PD169 Is China Embracing Innovation? An Analysis Of Early Access In The Boao Lecheng International Medical Pilot Zone

Katherine Leong and
Richard Macaulay (richard.macaulay@precisionaq.com)

Introduction: Since 2018, medicines approved by regulators outside of China (e.g., the United States Food and Drug Administration) can be used in China's Boao Lecheng International Medical Pilot Zone if approved by the Hainan authority. In 2019, the Implementation Plan for the Clinical Real-World Data Application Pilot was also introduced to facilitate real-world data generation in Boao Lecheng. This research examined the status of authorized medicines in Boao Lecheng.
Methods: Information on authorized medicines and insurance coverage was extracted from the Boao Lecheng Administration Bureau's website and official WeChat account. Regulatory information was extracted from the National Medical Products Administration (NMPA) website on 31 October 2023.
Results: To date, 101 medicines have been authorized for use in Boao Lecheng. Of these, 45 (45%) were included in the Lecheng Global Special Drug Insurance Scheme, which provides commercial supplementary insurance for Hainan citizens, and 28 (28%) had received NMPA approval. In addition, 10 (10%) were included in Boao Lecheng's Clinical Real-World Data Application Pilot, four of which have since received NMPA marketing authorizations using the real-world data generated to support their applications (pralsetinib, trilaciclib, inclisiran, and the fluocinolone acetonide intravitreal implant). Three of these four medicines passed preliminary review for the National Reimbursement Drug List (NRDL) in 2022, and one was listed on the NRDL in 2023.
Conclusions: Boao Lecheng has become a channel for providing foreign medicines with early access to the Chinese market, with a considerable proportion being covered by commercial supplementary insurance or subsequently obtaining NMPA approval. Although few products have gone through Boao Lecheng's real-world data pilot to date, early examples show that it offers a route for local real-world data collection to support NMPA marketing authorizations.

PD170 Modification Of The All Wales Medicines Strategy Group Appraisal Process Provides Faster Access To Children's Medicines In Wales

Kelly Wood (kelly.wood@wales.nhs.uk), Alice Varnava, Ruth Lang, Anthony Williams, Professor James Coulson, Andrew Champion and Claire Ganderton

Introduction: Medicines routinely funded for use in Wales undergo health technology appraisal by the All Wales Medicines Strategy Group (AWMSG) or the National Institute for Health and Care Excellence (NICE). This includes pediatric license extensions (PLE) notwithstanding any existing advice in adults. A review of the PLE process was conducted with the aim of providing faster access to children's medicines in Wales.
Methods: Data were collected for PLE appraisals of medicines previously approved for adults by the AWMSG or NICE that subsequently went through the original PLE process between January 2010 and December 2020, or a simplified PLE process between January 2021 and March 2023. Data were analyzed using descriptive statistics and a two-tailed t-test (unequal variance) to test the null hypothesis that the difference between the two means was zero. An alpha of less than 0.05 was considered significant. Feedback was obtained from relevant stakeholders including the Association of the British Pharmaceutical Industry (Wales) and the Royal College of Paediatrics and Child Health.
Results: The AWMSG issued positive recommendations for all PLE appraisals included in the data collected, and these were endorsed by the Welsh Government. Appraisals that went through the original PLE process (n=56) took a mean 229.8 days (standard deviation 55.6), whereas those that went through the simplified PLE process (n=15) took a mean 102.6 days (standard deviation 48.1; $p < 0.0001$). The rapid access to children's medicines was welcomed by the Association of the British Pharmaceutical Industry and the Royal College of Paediatrics and Child Health.
Conclusions: Review of the 2020 and 2023 PLE processes facilitated faster access to clinically effective and cost-effective medicines for children in Wales. In March 2023, the AWMSG and the Welsh Government reviewed these results and agreed that because all PLE medicines were approved for use within Wales irrespective of the process used, the AWMSG would no longer be required to routinely appraise PLEs.

https://doi.org/10.1017/S0266462324003957 Published online by Cambridge University Press