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Determinants of access to anticancer medicines in South Asia: a multimethod study

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ABSTRACT

Objective South Asia bears a high cancer burden, low universal health coverage and high out-of-pocket expenditure. Access to anticancer medicines is challenging and is influenced by determinants—National Essential Medicines List (NEML), registration and local production—yet these are rarely evaluated. This study evaluates these determinants in eight South Asian countries.

Design Multimethod study using a document analysis phase and semistructured interviews.

Setting Eight South Asian countries (Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka) for document analysis, with stakeholder interviews conducted in six countries, excluding Bhutan and Maldives.

Participants Data were collected from eight regulatory authorities and 30 interviews with drug supply chain stakeholders across six South Asian countries.

Main outcome measures The inclusion of 67 anticancer medicines from the 2023 WHO Essential Medicines List (EML) into NEML, their registration and local production, along with macrolevel indicators and stakeholders' perspectives regarding them.

Results The median number of medicines included in NEMLs, registered and locally produced was 23.5, 45 and 6.5, respectively. Local production correlated positively with NEML inclusion (ρ=0.884, p=0.004) and negatively with healthcare expenditure (r = −0.732, p=0.039). Three countries listed >50% of the WHO EML medicines on their NEMLs; six had >50% registered. Local production remained limited, with imports dominating supply. Qualitative analysis identified three key barriers to improving availability: financial constraints, a weak regulatory system and insufficient strategic planning.

Conclusions Access to anticancer medicines is constrained by systemic misalignment between NEML inclusion, registration and local production, undermined by weak regulatory coordination, limited strategic planning and financial constraints. Strengthening regulatory coordination, improving registration efficiency and supporting regional production strategies aligned with guided WHO guidance may help improve equitable access to cancer medicines in the region.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A multimethod design combining document analysis and semistructured interviews enabled triangulation of regulatory data with stakeholder perspectives.
⇒ Data were collected from eight South Asian countries using a standardised extraction approach based on the 2023 WHO Essential Medicines List, improving cross-country comparability.
⇒ Interviews were conducted in six of the eight study countries, which may limit regional representation.
⇒ The qualitative component used purposive and snowball sampling of stakeholders across multiple sectors, which may introduce selection bias.
⇒ Data extraction from regulatory authorities was challenging due to incomplete records.

INTRODUCTION

South Asia faces an escalating cancer burden with projections indicating that the incidence and mortality rates will double between 2022 and 2050.[1] This rise emphasises the urgent need for systematic cancer control policies aligned with WHO's recommendations to ensure evidence-based access and equity at both national and regional levels.[2 3] However, these policies—especially for innovative cancer treatments—mainly benefit high-income countries because these countries have stronger health system capacity, financing mechanisms and regulatory infrastructure to translate global guidance into national cancer control programmes and ensure timely access to essential treatments.[4] In contrast, individuals in developing countries—where most of the burden lies—face limited treatment options, with access often restricted to wealthier populations.[2 5] Inadequate availability of anticancer medicines poses a major barrier to cancer control in these regions, highlighting significant gaps in healthcare infrastructure and hindering

progress toward the Sustainable Development Goals (SDGs).[6]

The WHO Essential Medicines List (EML) is an international evidence-based benchmark for global medicine policy. Countries use this upstream tool to develop their National EMLs (NEMLs) to support progress towards universal health coverage (UHC) and SDGs.[7] These NEMLs subsequently function as policy instruments that guide drug selection, registration,[8] procurement,[9 10] reimbursement,[9] importation,[7 9 11] local production[11] and drug pricing policy development.[2 9] However, inclusion in the NEML does not guarantee market availability, as medicines must also obtain regulatory registration (market authorisation) before they can be legally marketed and supplied.[8] Registration, in turn, acts as a gatekeeper, ensuring that locally produced or imported medicines meet international safety and quality standards.[8] Complementing this, the WHO Local Production Forum underscores local production as a key strategy to strengthen drug supply chain resilience and improve access to high-cost medicines.[12 13] These three upstream determinants—NEML inclusion, registration and local production—represent sequential regulatory, policy and supply-side levers within the WHO Health Systems Framework that collectively shape access. However, the interaction of these upstream determinants in shaping access remains underexplored in South Asia.

Access to anticancer medicines is challenged at various levels of the drug supply chain. A critical first step in improving access is the alignment of NEMLs with the WHO EML.[1 14 15] Previous analyses from the WHO South-East Asia Region, which includes several South Asian countries, reported that NEMLs contained a median of 23.5 oncology medicines from the WHO Model List in 2014 (IQR 26).[16] Subsequent analysis reported that the median number declined to 21 medicines in 2016, highlighting persistent gaps in the inclusion of essential cancer medicines.[17] Even when formally included in national lists, as in Pakistan's 2019 NEML, many anticancer medicines remained unregistered and unavailable in practice.[14] Another important barrier in the supply chain is regulatory registration. Despite price reductions in India and Bangladesh,[18] driven by the growing biosimilar industry,[19 20] registration processes remain lengthy, reflecting procedural barriers that delay the market entry of anticancer medicines. In India, 42.9% of approval decisions took 2–4 years.[21] India improved its registration procedures to align with international standards between 2010 and 2019.[22 23] Meanwhile, Sri Lanka[24] and Nepal[25] struggled with import dependence and unstable access due to a limited number of registered products.[8 14 26]

South Asian countries—with large populations, heterogeneous healthcare systems, low healthcare expenditure, low UHC indices and high out-of-pocket spending among developing countries—face significant research gaps in access to anticancer medicines.[11 27 28] A focused literature review (2000–2025) found limited and uneven evidence, with studies limited to India, Pakistan and Bangladesh (online supplemental table S1-S3,figure S1). These studies primarily investigated compulsory licensing and intellectual property rights; few examined NEML inclusion, though one linked it with lower cancer mortality,[29] while others found evidence of delayed registration.[21] Most countries rely on imports for anticancer medicines, despite existing local pharmaceutical capacity.[27 30 31] Despite calls to expand local production for national, regional and global health security,[32 33] no regional multimethod study has integrated analysis of NEML inclusion, registration and local production of anticancer medicines across South Asia within the Health Systems framework. To address these critical gaps, this study assessed the NEML inclusion, registration and local production of WHO EML-listed anticancer medicines in South Asian countries, and examined how these three determinants interact to shape access within the WHO Health Systems Framework.[34] It also examined associations with macrolevel indicators (income level, cancer burden, gross domestic product (GDP) per capita and healthcare expenditure) and explored stakeholders' perceptions of facilitators and barriers influencing these processes.

METHOD

Study design

This study used a multimethod design to evaluate determinants of access to anticancer medicines in eight South Asian countries (Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka), corresponding to the member states of the South Asian Association for Regional Cooperation. The document analysis phase comprised secondary analysis of regulatory data (official NEMLs, registration and local production documents/databases).[35] The subsequent qualitative phase used semi-structured interviews to provide a contextual explanation of the first phase.[36] We then compared patterns across three determinants—NEML inclusion, drug registration and local production—to describe their relationships, and finally integrated the findings using a joint display (online supplemental table S8).

Conceptual framework

This study adapted the 2010 WHO Health Systems Framework, focusing on upstream determinants within the Access to Medicines block. We analysed three interlinked inputs—NEML inclusion, drug registration and local production—as a coherent access pathway. This operationalisation is informed by current WHO priorities: the WHO Local Production Forum emphasises local production for supply resilience,[12] while the Global Benchmarking Tools[37] prioritise efficient registration. Our framework thus diagnoses the policy, regulatory and supply-side determinants that shape the ultimate outcomes of availability and affordability. We did not measure availability and affordability directly, but proposed that these determinants are interlinked and shape access by improving health, responsiveness, financial risk protection and

efficiency[38] (online supplemental figure S2). Our framework recognises the connection between policy signals and the market. Although NEML inclusion is a governmental commitment, registration depends on the manufacturer's initiative based on market viability. However, NEML listing can serve as a market signal by indicating procurement potential, establishing a bidirectional relationship between these factors.

Document analysis phase

Using the 2023 WHO EML as a reference, we extracted data on 67 anticancer medicines (online supplemental table S4) included in NEMLs, registered and locally produced in eight South Asian countries.

Medicine selection

The study replicated the entire antineoplastic section of the 2023 WHO EML as structured by WHO. It focused on 67 anticancer medicines listed under Section 8 (Immunomodulators and Antineoplastics) of the 2023 WHO EML.[39] This includes two subsections: 8.1 (Immunomodulators for non-malignant disease: 4) and 8.2 (Antineoplastics and supportive medicines comprise cytotoxic medicines, immunomodulators, targeted therapies, hormones and antihormones and supportive medicines: 63). We used the 23rd list of 2023 WHO EML as a standard and reference for analysis because WHO recommends it for developing NEMLs and supporting local production to achieve UHC (online supplemental table S4).[2 11]

Data collection

The data on the latest available NEMLs, registered and locally produced anticancer medicines were requested from regulatory authorities via email by research collaborators from each country (May–June 2024). Validity and completeness were ensured through guided extraction, cross-referencing NEMLs with the WHO repository and pharmacist-verified validation of registered and locally produced medicines (online supplemental figure S3).

Other sources of data

Cancer burden data (mortality and morbidity rates) were sourced from GLOBOCAN,[40] while income levels, GDP per capita and healthcare expenditure were obtained from the World Bank (online supplemental table S5).[41]

Data analysis

Descriptive data were presented as medians with IQRs, given that the data did not follow a normal distribution; therefore, non-parametric tests were applied.

Spearman's correlation was used to assess the directional associations among three key variables (NEML inclusion, registration and local production) across eight South Asian countries. Correlation strength was classified as weak (ρ<0.3), moderate (ρ=0.3–0.5) and strong (ρ>0.5). Additionally, we explored the relationship between each of the three key variables with country-level socio-economic indicators (cancer burden, GDP per capita, income level and healthcare expenditure). Given the small sample size, these analyses were descriptive and exploratory. Pearson correlation was used only to assess the direction of associations.

No confounders were included in the model. Country-specific dynamics and discrepancies across countries and income levels are presented in the online supplemental method. All statistical analyses were conducted using R (V.4.4.2) and Statistical Package for the Social Sciences (SPSS, V.23).

Qualitative phase

The interviews aimed to investigate each determinant—NEML inclusion, registration and local production—and explore stakeholders' perspectives on how these determinants interact to shape access while identifying contextual barriers and enablers. The interview guide provided broad prompts on NEML inclusion, registration and local production, and additional probing questions were used during interviews to explore emerging issues in greater depth.

Interview guide

An interview guide was developed based on findings from the document analysis phase. It was first reviewed and piloted with two interviewees. The final interview guide was translated into the local language. Participants were asked about their preferred language and interviewer (online supplemental file).

Key participants and sample size

We identified key informants through policy documents, institutional websites, stakeholder referrals, professional networks, ResearchGate and LinkedIn. Invitations were sent to multiple professionals in each country; however, response rates varied across professional networks and countries, and no participants were recruited from Maldives and Bhutan despite several recruitment attempts. We interviewed a purposive sample (n=30) of key stakeholders between 1 March 2025 and 30 June 2025 across six countries (Afghanistan (n=5), Bangladesh (n=5), India (n=7), Nepal (n=5), Pakistan (n=5), Sri Lanka (n=3)). The invitation-to-acceptance ratio was low. Following the initial invitation, two reminders were sent at 1 week intervals. We sought to ensure stakeholder representation and adopted Malterud *et al*'s 'information power'[42] concept to guide the sample size (online supplemental file p 22). All interviews were audio-recorded with written consent, assigned a unique identifier to ensure confidentiality and transcribed verbatim (online supplemental method).

Analysis

Thematic codes (guided by the Braun and Clarke thematic analysis framework)[43] were deductively derived based on the conceptual domains of determinants. To probe links among determinants, we used double-coding/matrix analysis (segments associated with multiple determinants), examined pattern

co-occurrence across countries and wrote analytical memos on perceived mechanisms. Integration was accomplished through a joint display linking document-analysis results with qualitative mechanisms. Two members of the research team (SS and IH) coded the qualitative data using NVivo software (V.12).

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

RESULTS

Document analysis outcomes

NEML inclusion

The median number of anticancer medicines listed in the NEMLs across eight countries was 23.5 (range: 0–67, IQR: 30.5). Overall, three of the eight countries included at least 50% of the anticancer medicines, Pakistan included all, whereas Afghanistan's NEML included none. Among the five antineoplastics subsections, cytotoxic agents were the most frequently included (median: 15, range: 0–35, IQR: 22.8), followed by hormones and antihormones (median: 4.5, range: 0–9, IQR: 2.3). In contrast, targeted therapies were poorly represented (median: 1.5, range: 0–10, IQR: 2.8) (table 1; online supplemental figure S4).

Registered anticancer medicines

The median number of anticancer medicines registered across the eight countries relative to the 2023 WHO EML was 45 (range: 15–65, IQR: 17.8). Overall, six of the eight countries had registered more than 50% of the anticancer medicines from the 2023 WHO EML. Across the five antineoplastics subsections, six countries had registered anticancer medicines from all subsections. Cytotoxic agents were the most frequently registered (median: 23.5, range: 8–34, IQR: 6.5) followed by targeted therapies (median: 7, range: 0–10, IQR: 6.25) and hormones and antihormones (median: 5.5, range: 1–9, IQR: 2.5) (table 1; online supplemental figure S4).

Locally produced anticancer medicines

The median number of anticancer medicines locally produced across the eight countries relative to the 2023 WHO EML was 6.5 (range: 0–63; IQR: 35). Of the eight countries, six had pharmaceutical manufacturing capacity, and five reported local production of anticancer medicines. Of the five countries producing anticancer medicines, four manufactured medicines from all antineoplastic subclasses, whereas Sri Lanka manufactured only one medicine (prednisolone). Cytotoxic agents were the most frequently locally produced (median: 6, range: 0–33, IQR: 19.25) followed by hormones and antihormones (median: 1.5, range: 0–9, IQR: 4.25) and targeted therapies (median: 1.5, range: 0–10, IQR: 5.25) (table 1; Online supplemental figure S4). Detailed heatmaps are provided in online supplemental figure S5.

Table 1 Descriptive statistics for anticancer medicines in South Asia

Variable	Median (IQR)	Range
Anticancer medicines in NEMLs		
Number of anticancer medicines in NEMLs	23.5 (11–41.5)	0–67
Immunomodulators for non-malignant disease	2.0 (2–3)	0–4
Antineoplastics and supportive medicines	21.5 (8.75–39.25)	0–63
Cytotoxic medicines	15.0 (3.5–26.25)	0–35
Targeted therapies	1.5 (0–2.75)	0–10
Immunomodulators	2.0 (0–2)	0–4
Hormones and antihormones	4.5 (3.75–6)	0–9
Supportive medicines	1.0 (0–2.25)	0–4
Registered anticancer medicines		
Number of registered anticancer medicines	45.0 (32.75–50.5)	15–65
Immunomodulators for non-malignant disease	2.5 (1.75–4)	0–4
Antineoplastics and supportive medicines	41.5 (32.25–47.25)	14–61
Cytotoxic medicines	23.5 (20.5–27)	8–34
Targeted therapies	7.0 (1.75–8)	0–10
Immunomodulators	2.5 (1.75–8)	0–5
Hormones and antihormones	5.5 (1.5–4)	1–9
Supportive medicines	2.5 (1–3.25)	0–4
Locally produced anticancer medicines		
Number of locally produced anticancer medicines	6.5 (0–35)	0–63
Immunomodulators for non-malignant disease	0.0 (0–0.75)	0–3
Antineoplastics and supportive medicines	6.5 (0–34.25)	0–60
Cytotoxic medicines	6.0 (0–19.25)	0–33
Targeted therapies	1.5 (0–5.25)	0–10
Immunomodulators	1.0 (0–3)	0–5
Hormones and antihormones	1.5 (0–4.25)	0–9
Supportive medicines	0.0 (0–1.5)	0–4

NEMLs, National Essential Medicine Lists.

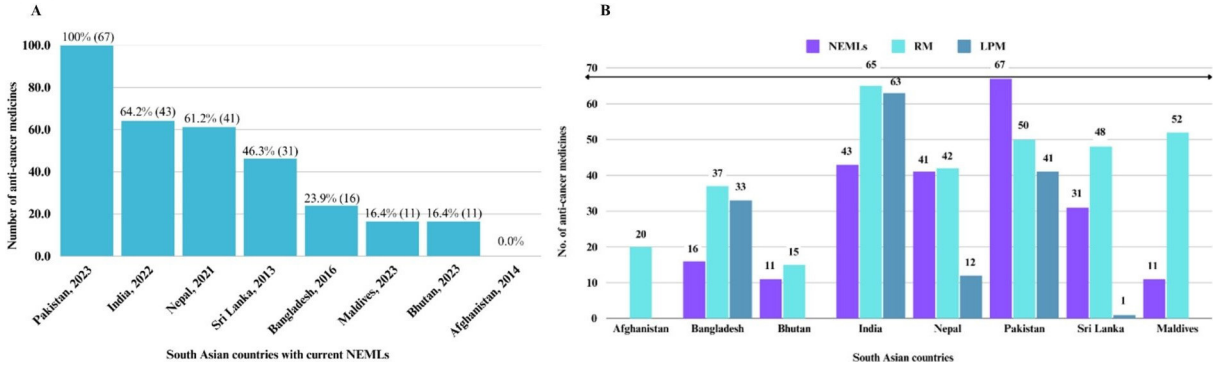

Figure 1 Alignment and status of anticancer medicines in South Asian countries. (A) Alignment of NEMLs with the WHO Essential Medicines List (2023), showing the percentage of anticancer medicines included in national lists and the year of the latest NEML update for each country; (B) Comparison of South Asian countries by the number of anticancer medicines included in their NEMLs, registered and locally produced. LPM, locally produced medicines; NEMLs, National Essential Medicine Lists; RM, registered medicines.

NEMLs alignment with 2023 WHO EML

Three countries (Bhutan, Pakistan and Maldives) updated their NEMLs in 2023, but the inclusion of medicines varied. India updated its NEML in 2022 and included 43 anticancer medicines (64.2%), more than Bhutan and Maldives, each of which included 11 medicines (16.4%). Similarly, Sri Lanka's 2013 NEML included more anticancer medicines than Bangladesh's 2016 NEML (figure 1).

Relationship among the number of anticancer medicines in NEMLs, registered and locally produced

Bivariate Spearman correlation analysis across eight South Asian countries showed that only the association between the number of anticancer medicines included in NEMLs and the number of locally produced anticancer medicines was statistically significant and strongly positive ($\rho\ (8) = 0.884$, $p=0.004$). This indicates that countries listing a higher number of anticancer medicines in their NEMLs tend to have greater local production of these medicines.

In contrast, the correlations between the number of registered medicines and locally produced medicines ($\rho\ (8) = 0.537$, $p=0.170$) and between the number of registered medicines and the number of medicines included in NEMLs ($\rho\ (8) = 0.599$, $p=0.117$) were not statistically significant (table 2).

Country-level descriptive comparisons of NEML inclusion, registered medicines and locally produced medicines are presented in online supplemental table S6. Furthermore, comparisons across countries and income levels showed no statistically significant differences in the number of anticancer medicines included in NEMLs,

Table 2 Bivariate analysis of anticancer medicines with cancer burden, GDP per capita and healthcare expenditure in South Asian countries

Variable	No. medicines in NEMLs ρ (p value)	No. registered medicines ρ (p value)	No. locally produced medicines ρ (p value)
No. medicines in NEMLs	–	0.599 (0.117)	0.884 (0.004)
No. registered medicines	0.599 (0.117)	–	0.537 (0.170)
No. locally produced medicines	**0.884 (0.004)**	0.537 (0.170)	–
Variable	**No. medicines in NEMLs r (p value)**	**No. registered medicines r (p value)**	**No. locally produced medicines r (p value)**
Incidence	−0.169 (0.690)	0.012 (0.978)	−0.086 (0.840)
Mortality	−0.275 (0.509)	−0.452 (0.260)	0.024 (0.954)
GDP per capita	−0.168 (0.691)	0.238 (0.570)	−0.268 (0.520)
Healthcare expenditure	−0.587 (0.126)	−0.119 (0.779)	**−0.732 (0.039)**
Income level	0.165 (0.697)	0.546 (0.162)	0.000 (1.000)

'ρ' is the Spearman's rank correlation coefficient quantifying the direction and strength of the relationship between two variables, ranging from −1 to +1. 'r' is the Pearson correlation coefficient quantifying the direction and strength of the relationship between two variables, ranging from −1 to +1. A positive value indicates a positive relationship, while a negative value indicates a negative relationship. The p value assesses the statistical significance of observed relations with a value less than 0.05 considered significant. Bold values indicate statistical significance ($p < 0.05$).
GDP, gross domestic product; NEMLs, National Essential Medicine Lists.

Table 3 Summary of interview participants (n=30)

	Afghanistan n (%)	Bangladesh n (%)	India n (%)	Nepal n (%)	Pakistan n (%)	Sri Lanka n (%)	Total N (%)
Interviewee	5 (16.7)	5 (16.7)	7 (23.3)	5 (16.7)	5 (16.7)	3 (10.0)	30 (100.0)
Profession							
Pharmacist	3 (16.7)	3 (16.7)	5 (27.8)	2 (11.1)	3 (16.7)	2 (11.1)	18 (60.0)
Oncologist	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)	1 (14.3)	1 (14.3)	7 (23.3)
Supplier	–	1 (33.3)	–	1 (33.3)	1 (33.3)	–	3 (10.0)
Policymaker	1 (50.0)	–	–	1 (50.0)	–	–	2 (6.7)
Experience							
<5 years	2 (22.2)	–	4 (44.4)	2 (22.2)	–	1 (11.1)	9 (30.0)
5–10 years	3 (21.4)	4 (28.6)	2 (14.3)	2 (14.3)	2 (14.3)	1 (7.1)	14 (46.7)
11–15 years	–	1 (100.0)	–	–	–	–	1 (3.3)
16–20 years	–	–	1 (50.0)	–	–	1 (50.0)	2 (6.7)
>20 years	–	–	–	1 (25.0)	3 (75.0)	–	4 (13.3)
Sector							
Government	4 (25.0)	4 (25.0)	–	4 (25.0)	1 (6.3)	3 (18.6)	16 (53.3)
Private	1 (9.0)	1 (9.0)	7 (100.0)	1 (9.0)	1 (9.0)		11 (36.7)
NGOs	–	–	–	–	3 (100.0)		3 (10.0)

NGOs, non-governmental organisations.

registered and locally produced (online supplemental table S7 and figure S6-S7).

Correlation with socio-economic indicators

Correlation analysis between anticancer medicine indicators (the number of anticancer medicines included in NEMLs, registered and locally produced) and socio-economic variables showed no statistically significant associations (p>0.05) for most indicators (table 2). However, a significant negative correlation was observed between healthcare expenditure and the number of locally produced medicines (r = −0.732, p=0.039), indicating that countries with higher healthcare expenditure tended to have fewer locally produced anticancer medicines. No statistically significant correlations were observed between NEML inclusion, registered medicines and the other socio-economic indicators.

Qualitative outcomes

30 stakeholders participated from six countries: Afghanistan, Bangladesh, India, Nepal, Pakistan and Sri Lanka. Most participants were pharmacists (60.0%), followed by oncologists (23.3%). Most participants were male (80.3%) and employed in governmental organisations (53.3%). Nearly half of the participants (46.7%) had 5–10 years of experience, whereas a few (13.3%) had more than 20 years of experience (table 3).

Four themes emerged: (1) NEMLs alignment to WHO EML, (2) registration and import of anticancer medicines, (3) local production of anticancer medicines and (4) integration of determinants. The themes, categories and associated quotations are presented in table 4.

Theme 1: alignment of NEMLs with the WHO EML

The qualitative findings highlighted two interconnected subthemes related to NEML alignment with international standards.

Health system resource and financial constraints

System-level issues restricting NEML alignment in most of these countries included financial constraints, weak healthcare infrastructure and limited resources. High costs and limited national budgets restricted the inclusion of several drugs and innovative agents within NEMLs, as this inclusion could not be translated into availability. In contrast, the alignment in India was satisfactory, involving an in-depth procedure.

> Due to the cost itself, they do not give much priority to this medicine list in Nepal. (Nepal Pharmacist 2)

> For NEML, regulatory authorities in India are doing a better job making sure the NEML is confined to whatever it needs. The WHO guidelines are being followed. (India Pharmacist 3)

Relevance of WHO EML to local disease burden

The NEML alignment with the WHO EML was also restricted by prioritising local disease burden, along with a delayed attitude towards adopting new molecules. The attitude was either due to a lack of knowledge or not prioritising NEMLs. However, participants affirmed the need for timely in-depth revision to adopt innovative treatment options.

Table 4 Themes, subthemes, barriers, facilitators/suggestions and related quotations

Subthemes	Barriers	Facilitators/suggestions	Related quotes
Theme 1: alignment of NEMLs with the WHO EML			
Health system resource and financial constraints	It included financial constraints, weak healthcare infrastructure and restricted resources. Financial constraints remain a major obstacle to including and providing anticancer medicines in NEMLs. Budget limitations, high drug prices and the cost of new innovative therapies make it difficult for low- and middle-income countries to incorporate and maintain these medicines in their national lists. Even when aligned with WHO guidance, implementation is often limited by affordability and procurement challenges, resulting in partial or selective adoption.	Strengthening healthcare infrastructure, expanding cancer care facilities (especially in rural regions) and increasing investment in health systems are essential for effective NEML implementation. Training more specialists and ensuring regular and timely revision of the NEML to align with WHO recommendations is needed, as seen in India.	"DRAP invited healthcare professionals to suggest drugs for NEML, …they received so many suggestions…, difficult to fulfill, especially due to affordability and preference issues. In the end, they stuck with WHO's list." (Pakistan Pharmacist 2). "Secondly, the revision duration of the NEML of Nepal is a little longer compared to the WHO. There is no policy or committee for that. And due to the limited human resources, revising every two year is very hard for our country." (Nepal regulator 1). "The regulatory authorities here in India are doing a better job making sure the EMLs are confined to whatever it needs. The WHO guidelines are being followed with respect to the EMLs." (India Pharmacist 3). "They do not give much priority to NEML in Nepal. Because of the cost itself. The government cannot purchase all medications listed in the NEML." (Nepal Pharmacist 2).
Relevance of WHO EML to local disease burden	Countries often face barriers when national priorities or local disease patterns do not fully align with the WHO EML, and cost-effectiveness, as well as the lack of inclusion of new or targeted therapies frequently approved elsewhere, further restricts effective coverage.		"National health authorities may prioritize medicines based on local disease patterns or cost-effectiveness data, which may not always align with the global WHO recommendations." (Afghanistan Pharmacist 1). "Basically, cancer is evolving and every day we are getting new drugs; these lists should be updated on annual basis." (India Oncologist 1). When they were developing, they asked relevant people from the pharma industry, as well as from hospital pharmacy, to help in revision." (Pakistan Oncologist 1).
Theme 2: registration and import of anticancer medicines			

Continued

Table 4 Continued

Theme 1: alignment of NEMLs with the WHO EML			
Financial barriers to registration and import	Suppliers were unwilling to register new medicines due to high costs, limited profit potential and small market size. All these factors make it difficult for suppliers to import oncology drugs, often resulting in drug shortages, delayed shipments and need-based imports. Financial constraints also impacted drug quality due to inadequate cold chain logistics. Additionally, high costs and limited national budgets restrict the inclusion of many drugs, newer, more effective anticancer drugs recommended by the WHO in NEMLs, as inclusion in NEMLs cannot be translated into actual availability.	To tackle the high-cost issue: (1) need-based registration and import were adopted in almost all countries, highly functional for the private sector; (2) some contract-based pool procurement for such drugs that may minimise their cost to some extent; (3) local production was another promising factor highlighted by most of them, as it leads to generics/biosimilars with affordable prices, available on time, with minimum shortages and better quality than grey market products.	"Private sector import process is smooth. Government hospitals face delays due to red tape, customs procedures and approvals take longer (time)…lacks coordination and capacity, leading to inconsistent availability." (Bangladesh Pharmacist 3). "To improve access, the government could subsidize or reduce registration fees for essential cancer drugs, streamline import procedures, and negotiate bulk purchase agreements with manufacturers." (Sri Lanka Pharmacist 1). "We have limited importers. So, importers…want profit. And if the market is very small, if only 40% complete the therapy. So that's why the importers are also not interested in importing these medicines." (Nepal Regulator 1).
Regulatory capacity and administrative processes	Weak regulatory capacity/resources, a lengthy registration process, short registration tenure, stringent requirements and a lack of flexibility significantly slow down registration and import. Even after initial registration, the annual renewal process can be tedious and discourage consistent supply, especially when it involves repeated visits and administrative delays.	Fast-track or special permission pathways—such as those that allow clinicians to recommend specific medicines for urgent patient needs—can greatly expedite access. Temporary or one-time registrations, issued on clinical recommendation, also help address urgent treatment gaps. Additionally, proactive engagement by regulatory authorities, including regular consultation with stakeholders and efficient procedures in the private sector, can speed up approval and import processes.	"The regulatory authority requires full dossiers for registration, but lacks inspection capacity at manufacturing sites." (Afghanistan Pharmacist 3). "In countries like Afghanistan and Pakistan, we've found that regulations are very strict, which makes it difficult to market and register our products." (Bangladesh Supplier 1). "…when I prescribed some new drugs first time, for example, third-line targeted therapy for breast cancer, or thyroid cancer, or some immunotherapies. In that scenario, when we ask or seek help from the importer, the DDA cross-checks us; they ask about the prescriber, the indication, and whether it is essential. Until now, I think the DDA is very supportive, and they have not restricted the drug that is prescribed by a clinician, especially a medical oncologist." (Nepal Oncologist 2).

Continued

Table 4 Continued

Theme 1: alignment of NEMLs with the WHO EML			
Supply chain constraints and cross-border dependence	Small market size, high treatment costs, border restrictions and political instability discourage suppliers from registering or importing anticancer medicines. Limited domestic availability forces patients to seek treatment abroad or rely on cross-border procurement and grey-market medicines, increasing out-of-pocket costs and risks related to drug quality and supply disruptions.	Regional pooled procurement, government incentives for drug registration and improved cross-border supply coordination could make smaller markets more attractive for suppliers and help ensure more reliable and timely access to anticancer medicines.	"Due to import policies and delay in manufacturing, sometimes they take 5–6 months to import. And the second is that the shortage increased consumption in hospitals." (Pakistan Supplier 1). "Even though the transportation charges of importing any medicine will be very high because the medicine should have a proper storage system." (India Pharmacist 1). "In Pakistan, the International Patent Law is another problem. While our neighbouring countries are not under patent rules. And they are even manufacturing the product, which has recently been granted FDA approval by the multinational company. So in Pakistan, we are bound to purchase only from the original manufacturer. And not the bio-similar products from India." (Pakistan Supplier 1).
Theme 3: local production			
Policy support and regulatory framework	Key issues include the absence of governmental support and the weakness of regulatory frameworks for bioequivalence studies and quality assurance. Regulatory challenges, such as complex and unclear approval pathways, persist in Afghanistan and Nepal. Concerns were also raised about inconsistent enforcement of standards and the lack of incentives for manufacturers.	Hospitals require quality testing before accepting local drugs. Some private hospitals even conducted such testing so that they may have affordable drugs in the country.	"DRAP must initiate bioequivalence studies for anti-cancer drugs or at least develop some criteria to compare chemical equivalence in comparison to references." (Pakistan Pharmacist 3). "Local production will increase access, but we might lose the quality of the product, so policies are needed for high-quality drugs." (India Pharmacist 3). "Trust in local production is growing. DGDA ensures some level of quality control." (Bangladesh Pharmacist 3).

Continued

Table 4 Continued

Theme 1: alignment of NEMLs with the WHO EML			
Prescriber influence and market viability	Healthcare professionals reported positive experiences with biosimilars and local generics. In several countries, trust in local production is growing, supported by affordability, availability and rising confidence in regulatory oversight. Patients' trust was dependent on prescribers' decisions.	Participants reported positive experiences with biosimilars and local generics. Prescriber trust is more dominant than patients' trust. In this scenario, generic prescribing could be a game-changer, as seen in only one institution in Pakistan.	"I have not seen any differences in results with the local drugs or from the originator molecule." (India Oncologists 1). "Biosimilars are widely used and trusted." (Bangladesh Pharmacist 3). "You cannot run a company, depending on the Nepal market. It will be a total financial collapse." (Nepal Supplier 1). "If the drug is approved by DDA, and if DDA says that this drug has a good quality, we accept that. We believe DDA." (Nepal Oncologist 1).
Manufacturing capacity	Barriers are limited facilities, inadequate industrial infrastructure, a shortage of skilled personnel, a lack of finances, dependency on imports for raw material, high import tariffs and limited laboratory infrastructure for quality assurance.	India demonstrates strong capability, followed by Bangladesh (companies like Beacon and Beximco), leading in the manufacturing and export of generic medicines and biosimilars. Pakistan stands next. In Nepal, Tizig Pharmaceuticals is the pioneer and only oral dosage producer.	"At present, due to a lack of facilities, it is not possible to manufacture these drugs in the country." (Afghanistan Pharmacist 2). "API import dependency is a bottleneck." (Bangladesh Pharmacist 3). "Unfortunately, we don't have a very good setup for the production and manufacturing of raw material. We are mostly relying on our neighboring countries, China or India or some other." (Pakistan Pharmacist 3).
Health system impact of local production	In many South Asian countries, patients have to seek treatment in other countries, so local production was a crucial factor to overcome this patient burden. However, substantial barriers hindered the impact of local production, such as the need for significant investment, long lead time, lack of resources and lack of capability to produce raw materials.	In some countries (India, Bangladesh, Pakistan and Nepal), biosimilars/generics production has reduced the number of patients travelling abroad for medicines. Moreover, the pharmaceutical sector has been trying to expand production capabilities.	"Local Production is increasing access by providing cancer medicines at low prices." (India Pharmacist 6). "There have been efforts by local pharmaceutical companies to expand production capabilities, including cancer drugs, mainly generics. Some hospitals have small-scale compounding or preparation units but not full manufacturing." (Sri Lanka Pharmacist 2).
Theme 4: interaction between NEML inclusion, registration and local production			

Continued

Table 4 Continued

Theme 1: alignment of NEMLs with the WHO EML		
Regulatory authorities were reluctant to add drugs to NEMLs because they cannot register and provide them in facilities due to financial constraints. Financial constraints limit both regulators and suppliers from registering and importing. Need-based imports, then, are dominant, leading to shortages, high-cost treatments and grey market substandard drugs.	Stakeholders identified local production as the most promising driver to overcome registration/financial/import barriers. Sustained quality-assured local production of biosimilars/generics eases registration, increases NEML's inclusion, limits import, reduces grey market and increases patient access.	"India is the largest market for pharmaceuticals. We have Eli Lilly, GSK, Novo Nordisk, and Novartis, manufacturing and marketing their products. We have a lot of biosimilars in India. They are good in quality." (India Pharmacist 3). Local production increases access and reduces cost." (Bangladesh Pharmacist 3). "Legal framework allows only licensed medicines. However, 40% of imports are illicit, especially through unsecured borders." (Afghanistan Oncologist 1).

EML, Essential Medicines List; NEMLs, National Essential Medicine Lists.

Theme 2: registration and import of anticancer medicines

Three interconnected subthemes were identified.

Financial barriers to registration and import

Financial and affordability constraints remained a significant barrier to registering and importing anticancer medicines across South Asian countries. All countries adopted a special permission (need-based) import to overcome such challenges. Financial constraints also impacted drug quality due to inadequate cold chain logistics and the grey market. To tackle these challenges, local production was the most promising factor for affordable generics/biosimilars.

> We have limited importers. Very few will go for the treatment. Out of those few people, only a few continue the full cycle. So that's why the importers are also not interested in importing these medicines. (Nepal Regulator 1)

Regulatory capacity and administrative processes

Weak regulatory capacity, lengthy processes and high fees, short registration tenure and stringent requirements significantly slowed down registration and import. Even after initial registration, the annual renewal process was found tedious and discouraged consistent supply. Special permission pathways greatly expedited access, as witnessed in India and Pakistan.

> Suppliers tell us that the high registration fees and importation costs make it unfeasible for them to bring in the full range of oncology medications. (Sri Lanka Pharmacist 1)

> Registration of the new drugs by our regulatory authorities is very tiring and very difficult because it requires a lot of time. (Indian Pharmacist 3)

> Approval delays due to limited inspection team capacity. (Afghanistan Pharmacist 1)

Supply chain constraints and cross-border dependency

The small market size, frequent border restrictions and the high cost of treatment discouraged importers and multinational companies from registering or supplying new anticancer medicines in these countries. In Afghanistan, Bhutan, Maldives, Nepal and Sri Lanka, patients often travel abroad, especially to neighbouring countries, to access treatment or obtain medicines that are unavailable or unregistered locally, leading to high out-of-pocket costs. In Maldives, treatment costs are covered by insurance.

> Imports are hard due to frequent border restrictions. Additionally, resources such as cold chain logistics and inspection capacities are often insufficient, which can impact timely clearance and storage. (Afghanistan Pharmacist 1)

Open borders between Nepal-India and Afghanistan-Pakistan enabled cross-border medicines trade, allowing

patients to seek treatment from neighbouring countries. While it provided short-term access, it often resulted in higher treatment costs and reliance on grey market drugs with questionable efficacy.

> Just to get better treatment, they have to travel to India or anywhere abroad. Because of the lack of proper medicine or the lack of the latest medicine, doctors are either recommending the patient to go to India or anywhere else to bring the medicine, or when the patient is thinking that if I have to go to bring the medicine, why don't we go and take the treatment in India only? So that causes unnecessary burden on the patient. (Nepal Supplier 1)

Theme 3: local production of anticancer medicines

The qualitative findings highlighted four subthemes in local production.

Policy support and regulatory framework

Participants highlighted the absence of governmental support and weak regulatory frameworks for local production and drug quality assurance as key regulatory barriers.

> There are no direct incentives like subsidies or tax breaks for local manufacturers. But if companies fail to meet quality standards, their licenses can be cancelled. (Bangladesh Supplier 1)

Prescriber influence and market viability

Many participants had good experiences with locally produced medicines, and some trusted local regulatory authorities. Patient trust was primarily directed towards prescribers. Eventually, prescriptions directed purchasing decisions, making patients' trust in local production a secondary factor.

> For cancer medicines, patients follow the oncologists. They will go for a drug prescribed to them, either locally provided or imported, without questioning drugs quality. (India Pharmacist 4)

> Trust in local production is growing. (Bangladesh Pharmacist 4)

Stakeholders consistently identified a small market size as a significant barrier to local production, especially for high-cost medicines.

> Some companies are hesitant to invest due to high costs and limited market size. (Sri Lanka Oncologist 1)

Manufacturing capacity

Manufacturing capacity-associated barriers included limited facilities, poor industrial and laboratory infrastructure, limited skilled workforce, dependence on imported raw material and high import tariffs.

> Domestic production capacity is absent due to a lack of investment, industrial infrastructure, trained workforce, raw material scarcity), and high import tariffs. Quality assurance is constrained for other essential medicines by limited laboratory infrastructure. (Afghanistan Oncologist 1)

Participants highlighted robust local production in India, followed by Bangladesh and medium in Pakistan, with India producing and exporting biosimilars and generics. In Nepal, local production of anticancer medicines is very limited, with only one domestic manufacturer currently producing oral oncology products.

> In terms of pharmaceutical production, Bangladesh stands next to India in the region. We are going to be a player in generic medicine manufacturing and have a growing export market. (Bangladesh Supplier 1)

Health system impact of local production

Stakeholders across all six countries affirmed that local production increases access to anticancer medicines by reducing drug prices, reducing imports, minimising shortages and streamlining the drug supply chain.

> Local production of cancer medicines could significantly improve access by reducing dependence on imports, lowering costs, and shortening supply chains. It could also help address frequent stockouts and import delays. (Sri Lanka Pharmacist 2)

In many South Asian countries, patients have to seek treatment in other countries, so local production was considered crucial for reducing this patient burden.

> If local production were established, many patients would no longer need to travel abroad because of drug shortages, thereby avoiding spending their resources overseas. (Afghanistan Pharmacist 2)

However, substantial barriers hindered the impact of local production, such as the need for significant investment, long lead time, lack of resources and lack of capability to produce raw materials.

> I feel that the price, if we are capable of producing raw material within our country, I believe we can easily overcome the substantial price issue. (Pakistan Pharmacist 4)

Theme 4: interaction between NEML inclusion, registration and local production

Stakeholders reported that regulatory authorities do not include anticancer medicines in NEMLs because it is difficult to register them and ensure supply to healthcare facilities after listing, especially due to financial constraints. Limited financing restricted both regulatory authorities and suppliers from registering or importing these medicines, with even more severe challenges for high-cost innovative medicines. Limited registration and import led to shortages and, reportedly, to the availability of substandard drugs through the grey market.

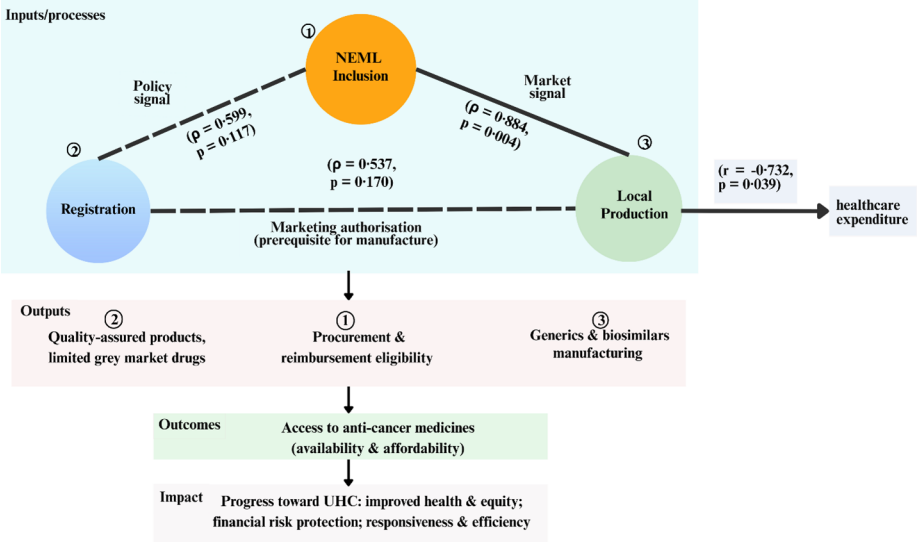

Figure 2 Results mapped to the WHO Health Systems Framework, 'Access to Essential Medicines' block. NEML, National Essential Medicines List; UHC, universal health coverage.

To address registration/import-associated challenges, most stakeholders identified local production as the most promising strategy to provide affordable quality-assured generics/biosimilars that can be registered, included in NEMLs and made available to patients (figure 2).

> The government cannot purchase all medications and give free supply to the hospital if listed in the NEML. They list only those medications that are of important use. (Nepal Pharmacist 2)

> Local production of anti-cancer medicines in Afghanistan could significantly improve access. However, this would require strong government support. (Afghanistan Pharmacist 1)

> Local production of cancer medicines could significantly improve access by reducing dependence on imports, lowering costs, and shortening supply chains. It could also help address frequent stockouts and import delays. (Sri Lanka Pharmacist 2)

Integration of both phases

Our multimethod findings complement the WHO Health Systems Framework. The NEML inclusion was positively associated with local production (document analysis), suggesting that countries listing more anticancer medicines tend to have more local production and vice versa, hence supporting access. But NEML expansion depends on registration, regulatory expertise and financial capacity (qualitative). In Pakistan, limited regulatory capacity led to mirroring the WHO EML, and in Nepal, the lack of financial capacity to provide anticancer medicines limited their inclusion in NEMLs (qualitative). Therefore, local production emerged as a lever to reduce the reliance on imports and increase registration by enabling the timely supply of affordable, quality-assured anticancer medicines (qualitative). Finally, increased local production can decrease healthcare expenditure (document analysis) and lead to improved health (UHC), equity and financial-risk protection at the impact level. Though local production is influenced strongly by industrial policy, manufacturing capacity and incentives, to address such challenges, pooled manufacturing is a solution (figure 2, online supplemental table S8).

DISCUSSION

This is the first multimethod study to systematically assess inconsistencies across policy (NEMLs), regulations (registration) and supply (local production) for anticancer medicines in low- and middle-income country (LMIC) settings, particularly in South Asia. These three upstream levers shape the downstream outcomes of availability and affordability. Although the WHO EML is well established, its adoption across countries has remained inconsistent and deprioritised. The findings revealed that most innovative agents rely on complex, need-based import pathways, a suboptimal solution driven by financial constraints and weak regulatory capacity. Local production emerges as a strategic yet underused lever to break this cycle; however, it requires streamlined regulatory policies, financial investments, strong healthcare infrastructure and regional collaboration.

The profound variability in NEML inclusion of medicines from the 2023 WHO EML—from complete adoption in Pakistan to complete absence in Afghanistan—signals major discrepancies in policy commitment and health system capacity.[44] Interviews with stakeholders confirmed these findings, complemented by financial constraints. Similar findings have been reported in other LMIC regions,[11 44] where NEMLs are documented but not operationalised. A comprehensive analysis of 101 countries found that most included less than 50% of anticancer medicines from the WHO EML,[15] a pattern also observed in sub-Saharan Africa[5] and other LMICs.[7 15 45 46]

Country-specific findings highlighted varied constraints impacting NEML alignment. For Pakistan, the rapid inclusion appears non-strategic,[9 47] with the NEML updated[48] only 3 months after the release of the 2023 WHO EML,[49] likely reflecting limited regulatory capacity, financial constraints and strategic planning as confirmed by the qualitative findings. At the other extreme, Afghanistan's complete lack of anticancer medicines from both the 2013 WHO EML[50] and 2023 WHO EML reflects the consequences of decades of conflict that have devastated its healthcare infrastructure.[51] For smaller nations such as Bhutan and the Maldives, alternative approaches—such as sending patients abroad,[11] using traditional treatment or relying on a reimbursement medicines list (Husnuvaa Aasandha in Maldives)[52]—appeared to deprioritise NEML development, although recent policy shifts advocate a growing commitment to an evidence-based list under the 'National Medicine Policy 2024–2030'.[53] In contrast, India adopted a rigorous process involving multistakeholders for its NEML update, which provided a benchmark for strategic alignment.[54]

Despite apparently high overall registration rates, our data highlighted a critical gap: drug registration is profoundly skewed towards old, cytotoxic anticancer medicines, while newer agents are largely excluded (table 1). This disparity between NEML goals (policy) and regulatory certainty creates access barriers,[2 8 9 44] as outdated NEMLs fail to guide procurement for innovative treatments. Our interview findings confirmed that most innovative and high-cost medicines are unregistered and require special registration, a commonly used approach to improve access, but one that is time-consuming and costly, and ultimately impractical for patients with cancer facing urgent treatment needs. Similar discrepancies were highlighted by Shukar *et al* in Pakistan.[26] Qualitative findings elucidate the mechanisms underlying limited registration. For countries heavily reliant on imports, a trifecta of weak regulatory capacity, high-cost drugs and small market size deters suppliers from formal registration. This trifecta negatively affects medicine quality, contributing to the proliferation of substandard drugs in the grey market and insufficient cold chain logistics.[55] Furthermore, patients travel abroad to seek treatment or purchase medicines not registered locally. Even in countries with local production capacity, stakeholders identified the lengthy registration process as a critical barrier. Therefore, need-based imports[26] appear to be a pragmatic regional stopgap, though suboptimal, whereas our data highlight local production as a fundamental long-term strategy to overcoming these barriers. The potential for local production seems vast yet unevenly realised, revealing the stark regional economic disparities. Our results revealed that India,[56] Bangladesh[44 56] and Pakistan[54] have manufacturing capacity supported by proactive industrial and regulatory policies. In contrast, Afghanistan, Bhutan, the Maldives and Sri Lanka remained entirely import-dependent[57] and patients in these settings often seek treatment in neighbouring countries, resulting in substantial out-of-pocket costs.[58] Nepal represents an intermediate situation, with limited but emerging local production of oncology medicines. However, even in countries where local production exists, strong regulatory commitment and policy support are essential to translate manufacturing capacity into registered and accessible medicines. Despite these efforts, patients with cancer across the region continue to face high treatment costs, highlighting persistent gaps in access.[59 60]

Our findings suggest that NEML inclusion, registration and local production operate as an integrated pathway that can improve availability and affordability. Local production may initiate the pathway by facilitating registration,[2 11] which in turn supports NEML inclusion. In South Asia, this coupling is constrained by financial limitations, a weak regulatory system and insufficient strategic planning, which also restricts local production. In this context, pooled manufacturing can partially relieve financial constraints by expanding market size through aggregation of fragmented national markets,[56 61] lowering prices by limiting imports, minimising healthcare expenditure[31] and attracting investments.[33 61] This can be achieved through shared facilities, guidance and expertise. This model has been advocated by the World Local Production Forum[32] and demonstrated in East Africa,[33] moving beyond isolated national strategies. It resonates as the most promising pathway for South Asia to increase access to anticancer medicines and achieve self-sufficiency.[62]

However, to realise the benefit of pooled manufacturing, strategic health policies—not merely financial capacity—are the main drivers of access. This is demonstrated by the lack of association between GDP per capita and three inputs (NEMLs inclusion, registration and local production).[63] The case of Maldives as an upper-middle-income country with limited inclusion exemplifies this principle. We propose that South Asia could improve progress to UHC by adopting a synchronised regional approach.[33] Such collaboration is the most effective strategy to simultaneously strengthen all three pillars of access—NEMLs inclusion, registration and local production—and accelerate the regional progress towards UHC. Moreover, to overcome the widespread technical struggle in maintaining evidence-based NEMLs, we advocate for WHO-facilitated support to strengthen the regulatory expertise.

Future studies should: (1) evaluate access to anticancer medicines based on prevalent cancer types/different health facilities/using longitudinal studies; (2) investigate regional pooled manufacturing models[64]; (3) evaluate patients' out-of-pocket costs and experiences with cross-country treatments.

The policymakers should prioritise: (1) strengthening national regulatory authorities by investing (human resources/infrastructure) to support NEMLs update, streamlined drug registration[9]; (2) targeted incentives (public private partnerships, subsidies) to promote local and active pharmaceutical ingredient production; (3)

regional collaboration for technical support, shared best practices and coordinated regulatory frameworks[11] for pooled manufacturing.

The findings of this study may be generalisable to other LMICs—at the country or regional level—in terms of NEMLs alignments, registration and local production to improve access, with caution given to heterogeneity across LMIC oncology-specific scope and regulatory systems. To our knowledge, this is the first multimethod study to assess upstream access determinants using a comprehensive approach: standardised with the 2023 WHO EML benchmark; multistakeholder triangulation. Finally, the regional pooled production offers a feasible pathway for improving access in LMICs.

The study has several limitations. First, data extraction from regulatory authorities was challenging due to inconsistent or incomplete records. To mitigate this, we cross-verified data with the WHO repository, and practising oncology pharmacists used collaborative data collection and adhered to the 2023 WHO EML adherence. The 2023 WHO EML (adult) was used as the benchmark, and paediatric anticancer medicines were outside the scope. However, we used generics without specifying dosage/strength. Second, availability and affordability (WHO core outcomes) were not directly measured; access was inferred from upstream determinants; future work should include outcome measures. Third, we interviewed 30 stakeholders using purposive sampling; Malterud's 'information power' supported analytical depth. The absence of participants from the Maldives and Bhutan limits the regional coverage. Nevertheless, 30 interviewees from six countries provided rich, representative insights. Lastly, we acknowledged the inherent subjectivity in self-reported data. To overcome it, we used a structured guide, diverse stakeholders and rigorous analysis. Future studies could expand sample size and adopt longitudinal designs to capture evolving dynamics.

CONCLUSION

The study reveals a systematic misalignment between NEML inclusion, registration and local production as a fundamental barrier to access to anticancer medicines in South Asia. This misalignment reflects region-wide gaps in regulatory coordination, strategic planning and financial investment. Our findings identify strategic health policy as the primary driver. Under WHO guidance and systematically reformed health policies, an integrated approach—simultaneously strengthening NEMLs inclusion, streamlining registration and supporting regional pooled manufacturing—offers a practical pathway to improve access and progress towards UHC.

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