



Is China Becoming More Attractive to Manufacturers of Innovative Medicines? Insights From the Boao Medical Pilot Zone

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INTRODUCTION

- Since 2018, medicines approved by regulators outside of China (e.g., the FDA) 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 (RWD) Application Pilot was also introduced to facilitate RWD generation in Boao
- This research examines the statuses of Boao-authorized medicines to evaluate how this pathway can support National Medical Products Administration (NMPA) regulatory approval, National Reimbursement Drug List (NRDL) listing and commercial supplementary insurance coverage in China

METHODS

- Information of Boao-authorized medicines and insurance coverage was extracted from the Lecheng Administration Bureau’s website and official WeChat account (31-Oct-2023)
- Regulatory information was extracted from the NMPA website (31-Oct-2023)
- Information of NRDL inclusion was extracted from the National Healthcare Security Administration (NHSA) website (13-Dec-2023)

RESULTS

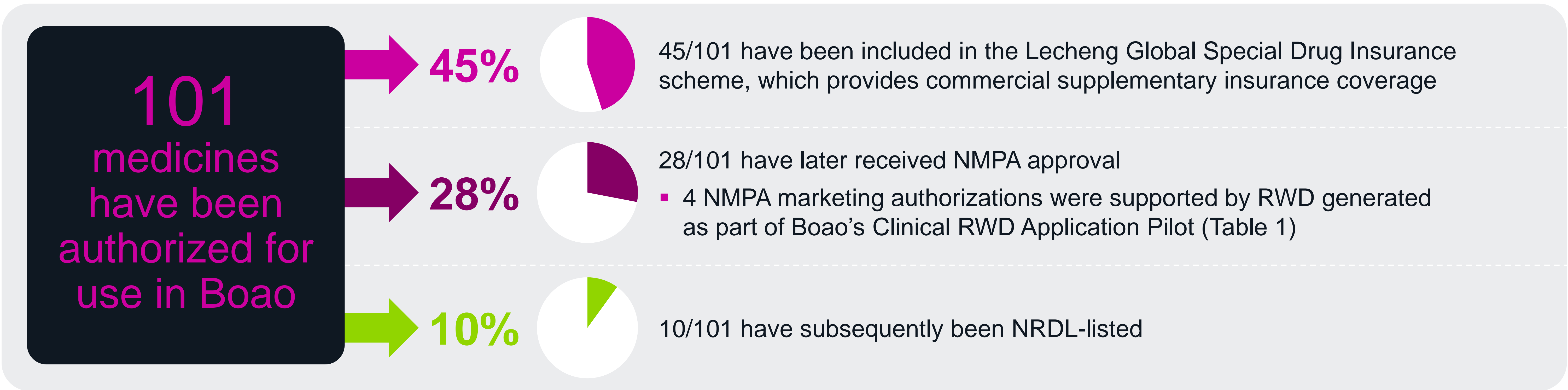


Table 1: Spotlight on four NMPA-approved medicines supported by Boao’s Clinical RWD Application Pilot

Company	Product	Indication	Approval timing				NRDL inclusion
			FDA	EMA	Boao	NMPA	
Roche	Gavreto (pralsetinib)	RET+ NSCLC	Dec 2020	Nov 2021	Sep 2020	Mar 2021	No (passed preliminary review only in 2023)
Novartis	Leqvio (inclisiran)	Primary hypercholesterolaemia or mixed dyslipidaemia	Dec 2021	Dec 2020	May 2021	Aug 2023	No
G1 Therapeutics	Cosela (trilaciclib)	Chemotherapy-induced myelosuppression	Feb 2021	-	May 2021	Jul 2022	No (passed preliminary review only in 2023)
Alimera Sciences	Yutiq (fluocinolone acetonide intravitreal implant)	Chronic non-infectious uveitis affecting the posterior segment of the eye	Oct 2018	-	Jul 2019	Jun 2022	Listed in NRDL 2023

CONCLUSIONS

- Boao has become a channel providing foreign medicines with early access to the China market, with a considerable proportion covered by commercial supplementary insurance, subsequently obtaining NMPA approval and NRDL inclusion
- Although few products have gone through Boao’s RWD pilot to date, early examples show that it offers a route of local RWD collection to support NMPA marketing authorization and subsequent NRDL inclusion

