

Workshop 3

Vaccination

Chairman: Remco Schrijver

Remco Schrijver: The least we could do as scientists is to agree on topics we should work on, probably not to expect that we would have the solution tonight. But at least we can have some hints on future work, future directions to help our authorities, to help the industry, to help Brussels in which way the regulation should go. Guus (Koch) and I tried to put a few dominant issues about vaccination on the slide:

1. Vaccination can support the eradication of AI
2. It should not have effect on trade, as shown by the Italian experience
3. Vaccination can protect rare breeds, which is a significant fact.

It would be important to discuss what kind of recommendations from this group we can agree on. Some topics we have briefly touched on, like, would it be helpful, or could we recommend vaccinating rare breeds? Other recommendations could be, is it wise to study how to employ containment emergency vaccination? One would be to vaccinate poultry at risk, considering the free-range poultry, let people have their own chicks in their backyards, provided that they are vaccinated, provided they are identified. What would be the way to have a preventive vaccination in the densely populated poultry areas? Shall we establish an international working group on targeted AI vaccination? Let's start with the first one: vaccination of the zoos. Would it be wise to extend it to rare breeds?

Ilaria Capua: I think we need to take a step backward. Before we decide what we're going to use vaccination for, we need to decide what vaccine we are going to use, because there is quite a lot of difference. I just had a conversation with Alberto Laddomada. What we are doing really is following what has happened for the other diseases, like foot-and-mouth disease. These processes are very slow. Even if you don't know yet when you are going to use it, you need to have an idea of what you are going to use, what you want, and answer some of Tom Mickle's questions. I think that your last point, the establishment of an international working group on targeted AI, would possibly be the first point. I don't know if you are aware that there is an opinion of the Scientific Committee on Animal Health and Animal Welfare. There is a recent document, which is the opinion on the use of vaccination and of diagnostic tests for classical swine fever, foot-and-mouth disease and avian influenza. Perhaps we could start from the recommendations of that document and then set up a working group to decide what and how we are going to organize the targeted vaccination, because this is a very complicated issue. Therefore we set up different scenarios and envisage the use of the product in different situations. But still I think we need to get the vaccine machine moving.

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Remco Schrijver: Maybe that would be the first question: can we support that vaccination plays a certain role in the control of AI? From what we heard here I think that's the case. That's a very good point you made. In fact the first step has already been taken by the ad-hoc group on vaccination, so that document is there. I don't know how many people here are aware of that document. Could it be the idea to bring it forward, to use that as a principle document, or indeed to establish a working group to elaborate on the vaccination issue? How many people are aware of that ad-hoc opinion group in Brussels?

Ilaria Capua: It's not an ad-hoc group. The Scientific Group of Animal Health and Animal Welfare adopted this document, which is the result of two different working groups: one on diagnosis and one on vaccination. It's 250 pages. You can see it on the website.

Peter Cargill: We are jumping forward again. It shouldn't be an international working group on targeted AI vaccination, it should be on targeted AI control, because we all know that vaccines can play an important role in the control of AI, but they are not the ultimate answer. You have to have lots of other things in place. I think we've got to be careful that we don't keep coming back to focusing on vaccination.

Remco Schrijver: I agree with your point. But only for this discussion we want to stick to vaccination, being aware that we are missing a few links.

Kennedy Shortridge: I just came from a meeting in Okinawa for the options of control of AI. One of the important issues there is disease burden. This relates to vaccine uptake and vaccine usage. It seems to me that certainly in this area, if you could identify what is the disease burden of AI, you are starting to make a little bit of progress into a rather ill-defined area. The difficulty with flu is that you are dealing with a variable disease with a multiple target. You've got to try to pour disperse pieces of information together to produce a picture which will be useful in terms of controlling a disease which is of economical importance. But what you got here is a value-added component if I can put it that way. It's not just an animal problem, but you're looking at a human problem. I think you should get that message across, that unless we can solve the problem at the avian level, at the animal level, we could be facing a catastrophic problem at the human level. I think these are the sort of representations at least from the perspective I look at things, that is, I am interested in animal influenza as a source of human influenza. It suggests to me that you will need at this point to liaise with WHO. If you could bring in the WHO dimension to support the dimensions of study of this ill-defined area, it would be very useful. We are looking at a common problem from human and animal point of view, we need to look at the wider ecological issues, the wider epidemiological issues. I always come back that we are potentially facing a human catastrophe and SARS was another warning signal this year. How can respiratory disease spread so readily? I think unless we are prepared for that, we are going to have a problem. Somewhat ironically, the person who is taking over in charge of flu in WHO is a vet. He is a man who was mobilizing on SARS, who showed the first time in the history the WHO has done a brilliant job in bringing people together. So that would be the perspective I would go forth, define disease burden, otherwise you are not going to get a clear picture on any of the avenues that you really want to define.

Remco Schrijver: I think that is indeed one of the recommendations or issues that come up from the discussion. There should be more relation between the human and veterinary authorities, could be WHO and OIE. But I would like to focus a little bit now on vaccination as a result of our last discussion.

Kennedy Shortridge: This is critical to vaccination. What are you going to vaccinate against? Unless you can get that human perspective into this well, you will still not be sure which H subtype you need to vaccinate against. Any stand at this moment is a lottery. We have to put our scientific sides together better and you can do that better by linking those human influenza people as well.

Remco Schrijver: That's a good idea. So in this approach you should also take into account human aspects if you would have a good approach.

Alberto Laddomada: I think that we must start from the fact that at least HPAI is a terrible disease, extremely difficult to control. This has a deep impact on animal health and a potentially very serious impact on public health. More and more we realize that although sometimes still needed, stamping out a large number of animals is ethically less and less accepted by the public. I don't think it's up to us to decide about ethics. If the public decided that killing so many animals is ethically acceptable, I think we cannot comment on that. So these are the points that should move us to think about vaccination as a potential way to better control AI. These form the basis for our wish to find better system to control this disease. And surely vaccination is in principle a system to better control infectious diseases. Then the issue comes out, when vaccination can successfully be applied and under which conditions. But this is the second step. I think the very important thing is to start from the right basis.

Remco Schrijver: If you consider the opinion as now being laid down, could that be something to elaborate on further, maybe with the expertise of the people in this group? About the document Ilaria Capua mentioned, since there is already an opinion available, would it be interesting to take up that challenge?

Alberto Laddomada: I think so.

Ilaria Capua: I think this working group needs to have an official status. The only thing I can do is to propose to the EU food-safety authority that they should address this topic and organize a working group on it. This the only thing I can see, and then within the EU food-safety authority, ask a person to take care of it, then we establish a working group, then within 6 months we have a document together. I can do it because I am on the Scientific Committee on Animal Health and Animal Welfare, but I would need some additional support from the commission, because obviously we have lots of things to address.

Dennis Alexander: It seems to me that the document you are talking about, which was accepted by that committee (Animal Health and Animal Welfare), was the second time visited about the vaccination. I found it difficult to see why there should be a third time, to go back to it again? I suggest that everybody read what the two documents say about vaccination and follow the recommendations.

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Remco Schrijver: So you think that document is OK and should be followed. Or, if you would start a new working group and give it a very good condition, what should it deliver?

Dennis Alexander: But I think the whole purpose of the Scientific Committee of Animal Health and Animal Welfare was to review exactly this sort of problems, which is what was done. I admit that between the document that was published in 2000 and the one which is published this year, there are some differences, but that doesn't mean that over those three years, people haven't changed and considered all the ramifications of vaccinations very carefully. I don't see why we shouldn't use their findings as a beginning to any further development. But since most of people here probably would appear on the working group that would be set up outside that committee and would probably not be too aware about what was discussed and what were conclusions they came up with, I would say the very minimum will be that those documents be revisited and the arguments put forward by that committee and the working group outside the committee.

Remco Schrijver: I think that would certainly be the idea to have a new group working on these issues and they should use these last opinions as a starting document.

Dennis Alexander: I don't want to be dismissive about any working group you set up, but it was a pretty good working group as far as influenza was concerned, and these were the conclusions they came to. I don't really see what would have been achieved by revisiting these documents with a different set of or perhaps the same experts. These were the conclusions.

Ilaria Capua: There are two different issues there. In the documents of 2000, we had to answer two questions: the definition and the use of vaccination. Then AI came in Italy and then AI came to The Netherlands so we had to put together a group on the use of vaccination like what vaccines you would suggest to use in the EU. But what Remco Schrijver is referring to here is the targeted AI vaccination, which means to exactly define or put together some scenarios in which you should use the tools that have been recommended in previous opinions. So this is more of a practical approach to a problem which has been addressed from a general point of view by the previous committees. So this is really the start of a European contingency plan, or we could rename it, say "study of a contingency plan including vaccination in the EU" or something like that.

Remco Schrijver: I would agree.

Peter Cargill: I think Dennis Alexander is totally correct. The document doesn't need reviewing. The document is good. It's good in evaluation of the situation. Where I am a bit lost is what happens now? We got the opinion, how do we get some actions for the opinion? To set up a working group is a mechanism issue. What we should do as a group is to move it forward in the areas we need to. That's the issue.

Alberto Laddomada: Tomorrow I will make my presentation so I will say something about that. But basically at this moment, we as a commission are looking at the problem of AI of course. We can also see that in many member states at least, they progress very cautiously in the sense that we still don't know what would be their position with regard to AI in future. This of course makes our life more difficult. And I would say it's even worse from a certain point of view than 8 months ago, when Italy was the only member state that was aware of the problem in Europe. Now it has changed because more than one member state is concerned and other member states start thinking that it could also happen to me. It was not just an exception, what happened in Italy could also happen in The Netherlands, Belgium, Germany or many other member states. Of course our intention is to review the legislation because we are aware that our legislation is outdated and does not correspond to the current knowledge and what is the problem today. Therefore to establish a working group that could specifically deal with scenarios in which vaccination might be used in the future could be a task for us, for the European commission to prepare new European legislation. But before arriving to that step, I want to be sure that actually this is the willingness from all the member states. Because politically speaking, we would present a proposal when there is good chance that it would be accepted. It is fundamental. It's not us in Brussels who decide, it is the Council, in other words, the government of member states and most likely, also the European parliament. Just to give a little opening to the problem in the European Parliament, I remind you that with regard to animal disease like classical swine fever or foot-and-mouth disease, the European Parliament just gave an opinion on the proposals submitted by the Commission. But finally it was the Council, so the member states that took the decision. But when we speak about zoonoses, then the European Parliament has the same legal power as the member states, this makes the procedure longer.

Now I still don't know and I can't tell you anything because the problem has not been raised yet at internal level, whether our proposal will follow the EU Parliament and Council procedure or the Council procedure plus the opinion of the Parliament. This depends on two things. The first thing is, what is the opinion of the legal service? Our legal service with disease is potentially zoonosis but it's not 100% clear. Secondly, that is the ongoing debate on the future of EU, inter-governmental conferences and all those things, whose outcome could be that any legal proposal, like the directive of AI, tomorrow will pass the European Parliament procedure, which is a much longer procedure. You see how many problems we have that are not of technical nature. For these reasons, it's for me extremely difficult to make a commitment. OK, you have raised the problem of how to use vaccination. This is for example an issue we have discussed so much in the context of classical swine fever directive, in the context of foot-and-mouth disease directive. We have gathered scientists, we have the formal opinions delivered by a scientific committee and we also have a number of working groups with experts who focus on specific problems. So I could say we would do the same for AI, but it's not serious for me at this moment to say I would do it because there are still some question marks. But it certainly could be our task to have two or three meetings in working groups to discuss some questions about the criteria for AI. If you have a look at the classical swine fever directive, there is an annex on criteria for emergency vaccination. In the FMD directive, there are two annexes. Tomorrow we might have an annex on the new AI directive where we say, these are the criteria for emergency vaccination or vaccination, if you wish. This could be possible but I don't want to make a commitment here this evening.

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Remco Schrijver: No, I think we are not asking for commitment. If I understood well, there is more work to do for the group concerning vaccination. That's why we gather here and have so many calls from the press in The Netherlands, because the problem here is compelling. I could imagine also in other countries like Italy, there would be a lot of support to tackle these problems. Then the question would be how to get it further. There has been an opinion. Maybe we want a group with some authority, the best would be to have some governmental authority, the Brussels authority. Another possibility would be a task force of European experts. With such experts, the individual initiatives could combine and provide agreed expert opinions, but of course, you would have less authority than within the European framework. What would be your constraint? When would you take it up? When would Brussels, not you personally, be ready to take it up?

Alberto Laddomada: At this moment, we are gathering the results for this survey for AI, which we have launched not by chance, well before the AI epidemic in The Netherlands. This was because of the opinion of the scientific committee in 2000. The first opinion of the group also included a recommendation concerning a survey for AI in poultry and wild birds. And this was done with the aim of better understanding the occurrence of LPAI in Europe, which could have the impact of changing the definition of AI in our legislation. So we did it and we are now collecting the results. Then the OIE is also working on the subject. We must in a certain sense co-ordinate the positions of the member states in front of the OIE. This debate will go on in the next month. We are trying by means of these actions to better understand what the position of member states is with regard to AI. And as I said before, the member states still are making up their mind.

Ilaria Capua: If I can just come back to what Alberto Laddomada was saying. Here we have a good representation of the Italians, a good representation of the Dutch, some Germans and French. Apart from people living in the Far East and the Americans who have nothing to do with the legislation of the member states, what I would like to point out is that member states do not agree on vaccination as a tool. So when the Italians and the Dutch are proposing this, they have to face the resistance of other member states as what Alberto was referring to. Although it seems very obvious to us because we were severely struck by AI, it is not so obvious to other member states that are against vaccination. That is also a consensus we need to find.

Peter Cargill: I think there are two separate issues when it comes to the member states deciding whether they would be for or against vaccination: this scientific discussion, which is easy to have and logical, and then the political discussion. I don't think you will get a general consensus in favour of vaccination across Europe because you have to remember you have primary breeders located in various spots of Europe. As soon as the country where a primary breeder is based encounters some trade barrier, what it all comes back to is the issue of the trade barrier. Whether it's logical or not, vaccination for AI will be used as a means of restriction in trade on a global market, that's a political issue. For that reason alone, I think if every member state gets the sort of outbreak as was in Holland, they might change their mind. But for the moment, for instance in Germany I was involved in a discussion around the time when they had a single outbreak there. Initially they wanted to vaccinate, then someone pointed out that there was a primary breeding company there, then all of a sudden, they didn't want to vaccinate. The politics is going to be the overriding issue here.

Alberto Laddomada: I am very much in favour of the EU. It's because in our view, I have seen the following: In the EU, we lean on scientific and technical advice. This has been proven to be the only way to prevent too much conflicting interest between member states as an outcome of political decisions. In other words, let's try to decide at the technical level, what is appropriate with regard to restriction in relation to vaccinations. Let's try to get politics as far away as possible, this is the only way that I could see that allow us to make progress. Given that I see more of politics at international than at community level. I think the duty of the scientific community is just to put forward, what is technically acceptable with regard to restriction to trade. The other issues, like the famous issue of meat vaccinated for foot-and-mouth disease, we should try as much as possible to prevent the dog-and-tail issue, which is, I don't vaccinate because I am afraid the supermarkets don't want to sell vaccinated products. The supermarkets don't want to sell because you are afraid of public-health risk. Therefore you don't want to vaccinate, etc. This is a dog-and-tail issue. We are technicians. What is the emotion of the public is something different. We are not talking about ethics. . We have imported vaccinated meat from America for ages and the Americans, the Argentinians, Uruguayan people have been eating vaccinated meat for ages, there is no problem for public health. There may exist a small risk for animal health, but we have decided that under certain conditions, this extremely small risk is acceptable, so let's make use of vaccination, which is helpful. Let's stick to the problem. I can tell you that my commission has been to the European Parliament several times. We told them: We don't want the emotions prevail on technical things. The risk for public health is practically zero; if this is not OK, we should not vaccinate against any other disease for which all our farm animals are vaccinated.

Remco Schrijver: That's a good point. I think it's important to have this scientific committee agree there is a challenge to gather the expertise for a scientific approach. Where vaccination has some prospect, how to bring that together, avoiding political issues, that will probably be the main challenge, also of this group. We have not yet defined the way to achieve that except gathering. Is there anyone who has a last comment on this? How to achieve the scientific elaboration on the control?

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Kennedy Shortridge: If there is no comment on that, I should say that time is running out. Each year brings us an increasing problem of AI, each year will bring us closer to pandemic, the human pandemic. The way the situation is shaping up at this moment is that pandemic could occur outside Asia. It could be the product of an outbreak in a poultry operation. It would not be nice if it occurs in Europe. It could have happened. It did not happen because of the awareness. It's formal preparedness and the need to react. I think the vaccine situations needs to be explored carefully. The most important is the awareness of human disease problem and I would urge that whatever way this committee or that committee will look at it, they do so with a matter of emergency. We had the last pandemic in 1968 and we believed we averted those in 1997, 2001, 2002, 2003 but there is no guarantee that H5 will not be a problem, it is shifting all around the world. We are not looking at an only local or regional disease, we are looking at a human potential catastrophe where history will repeat itself at 1918 scale.

Remco Schrijver: That's something to ponder about. It's time to close.