



Establishing Health Technology Assessment in Russia

An Interview with Vitaly Omelyanovskiy

Director, Center of Comprehensive Health Technology Assessment
Ministry of Health, Russian Federation



Vitaly Omelyanovskiy

Vitaly Omelyanovskiy, MD, PhD, DSc, is a Professor of the Presidential Academy, awarded the Certificate of Merit of the Federal Assembly of the Russian Federation, an initiative of the Federation Council Committee on Social Policy for his many years of dedication, hard work, and contributions to the improvement of the legislation of the Russian Federation on the issues of public health and health economics. He is a Head of the HTA Research Center, Institute of the Applied Economic Research, a Chairman of the Expert Board of Healthcare of the Russian Council Committee on Social Policy, a Chairman of the Board of the National Center for Health Technology Assessment in Healthcare of the Russian Federation, and the President of the ISPOR Russia HTA Chapter.

You have been given the responsibility for the establishment of the Center for Comprehensive Health Technology Assessment (Center) at the Russian Federation's Ministry of Public Healthcare. Congratulations on such an important and high profile position. I am sure this will have a great effect on market access in Russia.

Thank you. We have not yet finalized the establishment of the Center which I have led since May 2015. It was originally responsible for the certification of medicine, and we have been going through the process of evaluating the aim, goals, and responsibilities – as well as the name – to meet the changing needs of our healthcare system.

You said in a recent presentation that we will witness increasing transparency of health technology assessment (HTA) development in the years to come in Russia. I'm sure our readers will be pleased to hear this. Would you outline the motivation for this push for transparency?



This interview was conducted by Kevin Marsh, PhD, Senior Research Scientist and Senior Director, Modeling & Simulation, Evidera.

Discussions on HTA began in Russia in 2009 when the GDP was higher than it is now, and there was a significant investment in the healthcare system. Recently the economic situation has worsened, so we began working with relevant stakeholders, including medical societies, political officials, etc., to think about the need for HTA. There was an agreement that decisions about investments in medicines needed to be made in a more independent and transparent manner.

For the last three years, Russia has implemented a DRG [diagnosis-related group] system as a way of controlling hospital spending, so now we will have HTA and DRG approaches to control spending in our healthcare system and make the system more efficient and transparent.

Could you provide an overview of the process for implementing new HTA approaches in Russia and the timeframe over which this will happen?

Starting in 2014, our government implemented a system where a Minister of Health would invite experts from different federal organizations, such as universities and medical centers, to provide expertise on the inclusion of medicines on essential drug lists, reimbursement lists, etc.

Our work starts there. We have to coordinate this process and improve its transparency, including working with expert groups to assess their knowledge and use their expertise in the best ways; educating stakeholders in the use of HTA; and developing methodologies and decision-making criteria.

This process will begin in November 2015, and we need to do this before the next version of the Essential Drug List (EDL) is created, which will start in August 2016. My hope is that by then we will have an improved process based on different rules, skills and procedures. This gives us approximately six months to develop a new methodology and processes. Once the processes are established, we will communicate these requirements, guidelines, and methodologies to industry, expert organizations, and all key opinion leaders to ensure everyone's expectations are aligned. In the end, we want to ensure appropriate assessments are being made on every level.

I appreciate that the Center is still a work in progress, but can you say anything about the likely scope of the Center? For instance, one of the novel features of the Russian system is a mix of federal, regional and other funding

sources. Do you anticipate that system would remain the same? And if so, where does the Center fit in? Is the Center just intended to support federal decision making?

I see that both the federal and regional levels will still have a place in the system for at least the next five to ten years. Russia is a very big country and we have more than 80 regions with different systems and budgets. I believe we will have federal decisions, and the Minister of Health would like these to establish the minimum care that everyone would have the opportunity to receive, with individual regions being able to provide care on top of this minimum, but they would be obliged to at least meet this minimum.

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In terms of the specific technologies that the Center will consider, is the role of the Center to be assessing all technologies that are applying for the Vital and Essential Drug List?

First of all, let me say that in accordance with our federal law, HTA is only to be used for the assessment of medicines. Views are changing, however, and it is the hope that in the coming years HTA will be applied not only to medicines, but to different technologies like medical devices. I also expect to see potential changes in clinical guidelines in accordance with the principles of HTA.

Yes. The Essential Drug List is a federal responsibility, and all spending from the federal budget should be assessed by our Center. First we will start with medicines, but I hope this will eventually include medical devices and other technologies as well.

Would there be any special provision made for special cases like oncology or orphan drugs? And do you anticipate assessments being done retrospectively or just prospectively for new technologies?

This is a difficult challenge and a controversial topic. I believe we will be involved in these assessments since federal spending would be involved. Many of these products are very expensive, so input will be needed on which products should be prescribed. However, making the process transparent, and creating and disseminating a methodology, will be challenging. We will look at different approaches, such as multi-criteria decision making (MCDA), to help overcome these challenges. There is a huge lobby from orphan drug companies and patient groups to make these treatments available, so there is a lot of work to be done to identify how to make these treatments available, negotiate with all key stakeholders, and create agreement among all parties.

You mentioned MCDA. Is that a method that you would like to see play a role in Russia?

I would say yes. From my point of view, it is a very useful and effective system to make assessments. Unfortunately, conventional HTA cannot cover all the different aspects of decision making, especially when thinking about efficacy, safety, and economic issues. We know that MCDA could be used not only in medicine, but also in many different areas where we need to make decisions about investment where there are many factors to consider.

When we speak about MCDA in the healthcare system, I see this being used in something like orphan drug evaluation. We have to think about safety, efficacy, and economics, but also about when the disease will start, when it will end, and all the quality of life issues associated with it. MCDA would allow us to think more widely and incorporate the interests of the many parts of the society to come to an agreed upon decision. It is my dream to use MCDA and we are in the process of achieving this. We are thinking about how to use MCDA to prioritize the diseases where we need to provide treatment at a federal level. This methodology would help us in creating a transparent process and in pushing officials to think in this direction.

You alluded to the role of budget and price in the assessment of technologies. What role do you see the Center's methodology playing in determining the price of a technology ?

To be honest, I do not see that happening. I would say that the process of fixing the price and making a decision about inclusion on the EDL is a different organization, and we would not be involved in the process of negotiation

between industry and payers about the characteristic of the product and expected price. We dream about this type of involvement, and we have invited representatives from different countries to teach us about this negotiation pricing, but so far this does not exist in Russia. For now, we would like to connect the decision making process about inclusion on the EDL with fixed pricing by using economic studies, for example. When we ask companies to provide the needed clinical economic analyses, the companies should indicate their expected price and show the results of their economic studies. I do not see this happening within the next two years. This is very difficult, however, and is not my decision or the Minister of Health's decision; this would be a change to the federal law requiring a very long political process.

Do you anticipate that the assessments that the Center undertakes will be made public so that they are transparent?

The process of making these decisions, seeing who participated and what the arguments were on both sides, will be available on the Internet and visible to the public. Just over the last two weeks, there was a negotiation process about the revision of the EDL. My agency was not included because we officially start in 2016, but we contributed to the reporting of the decision. So the first achievement is visibility and transparency. Second is the criteria for decision making. There is still plenty of work to be done to optimize the process, and that is where our Center will begin.

Is there anything else you would like to share with our readers about the changes occurring in Russia's healthcare system and health technology assessment process?

There is a great deal of interest in this topic in Russia right now, and I am encouraged by the emphasis being put on the efforts to improve our overall processes. I realize that as head of the Center of Comprehensive Health Technology Assessment in Russia there is a great deal of work ahead of us and it will not be easy. Moreover, I fully expect there will be challenges along the way and it will take time to make these system changes, but I am also looking forward to the possibilities that lie ahead for us. The creation of my agency is movement in a positive direction to bring better processes, guidelines, transparency, and education to our healthcare decision making.