DCGI to ECs at the point of registration with the twin objectives of assessing them for content and directives.

METHODS

The letters issued by the office of the DCGI from February 8, 2013, up until December 1, 2015 were downloaded from the website of the CDSCO (http://cdsco.nic.in/forms/Default.aspx, last accessed January 1, 2016). The letters were evaluated by authors SB, MM and JK for the following: (1) Date of issue, (2) the number of directives issued per letter, (3) domains covered by the directives (general instructions, administrative requirements and quorum requirements), (4) median time to approval from application for registration, (5) time elapsed between date of application and approval of the ECs and whether there was a difference in this regard between Institutional and Independent ECs, and (6) state wise approvals. The study protocol was deemed exempt from review by the institute’s EC [EC/OA/34/2015]. Quantitative data were expressed using median (range). Normality was assessed using the Kolmogorov–Smirnov test and categorical data expressed as proportions. The difference between the time to approval between Institutional and Independent ECs and whether there was a difference in this regard between Institutional and Independent ECs was analyzed using the Mann–Whitney U-test. All analyses were done at 5% significance using Microsoft Excel 2010. Data analysis and interpretation was performed by senior authors UT and NG.

RESULTS

Demographic data

Of the total of 1036 listed ECs on the CDSCO website, the authors were able to download only 854/1036 (82.4%). The remainder (182, 17.6%) could not be downloaded despite repeated attempts. Of the 854, there were five letters that pertained to a change of address, seven that were repeat letters and one that was posted to an incorrect address. Subtracting these 13 letters from 854 gave us a working denominator of 841 letters. Of these, 650/841 (77.3%) were approvals for Institutional ECs and 191/841 (22.7%) were approvals for independent ECs. The first letter issued was on April 1, 2013, for an institutional ECs and on May 16, 2013, for an Independent EC. All letters carried a serial number barring five letters. In 10 letters, an Institutional EC was listed as an Independent EC or vice versa.

State wise distribution

The state of Maharashtra had the highest number of ECs registered (209/841, 24.9%) followed by Gujarat (97/841, 11.5%) and Karnataka (96/841, 11.4%). The least number of approvals were for the state of Himachal Pradesh (n = 2) and Jharkhand, Sikkim and J and K (n = 1 each). Some states and Union Territories, namely, Arunachal Pradesh, Manipur, Meghalaya, Tripura, Andaman and Nicobar, Dadra and Nagar Haveli, Daman and Lakshadweep did not have a single letter issued to them indicating the absence of ECs in these states.

Directives

The number of directives within each letter ranged from 8 to 22. The directives issued in the early months of 2013 were purely administrative in nature and subsequently increased to cover all three domains related to functioning, composition, and training of the EC members. The content of the approval letters showed improvement reaching 22 items covering all three domains over a period of 6 months.

Time to approval

The overall time to approval was 77.5 (24–919) days. The time to approval for Institutional ECs was 58 (5–919) days with 5 days being for Maharashtra and 919 for the state of Assam. The time to approval for Independent ECs was 165.5 (24–822) days with 24 days for Delhi and 822 for Goa, respectively. This difference was statistically significant (P = 0.002).

DISCUSSION

This study showed that the office of the DCGI had a very wide time range for approving the registration of ECs, from as little as a month to more than 2 years. Furthermore, it appears that priority was given to approval of Institutional over Independent ECs. The quality and nature of the directives improved with time. A study on similar lines done a few years from now will show whether or not the CDSCO has been able to address the findings of this study which at least in part can be attributed to the learning curve of this organization.

The large number of ECs in a single state and lack of even a single one in several others is reflective of the skewed nature of regulatory research and development in the country and needs to be addressed by policy makers and organizations like the Indian Council of Medical Research. The study is limited by the fact that almost a fifth of the letters could not be downloaded. In addition, we are unclear as to whether 1036 is the actual number of applications received by the CDSCO office. As India moves toward the next logical step of accreditation by the quality council of
India,[2] letters from the office of the CDSCO when issued for renewal of registration should have uniformity, and have greater clarity on desirable qualifications for an EC member and whether Independent ECs can move beyond reviewing Bioavailability studies into the realm of studies that are nonregulatory in nature. This will serve both the regulatory body and the ECs well.

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**Conflicts of interest**
There are no conflicts of interest.

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