Interview with Luís Mendão on Hepatitis C activism

Transcription

My name is Luís Mendão. I'm Portuguese, 58. I live with AIDS. I was until recently co-infected with hepatitis C. Hepatitis C was a very advanced liver disease. I was one of the people that could not be cured, but not only could not be cured, but could not stand the previous treatment of pegylated interferon with riba, or pegylated interferon, riba and any other drug because pegylated interferon was unbearable to me, apart from not working. The percentage of people living with HIV that were co-infected with hepatitis C in Italy, France, Spain and Portugal, was very high. Many other countries also, but let's say this was my pattern of reference. We started to see early 2000, people stopped dying from AIDS, and started to die, or be severely ill, from the decompensating liver cirrhosis and cancer from the liver, etc. The rate of death among us was becoming much higher because of liver disease and mainly hepatitis C infection than from AIDS itself.

In, I think, 2005, there was this first World Hepatitis Day that was celebrated in World Health Organisation Europe in Copenhagen. I was representing EATG to make a speech. I found it recently. In my opinion, it was very critical on what would be the strategy that the treatment activists and treatment advocates and research and development people would let … fight for getting better, safer, more efficient drugs for hepatitis C treatment. In 2006, 2007, EATG started an annual meeting with multiple stakeholders for two or three days in Sitges, a small village, fancy, in Spain, where we gathered the agencies, the pharmaceutical industry, the researchers, the specialists and the community to put the needs of people

co-infected – not only, but mainly because we had an AIDS organisation – not to be left out in the process of research and development.

I think we were very successful. Juan Tallada was the father of these initiative. In 2008, we had the third Sitges meeting where we met with North American treatment experts, with people from Europe, and also people from the mono-infected sides. EATG and myself at the time did propose to create a community advisory board for HCV alone, and it was called the HCV Community Advisory Board. It was the first time that I know that we were asking to meet all the companies that had portfolio in the pipeline on HCV that had joined or know the majority of the big experts from the community, from North America and Europe. It was opened to people outside of Europe and the United States, but it was the first time we had a small organisation very concentrated with a very defined mission that put together in the same room the activists and advocates from Europe, United States and Canada, of course.

I think that we were very successful. We met all the companies. We did exactly what the name stands for: Community Advisory Board. We were advising the pharmaceutical industry and the researchers about what we wanted to see, what we were not accepting about what we were seeing, and what would be the direction that we think would be important. At the same time, the Community Advisory Board also played a critical role towards FDA and EMA. I remember we did read together the new guidelines for development of DAAs from FDA and EMA in 2007, probably? We made several comments and I think only two small ones were accepted. I remember better the outcomes of the European situation. In 2009, and then it was adopted in 2010, we asked for a revision of these guidelines from EMA. Not only every single proposal that we made two years previous was accepted, but it also seemed a little conservative, the comments that we were putting. I think that, again, the clinical trial designs, the pathway to approval was really

deeply changed by the input of the community, that we would not have seen this 99% of cure rates for almost everyone with different genotypes, with different conditions, with different liver stages of disease, if it was not our meaningful contribution between 2007 to 2011 that were the critical moments to define this.

We had a huge fight, because many of us do understanding that the two first DAAs that came in market: one from Janssen, one from Merck or MSD in Europe, boceprevir and telaprevir, were an added value, but they were not suitable for the people that were most sick. They were very difficult to take. They had plenty of side effects. One year after they were approved, we were claiming that they would taken out of the market. This was a quite tense situation. Now, more or less, they are dead by natural death. But it was a fight because it was also one of the first times that there was something very important from the strategic point of view of a new drug, but immediately they come out of having a role.

The second situation was that many pharmaceutical companies, all the pharmaceutical companies at the moment developed new drugs with interferon, and we were very clear that we wanted a pathway to get rid of interferon. The companies and the regulators were resisting for two years to allow clinical trials without comparators, just historical comparators, etc. Also then, I think we did speed up the achievement of where we are now regarding hepatitis C. I think that the role of EATG and the European community from HIV was critical. I think that our legitimacy was also because some of us were living with hepatitis, so we were not giving lessons, we were talking about our lives. I think that we also did some good diplomatic efforts to put together the different sectors of the community: the mono-infected, those were infected through hospitals and medical care, those who were infected from the community of people using drugs. It was quite challenging, but I think that we did mainly have a big success on that.