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VIA ELECTRONIC MAIL

December 12, 2014

Joao Veiga Malta
Anne-Katrin Arnold
The World Bank
1818 H Street, NW
Washington, DC 20433

Subject: Global multi stakeholder consultation – Developing the Proposed New Procurement Framework

Dear Mr Veiga Malta, Mrs Arnold and the colleagues on the World Bank Procurement Policy Review Team

Attached, please find Medtronic's views and contributions to the Global multi stakeholder consultation, based on the analysis of the following documents:

- PROCUREMENT POLICY (DRAFT) – July, 8 2014
- PHASE II: DEVELOPING THE PROPOSED NEW PROCUREMENT FRAMEWORK – July, 8 2014
- BORROWER'S PROCUREMENT PROCEDURES (DRAFT) – July, 8 2014

This submission is courtesy of an expert, global team at Medtronic, composed of Joao Costa, Clare Pan Wang and Justin Koester. I am pleased and honored to submit this to you on behalf of Medtronic globally, a company with immediate activities in 150 countries and duties in every country of the world.

We hope you will find our submission useful and we look forward to discussing our submission at your earliest availability.

Yours Sincerely

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MEDTRONIC, INC.

GLOBAL MULTI STAKEHOLDER CONSULTATION
Developing the Proposed New Procurement Framework

VIEWS FROM MEDTRONIC, INC.

Executive Summary:

- Procurement operations when applied to the Healthcare Sector must pursue different and sometimes conflicting objectives such as maximizing patient access (to new and safe technology) and effectively lowering total healthcare spending. Medtronic acknowledges these objectives and is actively engaged in promoting best-in-class processes that permit meeting said objectives.

- The multiplicity of solutions (products & services) offered by Medtronic serves as great evidence of the need for a differentiated approach that must focus on outcomes better perceived under the societal magnifier.

- Benchmarking the medical technology market and understanding its local and global players and dynamics is critical when developing adequate methodologies to assess value and adjust the procurements to the needs of the patients and health care systems throughout the world.

- Value for money in health care should be determined based on patient health outcomes per unit of currency spent encompassing both cost and non-cost factors.

- Effective medical device procurement will contribute to controlling costs and improving the quality of the health care system as whole which would maximize the utilization of limited public resources. To achieve this, Procuring Entities should assess upfront the desired clinical, healthcare, economic, and social outcomes.

- Process transparency is guaranteed through adequate communication of results and rationale to all bidders but also by implementing mechanisms that ensure that suppliers in the field of medical technology comply with the existing Codes of Business Standards.

- In this document the industry provides some input on a variety of topics from the composition of the contract award criteria to suggestions on how to incorporate new technologies during the contract term alongside with insights regarding supplier performance management and accountability and some additional thoughts around framework agreements, e-auctions, the concept of variants and the importance of the division of procurements into lots.

- Medtronic hereby presents its views and suggestions to support the World Bank's endeavors to improve procurement practices and outcomes.

PROCUREMENT POLICY (DRAFT) – July, 8 2014

VIEWS FROM MEDTRONIC

Comments and suggestions in regards to the 'Core Procurement Principles'

I. The World Bank envisages the concept of '***value for money***' ([1]) as one of the main principles guiding the conduct of procurement under the World Bank's Proposed New Procurement framework. The proposed definition is forward-looking and imposes disciplines on both procurement officials and suppliers, as it requires procurements to seek *the effective, efficient, and economic use of resources, which requires an evaluation of relevant costs and benefits, along with an assessment of risks, on a whole-life or life cycle costs basis.* Medtronic readily subscribes to and seeks to partner around such concepts and disciplines.

The *"evaluation of relevant costs and benefits"* for medical technology is not an easy task when procurement officials are dealing with differentiated technologies such as implantable devices. The task is complicated when a host of usually thousands of other technologies are used in hospitals, community health centers or at home and for self-care, with a broad scale of technology to offer from different perspectives (patient, health system, society). The complexity is further exacerbated, when one layers on the services that can be provided e.g. to address the inherent risks/benefits and impacts on outcomes for patients by health care professionals responsible for their safe implant/use, and also the service solutions to ensure cost-containment and ecological benefits avoiding waste.

Medtronic is committed to working with the World Bank and with the Borrowers in developing methodologies that enable procurers to better understand such technologies. Equally, Medtronic seeks to work with the Bank as it needs to often adjust the procurements to the needs of the patients and health care systems throughout the world. Economic and relevant financial implications will be taken into consideration as health is a pre-requisite for economic growth.

Medtronic is dedicated to support the World Bank, all Governments, and Healthcare Institutions in its pursuit of *"whole-life"* and *"life cycle costs"* of medical technology. Equally, Medtronic stands ready to provide extensive evidence as to the Industry's commitment to deliver high quality products and services to enhance clinical outcomes with a strong commitment towards the sustainability of health care in general and contribution to economic growth. The long-term 'cost of treatment' for chronic disease patients will be an important concept to ensure cost-containment and address healthcare system stresses. This should be evident in our suggestions and comments to the "BORROWER'S PROCUREMENT PROCEDURES" draft document under consultation.

[1] *Procurement In World Bank Investment Project Finance Procurement Policy (draft)* July 2014 - Page K-3

Value for money is deeply connected to one of the New Proposed Framework for Procurement under consideration: ***'Fit for purpose'***.

As mentioned in the draft of the Procurement Policy the ***Fit for Purpose*** principle has two equivalent applications: on one hand the procurement must be well-structured from a procedural standpoint, and on the other hand it has to be structured in a way that allows for the most efficient method to achieve the *"intended outcomes* (and] *to meet the development objectives and project outcomes"* ([2]). This last part is of crucial importance when procuring medical technologies considering the associated risk, value of the contracts, and inherent complexity of such technologies. Underlining the complexity of technologies, as most diagnose, manage treat or control chronic, non-communicable diseases (NCDs such as cancer, cardiovascular, diabetes, lung disease, etc.) the World Health Organization, in its Global Action Plan for the Prevention and Control of NCDs, has focused on the need for multi-sectoral action and the need to partner with the private sector to address NCDs. The private sector and Medtronic in particular is a key partner in this process.

Procuring medical technologies under the ***'Fit for purpose'*** principles requires procurement officials to estimate upfront the desired clinical, healthcare, economic, and social outcomes. Medtronic is working with procurement officials globally to define the appropriate and practical ways to demonstrate the added value of innovative medical technologies and services. This enables procurement officials to assess priorities and define expectations and requirements. Additionally, we emphasize the importance of involving industry early in the project and procurement design process, transparently and appropriately, in order to avoid 'No Bid Decisions' and to maximize competition.

The multiplicity of solutions (products & services) offered by the medical technology industry serves as great evidence of the need for a differentiated approach to the MedTech sector. The provision of medical devices should not be an automated transaction that disregards the need for adequate training before, during and after the use (installation, implant, etc.) of a technology. The level of risk is significant and evident in the public health debate. In fact Medtronic has moved towards the development and delivery of more affordable and cost-containing technologies and offerings, adjusted to the specific needs of the populations we serve throughout the world, yet continuously supporting the training and education of Health Care Providers (HCPs) and patients.

The ***'Fit for purpose'*** principle is also intimately linked to the principles of ***'Efficiency and sustainability'*** ([3]) in the sense that it is paramount that *"specifications and processes (...) are proportional to the value and risks of the procurement"* and we would add that they must consider the overall development objectives, namely the provision of timely, adequately accessible and affordable care in emerging economies. Thus, when applying these principles to the procurement of medical technologies, the definition of the specifications (requirements)

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[2] *Ibidem.*

[3] *Procurement In World Bank Investment Project Finance Procurement Policy (Draft)* July 2014, Page K-3

must be transparent, evidence-based and supported by a reasonable prior consultation of the market.

Benchmarking the medical technology market and understanding its local and global players and dynamics is critical when differentiating between the "mandatory requirements" from the so-called "*nice to have*" requirements. "Nice to have" requirements may have some value but should be considered only in the contract award criteria, and thus should not limit access to applicants that meet the mandatory, but not the contract award criteria under the scope of the World Bank's procurement procedures.

II. In regards to '***Integrity***' and '***Transparency***' ([4]) Medtronic as a whole has undertaken significant efforts to develop and implement the "*highest standard of ethics*" in the interactions between the industry and our clients (Governments, HCP, patients). The Industry is focused on supporting all initiatives ([5]) that allow for the proper management of actual, potential, or perceived ***conflicts of interest*** as a safeguard for purchasers, suppliers but ultimately for the patients who benefit from our technologies.

On the other hand '***Transparency***' also means open, clear and publicly available information regarding procurement procedures. Medtronic is pleased to confirm our support for the World Bank's emphasis on making sure that all "*relevant information must be made in an open manner publicly available to all interested parties consistently and in a timely manner (...)*". We further confirm our support for the World Bank's view stated thus: "*Transparency is established when all relevant aspects of procurement in an entity are available for appropriate scrutiny, supported by comprehensive documentation and disclosure*" ([6]). These allow for accountability for all stakeholders involved reducing the risk of conflicts that may lead to unnecessary litigation that can prevent patients to have access to the needed technologies that are lifesaving in so many cases.

[4] *Ibidem.*

[5] In line amongst other initiatives with **OECD's,** *Principles for Integrity in Public Procurement* (2009) Available at: http://www.oecd.org/gov/ethics/48994520.pdf

[6] *Procurement In World Bank Investment Project Finance Procurement Policy (Draft)* July 2014 - Page K-3

PHASE II: DEVELOPING THE PROPOSED NEW PROCUREMENT FRAMEWORK

VIEWS FROM MEDTRONIC

The World Bank's Vision: "Procurement in Bank operations supports clients to achieve value for money with integrity in delivering sustainable development."

PROCURING MEDICAL TECHNOLOGY IN THE SERVICE OF DEVELOPMENT

The World Bank's procurement framework governs borrowers acquiring the most appropriate goods, service and technology to promote the best development outcome. The reform of procurement practices of medical technology is expected to reach the potential of procurement appropriate to the purpose of development.

The appropriate procurement of medical devices (including implantables, diagnostics and In Vitro Diagnostics) is essential to achieve the development goals of the World Bank. Medical devices are essential for safe and effective prevention, diagnosis, treatment and rehabilitation of illness and disease. The achievement of health-related development goals, including the Millennium Development Goals depends upon proper procurement, management and use of medical devices which are of good quality, safe and compatible with the settings in which they are used. These technologies are developed and produced by Medtronic which shares the same goal of delivering sustainable development.

Medical device procurement as a strategic policy tool, which allows the Bank to achieve one of the two ambitious goals to end extreme poverty as well as the Bank's Health, Nutrition, and Population (HNP)'s strategic goals to strengthen health systems: to improve the Level and distribution of key HNP outcomes, outputs, and system performance at the country and global levels to improve living conditions, particularly for the poor and vulnerable.[7]

Access to medical technology is still a vital component of fulfilling the right to health ([8]) consistent with the Universal Healthcare Access aspirations and goals, to which we all aspire. Certain segments of the population, especially the vulnerable and the under-served in most countries are still struggling with the basic human right of access to necessary medical technology and related health service. If the Bank supports the clients to strengthen their public procurement policy, the benefits brought by medical technology access is directly transformational to the citizens, especially to the poor and the under-served.

The procurement framework not only supports access to healthcare, but also to maintain or regain positive health outcomes, and human socio-economic activity and well-being. Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. Illness is a determinant of poverty due to both excessive health spending

[7] The World Bank Strategy for HNP Results
[8] The Right to Health - Fact Sheet no.31

and loss of income due to nonparticipating in the labor market [9]. Health shocks—illness, accidents, disability can throw a household into poverty or become an obstacle to overcoming it [10]. Proper procurement of medical devices will lower the cost of long-term economic and socio-economic burden of families who are hit by health shocks. For individuals who are ill, medical devices extend life, promote mobility, improve quality of life and employability, and thus free them from the poverty trap.

Effective medical device procurement will contribute to controlling costs of healthcare system and improving the quality of health care system as whole which would maximize the utilization of limited public resources. Expensive and wasteful medical device procurements have been seen before in various settings due to lack of good procurement framework and technical knowledge of medical devices and health policy. The Bank's new, proposed procurement framework will set up good practice standards to strengthen healthcare systems—and will address many of these key challenges.

> ***It is important to define a differentiated strategy for medical technology-related procurements.***

Developing a global plan of action to secure sustainable funding for accessible medical devices for diseases that affect developing countries is in the interest of the Bank, the client countries and Medtronic. Lower and Middle Income Countries now face a double burden of increasing chronic, non-communicable conditions, as well as the communicable diseases which traditionally affect the poor [11]. On the macro financing level, the sustainable financing scheme to support a robust procurement policy ensures the implementation of the procurement framework.

The value of Medtronic often falls short of its remarkable potential especially in lower income country's financial capacities due to a multiplicity of factors. Sustainable financing of health systems is a prerequisite for a steady supply of medical technologies. Per capita expenditure on health care tends to be low in low-income countries, no proper diagnostic, treatment or rehabilitation services could be provided without the access to basic medical technologies.

Financing shortages also lead to supply gaps in relation to needed medical technologies of adequate quality in a timely manner. Supply systems remain understaffed, lacking knowledge to establish proper procurement policies in many countries. Financing solutions from the Bank with procurement knowledge transfer to boost self-sufficient medical technology procurement policies is in high demand.

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[9] *The Global Economic Burden of Non-communicable Diseases. A report by the World Economic Forum and the Harvard School Of Public Health*, World Health Organization September 2011

[10] *Beyond Survival:* Protecting Households From HealthShocks in Latin America The World Bank Stanford University Press June 2006

[11] *Global health risks mortality and burden of disease attributable to selected major risks* World Health Organization, 2009.

Medtronic has long been supportive of innovative financing for medical device procurements. Many models have been provided to co-finance big diagnostic medical devices, such as leases, term loans, and equipment rental under the available financing schemes.

The Medical Technology Market is diverse, segmented, technologically complex, and socially relevant

Market specific issues should be taken into account in procurement, especially for the MedTech industry. The Bank needs to be more conscious about the impact of procurement of Medical devices on local industries, where present, and its social impact.

The MedTech industry is a segmented industry, with a diverse combination of companies of different sizes and development levels.

Appropriate procurement is good for local innovation. Medtronic has developed new technologies specially geared to certain needs in low resource settings. Robust procurement policy for medical devices signals back to the MedTech industry of the true need of the market. Appropriate procurement policies and proper execution would incentivize the MedTech industry to develop solutions to address the available infrastructure and workforce resources. Adapting products and solutions to serve lower resourced setting with affordable prices would be a win-win result from procurement policy for both local industry development and development in general. The Bank has a key mandate in this area, which is supported by the Bank's proposed procurement changes.

Evaluation of the procurement of medical technology should be aligned with the impact evaluation of the development programs. The true cost of medical devices is beyond the initial purchase price. The cost of maintaining, ongoing operation, upgrade and disposal costs need to be taken into consideration. At the same time, the societal benefits of promoting quality of life should be taken into consideration. This should be accounted in the evaluation of development programs and the procurement evaluation for medical devices.

Capacity building in borrower countries – the future role of the MedTech Industry

Capacity building is an important policy tool to develop client capacities, especially for the MedTech industry.

Many medical technologies are advanced products that can only be effective in conjunction with expert training, advice and other health services. Procurement policy has to cover the full procurement cycle of medical devices, considering the implication for the life of the patient. And the full procurement cycle of medical devices should consider: workforce training to operate, install, or monitor; and a concept for spare parts; economies of scale – whereby the procurement of a larger quantity of medical devices in a region makes servicing devices in a given area easier and more efficient.

Due to the complexity of the MedTech industry, the client country government's knowledge of how to implement the procurement policy on medical devices should also be taken into consideration. In relation to other industries, and though diverse within the spectrum of the industry the advanced medical technology industry is still in the early stages of globalization: sales networks reaching globally, but manufacturing still concentrated in the USA, EU and other advanced economies and very little, by comparison, manufacturing actually occurs in low-resourced countries. Thus, the Bank's mandate to provide assistance to these countries is critical.

The MedTech industry and Medtronic are committed to working with the Bank on both levels--providing our best knowledge and also willing to transfer knowledge if appropriate and necessary. A sample list of international and local medical device industry associations is in the **Annex** and could be involved in any stage of the procurement for technical assistance and general procurement advice.

TRANSPARENCY & INTEGRITY

As stated throughout the documentation under the Bank's consultation process, transparency is crucial to achieve good procurement results. A clear definition of process and requirements serves as leeway to ensure integrity and transparency.

Process transparency is guaranteed through adequate communication of results and rationale to all bidders but also by implementing mechanisms that ensure that suppliers in the field of medical technology comply with the existing Codes of business Standards (Advamed; Eucomed, Medded, etc).

Integrity is not only related to the procurement process itself, but is also connected with the Industry's commitment to deliver adequate affordable technology considering patients' needs and development objectives.

In this document this topic is developed further in the section dedicated to the BORROWER'S PROCUREMENT PROCEDURES (DRAFT).

VALUE FOR MONEY & MEDICAL TECHNOLOGY

Many medical technologies involve risk assessment and long-term (positive) impact that are best assessed at the tender award stage to enable buyers to purchase the best value for money, so Medtronic supports the World Bank's view that "*borrowers* [should] *apply life cycle cost and cost-effectiveness decision making, which can be used to mitigate any higher upfront cost exposure and ensure delivery of optimum value for money.*" ([12])

[12] Page 20 section 41 *PHASE II: DEVELOPING THE PROPOSED NEW PROCUREMENT FRAMEWORK.*

For Medtronic, achieving **value for money in health care** is all about "(...) *patient health outcomes per unit of currency spent*" and "*encompasses both cost and non-cost factors*" ([13]). The non-cost factors include for example: efficient delivery; technical benefits/merits; safety, i.e., ability to lower or minimize adverse events or complications including hospital readmissions; clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-reported outcomes and patient satisfaction and preference; expenditure reduction on other healthcare products and/or services; warranty, maintenance, customer care and clinical training and support.

Other non-cost factors that are also important to highlight are the societal benefits, e.g. improved patient quality of life, reduction in spend outside the health budget (i.e. productivity and social care gains due to fewer missed days of work). These overall objectives for the Health Care system are paramount and distinguish the sector.

Procurement operations, when applied to the **Healthcare Sector,** must pursue different and sometimes conflicting objectives that can summarize as follows:

- Maximizing patient access (to new and safe technology);
- Effectively lowering total healthcare spending (e.g. economies of scale);
- Ensuring competition amongst suppliers;
- Increase process transparency (reduce corruption risks); and
- Standardization of processes (administrative efficiency).

Medtronic acknowledges these objectives and is actively engaged in promoting best-in-class processes that permit meeting said objectives in a clear and transparent way with the ultimate objective of providing solutions that maximize value for each dollar spent with medical technology, because "*value-based purchasing means procuring medical devices with reference to healthcare outcomes and not merely to satisfy technical requirements*" ([14]).

Medtronic endorses the OECD's view in regards to (Public) procurement and its move ***"away from the transactional focus of purchase order processing to a strategic role in government (...)"*** as ***"Procurement professionals** are asked to carry out **market intelligence analyses, to state and pursue several co-existing objectives, to handle complex contracting arrangements** and to execute and administer them"* ([15]).

Regarding the 'Complex Issues' identified on Chapter IV page 16 a reference must be made to a key statement on section 28: "***Public procurement can be a contributor to positive economic growth, particularly by encouraging access to contract opportunities by small and medium enterprises***". Medtronic agrees with the above statement as we are predominantly composed of small and medium enterprises. However it is worth mentioning that procurement policy can also play a relevant role promoting economic growth and efficiencies by supporting health care institutions delivering optimal health care outcomes sustained by technology that helps

[13] *Good Practices for the Procurement of Innovative Medical Technology*, ADVAMED, Nov 2014, Page 4.
[14] Ibidem, page 5.
[15] Page 20 para. 61 *OECD: Discussion paper on public procurement performance measures (Feb 2012)*

HCPs serving patients in recognition of the importance of the value of product in 'patient pathway'.

The World Bank's focus on value for money (VfM) and the confirmation that *"the best value for money is determined by comparing relevant benefits and costs on a whole-of-life or life cycle basis"* ([16]) provides sufficient leeway for Borrowers to focus development objectives rather than solely on cost-containment goals. Lifetime costs should not be restricted to lifetime of product but should also include the lifetime of the patient (especially those facing chronic disease).

The award criteria has to be "(...) **specify upfront logical, clearly articulated, comprehensive, and relevant**" within a minimum of 60% of qualitative aspects to be weighted. A detailed list of features to consider are listed below in the comments to the **BORROWER'S PROCUREMENT PROCEDURES (DRAFT)**, specifically in regards to the Most Economically Advantageous Tender.

For the procurement of Medical Technology the definition of minimum quality requirements is advisable as it is to use the award criteria to value additional features or services that can be valued by the purchaser. Having this in mind Medtronic strongly advises the World Bank to target medical technology supply contracts for the use of VfM evaluation in order to promote the identification, assessment, and comparison of the risks and benefits of the available technologies.

It is important to clarify in the Procurement procedures specific provisions that allow for alternative bids from suppliers based on the multiple technologies available in the market. In the comments to the BORROWER'S PROCUREMENT PROCEDURES (DRAFT) we provide more inputs on this matter under the topic 'Variants'.

ENGAGING MEDTRONIC

The medical devices market is diverse, highly competitive, contributes to economic growth through research, development and manufacturing while improving the efficiency of health care systems through earlier disease detection and more effective treatments that reduce the economic burden of disease and the cost of care via innovations that help patients worldwide live longer, healthier, and more productive lives.

Considering this complexity indeed a ***"constructive and non-adversarial relationship with the supply market is quintessential to fully reap the benefits of well-designed public procurement processes"*** ([17]) so it is clearly a great step forward that the World Bank is taking the lead breaking down ideological barriers and dogmas that prevent buyers from reaching out to potential suppliers during a pre-tender stage as it is acknowledged by the Bank on page 18 section 35.

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[16] Page 17 section 32 *Phase II: D the proposed new procurement framework.*

[17] Page 22 para. 67 OECD: *Discussion paper on public procurement performance measures* (Feb 2012)

Engaging and working with experts is a best practice ([18]). It is recommended that experts, including industry experts, be permitted meaningful input into the price negotiations and product evaluations as Medical technology procurement by its very nature requires specialist procurement skills and cannot effectively be procured in the same way as commodities.

INNOVATION CYCLE

The innovation cycle of Medtronic is fast-paced and *"innovation is about finding new approaches – including new technology as well as new applications of existing technology, and new models for services and solutions - in order to improve patient outcomes, enhance efficiency, or extend the reach of care"*. Procurement procedures applied to the purchase of medical technology have to acknowledge this fact and must ensure adequate paths to allow for patient access to the newest technology available in the market at fair cost, as *"innovation can improve the quality and efficiency of health services, thus contributing to improved population health (social value). For example, innovation can decrease waiting times, length of hospital stays, morbidity and mortality. In addition to obvious social and patient care benefits, innovation also contributes to the affordability of healthcare services (economic value)"* ([19]).

An innovative technology can have a higher entry cost but can have a significant positive impact in terms of clinical outcomes. Hence it is crucial not to create any disproportional barriers to innovation such as very long term supply agreements that do not include provisions that incentivize suppliers to offer the best technology available to patients.

It is advisable, amongst other measures, to develop guidance for procurement professionals on how to develop pilot schemes for new medical technology based on the input from the Industry and the health care professionals- and other interested parties.

MEDTRONIC'S VISION ON THE ROLE OF PROCUREMENT

In the 'Conclusions' sections, namely on section 72 it is stated that the Procurement Framework recognizes two roles for Procurement: borrower capacity building and fiduciary assurance over the use of resources. The industry agrees with this statement. Nonetheless we believe a third role should be distinguished especially for medical technology and for health care as whole.

The third role is to serve as a policy tool to align the World Bank's economic and social development objectives and the Borrowers' own objectives. As stated above, Procurement is not just a purchasing procedure that can include services, works and products. For the health care system in particular wise, well thought-out procurement can have a significant impact in terms of clinical outcomes and driving efficiencies and economic and social development.

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[18] In line with the Bank's management views stated on Page 26 sections 64 and 67of *Phase II: Developing the proposed new procurement framework.*

[19] *Good Practices for the Procurement of Innovative Medical Technology*, ADVAMED, Nov 2014, Page 4.

A well-defined strategic plan for the procurement of medical technologies created and disseminated at the highest level will contribute significantly to "*achieve greater value for money and* [to] *ensure that limited public resources are spent wisely*". Indeed "*an informed focus on innovative, constantly evolving technology, procured with a full awareness of societal benefits and healthcare outcomes, is a critical factor in sourcing successful healthcare solutions*" ([20]).

[20] *Good Practices for the Procurement of Innovative Medical Technology*, ADVAMED, Nov 2014, Page 2.

VIEWS FROM MEDTRONIC

PROCUREMENT PLAN & NEEDS ASSESSMENT IN HEALTH CARE

As mentioned in page C-14 section 2.15 the minimum structure of the procurement Plan should include *"a brief description of goods, works, consulting and non-consulting services required for the project"* within this Plan the Borrowers should also reflect the Procurement Strategy set out previously. This strategy and the Procurement Plan must state the projected clinical outcomes ([21]) based on the identified need and the projected plan on how to fulfill that need.

Specifically for medical technology, identifying the most appropriate procurement strategy to achieve best value for money requires the following ([22]):

(a) Identification of the value deficit i.e. project-specific **health care development objectives** and **clinical needs/outcomes**;
(b) Assessment of the **borrower context** (epidemiology; health care professionals training and education needs; installed base) and **implementation capacities** (potential suppliers presence in the market and technical expertise), to identify physical, institutional, and skills constraints and risks (life-cycle costing approach; etc.);
(c) Risk analysis at the country and project level, and **risk management actions** to address the identified risks (assess potential conflicts of interest; engagement with the industry; assessment of compliance with Industry standards in terms of business conducts);
(d) **Analysis of the market** to determine its **national** and **international dynamics** and capacities.

The procurement strategy for the purchase of Medical Technology must have *"clearly defined objectives and needs that are specific, measurable, achievable, relevant, and time-bound"* each means that the objectives are to be aligned with the overall health care development objectives.

FINANCIAL THRESHOLDS & CONTRACT VALUE AND RISK

The supply of medical technology and the provision of related services should be aligned with the level of risk associated with the use and the life-saving features that many technologies have. The considerable impact on the health of the populations that will benefit from technology should increase the level of focus in regards to each procurement procedure.

[21] For additional guidance on 'Needs assessment' applied to medical technologies, see ADVAMED - Good Practices for the Procurement of Innovative Medical Technology, Nov 2014, page 11.
[22] Based on section 2.6 Page C-11 and Page 67 from *Borrower's procurement procedures (draft)*.

In response to the principle set out by the Proposed Framework for Procurement, Medtronic suggests the adoption of a specific financial threshold for supply contracts for medical technology.

The threshold should be defined to ensure that for medical technology ICB (International Competitive Bidding) is the rule, this should be reflected on the Procurement Procedures (Page C-16 Section B.1.1.) in line with the reference made on section 3.22 on page C-19.

The calculation of the estimated value of a contract (procurement) shall be based on the total amount payable, net of any applicable taxes, as estimated by the buyer, including any form of option and any renewals as explicitly set out in the procurement documents. In case the procurement is to be awarded in the form of separate lots, account shall be taken of the total estimated value of all such lots.

TECHNICAL SPECIFICATIONS & MEDICAL TECHNOLOGY

Technical Specifications (TS) must be set out in the procurement documents as they enunciate the **characteristics** required of works, service or supply in compliance with the Core Procurement Principles, namely the **Fit for Purpose Principle**, i.e., the TS must be linked to the object of the procurement and proportionate to its value and its objectives may also specify whether the transfer of intellectual property rights will be required.

For Medical Technology the abovementioned **characteristics** may include:

- levels of performance (e.g. number of algorithms in a pacemaker);
- design for all requirements (including accessibility functions for disabled persons);
- dimensions or safety (including the procedures concerning quality assurance);
- packaging, marking and labelling, user instructions and production processes and methods;
- user instructions, production processes;
- the specific process or method of production; or
- any relevant feature to assess the product life cycle.

Technical Specifications may be **Functional:** those which define the function or duty to be performed by the product; based on **Performance:** those which define the performance required from the device; or purely **Technical:** those which define the technical and physical characteristics of a device/technology in terms of such things as physical dimensions, power input and output, etc.

Technical Specifications should not refer to a specific make or source, or a particular process which characterizes the products or services provided by a specific company. As a rule no reference should be made to trade marks, patents, types or a specific origin or production as an exception any such reference could be made if accompanied by the words "or equivalent". That being said it is crucial to define coherent, patient centered TS that enable the buyer to get the best value for money in any procurement.

The minimum requirement (i.e. the TS) is the first step to define the acceptable quality level for the supply of the products and provision of services hence the buyer should collect information upfront about the technology to be purchased and apply high quality standards that ensure the adequate level of protection for HCPs and patients.

Notwithstanding **functional and performance specifications are preferred** because they encourage alternative innovative solutions with the focus on results, not on technical characteristics. These can be perceived as too restrictive increasing the risks of legal challenges to the procurement based potentially unjustified obstacles to competition. Frequently, the ecosystem of healthcare to deliver care faces several simultaneous breakdowns in the path to good care. Several procurements may resolve the breakdowns through technology acquisitions, but increasingly, a solutions-based approach, requiring functional and performance specifications may resolve the systems breakdowns more efficiently and aligns the incentives of both the procurer and solution-provider to perform optimally. For example, facing multiple ecosystem breakdowns to diagnose and treat chronic otitis in India, the Medtronic Shruti program designed an innovative smartphone-based otoscope and application [the technology], combined with health worker task-shifting and patient referral support. Launched in 2013 and currently operating in India and Bangladesh, Shruti has resulted in over 40,000 patient screenings by specially trained community health workers, and approximately 8,000 patients diagnosed with chronic ear infections and disabling hearing loss, all at an appropriate cost to the healthcare system in India. Suppliers/solution providers must be given the opportunity to adequately demonstrate compliance with the technical requirements.

THE MOST ECONOMICALLY ADVANTAGEOUS TENDER (MEAT)

The contract award criteria must be transparent and capture patient benefit alongside healthcare system benefits and broader socio-economic value (societal perspective). To determine the right aspects (factors) to consider under a contract award criteria the involvement of healthcare stakeholders (e.g. patients, users, clinicians and suppliers) is important to ensure alignment and ultimately value for money.

To evaluate the total cost of care over the patient lifetime using healthcare economic data can support the buyer to better understand the value of a therapy of product under a Total Cost of Ownership approach that requires collaborative work between the health care system and the industry.

The contract award criteria must reflect the World Bank's development objectives and promote a "system" perspective that looks at health outcomes and efficiencies at the healthcare system level, a real 'Fit for Purpose' approach to procurement.

To this point Medtronic would suggest adding the following to the list available on Section 2.8 Page C-12:

(a) Purchase price; up-front costs ([23]);

(a.1) Estimated savings in the mid- to long-term including efficiencies achieved in other areas due to introduction of the device;

(a.2) societal benefits, e.g. Improved patient quality of life, reduction in spend outside the health budget (i.e. productivity and social care gains due to fewer missed days of work).

(b) Installation and commissioning costs;

(c) Training **& Education costs or actual savings;**

(d) Servicing and maintenance **and projected upgrade costs;**

(e) Improved quality in delivery;

(f) Improved efficiency in delivery;

(g) **Reliability and service level of the vendor/manufacturer incl.** warranty periods and guarantees;

(h) Sustainability savings, e.g., lower fuel consumption; and

(i) Decommissioning and disposal costs;

(j) Technical benefits/merits;

(k) Safety features that protect Health Care Professionals & Patients;

(l) Clinical effectiveness, including reductions in morbidity or mortality or as **measured by patient-reported outcomes and patient satisfaction and preference; For therapeutic devices, outcomes appropriate to the intended use, such as improved exercise tolerance or range of motion activities of daily life. For diagnostic devices, earlier detection of disease enabling earlier diagnosis and staging, hence better choice of therapy or less intensive intervention.**

The Industry is of the opinion that the items listed above will help Borrowers to implement real fit for purpose procurements that pursuit *"the most advantageous combination of cost, quality and sustainability to meet development requirements"* ([24]).

Specific comments to **Section IV. DEVELOPMENT OF EVALUATION AND CONTRACT AWARD CRITERIA** on page C-42 and onwards:

In regards to section 4.1 (e) the sentence highlighted should be added:

> *"(e) The evaluation criteria are appropriate to the* **objectives/outcomes**, *type, nature, market conditions, and complexity of what is being procured; and"*

The same on section 4.3.:

[23] *"In this context, cost means consideration of the whole-life or life cycle cost, as appropriate; quality means meeting a specification that is fit for purpose and sufficient to meet the customer's requirements; and sustainability means economic, social and environmental benefits (...)"* Page C-15 section 3.1.
[24] Ibid.

"4.3 In evaluating bids/proposals, initial price may not always be the best indicator of value for money; therefore, as appropriate, life cycle costing should be considered **(e.g. for medical technologies).**"

For medical technology on Section 4.4. any domestic preference should be limited to presence of local technical support or technical consultants and not local production. This is important to ensure adequate quality of products for the protection of patients' safety.

On section 4.6 (b) a reference to the objectives of the procurement should be added in conjunction with the Borrowers' requirements:

"(b) ***Quality*** *means having sufficient well-developed and clearly stated specifications to ensure that the outcome of the procurement meets the borrower's* **objectives and** *requirements; and"*

On Section 4.10 the World Bank envisages the possibility for Borrowers to consider the past performance of bidders and/or consultants. Generally speaking this option is indeed advisable and can improve the outcome of procurement. However, this option includes some implementation challenges that can significantly increase the risk of future litigation if the assessment of said prior performance is not objective and transparent. Further guidance on this provision should be added in the Procurement Procedures.

Life cycle cost

On the Glossary section (Page C-50) to the concept of 'Life cycle cost' the following highlighted sentence should be added to fully capture the value inherent to these methodologies:

"Life cycle costing is applicable at activity level as evaluation criteria for the procurement of an asset once the best specifications to achieve value for money and fit for purpose have been determined. It includes the cost of an asset throughout its useful life such as initial purchase price, installation, operation and maintenance costs over the life of the asset, and residual value at the end of its useful life **including prospective savings for the Borrower and the overall development objectives.** *It is calculated on a net present value basis and it is only used for comparison of bids."*

Value for money

On Page C-51 the following should be included in the definition of 'value for money':

"(...)
Value for money is a central consideration through the strategy development and procurement planning process to ensure the most appropriate supplier(s) is selected for the right reasons and at a cost that represents the optimum combination of life cycle cost (costs of ownership over the anticipated life) and quality to meet the borrower's **objectives/projected outcomes and** *requirements.*
(...)"

Value adds ([25])

A "value-add" implies that something (a service or a product) is added to an initial offer (baseline offer). The baseline offer has a value of its own; however to increase its value within a procurement process, the supplier (proponent) may include in his offer additional services or features ("value-adds") that are connected (or not) to the provision of the services that are the object of the procurement initiative.

A value-add incentive is an offer by a supplier, over and above the primary goods or services (above the baseline) being purchased, with the intent to increase the total value received by the customer.

Requesting and/or evaluating value-add incentives may increase the level of risk within the procurement process and result in bid disputes if the value-added incentives are disproportionate or unconnected to the contract's object. Taking this risk into consideration the Ontario Ministry of Finance developed some rules (guidelines) applicable to Government Procurement for *the use of value-add incentives:*

> *1. Value-add incentives must be directly relevant and transparently connected to the given procurement;*
> *2. Organizations should openly state the desired enhancements. The procurement document should list the specific value-add incentives that would be considered beneficial to the organization and order of preference, such as on-site technical assistance or product upgrades;*
> *3. **Cash should never be requested as a value-add incentive and, if received, should only be used to reduce the final price of the bid;***
> *4. Organizations must establish criteria to evaluate value-add incentives prior to commencement of the competitive procurement process;*
> *5. The weighting assigned to value-add incentives must be stated in the competitive procurement document;*
> *6. Organizations should ensure that the weight assigned to value-add incentives demonstrates that they are not considered a major influencing factor;*
> *7. Value-add incentives that are outside the scope of the goods and/or services being procured or related operational improvements should not receive any points; and*
> *8. Value-add incentives should be evaluated as a separate and final step after all other rated criteria.*

Organizations willing to receive value-add incentives must ensure that they maintain the principles of open, fair and transparent procurement. *To maintain such transparency, value-add incentives must not be considered unless they are explicitly requested in the competitive procurement documents.*

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[25] This section contains extracts from Ontario's (Canada) Ministry of Finance *"Broader Public Sector Procurement Directive - Implementation Guidebook 2011.*

In these guidelines we can see the Bank's concern in having an open, transparent and fair public (Government) procurement so the acceptance of value-added incentives must directly connected to an *ex ante* general acceptance that allows all contenders to improve their offers with these incentives.

A specific reference to 'Value adds' could be included on Page K-93 section A5.32 as follows:

A5.32 These (...)
Examples of these are:
(...)
f) Value adds

The definition of 'Value adds' could be included on the GLOSSARY.

NEW TECHNOLOGY PROVISIONS

Considering that many device categories go through rapid and frequent incremental improvement, rapid innovation frequently lowers health system or societal costs by lowering patient risk, lowering radiation dosages, improving surgical approaches/techniques, enhancing robustness, extending product life, reducing the need for technical support, simplification and/or ensuring better/more consistent outcomes to patients and healthcare practitioners. Due to these often immediately quantifiable improvements, the procurement of medical technology should include mechanisms that are transparent and flexible enough that allow for the inclusion of new technology, oftentimes, even during the contract term.

The MedTech Industry is recognized for having a far faster development cycles than drugs for example. Therefore it is a reasonable practice from innovators to expect an increase in the price of the device supported by the added value to the patient and to the system. This can be achieved under the 'Price adjustments' provision described on Page K-91 section A5.26.

In short, medical technology procurements must take into consideration the medical devices fast paced innovation cycle and should consider including contractual mechanisms that incentivize companies to offer their most recent technological innovation at a fair price.

PRICE RENEGOTIATION, VOLUMES, PAYMENT TERMS

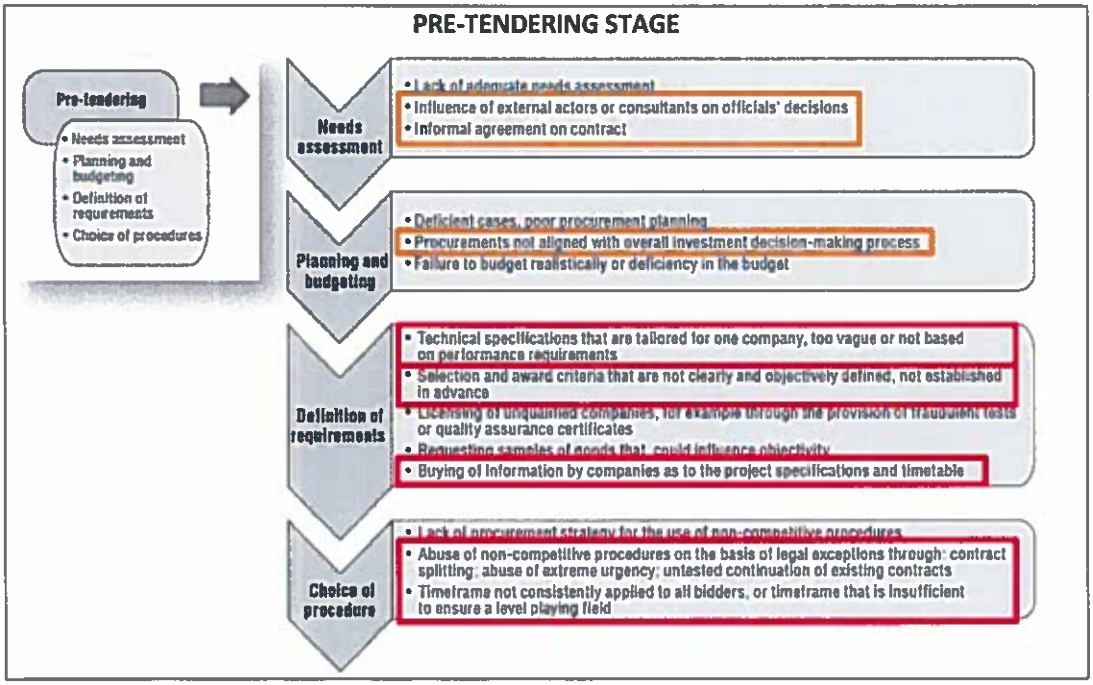
In line with our suggestions above we recommend consistent, enforceable contract terms and volume commitments that are known to suppliers at the outset of the tendering process, and advocate volume bands as one way to differentiate prices in the tender.

We recommend also the implementation of robust mechanisms to ensure payment of suppliers in due time. Thus providing suppliers enough confidence on the market that allow for even better commercial offers to be presented in each procurement.

ACCOUNTABILITY & SUPPLIER PERFORMANCE MANAGEMENT

"Providers awarded contracts must meet their contractual commitments, supporting the World Bank and its borrowers in maximizing development outcomes" ([26]): for Medtronic business conduct integrity and accountability are paramount for achieving our goals of adequately supporting health care system to treat more patients the best way possible.

Ensuring integrity and transparency throughout the procurement process must include specific measure to mitigate any risks during the various stages of the procurement cycle. Below we highlight the main risks within the different stages as identified by the OECD ([27]):



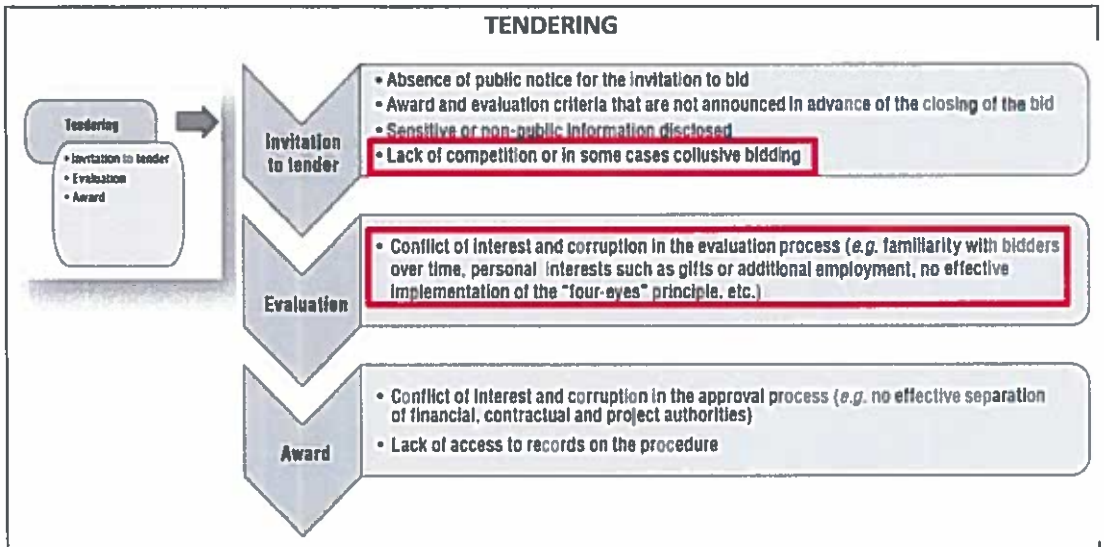
[26] Page C-4 *Borrower's procurement procedures (draft) – July, 8 2014*
[27] OECD: *Principles for Integrity in Public Procurement* (2009).

At the 'Needs Assessment' phase, transparent interaction between buyers and potential suppliers is crucial and the draft of the Borrowers' Procurement Procedures places sufficent emphasis on the matter so no additional measures or suggestions from our Industry.

At the Planning and budgeting stage we believe it would be worth having clear general guidelines from the World Bank to its Borrowers in regards to the inclusion of health care/clinical outcomes as an necessary objective to consider during the preaparation of procurements and related decision making process.

In regards to the drafting of technical specifications and award criteria our comments and recommendations are considered adequate to mitigate the identified risks.

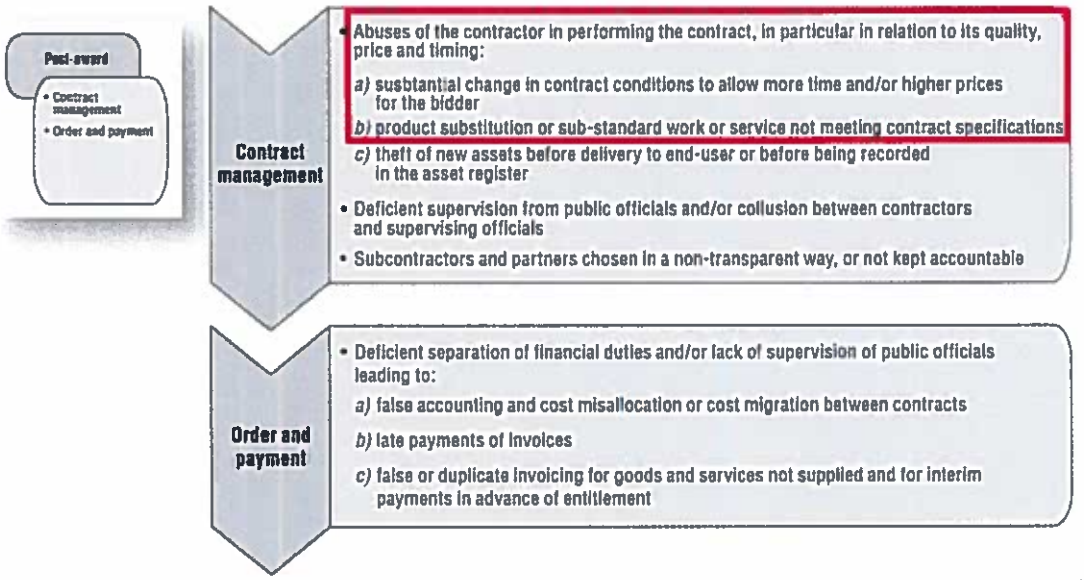
The inadequate choice of procedures is directly linked with our recommendation above regarding ICB and the financial thresholds.



The risks at the tendering stage are avoided by applying the transparency principles that the World Bank is considering in the new Borrowers' Procurement procedures but also by requiring from potential suppliers compliance with applicable Codes of Conduct coming from

the Industry itself.

POST-AWARD STAGE



The post-award stage must be carefully monitored in order to ensure compliance with the contract terms and agreed outcomes. Accountability from all parties involved is key to ensure real value for money.

FRAMEWORK AGREEMENTS & E-AUCTIONS

In the Procurement Procedures, namely on section B.1.1.7 Page C-17, Framework Agreements (FA), are categorized alongside Competitive Dialogue. Medtronic's view that FA and E-auctions should be mentioned separately as they are procurement tools and not necessarily procurement procedures as the Competitive Dialogue or the Modified ICB. This should be reflected in a rearrangement of section B.2.1.6. "Specialized Competitive Procurement". A separate section named "Procurement Tools" should be created to include Framework Agreements and e-Auctions.

A Framework Agreement can be a good tool to optimize processes and to help identify the adequate supplier(s) for a specific product or service in the Medical Technology Field but only for low-risk devices.

E-auctions that should not be used for the purchase of medical technology as it disregards non-cost factors that, as demonstrated above, as essential for good procurement of medical technologies. E-Auctions' focus on price and not on value for money do not fit the purpose when dealing with medical technology.

VARIANTS

For the procurement of Medical Technology, technical diversity available in the market should be embraced although bounded by adequate Technical Specifications as mentioned above. To allow for alternatives and innovation the proposed Framework should make clear reference to 'Variants' as a concept that allows for suppliers to propose alternative solutions that can meet the requirements but differs from the solution set out by the buyer. Variants must be evaluated under the same criteria as the base offer and its submission should only be possible where a tender which is not a variant has also been submitted.

A specific reference to the inclusion of ***Variants*** should be added to the above proposed section 'Procurement Tools' and on Section 3.98 page C-40.

DIVISION OF PROCUREMENTS INTO LOTS

The division of procurements into lots is an advisable way to promote the access to contracts to different companies, promoting innovation and technical differentiation.

The Borrower's should be able to decide whether or not that may award a contract in the form of separate lots and must also be able to determine the size and subject-matter of such lots.

The award criteria should apply individually to each Lot having in consideration that more than one lot may be awarded to the same tenderer.

The Borrowers may decide to award contracts combining several or all lots if expressly mentioned in the procedure official documentation. It is also advisable that Borrowers indicate the lots or groups of lots that may be combined.

A specific reference to the inclusion of ***Lots*** should be added to the above proposed section 'Procurement Tools' and on Section 3.98 page C-40.

REFERENCES:

ADVAMED: *Good Practices for the Procurement of Innovative Medical Technology*, Nov 2014
Available at: https://advamed.app.box.com/s/igezu5yezzpiov68pidt

THE CONFERENCE BOARD OF CANADA: *Innovation Procurement for Medical Devices: Driving Health System Improvement*, April 2014
Available at: https://advamed.app.box.com/s/igezu5yezzpiov68pidt

EUROPEAN COMMISSION, DIRECTORATE-GENERAL FOR RESEARCH AND INNOVATION: *Public Procurement for research and innovation - Expert group report - Developing procurement practices favourable to R&D and innovation* - September 2005 available here: http://bookshop.europa.eu/en/public-procurement-for-research-and-innovation-pbKINA21793/)

EUROPEAN COMMISSION, *GREEN PAPER on the modernisation of EU public procurement policy Towards a more efficient European Procurement Market*. COM/2011/0015 final Brussels, 27.1.2011. Available at:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2011:0015:FIN:EN:PDF

KAHLENBORN, WALTER; et al. *Strategic Use of Public Procurement in Europe – Final Report to the European Commission* MARKT/2010/02/C. Berlin: adelphi. (2011). Available at: http://ec.europa.eu/internal_market/publicprocurement/docs/modernising_rules/strategic-use-public-procurement-europe_en.pdf

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), *Principles for Integrity in Public Procurement* (2009)
Available at: http://www.oecd.org/gov/ethics/48994520.pdf

ONTARIO'S MINISTRY OF FINANCE, *Broader Public Sector Procurement Directive - Implementation Guidebook* Canada 2011
Available at:
https://www.doingbusiness.mgs.gov.on.ca/mbs/psb/psb.nsf/Attachments/BPSProcDir-Guidebook-pdf-eng/$FILE/bps_procurement_guidebook-pdf-eng.pdf

World Bank, Healthy Development, *The World Bank Strategy for Health, Nutrition, and Population Results, 2007*

World Economic Forum and the Harvard School Of Public Health, *The Global Economic Burden of Non-communicable Diseases, 2011*

World Health Organization, *The Right to Health - Fact Sheet no.31, 2007*

World Health Organization, *Global Health Risks Mortality and Burden of Disease Attributable to Selected Major Risks, 2011*

ANNEX: Sample (Non-Exhaustive) LIST OF INTERNATIONAL AND LOCAL MEDICAL DEVICE INDUSTRY ASSOCIATIONS

- Advamed
- EUCOMED
- MEDEC
- MITA
- Global Medical Technology Alliance (GMTA)
- AUSMEDTEC
- MITG
- MMDA
- KMDIA
- THAIMED
- IMEDA
- SK MED
- AUSTROMED
- UNAMEC
- CZECHMED
- BVMED
- APIDIM
- IMDA
- ASSOBIOMEDICA
- NEFEMED
- POLMED
- APORMED
- FENINMED
- Swedish MedTech
- FASMED
- CAMDI
- CIIFICCI
- AMDD
- CADIEM
- ABIMED
- ABIMO
- ABRAIDI
- ANDI
- AMID
- MECOMED
- SAMED
- ARTED