

Model Kebijakan Prediktif Pengembangan Obat Berbasis Riset Di Indonesia = Predictive Policy Model to Forecast Outcomes of Research-based Drug Development in Indonesia

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Deskripsi Lengkap: <https://lib.ui.ac.id/detail?id=20491809&lokasi=lokal>

Abstrak

Ketersediaan obat baru di Indonesia masih didominasi oleh produk impor dan terbatasnya industri farmasi yang menghasilkan obat berbasis riset walaupun pemerintah telah melakukan intervensi regulasi. Industri farmasi lebih banyak melakukan formulasi dan/atau pengemasan obat dibandingkan memproduksi obat berbasis riset. Produksi obat berbasis riset dibutuhkan untuk menjamin keberlangsungan ketersediaan obat. Penelitian ini bertujuan membangun model kebijakan yang mampu memprediksi dampak pengembangan obat berbasis riset di Indonesia. Penelitian dengan pendekatan kros sektorsial ini menggunakan metode kuantitatif dengan melakukan survei terhadap industri farmasi dan penentu kebijakan pengembangan obat di Indonesia; dan metode kualitatif dengan melakukan kajian masalah dari dokumen kebijakan dan wawancara terstruktur. Model kebijakan ditetapkan berdasarkan analisis pengaruh variabel kapabilitas industri farmasi dengan variabel mekanisme insentif dari pemerintah terhadap konteks fisibilitas politik yang mempengaruhi pengembangan obat berbasis riset, dengan pengukuran yang dilakukan terhadap indikator-indikator yang merefleksikan variabel tersebut. Model kebijakan diuji menggunakan structural equation modeling. Identifikasi kesenjangan (gap analysis) dilakukan sebagai upaya untuk meminimalkan perbedaan pandangan antara industri farmasi dan pemerintah terhadap kapabilitas industri farmasi dan mekanisme insentif dari pemerintah. Analisis determinan kebijakan dan dampak dilakukan untuk memprediksi keberhasilan model tersebut dalam memberikan dampak.

Hasil penelitian membuktikan bahwa kapabilitas industri farmasi, konteks fisibilitas politik, dan mekanisme insentif inovasi yang spesifik untuk kapabilitas industri farmasi, merupakan variabel yang berpengaruh kuat untuk memberikan dampak pengembangan obat berbasis riset, dengan indikator yang paling kuat memberikan pengaruh adalah peluang pasar, faktor penarik inovasi, sumber daya pemerintah dan program nasional. Walaupun hasil penelitian juga membuktikan bahwa regulasi, kapasitas industri farmasi, karakteristik obat, peluang pasar, faktor pendorong inovasi, faktor penarik inovasi, faktor penarik regulasi, aktor kebijakan, nilai kebijakan, sumber daya pemerintah dan program nasional merupakan indikator yang memberikan pengaruh dalam pengembangan obat berbasis riset, namun indikator-indikator ini belum mampu menjadi penguangkit dan memberikan dampak terhadap pengembangan obat berbasis riset di Indonesia. Prioritas kebijakan dan perbaikan harus segera dilakukan pada regulasi, peluang pasar, dan mekanisme insentif inovasi sehingga pengembangan obat yang diharapkan dapat terjadi.

Indonesia's supply of new drugs currently relies on imported drugs. Pharmaceutical companies appear to be hesitant to transform from being an inventor to being an innovator, and instead continue the process of formulation and packaging. Government regulation intervention has not led to any significant changes. Drug development involves the creation of an innovative drug that is not yet available in the country. Domestic development is needed to ensure sustainability of the access to research-based drug and to reduce the price of that drug that is currently imported. This study aims to develop a policy model that is

strategically able to predict an outcome of investment in research-based drug development. Several factors that could trigger domestic research-based drug development were explored and incorporated into a predictive model of an innovation policy. A data collection in this cross-sectional study used a quantitative and qualitative method to explore the policy making process. Data was collected using a structured questionnaire to pharmaceutical companies and policy makers, and also a document review and indepth interview. The process of modeling the policy was established based on the functional relationships between factors related to the capability of pharmaceutical companies in the development of research-based drug and government incentives to political feasibility to predict a drug development, validated using a set of techniques pertaining to the calculation of structural equations. Gap analysis was an effort for examining the similarities and differences in perceptions of capability of pharmaceutical companies and incentive mechanism to accelerate research-based drug development. The findings provided empirical insights on the gaps that can arise from inconsistent perceptions of potential and current situations between pharmaceutical companies and policy makers. The alignment between policy recommendations and intended outcomes was then analyzed using analysis of determinants of policy impact.

The study proves that pharmaceutical company capabilities, political feasibility and innovation incentives correlated to pharmaceutical company capabilities are major catalysts that encourage pharmaceutical companies to invest more in drug development, majorly explained by market opportunities, pull factors, government resources and national program. Although the study proves that regulation, pharmaceutical company capacities, drug characteristics, market, push-pull-regulatory pull factors, actors, values, government resources and national program are strong indicators relating to drug development, the study reveals that those indicators are not yet able to become leverage and make impact to drug development. Special attention on policy priorities and improvements have to be put on regulation, market opportunities, and push-pull-regulatory pull factors to make impact on drug development in Indonesia.</i>