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ECONOMIC AND HEALTH SYSTEM CAPACITY ASSOCIATIONS WITH BIOSIMILAR REGULATORY APPROVALS ACROSS COUNTRIES AND INCOME GROUPS

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Abstract:

This analysis examines whether economic resources, health financing intensity, and population correspond differently with biosimilar regulatory approvals across national markets. A descriptive cross-sectional dataset combines reported approval stocks with World Development Indicators for 20 countries in 2019. Distributional summaries, ranked group comparisons, Spearman correlations, and exploratory country exclusions assess the observed patterns. Population shows a positive rank correlation of 0.496 with approvals, compared with 0.129 for GDP per capita and 0.045 for health expenditure per capita. Median approvals reach 21.50 in the upper population half and 9.00 in the lower half. Population correlations remain positive across exclusions of India, China, and both countries, ranging from 0.445 to 0.746. Income category means and medians yield different rankings because authorizations are concentrated in particular countries. These findings distinguish potential market scale from financial intensity without identifying causal mechanisms. The contribution refines market capacity interpretation by demonstrating that its dimensions describe different authorization patterns. International benchmarking should distinguish cumulative approvals from active availability and patient access.

Key Words: Biosimilars; Regulatory Approvals; Market Capacity; International Comparison; Spearman Correlation

1. Introduction:

Biosimilar authorization creates an opportunity for competition in biological medicines, but national approval counts do not directly reveal whether economic resources, health financing, or market scale accompany that opportunity. Distinguishing these dimensions matters for international comparisons because a wealthy country, a high spending health system, and a populous market represent different commercial and institutional conditions. Treating them as interchangeable measures of market capacity can obscure the characteristics associated with regulatory entry. Simoens and Vulto, 2021, distinguish the authorization and uptake of biosimilars from the broader objective of making biological treatment available at sustainable costs. This distinction establishes the need to examine approval stocks as a specific regulatory outcome rather than a comprehensive measure of access. Biosimilar entry involves interdependent decisions by manufacturers, regulators, and purchasers. Manufacturers face development and registration costs, regulators assess evidence of similarity to reference products, and purchasers determine whether authorized products enter funded treatment pathways. Simoens, Verbeken, and Huys, 2012, explain that comparability requirements and economic considerations jointly shape market access. Moorkens and colleagues, 2016, identify manufacturing, regulatory, intellectual property, and commercial barriers within the European Union. These contributions establish that financial attractiveness alone cannot explain entry. They also distinguish the incentive to seek authorization from the institutional requirements governing whether authorization is granted.

Three dimensions of national market capacity follow from this reasoning. GDP per capita indicates average economic resources that could support demand for biological medicines. Health expenditure per capita captures the intensity of health financing, which may influence the commercial attractiveness of supplying treatment. Population represents potential market scale and the prospective volume over which suppliers might recover entry costs. These mechanisms do not imply uniformly positive relationships with approvals. Aggregate expenditure does not identify spending on biological medicines, population does not measure eligible patients, and economic resources do not directly measure regulatory expertise. Dylst, Vulto, and Simoens, 2014, found that hospital financing arrangements and stakeholder uncertainty constrained biosimilar utilization in Belgium. Their findings demonstrate why aggregate resources cannot substitute for direct measures of the incentives governing product use. Regulatory capacity provides a further boundary to economic interpretation. Kang and Knezevic, 2018, emphasize scientific assessment, monitoring, and continuing oversight throughout the product life cycle. These functions require institutional capabilities that GDP and expenditure indicators capture only indirectly, if at all. The global assessment by Kang et al., 2020, documents regulatory convergence alongside differences in national requirements and reported approvals. Consequently, approval counts reflect accumulated decisions within heterogeneous regulatory systems. Higher counts cannot automatically indicate more rigorous assessment, wider commercial availability, or greater patient access. A comparative analysis must retain these distinctions when relating authorizations to national market characteristics.

The closest reviewed contributions address different parts of this problem. European market access research identifies barriers and incentives, while the WHO assessment documents the international regulatory landscape and provides jurisdiction totals. The reviewed evidence does not establish whether economic resources, health financing intensity, and population show

similar descriptive relationships with those approval stocks when examined within a common country sample. The gap concerns the interpretation of observable market capacity dimensions rather than an unmeasured causal mechanism. Addressing it can clarify whether apparent differences between income groups reflect a broad ordering across countries or concentration in particular national approval histories. This analysis aims to examine how reported biosimilar approval stocks vary with GDP per capita, current health expenditure per capita, and population. The central research question asks which dimensions of national market capacity correspond most consistently with approval counts across the observed countries. The specific objectives are to describe approval variation across economic resource levels, assess its ordering by health expenditure, and compare that ordering with population size. Reconstructed income categories provide an additional descriptive perspective without serving as a moderator or an official historical classification.

The empirical setting comprises 20 countries observed in 2019. Approval totals are drawn from the regulatory assessment reported by Kang et al., 2020, and matched with World Development Indicators. The European Union is excluded to preserve the country unit of analysis. Approval stocks generally refer to August 2019, except China, whose count refers to June. The analysis combines distributional summaries, comparisons between ranked halves of the sample, Spearman correlations, and exploratory exclusions of India and China. This design enables transparent comparison across measured dimensions while retaining the cumulative nature of authorizations and the contemporaneous timing of annual indicators. It supports descriptive association rather than causal identification. The findings distinguish market scale from financial intensity. Population has a stronger positive rank association with approval stocks than either GDP or health expenditure per capita, and its positive ordering persists across the exploratory exclusions. Income category means and medians provide different rankings because approval stocks are concentrated in particular countries. The contribution is therefore a bounded empirical qualification of national market capacity: its dimensions describe different patterns and should not be collapsed into a single interpretation of regulatory development. For international benchmarking, the results support reporting approval definitions, timing, concentration, and country composition alongside aggregate economic comparisons. Their transferability concerns this measurement principle; the observed rankings remain specific to the countries and regulatory snapshot examined.

2. Theory, Conceptual Framework and Research Questions Development:

This analysis draws on the economics of market entry and regulatory capacity to examine biosimilar approval differences across 20 countries in 2019. Manufacturers must anticipate sufficient demand to justify development and registration costs, while regulators must assess evidence of product quality, safety and efficacy. These interdependent decisions connect commercial incentives with institutional requirements. Simoens, Verbeken, and Huys, 2012, explain that biosimilar market access depends on comparability requirements as well as costs. Economic resources may therefore support regulatory entry, but purchasing power alone does not establish how many products receive approval. The conceptual framework represents national market capacity through three observed dimensions: GDP per capita, current health expenditure per capita, and total population. These indicators capture economic resources, health financing intensity, and potential market scale, respectively. They remain separate measurements rather than components of a constructed index. The outcome is the reported cumulative number of biosimilar approvals at the regulatory snapshot. It measures regulatory authorization rather than commercial availability, prescribing, or patient access.

Regulatory institutions provide the boundary within which market capacity can translate into approvals. Kang and Knezevic, 2018, identify scientific assessment and continuing oversight as essential regulatory functions. Greater economic resources could support these functions, but GDP per capita does not directly measure regulatory expertise or assessment efficiency. Consequently, this analysis treats economic capacity as a contextual indicator and does not interpret it as an observed measure of regulatory performance. GDP per capita captures average economic output per person and provides an indicator of the resources potentially available to finance biological medicines. Higher purchasing capacity could make a national market more attractive to manufacturers seeking to recover registration and commercialization costs. However, affordability pressures may also strengthen interest in biosimilars where economic resources are constrained. Simoens and Vulto, 2021, distinguish sustainable competition and affordable treatment from biosimilar uptake itself. Their argument supports examining economic capacity without assuming that wealth necessarily corresponds to a larger approval stock.

RQ1: How do reported biosimilar approval counts vary across countries with different GDP per capita levels?

Current health expenditure per capita captures the intensity of health financing rather than the size of the overall economy. Greater spending could indicate a stronger financial base for biological treatment and a market capable of supporting multiple suppliers. Nevertheless, expenditure can also reflect high prices or financing arrangements that provide limited incentives to adopt alternatives. Dylst, Vulto, and Simoens, 2014, identified hospital financing arrangements, uncertainty about substitution, and stakeholder confidence as barriers to biosimilar uptake in Belgium. This evidence concerns utilization rather than approval, but it establishes why aggregate expenditure cannot be treated as a direct measure of biosimilar demand.

RQ2: How do reported biosimilar approval counts vary across countries with different health expenditure per capita levels?

Population represents potential market scale. A larger population could increase the number of prospective treatment recipients and strengthen the commercial incentive to seek authorization. This mechanism concerns potential demand because population does not measure disease prevalence, insurance coverage, or purchasing capacity. Moorkens and colleagues, 2016, identify manufacturing, regulatory, commercial, and stakeholder barriers to biosimilar market access. These constraints explain why a large population may coexist with limited entry and why population size cannot establish a uniformly positive relationship with approvals.

RQ3: How do reported biosimilar approval counts vary across countries with different population sizes?

The framework guides descriptive comparisons of approval count against each measured dimension. The analysis covers one observation per country, with approvals generally reported in August 2019 and the Chinese count reported in June 2019. The outcome is a cumulative stock, whereas the economic and demographic indicators describe the calendar year. Accordingly, the research questions concern observed differences across countries rather than changes over time or causal effects. Reconstructed income bands provide descriptive grouping labels rather than official historical classifications. The interpretation allows

increasing, decreasing, and irregular patterns without treating any pattern as evidence that national market capacity independently determines regulatory approvals.

3. Data:

This analysis links reported biosimilar approval stocks with economic, health financing, and population indicators for 20 countries in 2019.Source documentation, sample accounting, and variable definitions establish the basis for descriptive comparisons across countries.

3.1 Data Sources, Population, and Sample Construction:

The dataset combines regulatory approval counts from the WHO regulatory landscape assessment with four World Development Indicators series. Approval counts reproduce the country totals in Table 2 of Kang et al., 2020. The economic indicators are GDP per capita, series NY.GDP.PCAP.CD, and current health expenditure per capita, series SH.XPD.CHEX.PC.CD. Population uses SP.POP.TOTL. Atlas gross national income per capita, series NY.GNP.PCAP.CD, supports reconstructed income categories. The World Bank distributes these indicators through its public data portal and version 2 application programming interface. Health expenditure originates from the WHO Global Health Expenditure Database. The unit of analysis is the country. The empirical setting covers biosimilar regulation across countries in Africa, Asia, Europe, and the Americas. Each country contributes one observation, producing a cross section rather than an annual panel. Approval counts generally refer to August 2019, except China, whose count refers to June 2019. These counts are cumulative stocks and may include authorizations granted before the observation year. GDP and health expenditure represent annual monetary flows divided by population. Total population represents an annual demographic level. The target population comprises national jurisdictions regulating biosimilars. Its global size is not established by the supplied files. The accessible frame comprises 21 regulatory jurisdictions listed in the source table, including the European Union. The analytical sample retains national jurisdictions with a reported approval count and complete values for the three market capacity indicators. The European Union is excluded because its supranational structure is incompatible with the country unit. The United Kingdom is not assigned a separate observation because its survey response refers to the European regulatory framework.

Table 1: Sample construction

Stage	Units	Observations	Reason or Rule
Accessible regulatory frame	21 jurisdictions	21 jurisdiction records	Jurisdictions with totals in the source approval table
European Union exclusion	1 jurisdiction removed	1 record removed	Supranational jurisdiction
Eligible national sample	20 countries	20 country records	National regulatory jurisdictions
Matched sample	20 countries	20 country observations	Complete approval, GDP, health expenditure, and population values
Missing value exclusions	0 countries removed	0 observations removed	All required analytical variables populated
Final descriptive sample	20 countries	20 country observations	One observation per country

The workbook documents these selection rules but provides no dated protocol establishing when they were adopted. Its Sources worksheet retains the extraction date and indicator queries. No frozen World Development Indicators release identifier is supplied. The monetary and demographic observations therefore represent revised historical data rather than an archived information set available at the approval date. World Bank indicators carry Creative Commons Attribution 4.0 licensing, subject to the applicable dataset terms. The source article is distributed under a Creative Commons attribution licence.

3.2 Data Integration, Cleaning, and Quality Assurance:

The consolidated workbook identifies countries through names and ISO3 codes and assigns 2019 to every observation. The intended integration relationship is one regulatory record to one country record for each indicator. Inspection confirms 20 distinct ISO3 codes, with no duplicate country observations or missing values in the approval count, GDP, health expenditure, population, or gross national income fields. The final workbook contains no unmatched analytical records. Separate raw merge logs are not supplied, so intermediate matching failures cannot be reconstructed. The workbook records no imputation, interpolation, extrapolation, synthetic observations, or replacement of missing values with zero. All approval counts are positive integers, and all monetary and population measurements are positive. The consolidated sample retains the full observed ranges. No trimming or winsorization is documented. India’s approval count and China’s population remain valid extreme observations rather than automatically classified errors.

GDP, health expenditure, and gross national income are retained in current United States dollars using the provider’s published values. No additional exchange rate conversion, inflation adjustment, or purchasing power adjustment is applied. These monetary indicators therefore support comparisons in nominal dollars and do not measure equivalent domestic purchasing power. Temporal matching aligns the annual indicators with the calendar year of the regulatory snapshot. It does not establish that annual economic conditions preceded the recorded approvals. The economic series incorporate information covering months after the regulatory snapshot, while the approval stock accumulates decisions across earlier periods. Consequently, the dataset supports retrospective description rather than forecasting or causal attribution. Regulatory comparability remains a substantive limitation. The source assessment reports differences in terminology and approval requirements across jurisdictions. Its Indonesia total includes three products that were approved and subsequently withdrawn. This analysis retains the published total of 23 and interprets the outcome as reported cumulative authorizations rather than the number of products maintaining active authorization. No post inspection changes to the source totals are introduced.

3.3 Variable Measurement, Construction, and Validation:

National market capacity is represented by three separate observed indicators. GDP per capita measures economic resources, health expenditure per capita measures financing intensity, and population measures potential market scale. No latent variable, composite index, interaction, moderator, or additional control is constructed. Approval counts remain in their original units.

Table 2: Variable dictionary

Variable or Indicator	Analytical Role	Definition and Construction	Source and Identifier	Unit and Frequency	Transformation and Direction	Missing Value Rule	Coverage and Limitation
Biosimilar approvals	Outcome	Published jurisdiction total	Kang et al., 2020, Table 2	Product authorizations at regulatory snapshot	None; higher values indicate more reported authorizations	No missing observations	20 countries; cumulative counts with differing regulatory standards
GDP per capita	Economic capacity indicator	Annual GDP divided by population	World Bank, NY.GDP.PCAP.CD	Current USD per person, annual	None; higher values indicate greater output per person	No missing observations	20 countries in 2019; nominal monetary measure
Health expenditure per capita	Health financing indicator	Current health expenditure divided by population	WHO through World Bank, SH.XPD.CHEX.PC.CD	Current USD per person, annual	None; higher values indicate greater spending per person	No missing observations	20 countries in 2019; includes spending beyond biological medicines
Total population	Market scale indicator	Published population estimate	World Bank, SP.POP.TOTL	Persons, annual	None; higher values indicate larger population	No missing observations	20 countries in 2019; does not measure eligible patients
Atlas GNI per capita	Classification input	Published Atlas gross national income per person	World Bank, NY.GNP.PCAP.CD	Current USD per person, annual	None; higher values indicate greater income per person	No missing observations	20 countries in 2019; revised historical values
Reconstructed income category	Descriptive grouping	Threshold classification of Atlas GNI per capita	Workbook construction using World Bank thresholds	Categorical, single observation	Ordered income categories	No missing observations	Reconstructed categories rather than archived official membership

Income categories apply thresholds published by Serajuddin and Hamadeh, 2020. Values up to USD 1,035 identify low income, values above USD 1,035 through USD 4,045 identify lower middle income, values above USD 4,045 through USD 12,535 identify upper middle income, and values above USD 12,535 identify high income. Applied to the workbook's revised income values, these rules produce six lower middle-income countries, nine upper middle-income countries, and five high income countries.

Table 3: Descriptive statistics for the analytical sample

Variable	Valid Observations	Mean	Sample Standard Deviation	Median	Minimum	Maximum
Biosimilar approvals	20	17.50	19.46	13.00	1	93
GDP per capita, USD	20	17,162.46	21,095.14	8,317.76	1,258.99	66,068.70
Health expenditure per capita, USD	20	1,550.15	2,589.07	393.66	60.69	10,550.22
Population, million persons	20	221.14	412.36	61.64	5.70	1,407.75
Atlas GNI per capita, USD	20	16,965.50	20,524.31	8,040.00	1,380.00	65,840.00

These statistics were calculated directly from the 20 workbook observations. Population is expressed in millions solely for presentation. Means exceed medians across the numerical variables, indicating that larger observations influence sample averages. Medians and ranges therefore accompany means and standard deviations. Verification establishes completeness, identifier uniqueness, and admissible numerical values; it does not establish equivalence of national regulatory standards or independently validate every source estimate.

3.4 Analytical Framework, Identification, and Reproducibility:

The analysis is descriptive. Its quantities of interest are the observed distribution of approval stocks and their variation across measured economic resources, health financing intensity, population size, and reconstructed income categories. Comparisons concern countries represented in the accessible frame. They do not estimate population causal effects or establish that any capacity dimension independently determines approvals. The implemented analytical work comprises sample accounting, completeness and uniqueness checks, income category counts, and numerical summaries. No regression model, fixed effects, interaction, clustering procedure, or significance test is reported. Equations are unnecessary because the analytical variables retain their published levels and no numerical index is constructed. Interpretation is constrained by nonrandom jurisdiction coverage, differences in regulatory definitions, the cumulative nature of approvals, and contemporaneous annual indicators. National averages also cannot identify manufacturer decisions, prescribing behavior, or patient access. Retaining all observed countries avoids exclusions based on extreme values, but it does not remove selection arising from participation in the source assessment. No alternative sample or sensitivity result is claimed. The workbook preserves country identifiers, observations, variable definitions, source references, and indicator query routes. It does not include the original construction code, archived API responses, or a dated change log. Reproduction can therefore begin from the supplied consolidated values, while a fresh source extraction may differ because historical indicators are revised. The common country unit and observation year align the measurements for descriptive comparison, with the approval timing and regulatory differences retained as explicit limits.

4. Methods:

4.1 Research Design and Analytical Scope:

This analysis uses a descriptive cross-sectional design to examine how reported biosimilar approval stocks vary with economic resources, health financing intensity, and population. The unit of analysis is the country, with one observation for each

of 20 countries in 2019. The analytical targets are sample distributions, differences between descriptive groups, and unadjusted rank associations. These quantities address whether the three dimensions of national market capacity exhibit comparable patterns with regulatory authorizations. The analysis uses variation between countries rather than changes over time. Annual economic and demographic indicators are matched to the year of the regulatory snapshot. Because approvals accumulate across earlier periods, contemporaneous national indicators cannot establish the conditions preceding individual authorization decisions. The design therefore supports retrospective comparison without identifying causal effects or forecasting future approvals. The outcome remains the published cumulative authorization count. It is not interpreted as the number of distinct molecules, products maintaining active authorization, commercial launches, or patients receiving treatment. National differences in regulatory requirements also constrain comparability. These measurement boundaries follow the regulatory assessment by Kang et al., 2020, which provides the approval totals used in the analysis.

4.2 Descriptive Measures and Association Specification:

The sample construction rules and variable definitions are documented in Tables 1 and 2. Numerical summaries comprise valid counts, arithmetic means, sample standard deviations, medians, minima, and maxima. Sample standard deviations use the number of observations minus one as the denominator. Approval totals are summed across jurisdictions without treating the resulting sum as a count of globally distinct products. All analytical variables retain their original levels. Monetary indicators remain in current United States dollars per person. Population is divided by one million solely for presentation in the descriptive statistics table. No logarithms, normalization, composite scores, or weighting procedures are applied. Each country contributes equally to country averages and association calculations. Spearman rank correlation summarizes the ordering between approval counts and each capacity indicator. The calculation ranks both variables in ascending order, assigns average ranks to tied values, and computes the Pearson correlation between the resulting rank vectors. This implementation accommodates ties in approval counts. Positive values indicate that countries ranked higher on the capacity indicator tend to rank higher on approvals. The coefficient describes unadjusted sample ordering and does not measure the independent contribution of any indicator. Exploratory grouped comparisons provide an interpretable complement to the correlations. Countries are ranked separately by GDP per capita, health expenditure per capita, and population. For each ranking, the lowest ten observations form the lower half and the highest ten form the upper half. No boundary ties occur for these indicators. Approval means, medians, minima, and maxima are calculated within each half. These divisions create equally sized descriptive groups rather than estimated thresholds or treatment categories. Reconstructed income categories provide an additional stratification. Country counts, authorization totals, means, medians, and ranges are calculated within the categories recorded in the workbook. Gross national income supports classification rather than serving as a fourth explanatory indicator. Comparisons remain descriptive because the categories are reconstructed and the sample contains no low-income observations.

4.3 Computational Procedures and Verification:

Calculations use Python 3.12.14, NumPy 2.3.5, and openpyxl 3.1.5. The workbook is read using stored cell values. The computational sequence begins with extraction of the Dataset worksheet, followed by verification of country identifiers, observation years, numerical completeness, and admissible values. Numerical summaries, indicator rankings, grouped comparisons, income category summaries, and sensitivity calculations follow in that order. Inspection confirms one record for each of 20 distinct ISO3 identifiers. All required numerical fields are populated. Approval counts are positive integers, and the economic and population indicators contain positive values. No observation is removed through missing value deletion, and no imputation, interpolation, or replacement with zero is performed. The full sample retains extreme observations. No trimming, winsorization, or automatic outlier exclusion is applied. Means are interpreted alongside medians and ranges because large observations can influence averages. Spearman correlations complement these summaries by measuring ordering rather than linear association in the original units. The analysis reports descriptive coefficients without significance tests, confidence intervals, or population effect estimates. The accessible regulatory sample is not a probability sample, and no sampling-based generalization is claimed. No regression residuals, latent measurements, or temporal models are constructed; diagnostics requiring those objects are therefore outside the implemented procedure.

4.4 Sensitivity, Reproducibility, and Interpretive Limits:

Exploratory sensitivity analysis examines the influence of India and China. India combines the highest approval count with a large population, while China combines the largest population with the lowest approval count. Three alternative samples exclude India, exclude China, and exclude both countries. These comparisons contain 19, 19, and 18 observations, respectively. Ranks are recalculated within each restricted sample before computing the three Spearman correlations. Each comparison uses identical countries across the capacity indicators, allowing their descriptive ordering to be compared on a common sample. The analysis evaluates changes in direction, magnitude, and relative ordering rather than continued statistical significance. The exclusions are sensitivity exercises rather than corrections to the retained dataset. These checks assess dependence on particular observations but do not resolve confounding, jurisdiction selection, regulatory heterogeneity, or temporal mismatch. They also do not establish that the three capacity dimensions operate independently. Differences between correlations are interpreted descriptively without a formal test of their separation. The workbook preserves observations, country identifiers, definitions, source references, and indicator query routes. The formulas, ranking conventions, grouping rules, software versions, and exclusion procedures specified here permit replication of the reported calculations from those consolidated values. Source retrieval may produce revised historical indicators because a frozen source release is not supplied. The methodological contribution rests on transparent comparison and explicit measurement boundaries, rather than a new estimator or identification strategy.

5. Findings:

This analysis examines how reported biosimilar approval counts vary with economic resources, health expenditure, and population across 20 countries in 2019.Descriptive comparisons and rank correlations address the three research questions without imposing directional relationships. Exploratory sensitivity checks assess whether the observed patterns depend on India and China.

5.1 Sample Composition and Approval Distribution:

The analytical sample contains 20 countries with complete observations for biosimilar approvals, GDP per capita, health expenditure per capita, and population. Each country contributes one observation. The European Union is excluded because it represents a supranational regulatory jurisdiction. Approval counts generally refer to August 2019, with China measured in June 2019. The sample records 350 authorizations across national jurisdictions. This sum does not represent 350 distinct medicines because the same product can receive authorization in several countries. India accounts for 93 authorizations, equivalent to 26.57 percent of the sample total. China records one authorization, while Russia records 31. These differences concern the published approval stocks rather than medicines currently marketed or patients receiving treatment.

Table 4: Distribution of approvals and market capacity indicators

Indicator	Countries	Mean	Standard Deviation	Median	Minimum	Maximum
Biosimilar approvals	20	17.50	19.46	13.00	1	93
GDP per capita, USD	20	17,162.46	21,095.14	8,317.76	1,258.99	66,068.70
Health expenditure per capita, USD	20	1,550.15	2,589.07	393.66	60.69	10,550.22
Population, million persons	20	221.14	412.36	61.64	5.70	1,407.75

The approval mean exceeds the median by 4.50 authorizations. Removing India reduces the mean from 17.50 to 13.53, demonstrating its influence on the aggregate average. The monetary indicators and population also show means substantially above their medians. Comparisons therefore retain medians and rank correlations alongside means. Approval definitions constrain interpretation. Kang et al., 2020, document differences in national regulatory frameworks, and the source total for Indonesia includes three subsequently withdrawn authorizations. Consequently, larger counts cannot be interpreted as stronger regulatory performance or more currently available biosimilars.

5.2 Economic Resources and Health Financing:

The first research question concerns variation in approvals across GDP per capita levels. An exploratory comparison divides countries into two equal groups after ranking GDP per capita. The lower half records a higher mean approval count, but the upper half records a higher median. The difference between these summaries indicates that the apparent advantage of the lower half depends on unusually large approval counts.

Table 5: Approval counts across ranked halves of market capacity indicators

Ranking Indicator	Group	Countries	Mean Approvals	Median Approvals	Minimum	Maximum
GDP per capita	Lower half	10	19.60	11.50	4	93
GDP per capita	Upper half	10	15.40	15.00	1	31
Health expenditure per capita	Lower half	10	19.60	11.50	4	93
Health expenditure per capita	Upper half	10	15.40	15.00	1	31
Population	Lower half	10	9.80	9.00	4	15
Population	Upper half	10	25.20	21.50	1	93

The Spearman correlation between GDP per capita and approvals is 0.129, indicating limited positive ordering across the sample. Country contrasts reinforce the absence of a consistent increasing pattern. Singapore has the highest GDP per capita, USD 66,068.70, but seven approvals. India records USD 2,041.43 per capita and 93 approvals. These observations answer RQ1 descriptively: higher economic resources do not consistently correspond to larger reported approval stocks. For RQ2, health expenditure per capita has a Spearman correlation of 0.045 with approvals. The United States records the highest expenditure, USD 10,550.22 per person, and 23 approvals. India records the lowest expenditure, USD 60.69, and the highest approval count. GDP and health expenditure produce identical group summaries in Table 5 because they assign the same countries to the lower and upper halves. Those summaries therefore do not constitute independent evidence. These results concern authorization rather than the financing of treatment. Simoens and Vulto, 2021, distinguish market authorization, reimbursement, competition, and affordable access. The observed absence of consistent ordering between expenditure and approvals cannot establish whether spending supports biosimilar utilization or reduces treatment costs.

5.3 Population Size and Reconstructed Income Categories:

Population shows the strongest positive ordering with approvals among the three capacity indicators. Its Spearman correlation is 0.496. Countries in the upper population half record a mean of 25.20 approvals, compared with 9.80 in the lower half. Their respective medians are 21.50 and 9.00, a difference of 12.50 authorizations. Agreement between the mean and median comparisons indicates that the population pattern extends beyond the aggregate mean. The relationship is not uniform. China has the largest population but the lowest approval count. India combines the second largest population with the highest approval count. These contrasting observations prevent population size from serving as a sufficient explanation of national approval stocks. RQ3 is therefore resolved as a positive descriptive association accompanied by substantial country variation. Reconstructed income categories provide a complementary comparison.

Table 6: Approval counts by reconstructed income category

Income Category	Countries	Total Approvals	Mean Approvals	Median Approvals	Minimum	Maximum
Lower middle income	6	148	24.67	10.50	4	93
Upper middle income	9	122	13.56	13.00	1	31
High income	5	80	16.00	15.00	7	23

Group means do not increase consistently with income, whereas group medians increase from 10.50 to 13.00 and 15.00 approvals. India accounts for 93 of the 148 authorizations in the lower middle-income group. The divergence between its mean

and median therefore reflects concentration rather than a general approval advantage across that category. No low-income country is represented. These counts do not establish differences in clinical uptake. Dylst, Vulto, and Simoens, 2014, identify financing incentives and stakeholder confidence as barriers to utilization. Such mechanisms remain outside the measured outcome and cannot be inferred from the income comparisons.

5.4 Sensitivity and Resolution of the Research Questions:

Exploratory exclusions assess whether India and China determine the descriptive associations. Spearman correlations use average ranks for tied approval counts. All three indicators use the same countries within each comparison.

Table 7: Sensitivity of descriptive rank correlations

Sample	Countries	GDP Per Capita and Approvals	Health Expenditure Per Capita and Approvals	Population and Approvals
Complete sample	20	0.129	0.045	0.496
Excluding India	19	0.295	0.219	0.445
Excluding China	19	0.166	0.059	0.746
Excluding India and China	18	0.346	0.247	0.701

Population retains a positive association in every comparison. Its correlation decreases modestly when India is excluded and increases when China is excluded. The population pattern therefore does not depend solely on India, although China substantially attenuates its magnitude. GDP and health expenditure correlations increase after excluding India but remain smaller than the population correlation in every sample. The findings distinguish potential market scale from financial intensity. Population corresponds more consistently with reported approvals than either GDP or health expenditure per capita. Nevertheless, the associations do not isolate manufacturer incentives or regulatory capacity. Kang and Knezevic, 2018, identify regulatory assessment and continuing oversight as distinct institutional functions, which these aggregate indicators do not directly measure.

Across the three research questions, the evidence shows limited ordering by economic resources and health expenditure, alongside a more consistent positive ordering by population. Differences between means and medians reveal concentrated approval stocks, while sensitivity comparisons confirm substantial country influence. These conclusions apply to reported cumulative authorizations in the observed sample and do not establish effects on current availability, utilization, or patient access.

6. Discussion:

Population size corresponds more consistently with biosimilar approval stocks than national wealth or health expenditure in the observed sample. Table 7 shows a population rank correlation of 0.496, compared with weaker ordering for the two monetary indicators. Table 5 reinforces this distinction because both mean and median approvals are higher among countries in the upper population half. This analysis contributes a comparison of market scale and financial intensity within the same regulatory sample, showing that these dimensions cannot serve as interchangeable indicators of national market capacity. The pattern is consistent with market entry reasoning, under which prospective demand may support the recovery of development and registration costs. However, Simoens, Verbeken, and Huys, 2012, identify comparability requirements alongside costs as conditions of biosimilar market access. The findings therefore refine the interpretation of market capacity without establishing an independent population effect. The weak ordering between health expenditure and approvals separates aggregate financing intensity from regulatory authorization. Tables 5 and 7 show that greater spending per person does not consistently correspond to more reported approvals. This finding narrows the role that expenditure can reasonably occupy in explanations of regulatory entry: it measures financial resources rather than the incentives facing manufacturers, purchasers, or prescribers. Dylst, Vulto, and Simoens, 2014, identified hospital financing arrangements and stakeholder uncertainty as barriers to biosimilar utilization in Belgium. Their evidence helps explain why aggregate spending cannot substitute for direct institutional measures, although the present analysis does not test those pathways. The contribution is thus a clearer boundary between an observed national resource indicator and the organizational processes through which resources might influence market participation.

Concentration changes the interpretation of income differences. Table 6 places the highest mean approval count in the lower middle-income category, while medians increase across the three represented income categories. India's contribution explains much of this divergence, demonstrating that a category average can reflect a concentrated national approval stock rather than a common group characteristic. Table 7 further shows that population retains positive ordering when India and China are excluded, whereas the monetary associations remain smaller. This evidence distinguishes concentration in approval counts from consistency in country rankings; it does not decompose causal contributions. Simoens and Vulto, 2021, distinguish sustainable biological medicine competition from biosimilar uptake alone. The findings extend that measurement distinction by showing why neither income group averages nor authorization totals should be treated as direct summaries of competitive market development.

Regulatory heterogeneity limits the substantive meaning of numerical differences between countries. The cumulative outcome includes authorizations issued under different national requirements and, for Indonesia, products subsequently withdrawn. Consequently, the dispersion in Table 4 combines differences in reported authorization histories with differences in how those histories were constituted. Kang et al., 2020, document progress toward regulatory convergence alongside continuing differences across jurisdictions. This analysis shows why such differences matter for comparative economic interpretation: an additional reported authorization does not necessarily represent an equivalent increment in currently available treatment options. The international contribution is a qualification of approval counts as comparative indicators. They describe regulatory activity, but country rankings cannot establish corresponding rankings in assessment quality, commercial availability, or patient access.

International comparison therefore requires separate treatment of potential market scale, financial resources, and regulatory institutions. European evidence reviewed by Moorkens and colleagues, 2016, identifies manufacturing, regulatory, and commercial barriers that aggregate national indicators cannot distinguish. The contrasting country patterns in Tables 5 and 7 show that neither a large population nor high expenditure provides a sufficient description of approval stocks across the represented

economies. For decision makers, the immediate implication is to interpret approval totals alongside their dates, withdrawal status, and regulatory definitions before using them to compare national markets. Kang and Knezevic, 2018, emphasize assessment capacity and continuing oversight as distinct regulatory functions. Taken together, the evidence supports a framework that keeps these institutional functions separate from market capacity and treats authorization, utilization, and access as different outcomes requiring their own measurements.

7. Conclusion and Implications:

National prosperity does not translate uniformly into biosimilar authorization. This analysis shows that potential demand corresponds more consistently with reported authorization stocks than financial intensity, while concentrated national approval histories complicate comparisons across income categories. Its contribution is an empirical distinction between dimensions often grouped under market capacity: their descriptive relationships differ, and none alone establishes regulatory performance or treatment availability. This evidence refines market entry reasoning by separating commercial opportunity from the institutional processes governing authorization, without attributing causal effects to aggregate national characteristics. For international benchmarking, decision makers should assess the composition and concentration of authorization stocks before interpreting national rankings. Manufacturers can use these comparisons as contextual information when assessing prospective markets, while recognizing that the observed relationships do not predict successful entry. Regulators and policymakers should distinguish cumulative authorizations from active approvals and commercially available products. Recording withdrawal status, authorization dates, and applicable assessment standards would improve the interpretability of comparative reporting. These practices would support clearer strategic assessments and reduce misleading comparisons between jurisdictions. Their social relevance lies in making the distinction between regulatory activity and treatment access explicit, so that reported authorization growth is not mistaken for demonstrated improvements in affordability, utilization, or patient outcomes.

The single regulatory snapshot provides a foundation for longitudinal extensions that distinguish accumulated approvals from annual entry. Harmonized product records could separate active authorizations, withdrawals, commercial launches, and utilization. Broader jurisdiction coverage, including low income settings, would assess whether the observed ordering transfers beyond the accessible sample. Direct measures of assessment capacity, registration costs, procurement arrangements, and reimbursement could examine the proposed institutional pathways. Linking dated applications and decisions with information available beforehand would strengthen temporal alignment. Such extensions could evaluate mechanisms and conditional relationships while preserving the distinction between descriptive association and causal explanation.

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