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HMF scoring

The 16 market elements of the HMF were scored using an assessment tool developed for the cohort of experts involved in the HMF's creation and validation. For each element, the tool provided: (1) guiding questions to focus expert judgment; (2) explicit descriptions of what low and high maturity look like, anchoring the ends of the scale; (3) quantitative metrics that could be used to assess maturity; and (4) data sources that could inform each metric. This structure was designed to ground expert scoring in consistent, transparent criteria rather than unstructured opinion (Table S1, S2). Experts independently scored both the maturity and criticality of each element, and scores were averaged across experts for each element. The averaged scores were reviewed in group discussion in which experts examined the results, addressed points of disagreement, and adjusted their assessments where warranted. Following this discussion, the six priority elements were selected.

Table S1. Guiding questions to focus expert judgement for the 16 market elements of the insulin HMF.

Pillar	Element	Key Questions
Demand	Diabetes prioritized & funded by authorities	• **National strategy:** Is there a defined national plan or strategy for NCDs and diabetes? • **Funding:** Do national authorities dedicate sufficient funding towards NCD and diabetes? And is global funding dedicated by international authorities sufficient to meet need? • **Guidelines:** Do up-to-date evidence-based guidelines (national or WHO provided) exist for diabetes management?
Demand	Inclusive healthcare scheme(s)	• **Healthcare insurance:** What proportion of people with diabetes are covered by health insurance (public or private), and what breadth of treatments or services are included? • **Out of pocket:** What proportion of out-of-pocket patients can meaningfully afford all treatment aspect?
Demand	Informed population	• **Campaigns:** Are there national/regional health campaigns focused on raising awareness about diabetes? • **Education:** Do HCPs receive (ongoing) diabetes training and are they able to sufficiently support diabetes patients? • **Civil society/lived experience:** Does civil society advocate for diabetes care and how strong is the voice of people with lived experience in care advocacy?
Demand	Easy access to diagnosis	• **Screening:** Are there screening programs or guidelines in place (e.g., routine checkups at specific ages)? • **Location:** Is diagnosis available at all primary care locations (incl. pharmacies) and are there enough qualified HCPs to support it? • **Tools:** Are the materials and tools needed to perform and interpret diagnostic results readily available?
Demand	Easy access to prescription	• **Capabilities:** Does the prescription need to come from a specialist, or can it be provided by any healthcare professional, including nurses or pharmacists? • **Capacity:** Can prescriptions be made at all primary care locations, including pharmacies and do they cover a sufficient duration given capacity constraints? • **Guidelines:** Are HCPs trained, aware of and following guidelines; is stigma around insulin use minimized?
Demand	Easy access to delivery devices	• **Devices:** Do primary care locations, including pharmacies, offer affordable and readily available delivery devices, such as syringes or pens, along with essential consumables like needles?
Demand	Consistent (self-) monitoring & adherence	• **Titration:** Are there relevant tools, such as digital apps, available to support (remote) titration? • **Blood glucose monitoring guidance:** Are resources available to help people with diabetes learn to monitor their blood glucose levels? • **Consumables:** Are affordable and sufficient consumables (e.g., test strips) available to enable patients to self-manage their blood glucose levels?

Pillar	Element	Key Questions
		• **Check-ups:** Are adequate follow-up consultations with HCPs available after an insulin prescription? • **Vulnerable pops.:** Are there specific support programs for vulnerable patients (e.g., children, elderly & humanitarian)?
Supply	Robust insights for supply planning	• **Insights:** Are appropriate data, systems and capabilities in place to reliably forecast insulin demand? • **Forecast availability:** Are forecasts available to all relevant stakeholders for planning?
Supply	Supportive regulatory environment	• **Market authorization:** Do regulatory agencies require analyses beyond FDA/EMA/EML standards or WHO prequalification* for market authorization, and does this cause approval delays? • **Biosimilars:** Do regulatory authorities have capabilities to specifically review biosimilar applications?
Supply	Resilient supplier base	• **Reliability:** Do suppliers (if any present) have strong technical capabilities with track records of reliability? • **Risk exposure:** Is local/regional production of insulin in place, limiting geographical supply security exposure? • **Safety stock:** Are appropriate levels of local/regional insulin safety stock maintained?
Supply	Reliable distribution network	• **Reach:** Does the distributor network reach all parts of country/region? • **Reliability:** Do distributors have strong technical capabilities with track record of reliability? • **Infrastructure:** Can the distribution infrastructure meet all insulin requirements (e.g., thermostability)?
Supply	Stringent quality assurance	• **Counterfeit:** Is there a counterfeit mitigation strategy in place? • **Control:** Are appropriate quality assurance measures in place to ensure that all products sold comply with standards?
Supply	Adequate dispensing network	• **Coverage:** Does dispensing happen in primary care & pharmacies (vs. hospitals) with sufficient geographical coverage? • **Storage:** Do all dispensing facilities have proper storage to preserve insulin's efficacy and safety? • **Safety stock:** Do dispensing facilities hold adequate amounts of local safety stock?
Supply	Affordable and sustainable pricing	• **Market conditions:** Do market conditions encourage new entrants and healthy competition (e.g., pricing levels and parallel trade risk)? • **Procurement:** Is government's procurement capacity sufficient and processes well-established (e.g., structured tender processes, balance between price and supply security, innovative procurement models)? • **Competition:** Is there at least 2-3 players in the market, including in the biosimilars segment? • **Retail price:** Are retail prices sufficiently low and mark-ups regulated to ensure prices compatible with patients' purchasing power, both in private and public sector? • **Financial incentives:** Are import tariffs or tax breaks applied to diabetes products?

Pillar	Element	Key Questions
Product innovation	Innovative products available	• **Innovative APIs:** Are innovative APIs available in the market (e.g., analogues, newer generation insulin)? • **Innovative devices:** Are innovative devices and tech. solutions available in the market (e.g., digital apps, blood glucose monitoring packages/devices)? • **Intellectual property:** Does the IP landscape enable availability of innovative product (incl. APIs and devices)?
Product innovation	Products adapted to infrastructure and PwD	*Target population:* • **Local evidence:** Has evidence (e.g., RCTs and RWE) been generated to support efficacy and safety of products and devices in the target population? • **Pack size & dosage:** Are pack sizes, delivery devices and dosage options compatible with household purchasing power of the population? *Infrastructure:* • **API optimization:** Have API formulations been optimized (e.g., heat stability, shelf life and dosing) to meet potential constraints of low-resource environments (e.g., supply chain infrastructure and dispensing network)? • **Device optimization:** Have delivery devices been optimized (e.g., durable and temperature-stable) to meet potential constraints of low-resource environments (e.g., supply chain infrastructure and dispensing networks)?

* Some national regulatory authorities in LMICs (such as CDSCO in India, ANVISA in Brazil, NMPA in China, or SAHPRA in South Africa) may require local clinical trials

Table S2. Assessment guidance for demand, supply, and product innovation, including key questions to consider for each element, examples of what low and high maturity look like for each, suggested metrics for measuring element maturity, and potential data sources to draw on.

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Demand	Diabetes prioritized & funded by authorities	**National strategy:** Is there a defined national plan or strategy for NCDs and diabetes?	Lack of national NCDs and/or diabetes plans, or if they exist, they lack clear targets; fragmented efforts and inadequate prioritization of NCDs and diabetes care	Comprehensive national NCDs and diabetes strategies in place with measurable targets, progress reporting and active government commitment	• Existence of national strategies for NCDs and diabetes • Existence of targets for NCDs and diabetes • Published progress reporting	• WHO (e.g., GHO) • WDF • IDF Diabetes atlas • Health ministry websites • Development agency reports • Embassies
Demand	Diabetes prioritized & funded by authorities	**Funding:** Do national authorities dedicate sufficient funding towards NCDs and diabetes? And is global funding dedicated by international authorities sufficient to meet need?	Central authorities allocate no or minimal funding towards NCDs and diabetes, instead predominantly relying on fragmented donations; global funding is minimal and insufficient	Central authorities dedicate sufficient funding towards NCDs and diabetes care, with minimal need for external funding; where needed, global funding is sufficient	• % of NCD and diabetes/insulin-related health costs funded by national authorities • % of NCD and diabetes/insulin-related health costs funded by int. authorities • % of NCD/diabetes patients affected by stock-outs per year (for insulin if available)	• WHO (e.g., NCD progress monitor & GHED) • IDF Diabetes Atlas • National budgets • Health ministry websites • Development agency reports • National health accounts
Demand	Diabetes prioritized & funded by authorities	**Guidelines:** Do up-to-date evidence-based guidelines (national or WHO provided) exist for diabetes management?	Treatment guidelines for diabetes care are non-existing, outdated, or limited	Guidelines are available, developed based on international consensus, WHO recommendations, and health economic studies specific to LMICs, supporting practical, evidence-based diabetes care	• Existence of evidence-based guidelines from national authorities and WHO • Time since last guideline update	• WHO (e.g., GHO) • Patient associations • Medical associations • Local health agencies
Demand	Inclusive healthcare scheme(s)	**Healthcare insurance:** What proportion of people with diabetes are covered by health insurance (public or private), and what breadth of treatments or services are included?	Limited or no insurance coverage for diabetes care; most patients pay out-of-pocket for insulin, blood glucose testing supplies, and care, often restricting access due to high costs	Comprehensive insurance coverage for all types of diabetes (T1D, T2D and gestational), covering all treatment aspects, including insulin, glucose monitoring, and routine check-ups, making treatment accessible and affordable	• % of population with health insurance • % of private vs. public health insurance • Level of coverage limits (e.g. annual caps on insulin, supplies, services)	• WHO (e.g., GHO) • Local health agencies • IDF • Development agencies • Analytics companies (e.g. IQVIA, Simon Kutcher)

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Demand	Inclusive healthcare scheme(s)	**Out of pocket:** What proportion of out-of-pocket patients can meaningfully afford all treatment aspect?	High out-of-pocket costs for insulin and supplies make diabetes care unaffordable for many	Out-of-pocket costs are manageable for most patients	• % of average household income required to cover out-of-pocket diabetes treatment costs	• WHO (e.g., GHED) • World Bank Open Data • Local health agencies • IDF/WHO
Demand	Informed population	**Campaigns:** Are there national/regional health campaigns focused on raising awareness about diabetes?	Few or no diabetes awareness campaigns, leading to low public understanding of diabetes risk factors, symptoms, prevention strategies and associated stigma	Consistent national and regional diabetes-focused campaigns actively promote diabetes awareness, prevention, and early diagnosis, reaching diverse populations and contributing to increased knowledge	• # of diabetes-focused national campaigns per year • % of provinces or regions covered with diabetes-focused campaigns	• NGOs and civil society • Pharmaceutical companies • National Ministries of Health
Demand	Informed population	**Education:** Is the population educated by HCPs on diabetes inc. typical symptoms and how to detect them?	Limited or no education about diabetes, with few trained diabetes HCPs to support patients, resulting in poor disease management, low awareness of symptoms and stigma around diabetes/insulin	Trained diabetes HCPs & education informing HCPs on the most up to date treatment approaches are widely available, supporting symptom recognition, and improving care	• % of HCPs who have participated in diabetes-specific training within the last 12 months (inc. length of program) • # of key topics covered in training (e.g., prevention, diagnosis, treatment) • # of PwD per HCP w. diabetes training	• Professional Associations • National Ministries of Health • Education curricula pages from universities
Demand	Informed population	**Civil society/lived experience:** Does civil society advocate for diabetes care and how strong is the voice of people with lived experience in care advocacy?	Civil society activity is fragmented & uncoordinated, w/ limited diabetes-focused activity; PwD have little to no representation in health policy-making or care design processes	Well-organized diabetes advocacy groups at the national & local levels; PwD are included in policy-making processes & have a direct voice in shaping healthcare strategies	• # of active civil society organizations focused on diabetes advocacy • % of policy-making committees relevant to diabetes care that include PwD	• NGOs and civil societies • Local health agencies • KOLs • Patient associations

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Demand	Easy access to diagnosis	**Screening:** Are there screening programs or guidelines in place (e.g., routine checkups at specific ages)?	No standardized screening programs; diabetes diagnosis is usually reactive and occurs only after symptoms present, leading to late diagnoses and higher complication rates	Established, proactive screening guidelines with regular checkups for at-risk groups, ensuring early detection and timely intervention for diabetes	• Existence of national or regional diabetes screening guidelines • % of at-risk groups (e.g., adults 40+, pregnant people) targeted by programs • % of population screened for diabetes	• WHO (e.g., GHO) • National Ministries of Health
Demand	Easy access to diagnosis	**Location:** Is diagnosis possible at all primary care locations, including pharmacies, and are there enough qualified HCPs to support it?	Diabetes diagnosis is limited to specialized clinics or hospitals, with a shortage of trained healthcare providers, resulting in restricted access, especially in rural areas	Diagnosis is widely available at primary care facilities and pharmacies with adequate numbers of trained healthcare providers, ensuring easy and widespread access across regions	• % of primary care facilities equipped to diagnose diabetes • % of primary care centers staffed with HCPs trained in diabetes diagnosis • % of rural vs. urban primary care facilities with diagnostic capabilities	• WHO (e.g., GHO) • Professional Associations • Local health agencies • NGO and Advocacy Reports
Demand	Easy access to diagnosis	**Tools:** Are the materials and tools needed to perform and interpret diagnostic results readily available?	Limited availability of diagnostic tools (e.g., glucose meters, HbA1c tests), leading to gaps in accurate diagnosis and monitoring	Diagnostic tools are readily available and accessible at primary care level, ensuring effective diagnosis and ongoing monitoring	• % of healthcare facilities equipped with essential diagnostic tools for diabetes	• WHO (e.g., GHO) • Local health agencies • NGO and Advocacy Reports
Demand	Easy access to prescription	**Capability:** Can prescriptions be provided by any healthcare professional (including nurses or pharmacists) at primary care locations or pharmacies, or are they restricted to specialists, hospitals, or specialized clinics?	Prescriptions are restricted to specialists and limited to hospitals or specialized clinics, creating bottlenecks, requiring patients to travel long distances or wait for appointments, and limiting access, especially in underserved areas	Prescriptions are readily available at primary care facilities or pharmacies and can be provided by a range of healthcare professionals, including nurses and pharmacists, improving accessibility and reducing delays in treatment initiation	• % of prescriptions written at hospitals or specialized clinics vs. primary care facilities • Average time taken for a patient to get a diabetes prescription • # of PwDs per HCP able to prescribe • Average distance for PwDs to nearest prescription point • % of written prescriptions collected by patients	• National guidelines for essential medicines and prescribing authorities • Professional Associations • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Demand	Easy access to prescription	**Guidelines:** Are HCPs aware of and following guidelines; is stigma among HCP community surrounding insulin use minimized?	HCPs are unaware of treatment guidelines, or at least not following them, leading to suboptimal treatment practices and stigma	HCPs are aware of and following treatment guidelines, staying regularly informed of any updates, leading to best-practice treatment	• % of HCPs aware of national or international guidelines for diabetes • % of HCPs following national or international guidelines • % of patients/HCPs reporting stigma or reluctance to start insulin therapy	• Professional Associations • Interviews
Demand	Easy access to delivery devices	**Devices:** Do primary care locations, including pharmacies, offer affordable and readily available insulin delivery devices, along with essential consumables like syringes or insulin pens?	Delivery devices and essential consumables are often scarce or costly at primary care locations, forcing patients to seek out secondary sources or reuse supplies, increasing health risks	Affordable and readily available insulin delivery devices, along with essential consumables, are consistently stocked at primary care locations and pharmacies, making access convenient and safe for all patients	• % of primary care locations (including pharmacies) that stock delivery devices such as syringes or insulin pens • % of facilities with no stockouts in delivery devices/consumables in the past 12 months	• National health agencies • NGO and Advocacy Reports • Interviews
Demand	Consistent (self-) monitoring & adherence	**Titration:** Are there relevant tools, such as digital apps, available to support (remote) titration?	Minimal or no tools available for titration, leaving patients to manage dosage adjustments on their own, often resulting in poor glycemic control and complications	Digital tools and resources for titration support (incl. for illiterate PwD), including apps and remote guidance, are available to patients, enabling safer, accurate, and more accessible dosage adjustments	• % of PwD aware of titration support tools • % of PwD using titration support tools • % of PwD able to adequately titrate insulin dosing	• National health ministries • National diabetes associations • PwD survey

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Demand	Consistent (self-) monitoring & adherence	**Blood glucose monitoring guidance:** Are resources available to help people with diabetes learn to monitor their glucose levels?	Limited (in foreign language) or no structured education on glucose monitoring, with many patients unaware of proper monitoring techniques, contributing to poor diabetes management	Comprehensive educational resources and training on blood glucose monitoring are provided in local language, empowering patients to manage their condition effectively and independently	• % of PwD aware of blood glucose monitoring support resources • % of PwD who are trained/informed on glucose monitoring (in local language) • % of PwD able to adequately monitor glucose levels • Average frequency of blood glucose monitoring	• National health ministries • National diabetes associations • PwD survey
Demand	Consistent (self-) monitoring & adherence	**Consumables:** Are sufficient consumables (e.g., test strips) available to help patients monitor their blood glucose levels?	Limited availability of consumables, like test strips, force patients to monitor glucose infrequently or not at all, undermining effective management	Abundant supplies of consumables with full monitoring package, are widely available, enabling patients to monitor their glucose regularly and accurately	• % of PwD with consistent access to consumables in past 12 months • Average distance for PwDs to nearest health facility with consumables	• National health ministries • National diabetes associations • PwD survey
Demand	Consistent (self-) monitoring & adherence	**Check-ups:** Are adequate follow-up consultations with HCPs available after an insulin prescription?	Few or no structured follow-up consultations, leaving patients without guidance or adjustments in care, often resulting in suboptimal outcomes and higher complication rates	Regular follow-up consultations are available and encouraged, allowing for ongoing support, adjustments, and personalized care plans to optimize diabetes management	• % of healthcare facilities offering scheduled follow-up consultations • Average distance to HC facilities for check-up • Average # of follow-up consultations per PwD in first 3 mo. after initiation • Average # of follow-up consultants per annum for PwD with stable disease	• National health ministries • National diabetes associations • PwD survey
Supply	Available insights for supply planning	**Insights:** Are appropriate data, systems & capabilities in place to reliably forecast insulin demand?	Limited or unreliable data on diabetes prevalence, coupled with inadequate forecasting tools and capabilities, leading to stockouts or oversupply issues	Robust and reliable data on diabetes prevalence, supported by effective forecasting tools and capabilities, ensuring optimal inventory levels and preventing stockouts or oversupply issues	• Existence of centralized system(s) to collect annual data on diabetes prevalence and insulin use • Existence of formal insulin forecasting tools or models	• Local medicine procurement bodies • National health ministries • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Supply	Available insights for supply planning	**Data coordination:** Is demand data made available to all relevant stakeholders for volume planning?	Demand forecasts are siloed within certain organizations or government departments, preventing coordinated volume planning	Demand forecasts are shared openly among key stakeholders (e.g., health authorities, suppliers, NGOs), facilitating coordinated & responsive volume planning to meet demand	• Existence of publicly available up-to-date insulin forecasts (insulin market data bases) • Difference between forecasted and actual insulin usage (i.e. accuracy of forecasts)	• Local medicine procurement bodies • National health ministries • Interviews
Supply	Supportive regulatory environment	**Market authorization:** Do regulatory agencies require analyses beyond FDA/EMA/EML standards or WHO prequalification for market authorization, and does this cause approval delays?	Regulatory agencies have complex, additional requirements beyond international standards, resulting in lengthy delays for market approval of new insulin products vs. HICs	Regulatory agencies align closely with WHO prequalification or FDA/EMA standards, with streamlined processes to expedite approvals without unnecessary duplication, ensuring timely market access for new insulin products	• Average time for approval of WHO prequalified products • # and types of additional analyses required beyond FDA/EMA (e.g., local clinical trial or manufacturing inspections) • Participation in regulatory harmonization initiatives (e.g., African Medicines Agency)	• WHO • Global Data • Local regulatory bodies • Interviews
Supply	Supportive regulatory environment	**Biosimilars:** Do regulatory authorities have capabilities to specifically review biosimilar applications?	Limited regulatory capacity for assessing biosimilars, leading to restricted biosimilar availability	Strong regulatory capacity and established pathways for biosimilar approvals, enabling competitive options and broader access to affordable insulin biosimilars	• Alignment of biosimilar guidelines with WHO, FDA or EMA standards • Average time from submission to approval of biosimilars	• WHO • Global Data • Local regulatory bodies • Interviews
Supply	Resilient supplier base	**Reliability:** Do suppliers (if any present) have strong technical capabilities with track records of reliability?	No supplier, or suppliers have a history of production issues, technical failures, or disruptions, leading to frequent insulin shortages.	Suppliers demonstrate strong technical capabilities with a consistent record of reliable production and minimal interruptions, ensuring stable insulin supply	• % of insulin supply delivered on last 12 months time at quality standards • % of suppliers that are WHO prequalified	• Local medicine procurement bodies • Local health ministries • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Supply	Resilient supplier base	**Risk exposure:** Is there a local/regional production of insulin, limiting geographical supply security exposure?	Heavy reliance on imported insulin with no local production; Vulnerability to international supply chain disruptions and currency fluctuations	Local or regional insulin production established, providing greater supply security, reducing dependence on imports, and mitigating risks related to international logistics	• % of annual insulin volumes produced locally and/or regionally • Concentration of suppliers providing insulin • Existence of contingency plans for international supply chain disruptions	• Local medicine procurement bodies • IQVIA • National health ministries
Supply	Resilient supplier base	**Safety stock:** Are appropriate levels of local/regional insulin safety stock maintained?	Frequent stockouts and unpredictable supply gaps during emergencies or demand spikes	Adequate safety stock maintained at the local or regional level, providing a buffer against supply interruptions and ensuring consistent availability during high demand periods or crises	• # of months for which stockpiles can sustain insulin demand • Average # of stockouts reported annually	• Local medicine procurement bodies • National health ministries • NGO and Advocacy Reports • Interviews • PwD survey
Supply	Reliable distribution network	**Reach:** Does the distributor network reach all parts of country/region?	Uneven insulin availability, distribution is limited to major urban centers, with minimal or inconsistent access in rural and remote areas	Extensive distribution network reaches urban, rural, and remote areas, ensuring equitable access to insulin across all regions of the country	• % of regions/provinces receiving regular insulin supplies from distributors	• Local medicine procurement bodies • National health ministries • Interviews
Supply	Reliable distribution network	**Reliability:** Do distributors have strong technical capabilities with track record of reliability?	Frequent shipment delays and disruptions in the distribution network lead to inconsistent insulin supply and stockouts	Distributors demonstrate reliable, on-time delivery with low disruption rates, ensuring a stable and predictable insulin supply	• % of deliveries completed on time in last 12 months • Average delay (in days) for late deliveries	• Local medicine procurement bodies • National health ministries • Interviews
Supply	Reliable distribution network	**Infrastructure:** Can the distribution infrastructure meet all insulin requirements (e.g., thermostability)?	Distribution infrastructure lacks adequate cold chain and temperature control capabilities, leading to insulin spoilage and compromised quality	Distribution network is equipped with robust cold chain and temperature control, maintaining insulin quality from production to point of dispensing	• % of insulin deliveries monitored for temperature compliance throughout distribution process	• Local medicine procurement bodies • National health ministries • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Supply	Stringent quality assurance	**Counterfeit:** Is there a counterfeit mitigation strategy in place?	No or minimal counterfeit detection measures in place, leaving the insulin supply chain vulnerable to infiltration by counterfeit products	Strong anti-counterfeit strategies, including tracking systems and product authentication, minimize the risk of counterfeit insulin reaching patients	• Existence of national policy & legal penalties to combat counterfeit medicines (incl. diabetes) • Existence of surveillance systems to monitor counterfeit insulin • % of insulin samples tested and identified as counterfeit annually	• Local medicine procurement bodies • National health ministries • Interviews
Supply	Stringent quality assurance	**Control:** Are appropriate quality assurance measures in place to ensure that all products sold comply with standards?	Quality assurance is inconsistent, not aligned with international guidelines, with few controls or inspections, leading to potential variations in product quality and safety	Comprehensive quality assurance protocols (aligned with international guidelines) ensure that all insulin products meet national and international standards, with regular inspections and compliance checks	• % of manufacturing and distribution facilities inspected annually • % of diabetes related products sampled and tested annually • % of manufacturing & distribution found to be non-compliant w/ QA standards • % of products sampled found to be non-compliant w/ QA standards	• National health ministries • Interviews
Supply	Adequate dispensing network	**Coverage:** Does dispensing happen in primary care & pharmacies (vs. hospitals) with sufficient geographical coverage?	Insulin is mainly available in hospitals or urban centers, with limited dispensing points in primary care or rural areas, creating access barriers	Insulin is widely available in primary care facilities across urban and rural areas, ensuring comprehensive geographic coverage and ease of access for patients	• % of refills dispensed at hospitals vs. primary care facilities • Average distance for PwDs to nearest dispensing point in urban and rural areas	• National health ministries • Interviews • PwD survey
Supply	Adequate dispensing network	**Storage:** Do all dispensing facilities have proper storage to preserve insulin's efficacy and safety?	Many dispensing points lack proper storage facilities (e.g., refrigerators), resulting in potential degradation of insulin quality	All dispensing locations are equipped with proper storage (e.g., refrigerators, temperature monitoring), ensuring insulin is stored safely and retains efficacy	• % of insulin monitored for temperature compliance at dispensing facilities • % of dispensing facilities that meet quality standards	• Local medicine procurement bodies • National health ministries • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Supply	Adequate dispensing network	**Safety stock:** Do dispensing facilities hold adequate amounts of local safety stock?	Limited or no safety stock maintained, leading to frequent stockouts and unavailability of insulin during peak demand or supply disruptions	Adequate safety stock levels are maintained at dispensing sites, providing a buffer against supply chain interruptions and ensuring continuous availability	• # of months for which stockpiles can sustain insulin demand • Average # of stockouts reported annually • % of patients affected by stockouts annually	• Local medicine procurement bodies • National health ministries • Interviews
Supply	Affordable & sustainable pricing	**Procurement:** Is government's procurement capacity sufficient and processes well-established (e.g., structured tender processes, balance between price and supply security, innovative procurement models)?	Procurement is fragmented, lacks structure, and focuses on lowest price without considering supply stability, resulting in unpredictable insulin availability	Centralized procurement processed by government with structured tendering that balances price and security, ensuring consistent and affordable insulin supply; pooled procurement leveraged on a relevant scale	• Existence of national or regional procurement process • % of procurement contracts awarded via transparent tendering mechanisms • % of insulin procured through competitive bidding processes	• Local medicine procurement bodies • Interviews
Supply	Affordable & sustainable pricing	**Retail pricing:** Are retail prices sufficiently low and mark-ups regulated to ensure prices compatible with patients' purchasing power, both in private and public sector?	Most insulin volumes sold in private sector at higher price; high mark-ups by multiple intermediaries (distributors, wholesalers) significantly increase patient costs, making insulin less affordable	Sufficient volumes in public sector, with transparent and regulated mark-up policies minimizing additional costs, keeping insulin prices affordable for end-users and reducing financial barriers	• % mark-ups on ex-manufacturer prices (e.g., transport, distribution, and retail mark-ups) • % of annual household income spent on diabetes care per PwD • % of PwD unable to afford diabetes care based on household income	• Academic reports • World Bank • WHO (e.g., GHO) • ACCISS and MAIn tool assessments
Supply	Affordable & sustainable pricing	**Competition:** Are market conditions leading to 2-3 players in the market, including in the biosimilars segment?	Market is highly concentrated, with one or two suppliers dominating, limiting competition and often leading to higher prices and vulnerability to supply issues	Competitive market with multiple suppliers, including biosimilars, creating pricing flexibility and reducing supply risks	• Total number of manufacturers supplying insulin (incl. biosimilars) • % of insulin supply provided by top 3 players • # of players that supply 80% of the market volume	• IQVIA • Local medicine procurement bodies • National health ministries • Interviews

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Supply	Affordable & sustainable pricing	**Sustainable Pricing:** Are pricing and incentives offered to manufacturers high enough to attract a diverse range of players, sustaining market competitiveness?	Prices and incentives are too low to attract new entrants, resulting in limited competition, fewer manufacturers, and market concentration. Tenders often have only one supplier, increasing supply risks and stifling innovation	Adequate pricing and incentives attract a diverse range of manufacturers, including biosimilar producers, ensuring healthy competition and participation in tenders	• Average ex-factory prices and implied profit margin for manufacturers • Volumes required by manufacturers to be profitable • % of tenders with fewer than three competing suppliers	• Tender records and procurement data • National health ministries • Interviews • IQVIA data
Product innovation	Innovative products available	**Innovative APIs:** Are innovative APIs available in the market (e.g., analogues, newer generation insulin)?	Large majority of human insulin; few, if any, advanced APIs (e.g., next-gen insulins) are available, with a track record of significant delays in newer APIs becoming available after release in HICs	Broad portfolio of innovative APIs available, with a track record of novel APIs quickly becoming available in LMICs after release in HICs	• % of innovative APIs available in HICs available in market • % of total insulin sales volume accounted for by innovative APIs • Average time delay from product availability in HICs to LMICs	• Market data bases (e.g., Global Data, IQVIA) • Market research in approved products
Product innovation	Innovative products available	**Innovative devices:** Are innovative devices and tech. solutions available in the market (e.g., digital apps, blood glucose monitoring packages/devices)?	Few, if any, advanced products (e.g., BGMs and test strips) are available, with a track record of significant delays in new products becoming available after release in HICs	Broad portfolio of advanced products (e.g., BGMs and test strips) are available, with a track record of novel innovations quickly becoming available in LMICs after release in HICs	• % of innovative devices available in HICs available in market • % of total device sales volume accounted for by newer innovative devices • Average time delay from product availability in HICs to LMICs	• Market data bases (e.g., Global Data, IQVIA) • Market research in approved products
Product innovation	Innovative products available	**Intellectual property:** Are the majority of insulin products and devices under patents, restricting availability and limiting competition in LMICs?	A significant proportion of insulin products and devices remain under patent protection, limiting biosimilar entry and competition. Stringent IP policies and lack of voluntary licensing agreements restrict local manufacturing and innovation	A smaller proportion of products are under patent, fostering biosimilar entry and competition. Licensing agreements and favorable IP policies enable local and regional manufacturing, improving access to innovative products	• % of insulin products and devices under patent • % of insulin volume supplied by biosimilars or non-patented products	• Patent registries • Market data bases (e.g., Global Data, IQVIA)

Pillar	Element	Key Question	Low Maturity	High Maturity	Suggested Metrics	Potential Data Sources
Product innovation	Products adapted to target population	*[Target population]* **Local evidence:** Has evidence been generated to support efficacy & safety of products & devices in the target population?	Limited or no clinical trials and RWE for target LMIC populations, resulting in limited understanding of local efficacy, safety, and potential side effects	Comprehensive clinical trials are conducted specifically with LMIC target populations, supported by RWE, ensuring the safety, efficacy, and cultural acceptability of the APIs and devices used	• Existence of clinical trial data or RWE in the target population	• Clinical Trial Databases • Academic publications
Product innovation	Products adapted to target population	**Pack size & dosage:** Are pack sizes and delivery devices compatible with household purchasing power of the population?	Patients are limited to large pack sizes, requiring them to purchase a month's or more worth of insulin at once, which forces them to gather a lump sum for each purchase; some devices require a significant upfront investment or high-cost refills, such as multi-dose pens or pumps	Daily or weekly dosage packs allow people to buy insulin in smaller, more affordable quantities; low-cost devices, such as single-dose pens or reusable pens with affordable refills, make insulin more accessible	• % of products available in daily or weekly pack sizes • % of monthly household income spent OOP on diabetes treatment per single treatment purchase (based on standard pack size)	• Global Data • WHO (e.g., GHO) • World Bank • Interviews
Product innovation	Products adapted to target population	*[Infrastructure]* **API optimization:** Have API formulations and dosing been optimized to meet potential constraints of low-resource environments (e.g., supply chain infrastructure and dispensing network)?	Available API formulations require frequent dosing and are highly temperature-sensitive, increasing consequences of resource constrained markets and risk of spoilage	Available API formulations are longer-acting, requiring less frequent dosing, and heat-stable, reducing reliability on cold-chains; in turn, impact of resource constraints on insulin availability and quality is minimized	• Number and % of insulin products available with enhanced thermal stability or extended durations of action	• IQVIA • Market research in approved products • Interviews
Product innovation	Products adapted to target population	**Device optimization:** Have delivery devices been optimized to meet potential constraints of low-resource environments (e.g., supply chain infrastructure and access to HCPs)?	Available delivery devices are complex, not reusable and not easy to use, making them unsuitable for resource-limited settings in LMICs	Available delivery devices are durable, reusable and easy to use, making them accessible and usable for target populations, and lowering impact of resource constraints	• Number and % of insulin devices with product profiles suitable for LMICs (i.e. durable, reusable, and easy to use) at affordable costs	• IQVIA • Market research in approved products • Interviews

Note: NCDs = Non-Communicable Diseases; PwD = People with diabetes; HCP = Healthcare Professionals; LMICs = Low- and middle-income countries; HICs = High-income countries; RWE = Real-world evidence; BGM = Blood glucose meter; OOP = Out-of-pocket

MAP outcomes

The MAP translates the six priority market gaps outlined in the HMF into a focused strategy to address the most pressing barriers to insulin access. The strategy is structured around two primary goals: 1) secure supply for currently utilized insulin products and 2) increase affordability of high-quality insulin products for patients. Each goal is supported by targeted and cross-cutting objectives with specific key progress indicators (KPIs) to ensure accountability and impact. Additional information about the goals, the targeted actions for each and their enabling actions are included below (Table S3).

Table S3. Goals, targeted objectives, cross-cutting objectives and actions outlined in the insulin MAP.

Goal	Targeted Objective	Actions
Ensure stable supply of affordable, quality-assured insulin	Retain low-cost supply to L/MICs from current major suppliers	• Understand future supply strategies of innovator suppliers (including tech transfer) and implications for supply availability of insulin and GLP-1s • Secure clear, time-bound commitments from innovator companies to ensure adequate, reliable supply of quality assured affordable insulin to L/MICs
Ensure stable supply of affordable, quality-assured insulin	Diversify quality-assured L/MIC market supplier base with biosimilar and regional manufacturers	• Support biosimilar manufacturers to register products in additional countries where there is a reference product • Engage directly with potential biosimilar manufacturers to gauge interest and capacity to expand in L/MIC markets and help develop a commercially sustainable product mix and L/MIC-focused expansion strategy • Develop robust understanding of current and future production capacity across supplier base and assess individual supplier capabilities for the fill-finish and integrated production needed to accept a tech transfer • Increase biosimilar supplier capacity through more integrated tech transfers aligned with the capacity and needs of the receiving organizations
Increase affordability of quality-assured insulin products to patients	Lower the average procurement price for human and analogue insulin	• Pilot coordinated or pooled procurement with a small cohort of African countries • Evaluate opportunities for longer tenders, long-term agreements, bundled procurement (based on lessons learned from Diabetes CarePak), and other procurement strategies to reduce prices • Explore application of financial tools and pre-financing programs that could improve demand predictability and payment terms to enable a lower price (e.g., revolving drug fund, working capital facility, advance market commitment, or volume guarantee)

Goal	Targeted Objective	Actions
Increase affordability of quality-assured insulin products to patients	Increase diabetes prioritization and funding by authorities	• Support technical and advocacy efforts and monitor progress for increased country prioritization and funding of diabetes care (e.g., insurance inclusion, budget allocation)
Increase affordability of quality-assured insulin products to patients	Reduce excessive price markups between procurement and retail point	• Convene and facilitate workshops to design and test novel partnerships and platforms with supply chain partners to reduce the end price to the patient in private sector • Generate transparency on insulin pricing by mapping markups from procurement to retail, comparing to regional benchmarks, and publishing country-level affordability data • Develop a toolkit of policy and financing options (e.g., margin caps, tax exemptions, pooled procurement, payment guarantee, working capital facility) and share with governments and civil society groups to advocate for action
Cross-cutting	Strengthen demand predictability and procurement planning	• Generate a robust global demand forecast and insulin market report to guide strategic decision-making • Monitor and support WHO efforts to develop and update diabetes treatment guidelines • Support efforts to clarify treatment guidelines, train providers, and improve adherence in L/MICs • Increase visibility and understanding of public-sector procurement prices for stronger procurement negotiations • Enhance uptake of WHO NCD Forecasting qualification tool to support countries' insulin procurement processes • Support resource mobilization and procurement planning efforts
Cross-cutting	Reduce regulatory barriers to enter L/MIC markets	• Update existing landscapes of African country regulatory approval pathways and package into guidance for suppliers • Engage with AMA to understand and support regulatory harmonization efforts • Map options for pursuing alternate regulatory approval pathways, considering potential viable commercial strategies for expanding in L/MICs, i.e., WHO Listed Authorities, AMA regional approval, proxy SRA approval, or harmonization regional regulatory systems • Monitor and support WHO-led dialogues to streamline PQ process and supplier engagements
Cross-cutting	Support long-term insulin market sustainability amidst expansion of next-generation products (GLP-1s, once-weekly insulin)	• Monitor the impacts of next-generation diabetes products on insulin capacity and market dynamics • Encourage suppliers to explore access strategies for next-generation insulin products • Where not already in place, encourage suppliers to create clear, time-bound, evidence-based transition plans for donation programs to help countries plan and allocate resources effectively toward sustainable procurement processes