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APPLICATION PORTFOLIO COMPOSITION AND GENERIC MEDICINE REGISTRATION OUTPUTS ACROSS REGULATORY AUTHORITIES IN EMERGING PHARMACEUTICAL MARKETS

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Abstract:

This analysis examines whether application portfolio patterns correspond to generic medicine registration output, addressing the interpretation of administrative counts in international regulatory benchmarking. Published administrative records provide 20 complete annual observations across six East African regulatory jurisdictions between 2020 and 2023. Descriptive distributions, authority comparisons and exploratory sample restrictions distinguish incoming applications from completed approvals. Rwanda accounts for 88.20 percent of recorded new active substance applications, whereas mainland Tanzania and Uganda contribute 70.62 percent of generic approvals. Generic application receipts and approvals move together in some periods but diverge in others, while applications for medicines prequalified by the World Health Organization show no consistent correspondence with generic output. Among four continuously observed jurisdictions, generic receipts increased by 13.39 percent between the endpoints while approvals decreased by 75.76 percent. Excluding one disputed observation changes pooled magnitudes without removing this descriptive distinction. The findings refine a capacity constrained processing perspective by separating incoming demand from completed decisions. International benchmarking should preserve these distinctions and use linked application histories before interpreting annual volumes as regulatory efficiency.

Key Words: Regulatory Benchmarking; Generic Medicines; Application Portfolios; Administrative Data; Descriptive Analysis

1. Introduction:

Medicine registration systems must assess incoming applications while completing decisions that determine which products receive marketing authorisation. Application receipts and approvals therefore describe related but distinct regulatory activities. Confusing these measures can obscure changes in registration output and produce misleading comparisons between authorities. Ahonkhai et al., 2016, identify duplicated assessments, differing national requirements and delayed manufacturer responses as contributors to registration delays. Their findings establish why submissions received during a calendar year need not correspond to approvals issued within that year. Understanding how these annual flows differ is consequently important for interpreting regulatory activity and identifying the information required for meaningful performance assessment. Regulatory harmonisation addresses this coordination problem by supporting common requirements, shared assessments and cooperation between authorities. Its implementation nevertheless operates through institutions with different resources, procedures and responsibilities. Ndomondo-Sigonda et al., 2021, document improvements in regulatory capacity within the East African Community alongside differences in implementation. Research among pharmaceutical applicants also identifies difficulties involving submission procedures, application tracking and the completion of national registration processes, as reported by Ngum et al., 2022. These findings distinguish the establishment of collaborative arrangements from the administrative processes through which individual authorities' complete decisions. They also motivate examining application receipts and registration outputs separately within a shared regional setting.

A capacity constrained processing perspective provides the conceptual basis for this examination. Incoming applications create demand for assessment, while completed approvals reflect decisions reached after scientific and administrative review. Larger application volumes may enlarge the pool of products available for subsequent approval, but annual outputs also depend on when applications enter and leave the review process. Authorities with larger operations may receive more applications and issue more approvals, while changing submission volumes within an authority may coincide with different movements in completed decisions. These competing possibilities make a uniform directional expectation inappropriate when the available records contain annual counts without linked submission and decision histories. Application categories add a further measurement distinction. Applications for new active substances, generic medicines and medicines prequalified by the World Health Organization represent different components of reported incoming activity. Prior assessment evidence may support facilitated review where national procedures permit reliance, but the number of prequalified medicine applications does not establish whether such procedures were used. Keyter et al., 2021, examine review pathways in South Africa and report reduced review times for applications processed through facilitated procedures. Their process-based evidence cannot be reproduced through application category counts alone. The distinction matters because portfolio composition, review arrangements and completed registration output are separate objects of measurement.

The closest empirical source is Ngum et al., 2024, which evaluates review models and approval timelines among authorities participating in the East African Medicines Regulatory Harmonisation initiative. Its published table reports annual

receipts and approvals across application categories. This analysis reuses those records for a narrower purpose: to examine how the geographical concentration and annual movement of three application categories compare with generic medicine approval output. The contribution is an explicit descriptive comparison, rather than a new administrative dataset or an evaluation of harmonisation effects. The reviewed evidence provides institutional and procedural explanations for registration differences, but does not establish a general correspondence between the application volumes examined here and generic approvals. This analysis aims to describe how new active substance applications, generic medicine applications and applications for medicines prequalified by the World Health Organization vary alongside generic registration output. The central research question is how the distribution and annual movement of these application categories compare with generic approvals across regulatory authorities. Three objectives guide the investigation: identifying where new active substance applications are concentrated relative to generic output, examining whether generic receipts and approvals move together, and determining whether prequalified medicine application volumes follow a similar distribution to generic approvals.

The empirical setting comprises six East African regulatory jurisdictions between 2020 and 2023. The published frame contains 24 annual records, of which 20 provide complete information for all four measures. Mainland Tanzania and Zanzibar remain separate regulatory jurisdictions. The analysis uses descriptive distributions, authority comparisons and annual counts, supplemented by exploratory checks that hold authority composition constant and exclude a disputed source observation. This design enables transparent comparisons of reported activity while preserving the distinction between annual flows and matched application cohorts. It does not estimate causal effects, processing efficiency or approval probabilities. The findings show that the concentration of new active substance applications differs from that of generic approvals, while generic application receipts and approval outputs move together in some periods and diverge in others. Applications for prequalified medicines also show no consistent correspondence with generic output. Divergence between generic receipts and approvals remains within the continuously observed authorities. These results contribute a bounded measurement lesson with relevance beyond the regional setting: incoming regulatory demand and completed decisions require separate reporting and interpretation. Their practical value lies in clarifying what aggregate administrative counts reveal and where linked application histories are necessary for assessing regulatory processes.

2. Theory, Conceptual Framework and Research Questions Development:

This analysis adopts a capacity constrained processing perspective to examine medicine registration. Manufacturers submit applications, while regulatory authorities assess evidence and issue decisions within available resources and legal mandates. Application receipts represent incoming demand for assessment, whereas approvals represent completed regulatory decisions. These flows need not move together within a calendar year because assessment, applicant responses and administrative procedures separate submission from approval. Ahonkhai et al., 2016, identified duplicated assessments, differing requirements and delayed manufacturer responses as contributors to registration delays. Their evidence supports distinguishing regulatory inflows from completed outputs rather than treating annual receipts as applications immediately available for approval. Institutional coordination provides the broader setting for these processing relationships. Shared requirements and joint assessments can reduce duplication, but national authorities retain responsibilities that shape the completion of registration decisions. Ndomondo-Sigonda et al., 2020, describe regional harmonisation as a mechanism for strengthening regulatory systems through cooperation. Ndomondo-Sigonda et al., 2021, document improvements in regulatory capacity alongside differences in institutional implementation. Together, these contributions establish why authorities operating within a common regional initiative may nevertheless report different application and approval volumes. They do not establish that application volume independently determines registration output.

The conceptual framework connects three observed application categories with one observed output: annual applications for new active substances, generic medicines and medicines prequalified by the World Health Organization, considered alongside annual generic medicine approvals. These are administrative counts rather than latent constructs or a constructed portfolio index. Application portfolio composition therefore refers to the recorded pattern across categories, without combining them into an aggregate score or assuming that their classifications are mutually exclusive. The empirical boundary is six East African regulatory jurisdictions with observations between 2020 and 2023. Ngum et al., 2024, provide the underlying records and document differences in review models and registration procedures across participating authorities. New active substance applications represent a distinct component of incoming regulatory work. The theoretical mechanism is competition for assessment resources when application categories draw on shared personnel or administrative processes. Under constrained capacity, additional work in this category could coincide with fewer completed generic assessments. Conversely, authorities with larger operations could receive more applications across categories and issue more generic approvals. Ndomondo-Sigonda et al., 2017, identify variation in regulatory organisation and shortages of qualified personnel across African authorities, supporting capacity as a relevant contextual consideration. However, application counts alone cannot distinguish resource competition from differences in institutional scale. The first research question is therefore descriptive: How do reported new active substance application volumes vary across authorities and years alongside generic medicine approval volumes?

Generic medicine applications provide the closest observable connection between incoming demand and generic registration output. More submissions can enlarge the pool from which subsequent approvals emerge. Nevertheless, approvals recorded during a year may concern applications received earlier, while applications received during that year may remain under assessment. High receipts and low approvals can consequently reflect differences in timing rather than a lower probability of approval. This analysis compares the levels and annual movements of both counts without treating their ratio as an approval rate. The second research question is: How do generic medicine application receipts and approval counts vary together across the observed authorities and years?

Applications for medicines prequalified by the World Health Organization introduce a further distinction between incoming volume and the evidence available for regulatory review. Prior assessment can theoretically reduce duplicated work where national procedures permit reliance. However, the recorded number of these applications does not measure whether reliance occurred, how much assessment work was avoided or whether resources became available for generic applications. This analysis

therefore retains the published category as a separate observed count. The third research question is: How are reported application volumes for medicines prequalified by the World Health Organization distributed across authorities and years alongside generic medicine approvals?

These questions organise descriptive comparisons of observed levels, changes and contrasts across application categories and registration outputs. The framework assigns no predetermined direction to the observed relationships. Its contribution is to distinguish incoming regulatory demand from completed decisions while preserving the separate meaning of each published measure.

3. Data:

This analysis establishes the provenance, coverage and measurement of annual medicine application and registration records. It documents sample construction and data checks, then defines the descriptive comparisons supported by the available observations.

3.1 Data Sources, Population, and Sample Construction:

The dataset comprises administrative counts published in Table 1 of Ngum et al., 2024, in Frontiers in Medicine, volume 11, Article 1438041. The authors compiled information supplied by participating regulatory authorities and validated authority reports with their respective heads. The published article provides the source version, and its DOI supplies the stable access route. The article is available under the Creative Commons Attribution licence, permitting reuse with attribution. No separately versioned administrative database or application identifiers accompany the supplied workbook. Its extraction date is recorded in the source documentation, although a separate extraction log is unavailable. The unit of analysis is a regulatory jurisdiction observed annually. The accessible frame covers Burundi, Kenya, Rwanda, mainland Tanzania, Uganda and Zanzibar between 2020 and 2023. Mainland Tanzania and Zanzibar represent separate regulatory jurisdictions within one country. Applications received and approvals issued are annual flows, rather than cumulative registrations, pending application stocks or measures of processing duration. The substantive target population comprises medicine regulatory authorities in emerging pharmaceutical markets. The accessible sampling frame is narrower: six East African jurisdictions represented in the published table. Inclusion follows source availability rather than probability sampling. The source provides 24 jurisdiction and year records, of which 20 contain all four focal measures. These observations support comparisons within the documented jurisdictions and period, without establishing representativeness across emerging markets.

Table 1: Sample construction

Stage	Regulatory Jurisdictions	Annual Observations	Reason or Rule
Accessible published frame	6	24	Six jurisdictions observed across four calendar years
Exclusion of Kenya records for 2022 and 2023	1 affected	2 excluded	All four focal measures unspecified
Exclusion of Uganda records for 2020 and 2021	1 affected	2 excluded	New active substance application counts unspecified
Retained common sample	6	20	All four focal measures numerically available
Final descriptive sample	6	20	Common observation set used across indicators

The retained sample is an unbalanced annual panel. Burundi, Rwanda, mainland Tanzania and Zanzibar each contribute four observations, while Kenya and Uganda each contribute two. The annual distribution comprises five observations in 2020, five in 2021, five in 2022 and five in 2023. Equal annual totals therefore conceal changes in the authorities represented. The supplied workbook already separates the published records from the complete observation sample. No dated protocol establishes when its exclusion rules were adopted. This analysis preserves that separation and introduces no additional exclusions.

3.2 Data Integration, Cleaning, and Quality Assurance:

The workbook contains one published source, so construction requires no external merge or frequency conversion. Jurisdiction and calendar year jointly identify observations, while authority names provide institutional labels. Mainland Tanzania and Zanzibar remain separate throughout. Inspection identified no duplicate jurisdiction and year combinations in the retained sample, and all retained measures are nonnegative integers. Missingness is explicitly distinguished from reported zero. Across the 24 published records, new active substance applications have four unspecified values. Generic applications, applications for medicines prequalified by the World Health Organization, and generic approvals each have two unspecified values. Kenya accounts for missing values across all four measures in 2022 and 2023. Uganda contributes the additional missing new active substance counts in 2020 and 2021. Each measure therefore has either 20 or 22 valid published observations before the common sample restriction.

The analysis retains reported zeros and excludes incomplete records from the common sample. It applies no imputation, interpolation or replacement of unspecified values with zero. Hughes et al., 2019, explain that the suitability of missing data procedures depends on the missingness process and analytical assumptions. Here, the available records do not establish why particular values were unreported. Complete observation selection consequently defines a transparent comparison set but does not establish that missingness is random. The source contains a documented conflict for mainland Tanzania in 2021. Its table reports 975 generic applications and 383 generic approvals, whereas the accompanying narrative reports 704 and 503. The workbook consistently preserves the table values. These entries remain published but disputed observations, rather than independently verified administrative totals. The classification of Rwanda's new active substance applications also requires caution when comparing categories across authorities.

No numerical threshold was used to remove extreme observations, and no winsorisation, scaling or smoothing was applied. Large counts remain in their reported form because magnitude alone does not establish error. The dataset requires no currency conversion, inflation adjustment or fiscal calendar alignment. These records constitute a retrospective published compilation. They do not provide successive data releases, revision histories or information available at each historical decision date. The analysis therefore describes reported annual activity without reconstructing contemporaneous regulatory information.

3.3 Variable Measurement, Construction, and Validation:

Application portfolio composition is represented by three separately reported application counts. Generic medicine registration output is measured by the annual number of generic approvals. The measures retain their published categories and units. No composite index, portfolio share or total application denominator is constructed because the available documentation does not establish whether all application categories are mutually exclusive.

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
New active substance applications received	Application portfolio dimension	Reported applications received during the calendar year	Ngum et al., 2024, Table 1, NAS received	Applications per year	Untransformed count. Higher values indicate more reported receipts	Exclude unspecified entries from the common sample	20 valid published observations. Classification comparability requires caution
Generic medicine applications received	Application portfolio dimension	Reported generic applications received during the calendar year	Ngum et al., 2024, Table 1, generics received	Applications per year	Untransformed count. Higher values indicate more reported receipts	Apply the common sample restriction	22 valid published observations and 20 retained. Mainland Tanzania's 2021 value conflicts with the narrative
Applications for medicines prequalified by the World Health Organization	Application portfolio dimension	Applications received under the source's prequalification category	Ngum et al., 2024, Table 1, WHO prequalification received	Applications per year	Untransformed count. Higher values indicate more reported receipts	Apply the common sample restriction	22 valid published observations and 20 retained. Counts do not measure actual use of reliance procedures
Generic medicine approvals	Registration output	Reported generic medicine approvals issued during the calendar year	Ngum et al., 2024, Table 1, generics approved	Approvals per year	Untransformed count. Higher values indicate more completed approval decisions	Apply the common sample restriction	22 valid published observations and 20 retained. Approvals are not linked to submission cohorts

Validation consists of checking observation identifiers, numerical completeness, integer values, nonnegative counts and documented source discrepancies. These checks establish internal consistency without confirming the accuracy of the underlying authority records. Reliability coefficients and factor analysis are inapplicable because the variables are directly reported administrative counts rather than reflective indicators of a latent construct.

Table 3: Descriptive statistics for the common sample

Indicator	Valid Observations	Mean	Standard Deviation	Median	Minimum	Maximum
New active substance applications received	20	45.75	123.47	0.00	0	409
Generic medicine applications received	20	468.85	368.67	461.50	8	1,079
Applications for medicines prequalified by the World Health Organization	20	8.25	9.40	6.50	0	35
Generic medicine approvals	20	162.35	191.80	56.00	0	571

Standard deviations use the sample denominator. The difference between means and medians, particularly for new active substance applications and generic approvals, demonstrates why both central tendency measures are reported. These pooled summaries describe jurisdiction and year observations, rather than unique products or manufacturers. Applications received and approvals issued within the same year do not constitute a matched cohort. Their ratio would therefore fail to identify an application's probability of approval. Ahonkhai et al., 2016, document registration delays spanning multiple procedural stages, reinforcing the distinction between annual submission flows and completed decisions.

3.4 Analytical Framework, Identification, and Reproducibility:

The analytical framework is descriptive. Its objects are the recorded distributions of application receipts and generic approvals, together with differences across jurisdictions and years. The implemented summaries comprise valid counts, means, sample standard deviations, medians and observed ranges. All four indicators use the same 20 observations, ensuring that their pooled summaries refer to a consistent sample. The records support examination of how application volumes and approval outputs appear alongside one another. They do not identify the effect of additional applications on approvals because submissions are not linked to decisions, and institutional resources and processing durations are unmeasured. No regression, fixed effects specification, interaction, causal estimator or statistical significance test is implemented. Composition affects interpretation. Kenya contributes observations only in the first two years, while Uganda contributes observations only in the last two. Comparisons of pooled annual activity must therefore distinguish changes within continuing authorities from changes in the authorities represented. The common sample restriction also removes two otherwise observed Ugandan approval counts, so its summaries describe complete records rather than all published generic registration activity. The workbook preserves separate worksheets for raw published records, retained observations, and definitions and sources. This separation makes the exclusion rule and source priority decision inspectable. Peng, 2011, identifies access to data and computational procedures as central to

reproducible analysis, while Sandve et al., 2013, emphasise documenting analytical steps and preserving their provenance. The workbook provides the underlying counts and construction notes, although a versioned construction script and dated decision history are not supplied. Definitions, timing and units remain aligned across the four indicators: each is an untransformed annual count assigned to the reporting jurisdiction. Interpretation remains bounded by incomplete coverage, unmatched submission and approval cohorts, and the documented source inconsistencies.

4. Methods:

4.1 Research Design and Analytical Framework:

This analysis uses a retrospective descriptive design to examine how application receipts vary alongside generic medicine approvals across regulatory jurisdictions. The analytical targets are the distributions, geographical concentration and annual movements of three application categories relative to completed generic registration decisions. Comparisons use variation between authorities and within authorities over time. They describe recorded activity without estimating the effect of additional submissions on subsequent approvals. The framework distinguishes incoming regulatory demand from completed decisions. Applications and approvals recorded during the same calendar year are compared as separate flows because the records do not identify matched submission cohorts. Consequently, their ratio is not interpreted as an approval probability, and differences between receipts and approvals are not treated as changes in pending applications. The analysis follows three research questions. It examines whether the concentration of new active substance applications corresponds to the concentration of generic approvals, whether generic receipts and approvals move together, and whether applications for medicines prequalified by the World Health Organization show similar patterns to generic output. These questions are resolved through descriptive comparisons rather than directional significance tests.

4.2 Sample and Measurement Alignment:

The sample construction rules and variable definitions are documented in Tables 1 and 2. The primary analysis uses 20 complete annual observations across six regulatory jurisdictions between 2020 and 2023. Applying one common observation set ensures that comparisons across the four indicators do not reflect different missing data patterns. The panel is unbalanced. Four jurisdictions contribute observations throughout the period, while Kenya contributes two earlier observations and Uganda contributes two later observations. Authority comparisons therefore identify the observation window explicitly. Pooled annual comparisons are interpreted alongside a constant composition sample to distinguish changes in recorded activity from changes in the authorities represented. Each indicator remains an untransformed annual count. Application categories are analysed separately without constructing a composite index, portfolio denominator or aggregate application total. This choice preserves the published classifications without assuming that categories are mutually exclusive. Reported zeros retain their substantive meaning, while unspecified entries remain missing. The complete observation restriction excludes four published records. It establishes a consistent descriptive sample without assuming that excluded records are missing randomly. Hughes et al., 2019, emphasise that missing data procedures require assumptions appropriate to the available information. Accordingly, the analysis makes no population representativeness claim from complete observation selection alone.

4.3 Descriptive Calculations and Analytical Procedures:

Calculations were implemented in Python 3.12.14 using pandas 2.2.3 and NumPy 2.3.5. Workbook values were read using openpyxl 3.1.5. The analytical sequence comprised checking observation identifiers and numerical fields, calculating pooled distributions, grouping records by jurisdiction and year, and conducting exploratory sample restrictions. For each indicator, the pooled summaries comprise the valid observation count, arithmetic mean, sample standard deviation, median, minimum, maximum and frequency of reported zero. Sample standard deviations use the number of observations minus one as the denominator. These statistics describe dispersion across annual jurisdiction records rather than uncertainty around a population estimate. Authority summaries report arithmetic means over each jurisdiction's available years. Annual summaries sum counts across the authorities represented in that year. Concentration measures divide a jurisdiction's recorded category total by the corresponding category total across retained observations and express the result as a percentage. These shares describe the distribution of recorded activity and are not interpreted as contributions to a causal effect. Selected temporal comparisons report the absolute difference between observed endpoints and the percentage change relative to the initial value. Percentage changes are calculated only where the initial count is positive. Changes beginning from zero are described using count differences. Application categories are never combined when calculating concentration or temporal change. The analysis compares the direction and magnitude of movements without estimating correlations, regression coefficients or statistical significance. No population weights or precision weights are applied. Displayed statistics are rounded to two decimal places after calculation.

4.4 Quality Checks, Sensitivity and Reproducibility:

Quality checks assess the uniqueness of jurisdiction and year identifiers, completeness of the four analytical measures, and conformity of retained values to nonnegative integer counts. Published zeros are preserved. No imputation, interpolation, smoothing or removal based on numerical magnitude is performed. Large observations remain because an extreme count alone does not establish a recording error. Two exploratory sensitivity checks address specific interpretive threats. The first restricts the sample to Burundi, Rwanda, mainland Tanzania and Zanzibar, producing 16 observations with identical authority coverage in every year. Annual totals are recalculated within this sample to assess whether divergent movements in receipts and approvals persist when composition is held constant. This restriction changes the geographical coverage and is interpreted as a comparison of samples rather than a correction to the primary dataset. The second check excludes mainland Tanzania's disputed observation for 2021, leaving 19 observations. Pooled means and medians are recalculated without substituting the conflicting narrative values. The comparison assesses the influence of retaining that observation on descriptive magnitudes. Both checks were introduced during examination of the records and are reported as exploratory. The workbook preserves the raw published records, retained observations, and definitions and sources in separate worksheets. This structure allows the exclusions and calculations to be reconstructed from the supplied counts. Peng, 2011, and Sandve et al., 2013, identify accessible inputs and documented computational procedures as essential components of reproducible analysis. The software versions, grouping rules, denominators and sample restrictions specified here provide the implementation details needed to reproduce the reported summaries.

Interpretation remains confined to the observed records. The sensitivity checks assess dependence on sample composition and one disputed observation; they do not establish administrative accuracy, eliminate selection bias or identify regulatory mechanisms. Together, the procedures answer the descriptive research questions while preserving the distinction between application receipts, completed approvals and institutional performance.

5. Findings:

This analysis examines how three application categories vary alongside generic medicine registration output across regulatory authorities. The findings address each research question through comparisons of recorded volumes, distributions and annual changes. Exploratory sensitivity checks assess the influence of changing sample composition and a disputed source observation.

5.1 Sample Characteristics and Distribution of Regulatory Activity:

The analytical sample contains 20 complete annual observations across six East African regulatory jurisdictions between 2020 and 2023. Burundi, Rwanda, mainland Tanzania and Zanzibar each contribute four observations. Kenya contributes observations for 2020 and 2021, while Uganda contributes observations for 2022 and 2023. Four published records are excluded because at least one focal measure is unspecified. All reported values represent annual counts, with published zeros retained. Across the retained observations, authorities reported 9,377 generic applications, 915 new active substance applications and 165 applications for medicines prequalified by the World Health Organization. Generic approvals totalled 3,247. These category totals remain separate because the published classification does not establish that the application categories are mutually exclusive. Calculations use the administrative counts published by Ngum et al., 2024.

Table 4: Distribution of annual application receipts and generic approvals

Indicator	Observations	Mean	Standard Deviation	Median	Minimum	Maximum	Observations Reporting Zero
New active substance applications	20	45.75	123.47	0.00	0	409	16
Generic medicine applications	20	468.85	368.67	461.50	8	1,079	0
Applications for medicines prequalified by the World Health Organization	20	8.25	9.40	6.50	0	35	5
Generic medicine approvals	20	162.35	191.80	56.00	0	571	3

Generic approvals show substantial dispersion. The mean of 162.35 exceeds the median of 56.00, indicating that larger approval counts raise the pooled average above the central observation. New active substance applications are more concentrated: 16 observations report zero, while four observations contain the entire recorded volume. Generic applications occur in every retained observation, making this category more broadly distributed across the sample.

5.2 New Active Substance Applications and Generic Registration Output:

The first research question concerns the distribution of new active substance applications alongside generic approvals. Rwanda accounts for 807 of the 915 recorded applications, equivalent to 88.20 percent. Kenya accounts for the remaining 108. The other four jurisdictions report zero new active substance applications in their retained observations. This concentration does not correspond to a similar concentration of generic approvals. Mainland Tanzania and Uganda jointly account for 2,293 generic approvals, or 70.62 percent of the retained total, despite reporting zero new active substance applications. The authorities receiving new active substance applications therefore differ from those contributing most generic approvals.

Table 5: Mean annual application receipts and generic approvals by jurisdiction

Jurisdiction	Observed Years	Observations	New Active Substance Applications	Generic Applications	Applications for Medicines Prequalified by the World Health Organization	Generic Approvals
Burundi	2020 to 2023	4	0.00	161.75	0.75	50.75
Kenya	2020 to 2021	2	54.00	800.50	22.50	224.50
Rwanda	2020 to 2023	4	201.75	479.25	11.00	74.75
Mainland Tanzania	2020 to 2023	4	0.00	862.25	14.75	323.00
Uganda	2022 to 2023	2	0.00	854.50	6.50	500.50
Zanzibar	2020 to 2023	4	0.00	13.50	0.25	0.75

Within Rwanda, new active substance applications increased from zero in 2021 to 409 in 2022, while generic approvals increased from 55 to 147. Both counts subsequently declined in 2023, to 398 and 51 respectively. Kenya presents a different pattern: new active substance applications decreased from 55 to 53 between 2020 and 2021, while generic approvals increased from 81 to 368. The observed comparisons therefore show no uniform directional pattern between these application counts and generic output. Rwanda's reported category change also limits interpretation of its application increase as a comparable change in regulatory workload.

5.3 Generic Applications and Registration Output:

The second research question examines whether generic application receipts and approvals move together. Across jurisdictions, larger application volumes frequently coexist with larger approval volumes, but similar submission levels do not correspond to similar outputs. Mainland Tanzania and Uganda report mean annual generic receipts of 862.25 and 854.50 respectively, yet their mean approvals differ at 323.00 and 500.50. Their different observation windows prevent interpreting this contrast as an institutional performance difference. Within authorities, the relationship varies across periods. Uganda records increase in generic applications from 804 to 905 and approvals from 430 to 571 between 2022 and 2023. Mainland Tanzania instead records 631 applications and 499 approvals in 2020, compared with 764 applications and 51 approvals in 2023. Over those endpoints, applications increased by 21.08 percent while approvals decreased by 89.78 percent. Burundi provides another contrast. Generic applications increased from 80 to 342 between 2022 and 2023, while approvals increased from 36 to 57. Zanzibar's applications increased from 8 in 2020 to 22 in 2023, but approvals remained between zero and two throughout the period. These observations establish variation in the alignment of incoming applications and completed decisions. They do not establish approval probabilities because the annual counts do not link applications to their eventual outcomes. The distinction is consistent with the registration delays documented by Ahonkhai et al., 2016. That evidence provides a plausible timing context, although the present records cannot determine whether timing explains any particular authority's annual pattern.

5.4 Applications for Prequalified Medicines and Registration Output:

The third research question concerns applications for medicines prequalified by the World Health Organization. Kenya records the highest annual mean at 22.50, followed by mainland Tanzania at 14.75 and Rwanda at 11.00. Uganda records a lower mean of 6.50 while contributing the highest observed mean generic approvals. The distribution of prequalified medicine applications therefore does not reproduce the ordering of generic registration output. Annual comparisons also differ across authorities. In Kenya, these applications increased from 10 to 35 between 2020 and 2021 alongside an increase in generic approvals. In Uganda, they decreased from seven to six between 2022 and 2023 while generic approvals increased from 430 to 571. In Rwanda, the count decreased from 18 to seven between 2021 and 2022 while approvals increased from 55 to 147. The evidence thus identifies different patterns of movement across authorities rather than a consistent correspondence between prequalified medicine application volumes and generic approvals. These counts describe the applications received under the published category. They do not measure whether authorities used reliance procedures or whether those procedures changed assessment requirements.

5.5 Sample Composition and Source Sensitivity:

A constant composition comparison retains Burundi, Rwanda, mainland Tanzania and Zanzibar, yielding 16 observations across four authorities. This exploratory restriction removes the replacement of Kenya by Uganda in the pooled annual sample.

Table 6: Annual counts for four continuously observed jurisdictions

Year	New Active Substance Applications	Generic Applications	Applications for Medicines Prequalified by the World Health Organization	Generic Approvals
2020	0	1,329	24	656
2021	0	1,668	42	440
2022	409	1,563	23	542
2023	398	1,507	18	159

Between 2020 and 2023, generic applications increased by 13.39 percent in this constant composition sample, while approvals decreased by 75.76 percent. Divergent movements therefore remain when authority coverage is held constant. The pattern is uneven across jurisdictions, with mainland Tanzania contributing 448 of the aggregate reduction of 497 approvals between these endpoints. A separate exploratory check excludes mainland Tanzania's disputed 2021 observation without substituting the conflicting narrative values. Across the remaining 19 observations, mean generic applications decrease from 468.85 to 442.21, and mean approvals decrease from 162.35 to 150.74. Median generic applications decrease from 461.50 to 390.00, while median approvals change from 56.00 to 55.00. The separation between incoming application counts and completed approval counts remains visible, although pooled magnitudes depend on the retained records. Taken together, the findings answer the research questions through three observed patterns. New active substance applications are concentrated in two authorities, generic applications and approvals move together in some periods but diverge in others, and prequalified medicine application counts do not consistently track generic output. The constant composition comparison preserves the central finding that application receipts and approval output can follow different annual trajectories. These conclusions describe the published observations without identifying causal effects or comparative regulatory efficiency.

6. Discussion:

More applications do not necessarily coincide with more completed registrations. Tables 5 and 6 demonstrate this distinction across authorities and within a constant set of jurisdictions. The analytical contribution is to separate the distribution of incoming application categories from the distribution of generic approval output. Their divergence shows why annual application volume cannot serve as a sufficient indicator of completed regulatory activity. From a capacity constrained processing perspective, submissions and decisions represent different stages of a regulatory system rather than interchangeable measures of performance. Ngum et al., 2022a, identify procedural coordination challenges within regional joint assessment, providing institutional context for this distinction. The present analysis extends that discussion through comparisons of recorded inflows and outputs, without attributing their divergence to an estimated causal mechanism. The variation in applications for medicines prequalified by the World Health Organization further distinguishes application characteristics from regulatory processes. Table 5 shows that authorities receiving more applications in this category do not consistently report more generic approvals. These finding matters because the availability of prior assessment evidence and its actual use in national decision making are separate phenomena. Keyter et al., 2021, report shorter review times for applications processed through facilitated pathways in South Africa, where the

review pathway itself was examined. The present counts measure neither pathway selection nor review duration. Their contribution is therefore to clarify the boundary of inference: prequalification application volume describes incoming activity but cannot substitute for evidence that reliance procedures were implemented or improved generic registration output.

The concentration patterns reveal that different application categories describe different aspects of regulatory activity. New active substance applications are concentrated in Rwanda and Kenya, whereas mainland Tanzania and Uganda contribute most generic approvals in the retained sample. Table 5 consequently provides no basis for treating a portfolio containing more new active substance applications as a general indicator of greater generic registration output. This descriptive asymmetry refines the conceptual framework by preserving category distinctions instead of imposing a common workload interpretation on every application. Ngum et al., 2022b, document applicant concerns about submission processes, tracking and national implementation. Those concerns reinforce the importance of distinguishing the composition of incoming demand from the institutional processes through which decisions emerge. The observed concentration shares identify where activity occurs, rather than decomposing causal contributions to registration outcomes. The sensitivity results show that both sample composition and source consistency influence the interpretation of regulatory comparisons. Table 6 preserves divergent movements in generic receipts and approvals after restricting the analysis to continuously observed authorities. This establishes that changing authority coverage does not fully explain the observed divergence. However, mainland Tanzania contributes most of the reduction in approvals, limiting any interpretation as a uniform regional pattern. Excluding its disputed observation changes pooled magnitudes while leaving the distinction between receipts and outputs visible. These findings make comparability a substantive requirement for regulatory benchmarking. Keyter et al., 2019, compare registration processes across South Africa, Australia, Canada, Singapore and Switzerland using procedural characteristics. The present evidence indicates why comparisons based on annual volumes alone provide a narrower account than comparisons incorporating review processes and timing.

The international relevance lies in the measurement distinction rather than an estimated difference between regulatory systems. Tables 4 to 6 show that application receipts, application category and approval output capture separate dimensions of recorded activity. Decision makers should therefore report these measures separately and avoid interpreting approval counts as evidence of efficiency without information on timing and resources. Application identifiers linking submissions to decisions would permit more informative comparisons of completion and processing duration. Keyter et al., 2020, develop an abridged review framework around explicit reliance practices, illustrating the procedural information needed to examine how regulatory pathways operate. The present analysis contributes a complementary lesson: aggregate administrative counts can identify contrasting activity patterns, but explaining those patterns requires linked process evidence. This redirects future inquiry towards when and under which documented review arrangements incoming applications become completed registrations.

7. Conclusion and Implications:

Regulatory systems need evidence that distinguishes incoming demand from completed decisions. This analysis reveals that the concentration and movement of different application categories do not consistently correspond to registration output, even when the authorities compared remain constant. Its contribution is a descriptive distinction between portfolio composition and completed regulatory activity, rather than an estimated causal relationship. This distinction sharpens a capacity constrained processing perspective by showing why incoming volumes cannot independently characterise institutional performance. For international regulatory benchmarking, the implication is to preserve differences between demand, processing and completion rather than compressing them into a single performance indicator. Managers should interpret annual counts alongside their reporting coverage and avoid allocating resources solely according to submission totals. Policymakers should prioritise consistent category definitions, traceable reporting and comparable observation periods before using administrative statistics to assess institutional progress. Operationally, systems that connect submissions with subsequent decisions would support clearer monitoring of processing stages and outstanding work. These improvements could strengthen accountability and help authorities identify where further investigation is needed. Their potential social value lies in supporting better informed oversight of medicine registration, while recognising that the present evidence does not measure medicine availability, affordability or patient outcomes directly.

The available records provide a foundation for extending descriptive comparisons into process analysis. Broader geographical coverage and longer observation periods would help assess whether the documented patterns persist across institutional settings. Linked application histories could distinguish submission timing, assessment duration and completed decisions, while documented staffing and review pathways would enable examination of proposed capacity mechanisms. Harmonised classifications and reconciliation of conflicting source entries would strengthen comparability. Future research should evaluate whether observed differences reflect reporting practices, application characteristics or institutional processes, using designs that establish temporal ordering and support the intended explanatory claims.

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