Nathealth seeks subsidy on medical equipment import

Abhishek Chakraborty

Kolkata: Healthcare Federation of India (Nathealth) is demanding a reduction in the import duty of medical devices. According to its secretary general, Anjan Bose, the medical technology industry needs to be streamlined in order to thrive.

Bose told TOI: “While building a hospital, 35%-40% of the investment is on med-tech. Hence, import duty on medical devices needs to be rationalized. Inverted duty structure and increase of import duty to the extent of 7%-8% is adding to the cost of healthcare technology and delivery.”

The domestic demand for med-tech was relatively low. Hence, the government needed to work out ways in order to encourage the local manufacturers of healthcare devices, he added.
SMART HEALTHCARE
SPELLBINDING REALM MAKING IMPOSSIBLE POSSIBLE

SPECIAL ARTICLES
- HSCC (India) Ltd: Enhancing Healthcare Space via Innovative Patient Management Technology
- BECIL: Creating Synergy between Healthcare & Technology to Offer Healthcare at Doorsteps

SPECIAL FEATURE
ONLINE PHARMACY BUSINESS
Standing at Crossroads

Aloli Kumar
Mission Director (NHM) Department of Health & Family Welfare, Government of Uttar Pradesh

Aamir Bawas
Chief Executive Officer Sanwara Ventures

Herman Phitrad
Chief Operating Officer Bluear

Joseph Alexander
Chief Executive Officer eWise Healthcare IT Solutions Pvt Ltd
Inclusion of Stents in NLEM

Good or Bad?

Time to debate on the pros & cons of the inclusion of stents in NLEM to comprehend both pain & gain points

In order to comprehend the new changes in the healthcare sector, eHEALTH Magazine has started a new section ‘Current Debate’ to comprehend the overall consequences of all the new announcements. Of the all debates, the inclusion of stents in the National List of Essential Medicines (NLEM) caught not just ours but even the healthcare stakeholders’ attention. We aim to create right debates and arguments by bringing all opinions on one platform. In order to understand the entire debate, we raised the following question before the stakeholders:

Will the inclusion of stents in the NLEM put restrictions on patient choice & impact ‘Make in India’ campaign?

Read the excerpts below:

Dr Ashok Seth
Chairman of Fortis Escorts Heart Institute, New Delhi and Head, Cardiology Council of Fortis Group of Hospitals

Unquestionably, the cost of stents needs to come down. The cap on pricing is a good way to do it, but the methodology has to be sound. The pricing is just one of the aspects. The methodology needs to include all the stakeholders in a manner that we deliver the best to the patient at a low cost, of which capping of price is just one of the aspects. It cannot be at the expense of quality and at the expense of outdated products. It should also not stifle new technologies, new creations, new direction, and research and development (R&D).

In the medical device segment, especially in stents, in the last 20 years we have seen so many dramatic changes from crude stents to the finest stents to dissolvable stents, which have come with a large input of finance, research and science. By the way, research and development cost a lot of money. These ingredients bring up good stents. Stents manufactured in small outlets may or may not have the quality efficacy and can actually be sold at low cost, such as Chinese products. Until we actually have robust systems in place to say that the stents are safe and efficacious as are the stents approved by the Food and Drug Administration (FDA), then we would not be able to differentiate between good, bad and ugly. As such, price regulations are needed. The price regulation should be based on science, research and quality.

My first choice of stents would be a FDA-approved stent. For an FDA to approve a device, it has to be pivotal, large and randomised studies, which are monitored in a span more of more than 1 year. It needs to deliver the promised benefits without any side effects and not just ensure that the person survives. Our regulations allow a 6-month study on 100 people to determine patient safety. At the moment, the minimum sample for
No. The Indian Medical Association (IMA) also has been asking for their inclusion in the NLEM. Whether made in India or imported, as long as they are Drugs Controller General of India (DCGI) approved they are okay to be used in clinical practice. Bringing them under the NLEM Make in India campaign will have a boost. Capping is important in the stent price as 80 percent of the cost of treatment is borne out of our pockets.

Facts
- The high burden of coronary heart disease in India has made it a public health problem. Most blockages require either stents or a bypass surgery.
- Coronary stents now are labelled as essential drugs under the Drugs and Cosmetics Act. Stents can be indigenously made or imported. Based on efficacy, safety and performance, new generations of stents are made available in the market on a periodic basis.
- Drug-eluting metallic stents are of choice, though bare metal stents are still useful in selected situations. Currently, there is no definite superiority among currently available metallic drug-eluting stents in terms of mortality outcome.
- Stents are now in the national list of essential drugs under the category, bare metal stents; drug-eluting stents (includes metallic stents and bioresorbable vascular scaffold or biodegradable stents).

Anjan Bose
Secretary General, NATHEALTH

We have been constantly engaging with several government agencies to explain that due to their uniqueness, medical devices cannot be treated through policies and frameworks made for pharmaceutical products. However, the notification on 19th July shows that we still have some work to do.

If we are going to be a country producing cheapest stents not accessed for quality, this is going to impact patients adversely. At the end, no one is measuring the outcomes. In order to ensure larger benefits and also maintain the world-class quality, either the Government of India says that we will have capping on price, but there will be a differentiator, which is in terms of research, science and proof. The price capping is acceptable when we create ceiling in the entire system. There is also great discrepancy as not all stakeholders are included in the policy changes, which is a stumbling block.

We may fill our market with cheap alternatives of stents that go through substandard research and development (R&D). Our pricing policy should integrate the rewards for creating an effective device. The side effects of non-quality stents are that the stent may actually clot or rethrombose post implantation and thus needing reimplantation process.

We need to have profound regulations and involve experts in the entire policymaking. We need to bridge the gap between the private sector and government.
Dr Arun Kumar Chopra  
Interventional Cardiologist and Director, Fortis Escorts Hospital Amritsar

While evaluating the pros and cons of the recent inclusion of stents in the NLEM, it is important to keep the following points in mind:

Firstly, at present, the capping on stent prices is only applicable in government hospitals, and it has not been extended to private institutions in India.

Secondly, the price cap has also been implemented on only two categories of stents, namely drug-eluting stents and bare metal stents. There is as yet no guideline regarding the biocompatible stents, which are also available since December 2012.

And lastly, the exact price cap has not been finalised yet, making it impossible to determine if large stent makers will be able to provide latest generation stents at the given price.

Overall, the step has been welcomed by the medical fraternity, for it will help make quality heart care accessible to the masses. We can expect a large section of the society to benefit from the move for they will get access to reasonably good and sometimes very good stents at affordable prices. The tremendous variation in stent prices from one hospital to another will also disappear making the entire process more transparent.

Regarding its impact on the Make in India movement, it may or may not boost it. If international stents which are backed by years of research and data are available at the same price as locally made stents, people are bound to opt for them. However, if quality Indian stents are available at a much lower cost, then a majority of the population is certain to opt for them.

Talking about a restriction inchoate, those who do not have any financial constraints may be affected if the government does not allow a premium category of stents to continue to exist in the market. If they do, it really will be a win-win situation for all.

Dr OP Yadava  
CEO & Chief Cardiac Surgeon - National Heart Institute

The capping of price of drug-eluting and bare metal stents is indeed a welcome step and I applaud the efforts to this effect.

It will increase affordability and help bridge the gap between the demand of angioplasty or stenting procedures and the actual numbers carried out, a felt need of the medical fraternity – both the patients and the doctors.

This move will certainly give an impetus to the ‘Make in India’campaign as more and more entrepreneurs will be encouraged to develop quality Indian stents because their demand will increase, despite a part-pass reduction in their prices.

Corruption in medicine in the form of kickbacks for devices is an open secret and the culpable industry shall, hopefully, be constrained to address and eradicate this ubiquitous malady.

And as a domino effect, the menace of “Un-necessary” stenting shall be reigned in and transparency shall be the buzzword.

However, reduced funding for research and development (R&D) will lead to compromise in quality, especially sans any credible regulation. This proposal will succeed depending on the government funding for R&D.
NATHEALTH expresses concern over inclusion of stents in NLEM

Our Bureau, Mumbai

NATHEALTH, a forum comprising of both healthcare providers and medical technology companies, have taken strong exception to the inclusion of coronary stents in the National List of Essential Medicines 2015 (NLEM 2015) by the Union health ministry recently.

A coronary stent is an essential device for ensuring optimal outcomes for coronary/cardiac procedures. Selecting the appropriate stent for each procedure should be the choice of patients and medical practitioners in order to ensure such optimal outcomes. Bringing stents under the ambit of a pharmaceutical-style pricing control regime will restrict their inflow and usage into India, and thus, negatively impact patient choice and outcomes, NATHEALTH said.

“Medical procedures in India are among the most affordable in the world, which is a combination of cost of devices and services. Any notification should be considered only if it can bring down the overall cost of treatment for the patient without denying them the options to avail the treatment of their choice. Additionally, such notifications significantly impact the ‘Make in India’ attractiveness of the country,” said Milan Rao, chairman, Medical Technology Forum – NATHEALTH.

The inclusion of coronary stents in the NLEM is contradictory to the governments recently expressed desire to separate medical devices from drugs by proposing a new Act which is proposed to be tabled in the upcoming Winter Session. The government recently added coronary stents to the NLEM 2015. This will effectively bring the product under price control, NATHEALTH said.

Additionally, the committee of experts constituted by the health ministry, in its report of ministry of health, has indicated its desire to bring other cardiology products under NLEM as well. The reason cited for this action is the government’s desire to improve the number of percutaneous cardiac interventions (angioplasty).
Inclusion of Stents in NLEM

Good or Bad?

In order to comprehend the new changes in the healthcare sector, eHEALTH Magazine has started a new section ‘Current Debate’ to comprehend the overall consequences of all the new announcements. Of all debates, the inclusion of stents in the National List of Essential Medicines (NLEM) caught not just ours but even the healthcare stakeholders’ attention. We aim to create right debates and arguments by bringing all opinions on one platform. In order to understand the entire debate, we raised the following question before the stakeholders:

Will the inclusion of stents in the NLEM put restrictions on patient choice & impact ‘Make in India’ campaign?

Read the excerpts below:

Dr. Ashok Seth
Chairman of Fortis Escorts Heart Institute, New Delhi and Head, Cardiology Council of Fortis Group of Hospitals

Unquestionably, the cost of stents needs to come down. The cap on pricing is a good way to do it, but the methodology has to be sound. The pricing is just one of the aspects. The methodology needs to include all the stakeholders in a manner that we deliver the best to the patient at a low cost, of which capping of prices is just one of the aspects. It cannot be at the expense of quality and at the expense of outdated products. It should also not stifle new technologies, new creations, new directions, and research and development (R&D).

In the medical device segment, especially in stents, in the last 20 years we have seen so many dramatic changes from crude stents to the finest stents to dissolvable stents, which have come with a huge input of finances, research and science. By the way research and development cost a lot of money. These ingredients bring up good stents. Stents manufactured in small units may or may not have the quality efficacy and may actually be sold at a low cost, such as Chinese products. Until unless we actually have robust systems in place to say that the stents are safe and efficacious as are the stents approved by the Food and Drug Administration (FDA), then we would not be able to differentiate between good, bad, and ugly. As such, price regulations are needed. The price regulation should be based on science, research, and quality.

My first choice of stents would be an FDA-approved stent. For an FDA to approve a device, it has to be proved, large and randomised studies, which are monitored in a span more than 1 year. It needs to deliver the promised benefit without any side effects and not just ensure that the person survives. Our regulations allow a 6-month study on 100 people to determine patient safety. At the moment, the minimum sample for...
To: The Indian Medical Association (IMA), who have been calling for their inclusion in the NLEM. Whether made in India or imported, as long as they are Drugs and不容易 (Drugs and Control) approved, they are okay to be used in clinical practice. Bringing them under the NLEM makes this task a lot easier.

Campaign: It is important to focus on the need for an additional 50% per cent of the doses of medicines to come out of the private sector.

Facts
- The high numbers of coronary heart disease in India has made it a public health problem. Most blockages require either stents or bypass surgery.
- Coronary stents are now included as essential drugs under the Drugs and Control Act. Medicines can be independently made or imported. Based on efficacy, safety, and performance, newer generation of devices are made available in the market on a periodic basis.
- Drug-eluting metal stents are of choice, through balloon catheter placement in selected situations. Currently, there is a definite superiority among currently available metal drug-eluting stents in terms of mortality, stent thrombosis, and restenosis.
- Stents are now in the national list of essential drugs under the category, bare metal stents, drug-eluting stents (including metallic stents and biodegradable stents).

A clinical study by the FDA for a drug gave up to 90% patients, depending on the end point, and even up to 90% patients for 5 years. The FDA doesn't even recommend formal study and 100 people study and the medicine is 1 year study followed by 2 years and 5 years.

Recently, the opening of prices of stents will also ensure the expansion of access. As a result, we would not proceed from the present generation. We need to question the inclusion of stents that have gone through extensive clinical trials with smaller doses that haven't. This price opening offers innovation and foreign investment needed for encouraging research and technology. Part of the money comes out of research with the need to create new technology designs and concepts. Here all the multinational are looking at manufacturing stents locally. We also want to make sure that stents are now done worldwide results from across the world.

We are going to be a country producing stents and stents and assessing the quality. This is going to impact patients adversely. At the end, we can see measuring the outcomes to bring this number down to less than 50%. It is essential to maintain the world-class quality, unless the Government of India says that we will have opening on prices, but there will be a differentiation, which is in terms of research, science and proof. This price opening to acceptable when we see results leading to the entire system. There is also great disparity as not all stakeholders are included in the policy changes, which is a stumbling factor.

We may ask our market with cheap alternatives of stents that go through substantial research and development (R&D). Our pricing policy should integrate the rewards for creating an effective device. The side effects of poor quality stents are that the stent may actually clot or result in post implantation, thus needing explanation process. We need to have profound organization and involve experts in the entire policymaking. We need to bridge the gap between the private sector and government.

Anjan Bose
Secretary General, NAIHEALTH

We have been constantly engaging with several government agencies to explain why our efforts are needed to maintain medical devices cannot be treated through policy and frameworks made for pharmaceutical products. However, the situation on India is not that we still have some work to do.
**Dr Arun Kumar Chopra**
Interventional Cardiologist and Director, Fortis Escorts Hospital, Andheri

While evaluating the pros and cons of the recent initiative of steel in the NABH, it is important to keep the following points in mind.

Firstly, at present, the concept of steel prices is only applicable to government hospitals, and it is not been extended to private institutions in India.

Secondly, the price gap has also been implemented on only two categories of steels, namely drug-coated steels and bare metal steels.

There is no yet any guidelines regarding the reimbursement status, which are also available since December 2016.

And finally, the exact price gap has not been finalized yet, making it impossible to determine if large steel makers will be able to provide latest generation steels at the given price.

Regarding its impact on the Make in India movement, it may or may not boost it. If international steels which are backed by years of research and data are available at the same price as locally made steels, people are bound to opt for them. However, if quality Indian steels are available at a much lower cost, then a majority of the population is certain to opt for them.

Tapping into the restriction to states, these who do not have any financial constraints may be affected. If the government does not allow a premium category of steels to continue to exist in the market, then they do, it will really be a win-win situation for all.

**Dr OP Yadava**
CEO & Chief Cardiac Surgeon - National Heart Institute

The concept of drug-coated and bare metal steels is indeed a welcome step and I support it for essentially four reasons:

- It will increase affordability and help bridge the gap between the demand of angioplasty or stenting procedure and the actual numbers needed.
- As a result of the above, the medical fraternity – both the patients and the doctors - will certainly give an impetus to the Make in India campaign.
- More and more entrepreneurs will be encouraged to develop quality Indian steels because their demand will increase, despite a predetermined reduction in their prices.

Corruption in medicine in the form of kickbacks for doctors is an open secret, and the culpable industry shall, hopefully, be castigated to address the situation at hand.

And as a domino effect, the menace of “Unnecessary” stenting shall be reduced in and transparency shall be the buzzword.

However, reduced funding for research and development (R&D) will lead to commoditization in quality, especially in any credible regulation. This proposal will succeed depending on the government funding for R&D.