We have treatments, but can we afford them?

The incidence and prevalence of HCV infection is increasing worldwide. From this point of view, low-income countries are the most affected. Most countries cannot afford to introduce new therapies, with 98-100% chance of healing possibilities, because they are too expensive. On the other hand, manufacturers try to recover investments and obtain profit. Prof. dr. Mihai Voiculescu, president of the Romanian Association for the Study of the Liver, explains how the international community found an acceptable solution to all stakeholders regarding access to new therapies in hepatitis C.

We must continue to use interferon

Is treatment with interferon still a good choice?

In some selected patients we do not need to give up to a molecule which is a part of the immune response that our body itself has not given up yet. After all, interferon is a copy of one of the numerous interferon molecules that the body uses, synthetically made in the laboratory. Perhaps we have not copied the best one. For example, beta interferon beta unlike alpha interferon that we currently use is a better activator of the receptor of the two molecules. In fact, no country in the world has given up to treatment with IFN and Ribavirin. And during a period of financial negotiations it is not a good idea to give up these treatments without obtaining compensations for our patients. This treatment can be given to patients who were not given any other treatment (treatment-naive patients) and patients with CC genotype IL 28B. In addition to this, in cases of other HCV genotypes (genotype 3), where new molecules are not as efficient as type 1b, interferon continues to be used in a therapeutic combo. Moreover, we need to make a difference, on one hand between guidelines recommendations and shocking conference titles that want to attract and impress the audience, and on the other hand we have our everyday reality in which costs related to the treatment of HCV infection still overwhelm us throughout unacceptably high costs. Facing with this situation we cannot give up to any medication we have in our therapeutic arsenal. The percentage of patients with type IL 28B CC responsive to interferon in a whole infected population that has not been treated is probably between 10 and 15%, a number we cannot ignore given the current situation. You may notice that I am pleading for having a wider range of therapeutic options which through personalized treatment can cover various situations in order to optimize treatment. Given the fact that interferon and Ribavirin prices will drop, 10-15% of patients will continue to be treated with these drugs, especially if we do not need to wait 6 or 12 months to see the effects. At one and at three months have the so-called patient checkpoints, when we can verify the chances in patient therapeutic response and, therefore, we can decide whether to stop or to continue the treatment. This raises the advantage of a lower cost, a shorter treatment duration avoiding unpleasant side effects.

Low prices vs. profit: a financial dilema which don't feet very well with Hippocrate's lows

How does the lack of health insurance funds that want cheep drugs come together with the producers' aim of making profit?

The lack of funds of any Health Insurance House is a complex issue and it depends on two factors: the amount of the individual contribution and the number of participants. The more widening of the tax base could increase the funds. The problem of price medication is a far more complex issue and it is debated worldwide. Producers should take into account objective factors (the financial resources of the market) and also some humanitarian factors. I have participated actively at such debates, since 4 years ago. Even the US, the country hosting the company that marketed the first and most famous molecule with direct action - Sofosbuvir - concluded that the price was unacceptably high; the original price for a tablet was $ 1,005, which meant that a patient with Hepatitis C had to pay that sum daily for three months, in order to heal. This price was strongly criticized by the European community, because it exceeded by far the budget resources of any insurance houses – at one point, people talked about 85,000-90,000 € per treatment. Exactly one year ago, WHO summoned a group of experts from 148 countries at Geneva, who along with representatives of producers found solutions so that the current costs of one treatment with this molecule (leading to a 98% probability of healing) is somewhere around 55.000 €, which is still excessively high. I had the honor to attend to that meeting. Moreover, I was one of the eight reporters of the meeting and I filed a motion to ask international solidarity and the creation of a consortium of countries with limited budgetary resources in order to adapt the costs. We are still far from reaching the level that I hoped, given that Egypt walked on a different path and succeeded through direct negotiations between the Government and the industry to acquire this molecule with 10% less of the original price. In other words, we are currently at the end of the scientific testing phase of anti HCV treatments, having an overflow of molecules with an 90-100% cure rate. From now on it is required cost-volume financial negotiations between governments or health insurance houses and manufacturers to reach a bearable cost per successful cure even for low-income countries. Together with a team of experts from Sweden I participated under the aegis of ELPA to the development of a mathematical model for reimbursement of costs for low-income countries with high prevalence rates of HCV infection. The model we used for the low-income countries was the Romania, while France was the model for countries with large budgets and low prevalence rates. We tried to show that treating patients now, the total costs will be significantly lower than long-term costs of untreated and unhealed patients.

Once surpassing the phase of negotiation, remains another problem, perhaps more complicated: the distribution of medicines - still insufficiently – to a population that has been waiting them for years. To whom and in what order we give the drugs?

The criteria must be well weighed and respected. This is no place for innovation – it is better to learn from the other countries experience that had and still have this problem. There will be prioritized patient groups, such as those with cirrhosis, or the patients who are preparing for transplant or patients with comorbid conditions. Criteria will be split into two main families similar to the allocation of organs: biological criteria, based on disease severity and urgency of treatment administration, and social and legal criteria, taking into account how much time the patient had to wait for the treatment. Obviously, the first criteria are more important. We have to remember that no country is exempt from such problems and that no one has found the magic formula. It is important to call on our specialists with local and international experience starting from the EASL recommendations and adapting them to the particular conditions of each country. These experts with proven experience in the field can prevent waste and minimize the adverse effects of these expensive drugs.

ARSF - a quarter century of existence

You are the president of the Romanian Association for the Study of the Liver (ARSF). How this association addresses the problem of HCV infection?

Founded 25 years ago by Professor Lucian Buligescu and me, ARSF brings together physicians from the most diverse medical specialties with a common interest in liver diseases. Each year, ARSF organizes an annual congress hosting some of the most brilliant minds in world in the field of Hepatology. At our first congress attended professors Jean-Paul Benhamou (France), Kunio Okuda (Japan), R. Rhodes (Spain), Harold Conn (USA). That, in a time when no foreign professor visited us.

And how did you managed to bring them?

Due to the reputation of professors Lucian Buligescu and Marin Voiculescu and thanks to the exceptional scientific meetings that ARSF had organized every year. Their scientific endorsement was enough.

When will this year's congress take place and what foreign specialists will be present?

The 25th ARSF Congress will be held on 24-26th of September in Bucharest. There will be present new experts, such as professors Didier Samuel, the President and General Secretary of the European Journal of Hepatology, Patrick Marcellin, Tarik Asselah, Lawrence Serfaty, Fabien Zoulim, Manuela Neuman, Arun Sanyal, Jordi Bruix, Peter Ferenci, Vlad Ratziu, Mona Munteanu Monica Acalovschi Anca Trifan, Cristina Cijevski, Dan Dumitrascu, Carol Stanciu and many others. We are expecting 45 such brilliant professors.

What can you tell me about the main discussion theme?

The main theme is the implementation of guidelines for viruses B and C in low-income countries. Other important subjects will be alcoholic fatty liver (ASH) and nonalcoholic fatty liver (BNASH), while the tip of the spear will be the problems raised in modern approach of liver cancer treatment, counting on the participation of professors Joedi Bruix and Arun Sanyal and also on a group of experts from Israel. We have a rich and greatly enhanced agenda so that we can please any need of knowledge from a wide range of medical specialties: primary care, internal medicine, gastroenterology and infectious diseases.

You also activate in European structures in the field of Hepatology. At what are you working now and what we should expect in the future?

As president of ARSF, I was invited in 2013 to hold a conference in Brussels on the viral infection status in Romania and also to participate in preparing the European strategy until 2020 on HCV infection. Romania has allocated two pages in this guide, with extremely precise and relevant recommendations made by a commission which showed great kindness in assessing the situation in which we find ourselves. Then, in 2014, I was recruited to be part of the team in charge with developing the WHO global guidelines on detection and treatment of HBV infection. These guidelines will appear this year.