Do We Have The Right Medicines?

Every time we hear that patients in the region have access to much more advanced medicines than us, despite paying the same or less than us for healthcare, we wonder what's wrong with our system. The answer is a complex one

We asked our respondents, among them leading practitioners and managers of health institutions and pharmaceutical companies, where Serbian health insurance stands today, in relation to the EU and the countries of the region, when it comes to the procurement of adequate and modern medicines to treat serious illness.

ANA GOVEDARICA
GENERAL MANAGER, ROCHE SERBIA

MONEY IS JUST HALF THE STORY

THOUGH SOME SIGNIFICANT IMPROVEMENTS WERE MADE OVER THE LAST THREE YEARS, SERBIA STILL LAGS BEHIND BOTH EU AND NEIGHBOURING COUNTRIES. HOWEVER, THE OPENNESS OF THE PAYER AND THEIR READINESS TO NEGOTIATE WITH THE INDUSTRY HAS GREATLY INCREASED

Generally speaking, low GDP determines, or specifically limits, the ability of a country to fund its health system, including medicines. However, it is very indicative that Serbia invests more in its health system as a whole than Bulgaria (€295 vs. €272 per capita) and slightly less than Romania (€295 vs. €328 per capita), but Serbia, on the other hand, has the lowest level of funding for innovative medicines (€59 vs. €83 and €59 vs. €84 respectively). This is just a short monetary illustration of deviations in health system funding that doesn't favour the availability of modern medicines. As we all know, the timing of availability is as important as the level of funding. In this context, the average time for patient access – equating to the period from drug registration to the granting of reimbursement – is around 900 days in Serbia, whereas the same parameter in Slovenia is 494 days, in Bulgaria 535, in Croatia 479 etc.

The openness of the payer and readiness to negotiate with the industry has increased greatly. This resulted in more than 30 manage entry agreements signed with several payers who are on hold, awaiting the additional budget that's expected to be granted from the central budget.

It is evident in all EU countries that finances collected from mandatory health contributions are insufficient when it comes to meeting patients' needs for medicines. Thus, through analogy with essentially all EU countries, where the state intervenes and provides additional funding for innovative drugs, Serbia has to undertake the same – to coordinate state finances with the finances of the Health Insurance Fund in order to compensate for the shortfall between the level of health contributions collected and real patients' needs.

New reimbursement models should also be introduced. Manage entry agreements helped in taking a significant step forward, but it is time for new models, such as sharing risk models, which are also well known as pay per performance.

IN LINE WITH ESSENTIALLY ALL EU COUNTRIES, WHERE THE STATE INTERVENES AND PROVIDES ADDITIONAL FUNDING FOR INNOVATIVE MEDICINES, SERBIA NEEDS TO UNDERTAKE THE SAME – TO COMPENSATE FOR THE SHORTFALL BETWEEN THE LEVEL OF HEALTH CONTRIBUTIONS COLLECTED AND REAL PATIENTS' NEEDS

Pharmaceuticals companies in Serbia register all innovative medicines they have in their portfolio. The quality of available medicines definitely meets international standards fully, thanks to EU process mirroring by ALIMS, as well as the very stringent policies of all pharma companies present on the local market. Those innovative medicines are manufactured in the same manufacturing plants, using the same quality of starting materials and the same technology as for EU countries.

KSENIJA PURKOVIĆ

COUNTRY DIRECTOR
AT ASTRAZENECA, SERBIA

GOOD WILL IS HERE

COMPARED TO OTHER COUNTRIES IN THE REGION, SERBIA MANAGED TO INTRODUCE SOME NEW MEDICINES IN THERAPIES IN A TIMELY MANNER, WHILE IT COULD HAVE BEEN QUICKER IN SOME OTHERS. THIS DOESN'T MEAN THAT THE HEALTH INSURANCE FUND OR THE MINISTRY OF HEALTH DON'T HAVE AN EAR FOR PATIENTS' NEEDS

AstraZeneca is among the world's leading pharmaceuticals manufacturers and research & development companies, with nearly 65,000 employees worldwide. As such, we are improving the lives of millions of patients across the globe, primarily in four main therapy areas – oncology, respiratory, cardiovascular and metabolic diseases. We have been present in Serbia for nearly two decades, with a relatively modest presence in medications, but we look forward to working more closely with our partners – the Ministry of Health and the Health Insurance Fund – and have more room to contribute to patients' well-being locally.

The Serbian population has relatively good access to innovative medicines, but – given that research in the pharmaceutical sector is quite dynamic and productive in global terms – Serbia and other countries of the region obviously cannot afford to include all products that are available in other more developed and financially potent countries. To be more precise, compared to other countries of the region, Serbia manages in some therapy areas to introduce new medicines in a timely manner, while in some other areas, such as those that are more narrowly focused, it could have been quicker. This does not mean that the Health Insurance Fund or the Ministry of Health don't have an ear for patients' needs, especially nowadays, but rather that some other areas were simply more in focus and within available budgets at the time. In terms of our portfolio, we still haven't had a chance to

ASTRAZENECA WILL TRY TO BE A CONSTRUCTIVE PARTNER TO THE GOVERNMENT OF SERBIA, AND TO EXERT ADDITIONAL EFFORTS TO MAKE SOME OF OUR FLAGSHIP PRODUCTS AFFORDABLE LOCALLY, IN PARTNERSHIP WITH INSTITUTIONS

introduce to patients some of our leading products for the treatment of lung cancer, ovarian cancer, type 2 diabetes and acute coronary syndrome. When they become available locally, these products will significantly improve the quality of life of patients and we sincerely hope they will find their way to patients soon.
Nevertheless, we are happy to see the genuine commitment of institutions to improving the situation. Both Serbian Health Minister Zlatibor Lončar and National Health Insurance Fund Director Sanja Radojević-Škodrić are working hard with their teams to ensure the availability of new innovative medicines to the population, despite limited funding. This means that manufacturers also need to be open to dialogue with institutions and to help them bridge the financial gaps whenever possible.

COLONEL RANKO RAIČEVIĆ PH.D.

HEAD OF THE NEUROPSYCHIATRIC CLINIC OF THE MILITARY MEDICAL ACADEMY (VMA), PRESIDENT OF THE SOCIETY OF SERBIAN NEUROLOGISTS

HUGE ADVANCEMENT MADE

WITHIN THE SCOPE OF ITS ECONOMIC CAPACITIES, THE REPUBLIC OF SERBIA IMPROVES, RESPONSIBLY AND CONTINUOUSLY, THE SCOPE OF TREATMENT AND DIAGNOSTICS OF THE TOUGHEST MEDICAL CONDITIONS AND DISORDERS, AND IN THAT SENSE WE CAN TALK ABOUT AN IMPROVED AND MORE CERTAIN PERSPECTIVE FOR THE PERIOD AHEAD

At the very start of this conversation, I must note point out that there are many more competent respondents to provide answers to these questions in our country, both in the field of medical workers and, especially, in the Serbian Ministry of Health and RFZO [National Health Insurance Administration]. However, as a doctor, citizen and member of professional expert organisations, I will present my position, first for neurological conditions and diseases, and then my general stance regarding the quality of healthcare.
Thus, as president of the Society of Neurologists of Serbia, I claim responsibly that the neurological service in Serbia ranks among the best European neurological schools in terms of education, competence and monitoring of the latest findings and achievements in both a diagnostic and a therapeutic sense. This is also my impression of the overall medical community in Serbia, which is testified to by the results of the recent ranking of our healthcare system, which has advanced significantly in all segments. Nevertheless, there is awareness in the neurological community of the fact that modern

therapies are not available to all patients, especially when it comes to innovative medicines. This particularly applies to patients with multiple sclerosis. However, as a member of the RFZO Central Committee for Medicines, I have witnessed huge efforts of all structures in the country to improve this situation in the more recent period. We have already achieved some progress in terms of increasing the number of patients on immunomodulatory therapy, with medicines already registered and approved by the RFZO of the Republic of Serbia. Given that "people are happy to believe in that which they love", I, as a neurologist, primarily want to see shifts in neurology, and they are already happening, but we must all together – in the medical professions, but also in society as a whole – be aware of the fact that numerous serious illnesses, conditions and disorders exist that also require some new therapy.

With this in mind, last year alone, the Republic of Serbia – with Ministry of Health and RFZO, and on the basis of proposals from the National Commission of Experts, and with the great work of the RFZO Central Commission for Medicines – managed to provide innovative medicines for melanoma, psoriasis, hepatitis C and other diseases, which is a huge advance in the treatment of these patients. Within the framework of its economic capacities, the Republic of Serbia works responsibly and continuously to improve the scope of treatment and diagnostics of the most serious medical conditions and disorders, and in that sense we can talk about a better and more certain perspective for the period ahead.

What can we do that doesn't just boil down to modern therapies with innovative drugs?

It is very important to have constant awareness and to build empathy and solidarity in our society at all levels, because sick people don't only have health problems, but also social, economic and personal problems. They don't only feel muscle weakness, deformities, surgery, high pressure and stomach pains, rather there are many other situations in which they feel unequal and deprived – and whether that's objective or subjective is not the most important thing. What can we do as a society, as individuals, neighbours, friends, doctors? We can provide them with access to a swimming pool, walking promenade, theatres and their own buildings; ease their search for employment, organise educational actions, interactive workshops, talk, advise, listen, console. These solutions that are seemingly only technical can improve their quality of life significantly, regardless of the type of therapy they receive. We have to grow accustomed to thinking differently. Society, and each one of us individually, should endeavour to enable these people (and not only those suffering from neurological diseases) to feel like equal members of society, because we shouldn't forget that we can all find ourselves "on the other side" at one point.

INTRODUCING INNOVATIVE DRUGS IS IMPORTANT, BUT IS NOT ENOUGH. IT IS NECESSARY FOR NEUROLOGISTS TO RETURN TO HEALTH CENTRES, AS THIS WILL HAVE FAR-REACHING POSITIVE ONSEQUENCES ON THE QUALITY OF TREATMENT AND SAVINGS IN DIAGNOSTICS AND THE TREATING OF NEUROLOGICAL DISEASES

This doesn't mean that there's no need to insist on an even greater degree of availability of innovative therapies, but I will use this opportunity to again emphasise the need to return neurologists to health centres, as that will also have far-reaching positive effects on the quality of treatment and savings in diagnostics and the treatment of neurological diseases and disorders, first and foremost in preventative programmes that are high quality but less expensive.

SANJA RADOJEVIĆ -ŠKODRIĆ PH.D.

DIRECTOR OF THE NATIONAL HEALTH INSURANCE FUND

MODERN THERAPIES AVAILABLE TO PATIENTS

MANY INNOVATIVE DRUGS WERE INTRODUCED IN THE PREVIOUS PERIOD THAT WILL IMPROVE THE QUALITY OF HEALTH OF THOSE SUFFERING FROM DISEASES. SOME OF THEM AREN'T EVEN AVAILABLE TO PATIENTS IN COUNTRIES THAT ARE RICHER THAN OURS

The shared aim of the Ministry of Health and the National Health Insurance Fund (RFZO) is to provide modern therapy with affordable access to insured people, and to this end we are undertaking activities in order to ensure continuity in the placement of new innovative medicines on the List of Medicines in accordance with professional opinions and available financial resources.

Thus, in mid 2018, a new list of medicines was published that included the addition of new innovative drugs for the treatment of chronic lymphocytic leukaemia, hepatitis C and breast cancer, which represent extremely expensive therapies, but also the latest therapies used in the most developed European countries. By placing on the list two new innovative medicines for the treatment of breast cancer that are used in Europe's most developed countries (Germany, France, Italy etc.), an enormous advance has been ensured in terms of the treatment of this most common malignant disease among women.

Likewise, the RFZO adopted its List of Medicines at the end of December 2018 which, in accordance with expert opinions and the financial resources available, included the addition of two new innovative medicines for the treatment of psoriasis, which provides access to modern biological therapies at the expense of the RFZO for those afflicted with this disease. Moreover, for those suffering with metastatic melanoma, a new therapeutic option has been provided because the group of immunotherapy options contained on the List for the treatment of BRAF negative metastatic melanoma

has been extended to indicators for the treatment of BRAF positive metastatic melanoma.
It is emphasised that providing innovative therapy, coupled with the sustainability of healthcare financing, is a global challenge that's also being faced by much richer countries.
Thus, in terms of the use of medicines from List C of the List of Medicines, which lists the most expensive innovative medicines for treating the most serious diseases, the resources of the RFZO to compensate for these medicines has increased by about four billion dinars over the past five years. Specifically, RFZO funding available in 2014 for medicines contained on List C List of Medicines amounted to around 5.67 billion dinars, while RFZO funding for these same drugs in 2018 amounted to about 9.7 billion dinars. It is notable that there is an enduring growth tendency in terms of the number of patients being treated with these medicines (both among newly diagnosed patients and those who were previously diagnosed and are being treated with specific medicines for the first time), and the financial effects represent the result of treatments of a larger number of insured persons, as well as the effect of adding new original/innovative medicines to the List of Medicines.
The List of Medicines that are prescribed and issued at the expense of compulsory health insurance is being extended with medicines that have received permission to be placed on the market by the Agency for Medicines and Medical Devices of Serbia, with which the quality, efficiency and safety of those medicines has been confirmed.
Apart from innovative medicines for the treatment of serious diseases that are contained on the List of Medicines, innovative medicines for the treatment of rare diseases – in accordance with the conclusion of the Government of Serbia, are also secured with funds from the budget allocated for the treatment of rare diseases. Funds allocated from the budget for the treatment of rare diseases are increased annually. Thus, in 2012 these funds amounted to 130 million dinars, while in 2019 they amount to two billion dinars. Thanks to this, the number of patients being treated with funds from the budget has increased approximately 25-fold over the last six years (as the number of rare diseases treated with budget funds has increased from 2 to 19 different types of rare diseases that are among the group of congenital metabolic diseases, rare tumours, hereditary angioedema, pulmonary arterial hypertension and spinal muscle atrophy. When it comes to the treating of rare diseases in Serbia compared to other countries of the region and Europe, certain rare diseases that aren't treated in much richer countries can be treated in Serbia, or many more patients are being treated for individual rare diseases in Serbia.

FUNDS ALLOCATED FROM THE BUDGET FOR THE TREATMENT OF RARE DISEASES ARE INCREASED ANNUALLY. THUS, IN 2012 THESE FUNDS AMOUNTED TO 130 MILLION DINARS, WHILE IN 2019 THEY AMOUNT TO TWO BILLION DINARS

DR ZSOFIA PUSZTAI
WHO REPRESENTATIVE IN SERBIA

THE RIGHT CHOICE IS NOT JUST ABOUT NOVELTY

CHOICES OF MEDICINES SHOULD BE BASED ON EFFECTIVENESS AND NOT JUST NEWNESS, INNOVATION OR THEM BEING 'MODERN'

We would like to refer to the WHO's normative role in this area, along with our guidance to countries in implementing international standards. Regarding the selection of medicines by the Health Insurance Fund, the WHO supports a transparent process using defined criteria and guidance to help make decisions regarding which medicines to reimburse. The choice of medicines will also depend on the scope of the reimbursement programme.
Selection should be based on the careful assessment of benefits and harms, availability of alternative treatments, cost of treatment for one patient, budget impact to the healthcare system to ensure the best use of limited healthcare resources. Choices are based on effectiveness and not just newness, innovation or them being 'modern'.

THE SERBIAN NRA HAS RECENTLY CARRIED OUT A SELF-ASSESSMENT OF ITS FUNCTIONS USING THE WHO BENCHMARKING TOOL, WHILE WHO BENCHMARKING FOR VACCINES HAS ALSO TAKEN PLACE AND MORE INFORMATION WILL SOON BE AVAILABLE IN THE PUBLIC DOMAIN

The function of the National Regulatory Authority (NRA) is to ensure that medicines on the markets and in circulation at the national level are of the required quality, safety and efficacy, and the WHO Regional Office for Europe has no data to suggest that there are any general issues in Serbia. The WHO develops international norms and standards, so that countries are able to regulate health products and technologies consistently worldwide. In parallel, the WHO facilitates access to quality-assured, safe and effective health products by assessing medicines, vaccines and medical devices for priority diseases. The WHO also aids countries in strengthening regulations, including post-marketing surveillance, and in eliminating substandard and falsified medicines.