Johnson & Johnson

WORLDWIDE GOVERNMENT AFFAIRS & POLICY

COMMENTS ON HEALTH MARKET INQUIRY PROVISIONAL REPORT

07 September 2018

Contents

1. Executive Summary

In line with its other recommendations relating to regulatory frameworks, the Health Market Inquiry (HMI) should note the lack of implementation of the regulatory reform relating to medicines and medical device registration, etc., as listed below. The adverse impact that the non-implementation of these frameworks has on the market, affecting competition, and the clear impact on patient access and choice to medicines and regulated (i.e. safe, quality) medical devices, should be acknowledged.

The implementation of the medicines pricing framework should be re-considered, to create a more agile system that is responsive to the market and pro-competitive forces, always considering the impact of regulatory implementation on access to medicine.

A regulatory framework as recommended by the HMI for Alternative Reimbursement Models (ARMs) should not only focus on issues such as the Health Professions Council of South Africa (HPCSA) but also scheme reluctance to adopt such models. The implications of ARMs on suppliers of medicines and medical devices and the associated indirect impact on patients have not been considered. It requires price flexibility for medicines, and the acceptance of risk-sharing models and incentive schemes that may fall foul of the Single Exit Price (SEP) regulations and/or sections 18A and 18B of the Medicines Act.

In addition, the process of expanding Prescribed Minimum Benefits (PMBs) to include primary and preventative care should be transparent and inclusive of all role players including representatives of pharmaceuticals and medical devices. The inclusion of primary and preventative care should not compromise care for chronic and critical conditions given the resources available.

It is recommended that the latest proposals in the Medical Schemes Amendment Bill (MSAB), be considered by the HMI. It runs counter to the proposals of the HMI to address PMB uncertainty through coding, price negotiations and standard treatment guidelines.

The introduction of risk equalisation mechanisms for the medical schemes industry is strongly welcomed.

Where a network or Designated Service Provider (DSP) arrangement includes medicines and/or devices, it must be noted that a mechanism must exist to ensure the appropriateness of care for all patients. The definition of evidence-based medicine, and the exceptions created to ensure appropriateness of care, and the avoidance of harm to patients, as currently encapsulated in regulations 15G, H and I, should be also entrenched in relation to DSPs and networks.

A regulatory impact assessment should accompany any new proposed structure, and the timelines for creating new statutory bodies, and the teething problems associated with that, as is currently the case with the MCC's conversion into SAHPRA, should be accounted for.

2. About Johnson & Johnson

Johnson & Johnson (J&J) welcomes the opportunity to comment on the Health Market Inquiry (HMI) Provisional Findings and Recommendations Report, as released on 05 July 2018. Johnson & Johnson has been operating in South Africa for approximately 88 years across three main sectors: pharmaceuticals, medical devices (consumables as well as larger capital equipment), and consumer products. Today, as the world's largest and most broadly-based healthcare company, we are committed to using our reach and size for good. We strive to improve access and affordability, create healthier communities, and put a healthy mind, body and environment within reach of everyone, everywhere.

3. Introduction

Johnson & Johnson, has participated in the HMI since its inception, and welcomes the Draft Report and Recommendations.

Our comments to the HMI will focus on the following:

- **The impact of regulatory failures in the health goods (medicines, including over the counter medicines and medical device) markets**
- **Alternative Reimbursement Models (ARMs), value-based contracting [chapter 7] & risk-sharing agreements (RSAs)**
- **Outcomes measurement (OMRO)**
- **Supply-Side Regulator for Health: Health Technology Assessments**
- **The Prescribed Minimum (PMBs) and the standardised benefit package**
- **Risk Adjustment Mechanism (RAM)**
- **Supplier-induced demand as it pertains to the provision of goods**
- **Regulatory complexity, oversight and enforcement, in particular, structures, governance, cost and overlaps with existing mechanisms**

4 The impact of regulatory failures in the health goods (medicines and medical devices) markets [findings contained in Chapter 2 of the HMI report]

The Report refers in several places to the regulatory frameworks, the failures of which impact the health market. Although included in the Statement of Issues[1] and Terms of Reference,[2] the roles of the regulatory bodies and systems (save for the HPCSA and to a lesser extent the CMS) have not been investigated, and no recommendations or findings have been made in this regard. This is assumed to be the result of too few submissions on this aspect of the healthcare system, and the core focus of the HMI not being on medicines. The inclusion of two sets of regulatory matters that affect the health products market in South Africa, both of which are contained in the Medicines and Related Substances Act, 1965 ("Medicines Act"), and its accompanying sets of regulations are critical to the overall efficiency of the healthcare system.

4.1 Medicines and medical device regulatory system

The regulation of medicines, medical devices and IVDs is a critical component of every country's health system. An effective medicines regulation system promotes and protects public health by ensuring that medicines are of the required quality, safety and efficacy.[3]

It is widely known that the Medicines Control Council (MCC) was beset by backlogs and suffered from regulatory delays in the review of applications for registration of medicine due to resource constraints. This had an impact on the availability of medicines with adverse consequences for public health. In recognition of the challenges MCC faced, government has established a new regulatory authority, the South African Health Products Regulatory Authority (SAHPRA), which has replaced the Medicines Control Council (MCC). To address the operational and technical issues faced by the MCC, SAHPRA has established a Technical Operations and Regulatory Strategy (TORS) Committee with the mandate of developing an integrated plan to address the backlog of all products in a defined and achievable timeline[4] which is important but insufficient, as it will not create sustainable change which is required to set SAHPRA onto a new path. Other unimplemented aspects of the regulatory framework, such as a published staffing structure, recognition agreements with other authorities, etc. are all needed to effect the necessary sustainable change.

---

[1] HMI Final Statement of Issues, 1 August 2014, paragraph 47.
[2] Government Gazette No 37062 of 28 November 2013, par 2.1.3.
[3] Ndomondo-Sigonda M, Miot J, Naidoo S, Dodoo & Kaale E., 2017. Medicines Regulation in Africa: Current State and Opportunities. Pharmaceutical Medicine. 2017;31 (6):383-397.
[4] Parliamentary Monitoring Group.,2018. *SA Health Products Regulatory Authority (SAHPRA) Annual Performance Plan; Health Department APP: analysis.* Accessed at https://pmg.org.za/committee-meeting/26138/ on 8/22/2018.

It is also important to transfer critical evaluation skills to SAHPRA staff through training and capacity building, additional technical staff need to be recruited to address the regulatory workload and a well-functioning Information Technology (IT) system is a key support component in resolving current delays in regulatory decision-making and would ultimately contribute to improving operational efficiency, delivery of quality services and to improve transparency. At this stage, there is little evidence to suggest that these elements are being considered for implementation by SAHPRA.

The regulatory framework created by the amendments which came into effect on 1 June 2017 are largely unimplemented. These amendments include, for example, the promulgation of timelines[5] and staffing structures.[6]

Given the current and previous backlogs in medicines registration, regulatory updates (such as package insert changes) and amendments (e.g. new product owner), the market has, and will continue to be negatively impacted by these delays through the subsequent inability to bring competitors, or innovations that benefit patients to market within a reasonable timeframe.

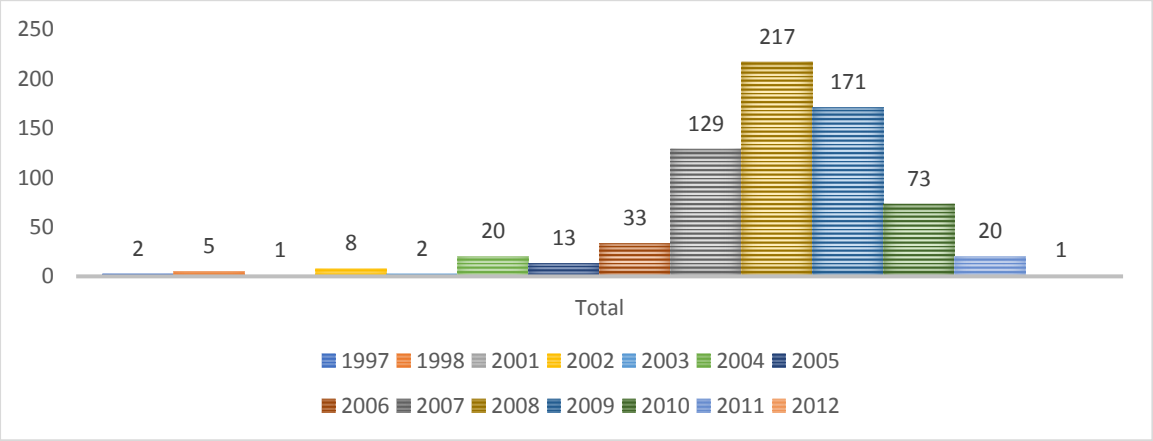

FIGURE 1: MEDICINES REGISTERED BY THE MCC IN 2012, WITH ESTIMATED SUBMISSION YEAR (N=695)[7]

[5] Section 35(1)(xliii).
[6] Section 35(1)(xxxvii).
[7] Based on registered medicines list, as published on the MCC website, www.mccza.com

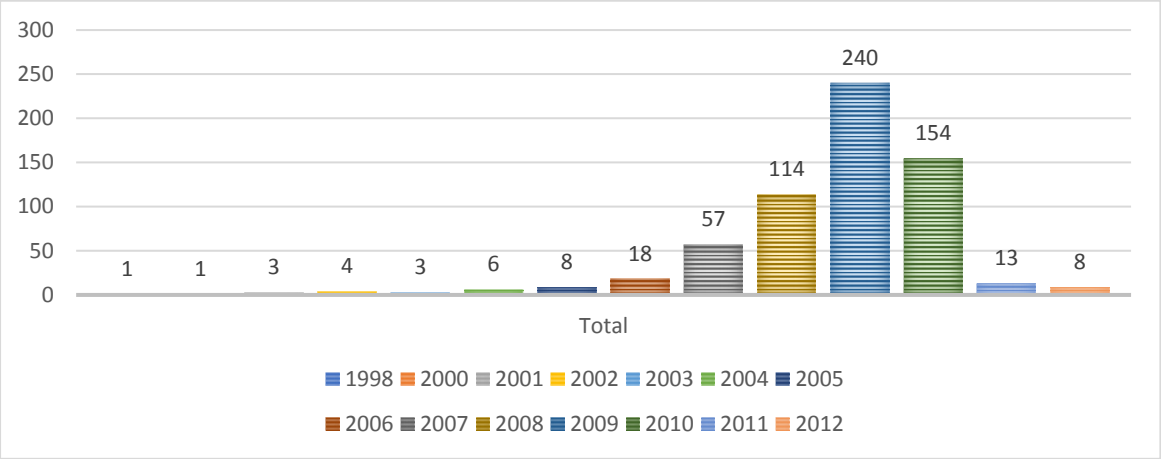

FIGURE 2: MEDICINES REGISTERED IN 2013 (N=630)[8]

In 2012, according to the list of registered medicines on the MCC website, 695 medicines were registered of which only 15 were new chemical entities. This implies that the majority of the rest were generics with a few being classified as veterinary medicines. The majority of applications were made during 2007, 2008 or 2009, which suggests an estimated review and approval timeframe of 3 to 5 years. Similar calculations can be made for data obtained for medicines registrations for 2013 (n=630). During a similar timeframe (2011-2012), the median regulatory approval time for new medicines from the EMA was 1.18 years (434 days) and FDA was 0.81 years (296 days).[9]

Since the majority of medicines registered were in fact generic medicines, these should not take such a prolonged period to review and approve, especially in light of the fact that South Africa already has a bolar provision in place in the Patents Act.[10] These significant regulatory delays have a negative impact on medicine availability, patient care and public health.

The newly established SAHPRA has an expanded mandate which includes regulatory oversight of medical devices and the recommendations made in the Provisional HMI Report on par 14 on page 35, are also challenging, i.e. that medical devices should be subjected to health technology assessment (HTA),[11] since there is currently no system in place for registration of devices, old or new, nor does SAHPRA have the technical skills and capacity to have sufficient regulatory oversight of this sector at this stage. Health technology assessment should follow on, and not precede evaluations as to the safety, quality and performance of medical devices.

[8] Based on registered medicines list, as published on the MCC website, www.mccza.com
[9] http://www.cirsci.org/wp-content/uploads/2017/11/CIRS-RD-Briefing-65-20112017.pdf
[10] Section 69A.
[11] Par 347 and 348, page 223; par 305, page 361; par 94ff page 467.

To conclude that the regulatory failure, in particular, the absence of HTA has led to "increased expenditure" is not accurate, but rather this is related to multiple factors including incorrect attribution of "increases" in expenditure of medical devices (par 348 on page 233) and to the growth in the medical device market as recorded in the paragraph before (par 347, as per the SAMED-commissioned Deloitte study on the medical device market).

J&J has, as per the previous submission to the HMI provided information on price stability in the medical devices portfolio. It is clear that a thorough assessment in this regard is lacking, in particular as medical schemes data often do not separate out medical devices and/or technology use.

In line with its other recommendations relating to regulatory frameworks, the HMI should note the lack of implementation of the regulatory reform relating to medicines and medical device registration, etc., as listed above. The adverse impact that the non-implementation of these frameworks has on the market, affecting competition, and the clear impact on patient access and choice to medicines and regulated (i.e. safe, quality) medical devices, should be acknowledged.

4.2 Pricing - medicines

Medicines, as is noted in the Report, are subject to price regulations, issued in terms of section 22G of the Medicines Act in the form of the 2005 Pricing Regulations ("SEP regulations"). Although it is acknowledged that these regulations have stabilised prices (par 321 at page 57), and that, despite the volume and utilisation increases noted throughout the report, the expenditure on medicines have remained stable.

An aspect that has not been explored are the unintended consequences of the pricing system as implemented. As with other regulatory processes, effecting even minor changes on the centrally-administered price database is accompanied by excessive administrative requirements and delays. Most of these rules set for implementation are not contained in the SEP regulations. This means that the pro-competitive responsiveness of suppliers to market changes are hampered. The delays in implementation of the annual SEP, new product prices and the process of granting regulation 9 extraordinary increases also place the availability of products, and therefore the access of these medicines to patients, at risk.

The implementation of the medicines pricing framework should be re-considered, to create a more agile system that is responsive to the market and pro-competitive forces, always considering the impact of regulatory implementation on access to medicines.

For direct-to-consumer (or, as it is also referred to "over the counter") medicines, there has been an exemption for schedule 0 medicines from the SEP and section 18A[12] of the Medicines Act since the

[12] The prohibition on the supply of medicines according to a bonus, rebate or incentive scheme.

inception of the regulations in 2005. This exemption has now been in place for more than 13 years and should bear testimony to the fact that the market is working for these types of medicines by contributing to market competition and consumer choice. The costs of making these exemption applications every three or five years, which contributes to the cost of doing business and the prices of products, can therefore be avoided.

"Regulation by exemption" is not a desirable nor an effective form of regulation from a constitutional perspective[13] Having exemptions in place for limited periods of time introduces regulatory uncertainty into the market, as it is not known whether an exemption will be granted for the following period or not, which makes product and market planning, even production planning and new investments challenging.

Free pricing for non-reimbursed and direct to consumer medicines should be the norm as is the case internationally. According to the Word Self-Medication Industry (WSMI) organisation:

"*While recognizing that many governments have some form of price control or cost-containment measures in place for reimbursed medicines (be they prescription or non-prescription), WSMI urges governments to allow manufacturers to set their own prices for non-prescription medicines which are not reimbursed based on market conditions."*[14]

The European Commission stated in 2007: [15]

"Price control is not necessary for non-reimbursed medicines. For these products, price competition can steer the price evolution sufficiently well. Therefore, Member States should abstain from price-control."

In the interest of a stable, predictable market, where market forces set conditions for competition, the SEP and section 18A should not be applicable to direct to consumer medicines, and section 18A should not be applicable to direct to consumer medical devices and IVDs, to ensure continued access for patients to the tools of self-care, which saves on costs to the health system and provides patients with choices.

[13] Section 9 of the Constitution requires equal application of the law, and section 1(c) makes the rule of law, and its associated legal certainty, supreme – both of these principles are violated in regulation-by-exemption.
[14] http://www.wsmi.org/policy-principles/pricing-matters/.
[15] EU Pharmaceutical Forum, Second Progress Report, 26 June 2007
http://ec.europa.eu/health/ph_overview/other_policies/pharmaceutical/pharma_forum_progres_report062007_en.pdf

4.3 Regulation affecting commercial matters – medical devices & IVDs

The HMI report notes the submissions made in relation to bonuses, rebates and the likes, in particular, in the hospital sector (footnote 72 on page 57, par 353 on page 233 and par 366 page 236). This matter is very relevant within the context of incomplete regulatory measures, which can be addressed immediately through the implementation of, for example section 18A and 18B of the Medicines and Related Substances Act, 1965.

Regulatory uncertainty has been created in the medical devices and IVD sector much to the detriment of public health and patients. Despite ongoing efforts to engage SAHPRA and the Department of Health, there is currently no sustainable solution forthcoming. A temporary exemption has been granted for medical devices and IVDs from sections 18A (bonus, rebates, incentive schemes) and 18B A (no free supply), but the regulations envisaged, have not been completed.

Regulations are envisaged to detail what would be acceptable, and unacceptable business practices under these sections. Draft regulations were issued on section 18A, but there are no regulations to govern the supply of medical devices for appraisal purposes and regulations for the donation of medical devices into the public- or not-for-profit sectors., i.e. under section 18B.

An example of the implications of this is for instance in the case of trauma cases in the public sector, where we supply loan sets and implants to hospitals free of charge so that they are available when needed. This will not be possible once these sections in the Medicines Act become effective, without delineating in regulations what would be perverse, and what would be acceptable, therefore leaving patients in a dire situation.

Legislative frameworks in relation to sections 18A and 18B of the Medicines Act must be completed and implemented appropriately, also to address any remaining concerns on the effect that rebates, or other practices may have on the market and not disadvantage patients. This is also necessary to ensure legal certainty and an equal playing field for all suppliers and to avoid "regulation by exemption".

4.4 Impact of the unimplemented sections of the National Health Act on the market

The HMI at par 6 of page 21, in the Chapter on the Regulatory Framework refers to the failure to implement the National Health Act, 2003. A list of the NHA unimplemented provisions are included in par 45 and 46, on page 30. There are very specific provisions in the NHA that impact the supply of medicines and medical devices into the market, not listed as part of the findings, all of which could assist in enhancing the operation of the market. These include:

- The absence of regulations on the setting of the essential medicines list and the essential equipment list (section 90(1)(d));

- The absence of regulations on standardised record-keeping, which affects the standards set for health facilities and the reports of medicines and medical device adverse events, quality concerns, and general record-keeping on device maintenance and the likes (sections 74, 90(1)(d), and(t));
- The absence of regulations on human resource development, as inclusive of the availability of regulatory experts, engineers and the likes required to not oversee medicines and medical device regulatory matters, but also maintenance, ensuring correct procurement, etc. (sections 21 and 52);
- The absence of regulations on the mechanisms to "enable a co-ordinated relationship between private and public health establishments in the delivery of health services" (section 45).

5 Alternative Reimbursement Models (ARMs), value-based contracting [Chapter 7, HMI report] and risk-sharing agreements (RSA's)

The HMI Report recommends "strongly" the transition from fee for service (FFS)-based reimbursement models to alternative reimbursement models, such as global fees/bundled payments, capitated fees, outcomes-based models, such as value-based contracting, etc. (par 30, page 457 and par 145-6 on page 474 in chapter 10). The importance of ARMs is such that it features in nearly every chapter of the report. It ensures sensitivity to costs, promote co-operation between various service providers and suppliers, ensures the sharing of risk and rewards good behaviour in terms of compliance with treatment protocols, measurement of outcomes, etc.

These models directly impact the suppliers of medicines and medical devices, as it could limit choice, exclude certain products or product types, and/or not align with evidence-based medicine or longer-term patient outcomes. It may, for example, set the fee so low that many, or most of suppliers are unable to participate in ARMs, as they are unable to complete in models that are set on price alone, or where other parts of healthcare services or goods crowd out the cost of a medicine or device.

For medicines the existence of the Single Exit Price would, by definition, prohibit or at least seriously limit participation in ARMs. For medical devices, a global fee in which medical devices are included based on a tender might fail to consider patient sub-groups for whom such an implant may not be clinically appropriate. The exclusion of certain medicines, due to cost, may leave patients without options where treatment failure or adverse events are observed. This goes to the heart of the HMI findings in relation to concerns expressed on poorly conceived ARMs. Such oversights will disadvantage patients to the extent that they will ultimately impact their health outcomes.

A regulatory framework as recommended by the HMI for ARMs should not only focus on issues such as the HPCSA and scheme reluctance to adopt such models. The implications of ARMs on suppliers of medicines and medical devices have not been considered. It requires price flexibility for medicines, and the acceptance of risk-sharing models and incentive schemes that may fall foul of the SEP regulations and/or sections 18A and 18B of the Medicines Act.

Most ARMs currently appear to focus on price/volume, and some short-term outcomes measurements. The HMI notes the finding by Towers Watson that ARMs currently in the market are not effective at reducing costs (par 303, page 222).

The HMI findings include the concerns relating to ARMs (par 477, page 158) as inclusive of:

- the risk of under-servicing,
- poorly conceived programmes and
- the lack of independent oversight.

Further concerns relate to, amongst others:

- the entry and exit criteria of certain types of ARMs, including the risk of cherry-picking patients, avoiding more complex, and needy patients, thereby negatively affecting the access to healthcare rights of more vulnerable patients.
- selection bias in that inexperienced practitioners will not gain experience and reach treatment targets or outcomes associated with ARMs.
- Providers being held accountable for aspects of care not under their control, e.g. nursing staff or other healthcare professionals.
- Unsuccessful cases in short, medium or longer term being passed on to the public sector, as benefits would have been exhausted under the ARM.
- Risk of perversity “what you save you get into your own pocket”.
- Lack of transparency towards patients and the limitations on choices and care options that may accompany an ARM. In addition, there is reduced granularity in terms of patient cost information (par 299, page 222).

The SSRH will use, so it is proposed on page 362 at par 312.2, the practice code numbering system to over time no longer provide individual practice codes and would require practitioners to demonstrate that they participate in risk-sharing models.

Apart from the practice code numbering system, it is unclear how the proposed SSRH and/or existing or new legal frameworks will address the concerns in relation of ARMs to ensure effective enforcement of patient rights, if required.

Given the limitations of other reimbursement models, value-based contracting, as also referred to by the HMI in various places in the Report,[16] is recommended as a sustainable reimbursement model. By definition, value-based contracting is a contract with a provider that contains alternative payment methodologies, where a portion of the provider's total potential payment is tied to a provider's performance on cost-efficiency and quality performance measures.[17] For value-based contracts, payment is enhanced if the provider meets cost efficiency and quality targets. In addition, clinical integration fees could be paid to providers contingent on the provider engaging in practice transformation to adopt technology and processes that alter the manner in which they deliver care. Improvements in processes which can drive value include being accountable to the patient, creation of advanced care teams, and automated processes to address prevention and wellness. The use of evidence-based medicine is critical to drive quality and efficiency[18].

There appears to be only a handful of true value-based reimbursement models in the market, which should be differentiated from, for example, "capped" event-based fees, with no or limited outcomes measurements. A value-based model for medicines and medical devices should be guided by the following principles:

- The value for money that the product provides, i.e. the inherent value for money of a product encompasses its clinical benefits, but also the patient experience and health economic benefits.
- The need to provide a sustainable environment to support ongoing innovation, which there is continued incentive to invest in new technologies and drive access to better levels of care.
- The need to ensure that necessary post-market activities can be undertaken, in the interest of patient access, safety and quality. In particular, with medical devices, the cost of training healthcare professionals and patients on correct product use, providing product use support, product maintenance support, etc. The post-market regulatory and product/consumer rights support are different for medical devices to that of medicines.

[16] Par 18 on page 456; par 146, page 474; par 176.3, page 478;
[17] United Healthcare, 2012, Shifting from fee-for-service to value based contracting model. https://consultant.uhc.com/assets/vbc_overview_flier.pdf
[18] United Healthcare, 2012, Shifting from fee-for-service to value based contracting model. https://consultant.uhc.com/assets/vbc_overview_flier.pdf

The development of value-based models of reimbursement should be guided by the principles of a balanced focus between cost savings and quality of care; patients must have access to the most appropriate care and providers; and there must be ongoing access to innovative treatments. These models should be included in the Regulations to the Medical Schemes Act, to avoid the concerns and/or unintended consequences raised by stakeholders in relation to ARMs.

For medicines, the *principle* of transparency of SEP legislation in the private sector is supported. However, the inflexibility of the system limits access for innovative technologies as these often come at an inflated cost, especially in specialized, low incidence disease areas.

The SEP for medicines is an example of regulatory system that does not allow the market to be responsive to alternative reimbursement mechanisms. The recommendation is for a robust mechanism that allows flexibility around SEP to improve affordability and access, whilst demonstrating value and improved outcomes. Examples of such mechanisms that are implemented successfully in other countries, including other emerging markets, include ARMs, managed entry agreements and risk sharing models.

Risk-sharing agreements (RSAs) as an agreement between a funder and a manufacturer where the price level and/or revenue received is related to the future performance of the product in either a research or real-world environment.[19] RSAs can be financial, or outcomes-based, with the latter regarded as complex and costly, and perhaps more suitable to select diseases and technologies.

For medicines, the wide variety of RSAs need to be considered on a case by case basis including, but not limited to, cost-sharing, dose capping, as well as pay-for-results options as mechanisms to improve broader, more equitable access for patients.

6 Outcomes measurement ("OMRO") [Chapter 9 of the HMI report]

In an environment that rewards value and quality, attention to outcomes measurement and improvement will be essential to the success of organizations across the healthcare system. Health Outcomes Measurements are a rational, scientific response to address issues of asymmetry of power, and lack of information and is preferred as a pro-competitive measure, compared to price regulations currently implemented in the private sector for medicines and potentially in future for devices which only considers acquisition costs and does not consider value nor health outcomes nor downstream cost impacts on the healthcare systems.

[19] Saggia, M., 2016. Risk Sharing Agreements (RSA): Exploratory Analysis of the Current Situation in Developed and Emerging Markets. *Value in Health,* Volume 19, p. A499.

The implementation of outcomes measurement, and the linkage of such mechanisms to reimbursement models are strongly supported. The HMI (par 32 to 38, page 441ff) recognises that there is a legal framework in place to ensure data collection through the national health information system, and that the Council for Medical Schemes (CMS) has the power to make recommendations to the Minister on the criteria for the measurement of quality, and that the Office of Health Standards Compliance (OHSC) also has some functions that incorporate quality measures. Notwithstanding, the HMI recommends that a separate entity be set up (par 65ff on page 448ff and par 98 on page 453), the Outcomes Measurement and Reporting Organisation ("OMRO").

Instead of setting up a new statutory body, which will be costly and involve various stakeholders and a long legislative process, the HMI should propose that this function be included under the National Public Health Institution of SA ("NaPHISA") Bill,[20] currently making its way through Parliament.

This Bill aims to collect information, including disease surveillance, for planning, disease management, etc. One of the key components is that it also incorporates into its system the cancer registry, which is currently a mandatory registry based on regulations[21] made in terms of the National Health Act. It is, however, not successful at all, despite it being legally binding. It also suffers from a lack of funding. In this regard it is similar to other registries, the success of which depends largely or wholly on private sector donations. It would make sense, therefore to also house other registries under the NaPHISA fold.

A thorough analysis should be undertaken on the challenges experienced by registries in the market at present. Those challenges must be overcome, before the registries are scaled up to establish OMRO. It would be imperative to have multiple stakeholders input for a comprehensive analysis, including the private sector.

The health outcomes measurement as part of the concept of value-based contracting is supported, so that patients can make value-based choices, and contracts are done according to value-based parameters. A shift to value-based competition is important, which goes beyond a mere price-by-price comparison, or a race for the lowest price, instead of cost-effectiveness being the criteria.

To address information asymmetry – currently also affecting suppliers such as J&J in their negotiations with funders, the results of the various sets of outcomes data must be nationally available. It is difficult to enter into negotiations with funders, who have access to all aspects of a patient's journey – hospitalisation, diagnostic and other tests, healthcare provider visits, hospitalisation, etc. into which a supplier has no insight or access to.

[20] http://pmg-assets.s3-website-eu-west-1.amazonaws.com/B16B-2017.pdf.
[21] GNR.380 of 26 April 2011: Regulations: Cancer registration (*Government Gazette* No. 34248).

7 The Supply-Side Regulator for Health: Health Technology Assessment [Chapter 10 of the HMI report]

HTA is considered by the HMI in its report as the solution to information asymmetry (in particular between patients and providers, and also for providers towards suppliers). It must be noted that, even where HTA results are made known, it would not be possible to make product or brand names known to the public, as a result of the advertising prohibitions currently found in the Medicines Act and the Medicines and Medical Devices Regulations thereto. Informed consent processes (set in ethical rules and the National Health Act's section 6) require of the healthcare professional to discuss treatment options, benefits, risks, costs and implications with patients.

It is doubtful that HTA processes will filter through to patients, be used by patients or be understood by patients. Its value rather lies in information to health policy-makers and funders, as one of the factors on which decisions on benefits and reimbursement can be made.

As stated above, in the absence of an efficient regulatory framework for medicines, and in the absence of the implementation of a regulatory framework for the registration of medical devices and IVDs, the benefits of an HTA system may be limited.

The implementation of an HTA system for medical devices should only follow-on, and not precede, medical device registration by SAHPRA.

Most importantly, HTA needs to consider the key principles of transparency, stakeholder engagement and independence to ensure full collaboration of stakeholders and to maintain rapid patient access to innovative medicines and procedures. HTA should remain independent of the regulatory process. All stakeholders should have reasonable access to the HTA process at all stages. Decisions should always involve input from specialists in the therapy area on the full range of benefits delivered by the technology.[22] The independence of HTA agencies should be favoured over a process that is guided by political expediency; independent reviews lend greater transparency and bring broader perspectives to the assessment process. Decisions on pricing should be left to the developers of innovative technologies according to free market principles and not be linked to classifications based on the outcomes of HTAs. Specific cost-effectiveness thresholds may compromise the ability of manufacturers to decide on price, and funders on reimbursement levels.

[22] Kuchenbecker R & Polanczyk CA., 2012. Institutionalizing Health Technology Assessment in Brazil: Challenges Ahead. Value in Health Regional Issues 1 (2012) 257-261.

The current pharmaco-economic guidelines, issued by the DG of Health under the SEP Regulations, 2005, is an example of an HTA mechanism that has not, and could not, be implemented. The reasons for this are not known to industry but may relate to the unavailability of (local) data, skills and the fact that, in spite of this, funders must, in terms of the Medical Schemes Act, still make their own decisions.

Lessons must be learnt from this experience, prior to attempting to implement yet another structure with its own sets of rules, to address HTA for medicines. These lessons learnt could also be applicable to medical devices.

HTAs should help to speed up patient access to innovative medicines, devices or procedures if these are found to be cost-effective or to fill an unmet medical need. HTA should not be used covertly for justifying rationing or for cost containment. With HTA playing an increasingly important role in reimbursement decisions, governments must commit to rewarding advances in medical technology.

The following pointers are of value in the decisions relating to an HTA agency:

Devices are different from medicines

HTA should be fit for purpose and should consider the key issues that differentiate medical devices from pharmaceuticals such as difficulties achieving blinding and user 'learning curves'.

Role of early scientific advice

Early scientific advice from HTA agencies can be useful in identifying the evidence requirements of key decision-makers, thereby reducing the uncertainty of drug development programmes. While early scientific advice has clear value in pharmaceutical development, its value remains unclear for medical devices until interactions between regulatory, HTA and procurement become aligned.

Use of QALYS in decision making

The quality-adjusted life-year (QALY) should be only one of several factors considered by decision makers in determining whether or not a new healthcare technology should be reimbursed. Other considerations should include: burden of disease, including disease severity and unmet clinical need; therapeutic gain; efficacy and safety; budget impact; societal impact; degree of innovation; and other commercial arrangements such as access schemes and coverage with evidence development. The methodological limitations of the QALY should be explicitly recognized.

Coverage with Evidence Development

Coverage with evidence development (CED) is an appropriate tool to provide access to innovative technologies when there is significant uncertainty related to the use of that technology in routine clinical practice. Requests for CED need to balance the expected benefit of a technology with the additional value of further research. CED should not be used as an output of the HTA process to restrict access to innovative medicines merely on the grounds of costs.

Use of non-randomized controlled trial data

Developers should be able to demonstrate clinical efficacy/effectiveness of a medical technology using the most appropriate evidence available. Although RCTs are often considered to be the 'gold standard', in some circumstances they may be inadequate. Other forms of assessment, including observational studies, should therefore be accepted by health technology assessors.

In addition to the scientific methodology, developing a rigorous HTA also requires identifying and allocating human and financial resources to support the process. It also hinges on the availability of local data, from both sectors and in a format that is usable. It is well-known that the national health information system has not been established, and where it has, has not been adhered to or implemented. Securing and retaining these resources can be challenging, especially for countries without well-established HTA programs.

It will therefore be of importance to have a phased in approach where adequate information is available, human resources are adequate to undertake assessments, and for companies to make HTA submissions and that relevant legal frameworks are considered to maximize the opportunity for success by allowing adequate time for technical/scientific process development and human resource and skills development.

We take this opportunity to submit as Annexure 1, a comprehensive proposal on the principles pertaining to the implementation of HTA.

8 The PMBs and the standardised benefit package [par 36ff, page 459]

HMI's recommendation to standardise the basic obligatory package across all the medical schemes is positive in that it will create a level of transparency and go a long way in addressing the issues of information asymmetry. This should, however, already be the case within the PMBs. The view of the PMBs as "in-hospital" benefits (par 33.1, page 459) is more a function of non-implementation, and non-promotion of the PMBs as also being out of hospital benefits, i.e. an implementation regulatory failure, than an in-principle design failure. Explanatory note 2A to the PMB List, attached to the Regulations to the Medical Schemes Act, already encapsulates this:

2A … Note (2) does not restrict the setting in which the relevant care should be provided and should not be construed as preventing the delivery of any prescribed minimum benefit on an outpatient basis or in a setting other than a hospital, where this is clinically most appropriate.

The reasons why medical schemes tend to fund PMBs in hospital at a better level than out of hospital, must be explored. The problem is not that of legal provision, which has been borne out by the Towers Watson Reports on the level of reimbursement of PMBs in- and out of hospital.

It is noteworthy, that the PMBs are not the primary driver of cost escalation in the private health market (par 73, page 91). The contention that the PMBs are a key component of universal coverage, ensuring at least a basic level of care for members of schemes is supported (par 76, page 91).

The proposal of expanding Prescribed Minimum Benefits (PMBs) package to include primary and preventative care is positive for patients in creating comprehensive care; it should be ensured that PMBs are reviewed and updated at least every two years, as is provided for in the law (par 33.5, page 459). The review process should incorporate new and innovative technologies and advances in medical devices and pharmaceuticals, as is set by the Annexure to the Regulations.

However, in the absence of measures designed to equalise risk between schemes, and to ensure a continued supply of young and healthy members, the only effect of an expanded package will be that the level of care may drop below what would be regarded as evidence-based medicine. One may even see that the basic premise of the PMBs, namely to prevent the unfunded utilisation of the public sector, is undermined if inadequate levels of care are provided.

The process of expanding PMBs to include primary and preventative care should be transparent and inclusive of all role players including representatives of pharmaceuticals and medical devices. The inclusion of primary and preventative care should not compromise care for chronic and critical conditions given the resources available.

In terms of substance, the primary and preventative healthcare package should Include screening/preventative treatment for diabetes, hypertension, HIV, oncology; allow for basket of diagnostic tests blood tests and x-rays) for the defined PMB conditions; vaccinations for children; and basic maternity benefits.

It is recommended that the latest proposals in the Medical Schemes Amendment Bill (MSAB), be considered by the HMI. It runs counter to the proposals of the HMI to address PMB uncertainty through coding, price negotiations and standard treatment guidelines.

This proposal in the MSAB recommends a fundamental shift from the current diagnosis-based approach to the PMBs. It proposes so-called “service benefits” (not defined). A potential shortcoming is that these capped service benefits will lead more ill patients exposed to levels of services that are inappropriate or inadequate for their needs, leading to exactly the unfunded utilization of the public sector, or unfunded out of power payments by consumers.

9 Risk-Adjustment Mechanism (RAM)

The introduction of a risk equalisation mechanisms for the medical schemes industry is strongly supported.

The implementation of a RAM is important for ensuring sustainability of medical schemes, given the varying risk profiles of schemes driven by age, gender, morbidity structure and the size of membership. While the proposal for a RAM is not new in South Africa, it is the recommended that the work already started by the Council for Medical Schemes (CMS) should be concluded and implemented on this matter.

For instance, already in 2004, the Formula Consultative Task Team established that "age profiles differ considerably between the schemes, so that the difference in average cost is a factor of four between the cheapest and the most expensive scheme. This very large distortion in risk exposure of medical schemes is too large to be considered random".[23]

In addition, the CMS has been working over the years on a Risk Equalization Framework-which has unfortunately stalled. With reference to the specific recommendations of the HMI on the implementation of the RAM, the following should be taken into account:

- The CMS should facilitate the initial RAM discussions given previous work done by the CMS in this area;
- The development of the final RAM should include all the stakeholders in the process, including representatives of pharmaceutical and medical devices industries;
- The administration of tax credits is not the most pressing matter, but the important question to consider is whether the tax burden of medical scheme members will increase, or not should the tax credit be removed. In a study conducted by Econex on medical scheme tax credits and affordability, the study found that removing the "rebate will likely have the effect of rendering medical scheme membership unaffordable to 22% of current beneficiaries, with the impact falling largely on poorer medical scheme beneficiaries"[24] (cf. par 43 of 460). This is important to consider in assessing the likely consequences of removing medical scheme tax credits given that the fact that low income earners could lose their medical scheme benefits. In this regard, it is proposed that the establishment of a RAM should not increase the tax burden of medical scheme members by removing the tax credits. Furthermore, with the current tax credit system remaining intact, the South African Revenue Service remains the relevant authority to manage tax credits;
- The proposal for a legal requirement for all medical schemes to belong to the RAM is supported;
- The development of a database of all insured beneficiaries is important, to support the effectiveness of the RAM. For example, in the Council for Medical Schemes REF Shadow return

[23] Report to the South African Risk Equalization Fund Task, Group
https://www.medicalschemes.com/files/Risk%20Equalisation%20Fund/REF_InternationalReviewPanel_Jan_2004.pdf
[24] Armstrong P, (2017), Medical Scheme Tax Credits and Affordability,
https://www.mm3admin.co.za/documents/docmanager/1E9AEA2C-B58D-4AED-B5A2-96187D705AEE/00126402.pdf

analysis, 17%-34% of data submitted was of poor quality[25]. In this, regard, the success of the RAM will depend on accurate data. In addition, the cost of establishing the databases should be managed in a manner that does not increase the administrative costs of medical schemes;

- The cost of establishing an independent RAM administrator should not be exorbitant to ensure that administrative cost of healthcare remain reasonable; and
- A mechanism should be put in place to ensure that the push factors from the RAM to lower costs does not impact patients negatively, through a race a race to the bottom for the lowest price which does not take outcomes and quality into account. In this regard, measurement of outcomes in healthcare should be closely linked to the RAM. Given that the HMI proposes for both the OMRO and the RAM, a mechanism should be established to ensure that the RAM considers patients outcomes in its distribution of funds, with medical schemes being incentivised to produce better outcomes.

10 Supplier-Induced demand as pertaining to medicines and medical devices [par 172 – 3, page 478]

Johnson & Johnson Companies in South Africa, as companies operating in South Africa, are subject to the US-Foreign Corrupt Practices Act, the UK Anti-Bribery Act, the Prevention of Corrupt Activities Act, as well as local and internal codes of practice, in particular relating to the manner in which it interacts with healthcare professionals.

Therefore, our sponsorships, grants and other contributions to the health sector and to health professionals are curtailed by law, codes and internal company rules. When matters of a medical and clinical nature are included in interactions between Johnson & Johnson Companies in South Africa and health care professionals who are its customers, such as the regulatory required procedure training, and other interactions with health care professionals (HCPs), such as fellowships, which matters are strictly controlled by appropriate staff, to ensure the removal of any undue influence.

Johnson & Johnson Companies in South Africa allocate resources to provide bona fide professional medical education to health care professionals and organizations, to assist them develop knowledge and increase skills that lead to improve patient health outcomes. This is materialized through educational grants to accredited providers of postgraduate medical education and fellowships and similar programs (typically, universities or teaching hospitals), and development and dissemination of educational materials or medical equipment for training purposes.

[25] The analysis of REF shadow returns 2010, https://www.medicalschemes.com/files/Risk%20Equalisation%20Fund/REFShadowReturns2010Report.pdf

Our companies educational support is independent from the commercial strategies and plans. It is not determined in a manner that takes into account the volume or value of any past, present or future business otherwise generated between a Johnson & Johnson Company in South Africa and the recipient of the professional education support, nor does such support obligate the recipient health care professional to purchase, use, recommend, or arrange for the purchase, use, recommendation of any Johnson & Johnson Companies in South Africa product or service or its affiliates, or is a form of hidden discount to a health care professional or organization.

To ensure this, our organizations have separate plans, budgets, decision-making processes, teams and management for professional education, and for product promotion. In accordance with our corporate policy, the sales and marketing units at Johnson & Johnson Companies in South Africa are unable to take advantage of or use our professional education programmes and initiatives for commercial purposes.

Following the requirements set forth in the industry self-regulation codes (such as, MedTech and SAMED), educational support is offered to health care professionals and organizations in a transparent fashion, by serving notifications to the employer or supervising body (as applicable) of its beneficiaries, where the support being offered is disclosed, and by executing contracts in writing, outlining the terms of the support provided by our company to health care professionals and organizations. Johnson & Johnson Companies in South Africa also monitor the fulfilment of their professional educational arrangements, by reconciling the related interactions upon their completion.

The independence of healthcare professionals, and non-interference with their professional judgement is, and should be, inviolable. Johnson & Johnson Companies in South Africa therefore welcome local initiatives from industry, as well as healthcare professional groups, to tighten and enforce these rules, so as to make the playing field equal between all suppliers of goods into the health sector.

11 Structures, governance, costs and overlaps

One of the concerns relating to the implementation of the recommendations by the HMI is the two main structures to be set up, namely the Supply Side Regulator for Health (SSRH) and OMRO. Whereas interaction between OMRO and the OHSC is acknowledged in the HMI Report, the various components of the SSRH overlap with existing bodies and their powers and functions. Implementing aspects of the SSRH as independent, statutory bodies may also be quite costly, and draw from already scarce resources in the health sector or rely on skills that are virtually unavailable in the country (e.g. health economists with experience in HTA).

A regulatory impact assessment should accompany any new proposed structure, and the timelines for creating new statutory bodies, and the teething problems associated with that, as is currently the case with the MCC's conversion into SAHPRA, should be accounted for.

In general, the various findings of the preceding chapters should find application in chapter 10, and should therefore clearly respond to market failures, or risks of market failures, alluded to in such chapters.

The overlaps in the SSRH structure identified, include:

- Under the National Health Act's sections 36 – 40, the system for licensing of all health establishments, including private hospitals, must be set. This will be under the control of the National Department of Health, under the Director-General of Health. If properly implemented, there is no need for this.

The HMI should recommend criteria for licensing to be included to prevent, avoid or address issues identified in chapter 5 of the HMI Report in relation to the failure of the hospital-market.

- The coding system in terms of practices is a function allocated by law to the Council for Medical Schemes.

The HMI should recommend how the practice or facility coding system should be amended to address market failures and/or risks of anti-competitive behaviour and link the licensing system to the PCNS – practice code numbering system.

- Procedural and healthcare activity coding could be mandated and regulated under the National Health Information System and the relevant provisions requiring regulations on records and information under section 90(1) of the National Health Act. This is an absolute necessity in order to undertake health economic assessments and develop Alternative Reimbursement Models and, as the HMI points out, failed capitation models.

The HMI should recommend the implementation of the empowering frameworks to standardise and formalise the health services, medicines and device coding systems, including mandating ICD10-oding throughout the system.

- In terms of treatment guidelines, these already exist in the form of professional societies, including academics, the Essential Medicines List and Treatment Guidelines and the CMS treatment algorithms. Two pieces of legislation authorise their development – the Health Professions Act, 1974, setting scopes of professions and the specific professional activities, as well as training standards (i.e. how a healthcare professional should be trained to be competent as a professional) and the National Health Act's section 90(1) on the essential

medicines and equipment lists authorisation regulations on how these are to be set. The regulatory failure is last-mentioned.

The HMI should recommend the drafting and promulgation of regulations on the Essential Medicines- and Essential Equipment Lists under section 90(1) of the National Health Act.

- On the Pricing Regulator, the linkages to the previous RPL mechanism (under the National Health Act), if any, must be made clear. It should also be clear where the Medicines Pricing Committee (under the Medicines Act), if at all, would fit, and under which legal framework these price-regulatory or price-negotiation activities would take place. It also seems clear that, in order for healthcare professionals to enter into negotiations on price, or even on networks and ARMs, some leniency under the Competition Act would be required. It should also be borne in mind that many billing codes include or imply medical devices and/or medical device usage. There should be some space for input by the medical device industry in this regard.

The HMI should make clear where it envisages the Pricing Regulatory to be placed, legally, and how competition law constraints in these models, as well as learnings from the RPL High Court case will be overcome or addressed.

We take this opportunity to submit as Annexure 2, a diagram on the overlaps between the proposed regulatory bodies and existing bodies.

12 Conclusion

In broad terms, the regulatory framework forms the main thrust of the HMI Report. In this regard, incomplete and lack of implementation of regulatory frameworks that are in existence is one of the main challenges in the health market. The adverse impact that the non-implementation of these frameworks has on the market, impact on competition, impact on patient access and choice of medicines and regulated (i.e. safe, quality) medical devices needs to be carefully considered. In addition, where the answer has been the establishment of new regulatory structures to regulate and enforce, the transition has proven to be challenging, with the recent transition from the MCC to SAHPRA being a good example, where change management and organisational design seem to be vague and devoid of key stakeholder consultation.

In considering the establishment of new structures and regulations to address the concerns of the HMI, the first point of call should be ensuring the implementation of regulations already provided for in law. In addition, the proposal to establish new bodies/structures should be preceded by a process of assessing the mandate of existing bodies, the required resources (both financial and human capital) and the possible overlaps in mandates, i.e. it is recommended that a detailed regulatory impact assessment is conducted before any new entities are established.

Johnson & Johnson
WORLDWIDE GOVERNMENT AFFAIRS & POLICY

13. For further information

For further information or questions, please contact:

Kirti Narsai
Senior Director, Government Affairs & Policy, Sub-Saharan Africa

Johnson & Johnson WORLDWIDE GOVERNMENT AFFAIRS & POLICY

Johnson & Johnson
2 Medical Street
Midrand
South Africa
T: +27-11-265-1131
M: +27-82-901-2994
F: +27-11-265-1310
knarsai@its.jnj.com
www.jnj.com

Annexure 1
Principles to Consider when establishing HTA

Health technology assessment (HTA) needs to take into account the key principles of transparency, stakeholder engagement and independence to ensure full collaboration of stakeholders and to maintain rapid patient access to innovative medicines and procedures. HTA should remain independent of the regulatory process. All stakeholders should have reasonable access to the HTA process at all stages. Decisions should always involve input from specialists in the therapy area on the full range of benefits delivered by the technology. The independence of HTA agencies should be favoured over a process that is guided by political expediency; independent reviews lend greater transparency and bring broader perspectives to the assessment process. Decisions on pricing should be left to the developers of innovative technologies according to free market principles and not be linked to classifications based on the outcomes of HTAs. Specific cost-effectiveness thresholds may compromise the ability of manufacturers to decide freely on price.

Regulatory bodies, HTA and coverage bodies should work together to reduce uncertainty in product development for manufacturers, improve understanding of agencies' requirements and streamline access to new technologies for the benefit of patients. The regulatory decision on the safety and efficacy of a new technology (based on objective scientific evidence) should not be influenced by any potential 'non-coverage' decision (based on relative value). HTAs should help to speed up patient access to innovative medicines, devices or procedures if these are found to be cost-effective or to fill an unmet medical need. HTA should not be used covertly for justifying rationing or for cost containment. With HTA playing an increasingly important role in reimbursement decisions, governments must commit to rewarding advances in medical technology.

Devices are different from drugs

HTA should be fit for purpose and should take into account the key issues that differentiate medical devices from pharmaceuticals such as difficulties achieving blinding and user 'learning curves'. HTA hurdles need to be applied equitably with no inappropriate application of the evidence from one device to the class as a whole; therefore, all market entrants should be required to demonstrate the same degree of evidence as the innovator. The limitations of data from randomized controlled trials (RCTs) should be recognized and the validity of alternative sources should be considered by HTA agencies and decision-makers.

Role of early scientific advice

Early scientific advice from HTA agencies can be useful in identifying the evidence requirements of key decision-makers, thereby reducing the uncertainty of drug development programmes. For maximum

value, the advice needs to be available in time to inform key decisions relating to phase 2 or 3 development plans. Health technologies are developed for regional and global markets; therefore, early scientific advice on development programmes is likely to be sought from multiple decision-makers. Scientific advice should not be binding on any party, because it is impossible to address the needs of all stakeholders and decision-makers. The aim of early industry engagement is to reduce uncertainty in the development programme. While early scientific advice has clear value in pharmaceutical development, its value remains unclear for medical devices until interactions between regulatory, HTA and procurement become aligned.

Use of QALYs in decision making

The quality-adjusted life-year (QALY) should be only one of several factors considered by decision makers in determining whether or not a new healthcare technology should be reimbursed. Other considerations should include: burden of illness, including disease severity and unmet clinical need; therapeutic gain; efficacy and safety; budget impact; societal impact; degree of innovation; and other commercial arrangements such as access schemes and coverage with evidence development. The methodological limitations of the QALY should be explicitly recognized.

Patient Access Schemes

Patient Access Schemes (PASs) should be considered only when all other options for achieving market access have been exhausted, and the pros, cons and effects of a risk-sharing agreement have been analysed. PASs should not be used simply to drive down the acquisition costs of innovative technologies. Access schemes should be time-limited, with transparent and specific review criteria. Access schemes provide a mechanism for ensuring medicines or medical devices are available to patients, while addressing concerns about uncertainty of cost-effectiveness and/or treatment effectiveness. They are not a replacement for evidence generation. PASs are not new to healthcare; industry has entered into these schemes since 1994.

Coverage with Evidence Development

Coverage with evidence development (CED) is an appropriate tool to provide access to innovative technologies when there is significant uncertainty related to the use of that technology in routine clinical practice. Requests for CED need to balance the expected benefit of a technology with the additional value of further research.
CED should not be used as an output of the HTA process to restrict access to innovative medicines merely on the grounds of costs.

Companion Diagnostics

There is a need for enhanced pricing and reimbursement (P&R) paradigms that incentivize manufacturers of therapeutics to develop and introduce 'companion diagnostics'. Such paradigms should be considered along with other incentives through regulatory or industrial policy. It is important to align reimbursement with demonstrated clinical and/or economic value to health systems in order to encourage manufacturer investment in research and development programmes that will meet market access needs. When a companion diagnostic is part of the indication for use, policies are required on where the value is captured; such policies should be sufficiently flexible to account for situations in which a diagnostic may have value beyond its use in a particular personalized medicine (PM) strategy.

Role of indirect comparison

Health technologies are developed for regional and global markets; it is very unlikely that one development plan would be able to address all possible comparators desired by national agencies. A development plan should seek to demonstrate value against the key comparators for the majority of decision-makers and be designed so that data collected can be compared with external sources of evidence through validated indirect comparison techniques. The indirect comparison of two interventions is valuable in many situations and there is increasing use of this methodology.

Use of non-randomized controlled trial data

Developers should be able to demonstrate clinical efficacy/effectiveness of a medical technology using the most appropriate evidence available. Although RCTs are often considered to be the 'gold standard', in some circumstances they may be inadequate. Other forms of assessment, including observational studies, should therefore be accepted by health technology assessors. Evaluating new technologies solely in the clinical trial setting may, in certain circumstances, be misleading. Real-world data can be useful and are sometimes essential for valid HTA. Manufacturers should be able to submit health outcomes data to decision-makers throughout a product's life cycle. This evidence should receive appropriate attention and reward from HTA authorities and payers.