How can iDSI add value to and leverage the private sector?

Health technology assessment (HTA) can help to address market failures in the healthcare industry, making the 'rules of the game' and information about cost and value more transparent, enabling fairer, more stable markets for medical technologies, health insurance and healthcare providers. These in turn incentivise public and private investment, and ultimately improve access to high-value and appropriate products. iDSI can provide a platform for engagement and collaboration between industry, governments, and funders, and work directly with various stakeholders to achieve win-win solutions.

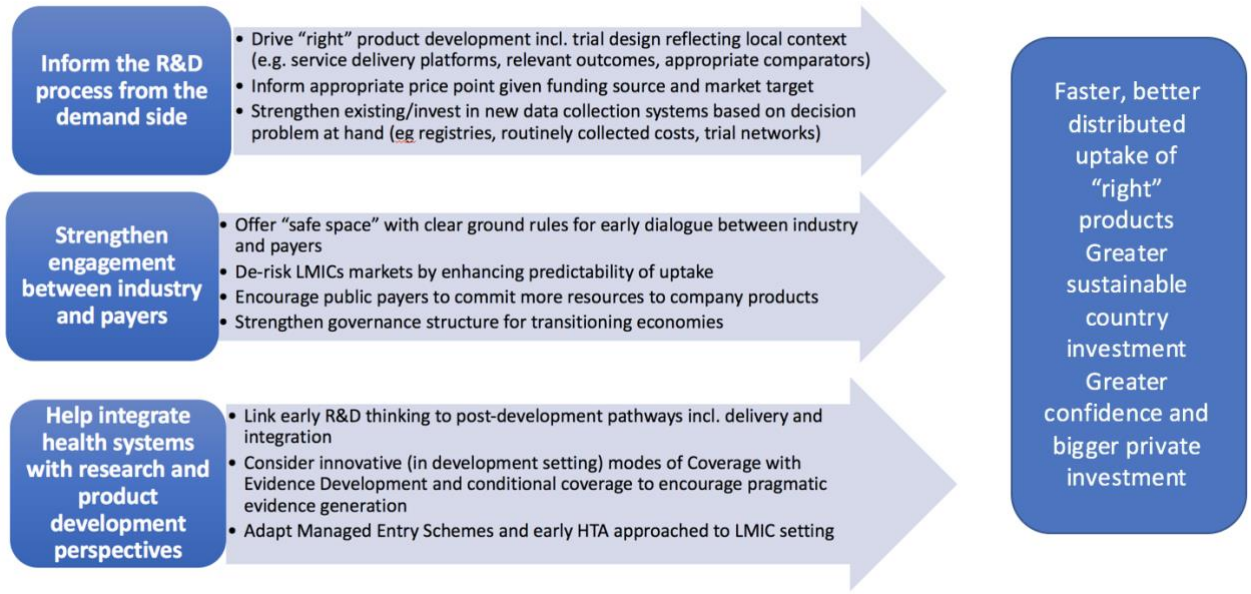

Figure 1. How HTA can drive greater value from healthcare R&D and in-country implementation, and ultimately improve access

Pharma and devices manufacturers: HTA offers a managed, predictable space and a level playing field for government-industry engagement, enabling high-income country (HIC) multinationals to invest and operate safely in valuable emerging markets with clear mutual understanding about the rules of the game but also conditioning BRICS industries to operate in a global setting in terms of data requirements and making investment cases to HIC payers. An HTA process that is explicit, systematic and institutionalised at the policy level – and that is well-aligned with the rule of law[1] – can help reduce uncertainty and mitigate some of the business risks and pitfalls of country politics. This is especially important where competitors attempt to seek unfair advantage through direct lobbying or backhand approaches in the absence of clear rules of engagement being established or enforced.

- iDSI has actively engaged with the pharma industry, including participating an open and collaborative policy dialogue in SE Asia between senior leaders in government and multinational Big Pharma, seeking to establish common ground in the operationalisation of HTA[2].
- In the iDSI and HTAi first joint conference on HTA in Africa, to be held in Accra, Ghana (26-27 September 2018[3]) there will be a strong emphasis on the private sector given its importance in the African healthcare market.

[1] Dittrich et al. (2017) The Right to Health and the Health Benefits Package: Accounting for a Legal Right to Health When Designing a HBP. In What's In, What's Out: Designing Benefits for Universal Health Coverage. A Glassman et al. (eds) https://www.cgdev.org/sites/default/files/whats-in-whats-out-designing-benefits-final.pdf

[2] See http://www.meteos.co.uk/resources/idsi-stakeholder-engagement-report/ and http://www.meteos.co.uk/wp-content/uploads/The-Groundwork-Framework.pdf

[3] Flyer: https://imperialcollegelondon.box.com/s/ewhue6rju9yupmy9usq0yr1n8ynlz4lf

- In the future, iDSI will seek to support the Foundation and regional intermediaries to explore ways of harmonising HTA and regulatory requirements, leveraging the recently launched African Medicines Agency (AMA)[4], in turn making it easier for manufacturers to harmonise their market access strategies across the region and deliver greater scale.

Where manufacturers have genuinely innovative or much needed products to bring to the market, HTA provides a platform for articulating the potential value of products to different clients, and informing and negotiating pricing decisions and special access schemes. Smart purchasing policies based on HTA value-for-money principles creates markets for off-patent generic drugs and devices, particularly benefiting LMIC manufacturers (e.g. Indian generics industry), often substantial in volume with common and high-burden diseases (such as NCDs[5]) and UHC schemes. And for uniquely innovative high-cost, high-value drugs, HTA has to be preferable for Big Pharma to compulsory licensing, which may in certain contexts benefit patient access (and domestic generics manufacturers) but at considerable cost in lost revenue to the patent holder.

Product development partnerships (PDPs) can similarly use HTA to assess value in advance of development and identify appropriate price points depending on degree of co-financing and overall budgetary constraints. As most BMGF-supported countries are likely to rely on external funding for the foreseeable future, PDPs are likely to remain as a model for supporting affordable R&D serving the needs of both PDPs and BMGF. A resource providing systematic payer scientific advice (PSA) on HTA targeting the LMIC market can at early development stages help fine tune trial design, including appropriate end points, context-relevant comparators, and structural assumptions regarding delivery platforms. Downstream, PSA would inform pricing and market segmentation strategies, encouraging cross-subsidisation and possibly commercial returns through price-volume agreements and other means of price differentiation even in the poorest markets. PSA would also help to set realistic KPIs for PDPs, informed by demand side characteristics such as empirically-derived cost-effectiveness thresholds.

Investors and venture capitalists benefit from better governance, clearer rules of the game, and improved data capacity, all of which should in principle de-risk investment where private sector growth is constrained, including in innovative products and health insurance markets. HTA and the data it necessitates (such as cost, activity, and outcomes) can help crowd in investors in the pharma and devices industry by increasing predictability and improving information available to investors including market size, cost base, performance, and growth trajectories.

Private healthcare providers. Evidence-based clinical guidelines and quality standards set out the clinical interventions that are safe, effective, cost-effective, and contribute to positive patient experience. They can help private and public providers alike address concerns about poor quality of care (actual or perceived), common in LMIC settings. Robust regulation with clear standards help providers in identifying necessary investments, workforce planning decisions, and processes to be put in place enabling quality services to be delivered. These can be easily extended to become 'marking schemes' for quality inspection, grading, and accreditation; demonstrating high standards becomes a competitive advantage, helping to engender patient trust and ultimately driving business. And quality regulation is crucial for eliminating unethical or unsafe practices – including by underqualified or even unqualified providers – which can only be beneficial for the industry in the long run.

- In **Kerala, India**, private hospitals play an important role in providing women with antenatal and perinatal care, helping to alleviate pressures in overstretched public facilities. iDSI worked closely with State authorities and clinicians from private and public settings to develop and implement measurable quality standards for reducing post-partum haemorrhage. Thanks to iDSI's support, Kerala has now reached a milestone: having reduced its MMR to 46 per 100,000 for the first time[6]. Similar work on developing maternal care quality standards is now under way in **South Africa**.

[4] https://au.int/en/documents/20170829/african-medicines-agency-meeting-victoria-falls-29th-august-2017-documents

[5] Chalkidou K, Lord J and Gad M. Improving the quality and efficiency of healthcare services in Ghana through HTA [version 1; not peer reviewed]. *F1000Research* 2018, **7**:364 (document) (doi: 10.7490/f1000research.1115326.1)

[6] https://indianexpress.com/article/india/kerala/keralas-maternal-mortality-rate-drops-to-46-eyes-30-by-2020/

In addition, hospital-based HTA can help private and public healthcare providers alike make informed decisions at the margin on what drugs or equipment to invest in or disinvest from.

Private healthcare payers (insurers) – provider payment mechanisms: Private and state-funded health insurance schemes face fundamentally similar challenges of setting priorities within finite budgets, and face similar kinds of trade-off in deciding what goes in and what comes out of a health benefits package. Again HTA and related approaches such as clinical guidelines, standards and pathways can inform provider-payment mechanisms including pay-for-performance (results-based financing) frameworks, regulation, contracts, and bundled payments reflective of appropriate use.

- Building on our work in Kerala, iDSI supported **India**'s RSBY (the national social health insurance scheme for Below Poverty Line households) to develop quality standards for high-volume claims such as hysterectomy and cataract surgery[7]. This helped to streamline and standardise the claims and pre-approval process (which benefits both the insurer and the empanelled healthcare provider); inform reimbursement rates; and reduce inappropriate, unnecessary or even fraudulent claims. With Gates ICO support we are in discussions at the request of the Government of India to scale up such efforts to through developing 100 Standard Treatment Guidelines for the National Health Protection Scheme.
- iDSI can also draw on the rich experience of public payers such as the UK NHS and Thailand's National Health Security Office in building LMIC payers' capacity to use evidence to optimise supply chains and strategic purchasing, shape markets, and improve access.

Regulation of the private sector: In budding national health insurance systems, private sector provider capacity is often needed to ensure whole population coverage. Also many healthcare systems have regulators overseeing private insurers, including their premiums and benefits, such as in South Africa (Council of Medical Schemes, CMS), Colombia (Supersalud), Brazil (ANS) and Chile (ISAPRES supplementary insurance systems). However, there is little empirical evidence as to how best to manage the LMIC private insurance sector and, subsequently, private providers. HTA data platforms combining data about cost, utilisation and quality can help inform efficient and effective approaches to regulation, ensure that health benefits packages are appropriate and affordable, and that the private commissioning function is used to its full potential.

- A recent Competition Commission inquiry[8] in **South Africa** identified significant market failures in the healthcare industry and recommended HTA as an important means of reining in expenditures and increasing competition, and as a regulatory lever. iDSI is in discussion with CMS to help them evaluate their Prescribed Minimum Benefits content and methods/processes. Being able to access real anonymised billing data would help identify priorities for further analysis and for potential efficiencies. This could in turn result in better data for informing premiums, forecasting spending for investments in primary health care (PHC) and prevention, and develop regulatory tools.

> ***Recommendations from the Competition Commission Health Market Inquiry:***
>
> "Standards of care, evidence-based treatment protocols and processes for conducting [HTA] to assess the impact, efficacy and costs of medical technology, medicines and devices relative to clinical outcomes must be developed. Findings... should be published to **stimulate competition** in the market, to **mitigate information asymmetry**, and to **inform decisions about strategic purchasing** by the public and private sectors."

- In **Indonesia**, iDSI has supported HTA institutional capacity development, including that of BPJS (the national health insurer) to commission and use locally generated HTA evidence for sustainable

[7] Another example of using billing data in India for RSBY here

[8] Competition Commission South Africa (2018) Health Market Inquiry. Provisional Findings and Recommendations Report. http://www.compcom.co.za/wp-content/uploads/2018/07/Health-Market-Inquiry-1.pdf

benefit package selection of its JKN (UHC) scheme. Further strengthening the role of HTA among both JKN and private sectors including better use of claims data could help to improve accountability and transparency, reduce information asymmetry, and improve patient access to appropriate technologies either cost-effective within JKN or privately through top-up payments[9].

Expanding Markets while Improving Health in Indonesia. The Private Health Sector Market in the JKN Era (Britton et al 2018)

"The current government system of JKN does not link the clinical and economic assessment of drugs to price negotiation and tariff setting, which can lead to cost-effective drugs not being available to providers at an affordable rate (or conversely, the reimbursement rate not accounting for the market price of this drug)... The **price-quantity negotiation process should… reflect the HTAs/Economic Assessment** results more broadly beyond certain high-price but low-volume top-up drugs, **reflecting the affordability and cost-effectiveness thresholds** that Indonesia wants to set..."

Appendix 1.

Summarised from Meteos (2015) *The Groundwork Framework: Seven Steps to Successful Healthcare Priority-Setting. The Roles of Government and the Pharmaceutical Industry.* http://www.meteos.co.uk/wp-content/uploads/The-Groundwork-Framework.pdf

Groundwork identified the following seven steps to ensure that the introduction of priority-setting results in people getting the medicines they need, at an affordable price:

1. Strong government commitment
2. Adoption of a strategic plan
3. Creation/strengthening of priority-setting structures
4. Introduction of processes for priority-setting and decision-making
5. Processes for review and appeals
6. Allocation of resources for data collection and monitoring
7. Commitment to stakeholder consultation

[9]Britton et al (2018) Expanding Markets while Improving Health in Indonesia The Private Health Sector Market in the JKN Era. http://www.healthpolicyplus.com/ns/pubs/8224-8401_MarketReport.pdf