Common Frameworks Scrutiny Committee

Corrected oral evidence: Post-Brexit common frameworks

Tuesday 25 May 2021

10.30 am

Watch the meeting

Members present: Baroness Andrews (The Chair); Lord Bruce of Bennachie; Lord Caine; Baroness Crawley; Lord Foulkes of Cumnock; Lord Garnier; Lord Hope of Craighead; Lord McInnes of Kilwinning; Lord Murphy of Torfaen; Baroness Randerson; Baroness Redfern; Baroness Ritchie of Downpatrick; Lord Thomas of Cwmgiedd.

Evidence Session No. 9 Virtual Proceeding Questions 103 - 116

Witnesses

I: Dr Julie Cavanagh, Convener, Faculty of Public Health in Scotland; Mark Dayan, Policy Analyst and Head of Public Affairs, Nuffield Trust; Ian Rees, Manager, Inspectorate Strategy and Innovation Unit, Medicines and Healthcare products Regulatory Agency (MHRA).

Examination of witnesses

Dr Julie Cavanagh, Mark Dayan and Ian Rees.

Q103 **The Chair:** Good morning, everyone. Welcome to the ninth oral evidence session of the Common Frameworks Scrutiny Committee. It is a great pleasure for me to welcome our three very distinguished witnesses from the health community. Mark Dayan is the policy analyst and head of public affairs at the Nuffield Trust, Dr Julie Cavanagh is the convener of the Faculty of Public Health in Scotland, and Ian Rees is the manager for the Inspectorate Strategy and Innovation Unit at the Medicines and Healthcare products Regulatory Agency, the MHRA.

The committee is very conscious of how busy you must be and we are very grateful for your time and expertise on the issue of the common frameworks. The session is broadcast on parliamentlive.tv, and we will send you a transcript for any corrections. We welcome anything you have to say in response to the questions that we will put to you today.

We are looking at the co-operation between the four Administrations. This morning we are looking at health, and there are three frameworks in this area that are of particular interest to the committee: the blood safety and quality framework, and the organs, tissues and cells framework, which each create a joint risk assessment process for assessing and investigating the safety of new policies in their respective areas, as well as setting up more standard methods of communication between the four Administrations. The public health protection and health security framework is the third and is particularly topical. The Government have chosen not to publish this framework, as you know, because they believe that the area is particularly sensitive to the current pandemic and that the framework is also bound to be changed by the trade and co-operation agreement with the European Union.

We know that today you will be able to give us three different perspectives on these issues. We hope that Mark will give us the broad policy context from the think tank perspective, Ian from the MRHA will be able to give us an operational perspective on the regulator for blood products, and, Julie in Scotland, we are looking forward to your contribution to help us understand the public health framework from your experience as convener of the Faculty of Public Health.

We are looking at co-operation, as I have said, and the development of the frameworks, possible policy divergence, the effective divergence in Northern Ireland, the United Kingdom Internal Market Act and so on.

I want to start with a broad question, which I hope will set the framework for the other more detailed questions that follow. Could you start by setting a broader context for us and tell us briefly about your current roles and the extent to which you might expect to intersect with the frameworks as they go forward? I will start with you, Julie, to give us the public health context, and then go to Ian and Mark.

Dr Julie Cavanagh: Hello. Thank you for inviting me to give evidence. I am very pleased to be here on behalf of the Faculty of Public Health in Scotland. Just very briefly for colleagues around the table, the Faculty of Public Health is the professional organisation for specialists in public health. We advise the regulatory bodies on the content of standards for professional regulation of specialists, so the General Medical Council, the UK Public Health Register and the General Dental Council in particular.

As a professional organisation, we are the parent royal college of all public health specialists and all those in training to be public health specialists in the UK. We are not a royal college. We are a faculty of a royal college—in fact, a faculty of three royal colleges, although the Royal College of Physicians is the UK, just to set us in context.

We have always had a Faculty of Public Health presence specific to Scotland because of various differences in how Scotland works. Long before the Scottish Parliament, there was already a feeling that we needed to be able to reflect the very specific issues of Scotland in our public health practice, so we have a strong presence in Scotland. In fact, that is made up of specialists who mostly work in health boards across Scotland, so we have people who are members working in public sector agencies right across Scotland—the remote and rural parts, the central parts—and the very specialist organisations.

We also have academics working with us who are members of the faculty. In giving evidence today, I will draw on all their experience. Each of us in our day jobs, as we call them, which are about delivering on public health practice in one form or another. We will do that as a matter of course, but we realise that between us we have a collective expertise and a passion for public health that made us go into it in the first place. That makes us want to be together in offering that expertise as an independent voice to anyone who will listen, essentially. That is the speciality of public health.

I have been the convener for the last six years. I was due to give up that post next month, but because of Covid I have agreed to stay on for another year to try to help support the speciality through very challenging times. They are challenging times for almost all our members. Many of them have been deployed in health protection work specifically, whereas perhaps in their day job they might do a mix of health promotion, health improvement work, some health services, base public health work.

My own work, for example, was in public health screening programmes, the adult cancer screening programmes. A lot of health service-specific work is done, but over the year or more of the pandemic, most people have been redeployed at least for part of their time doing something specific to Covid and we are still, as a speciality, redeployed in that way. The pressure on the NHS as a whole—you will be familiar with the pressure on the public health services—just continues because our job involves managing outbreaks and hopefully trying to prevent outbreaks and all that sort of thing.

Q104 **The Chair:** Julie, have these two frameworks on blood and organs crossed your radar yet?

Dr Julie Cavanagh: Drawing on the advice I have taken from various members—to be perfectly honest, it has also been really difficult for us during the pandemic—we have some experts who I have not been able to get information from yet but who I know may be able to make a contribution to this. Aside from the health protection one—of course, the difficulty is that we do not have it—the others are not so much on our radar.

The Chair: That in itself is very helpful, and we can come on to other expertise. Mark, can I ask you to give us your perspective from the Nuffield Trust?

Mark Dayan: Yes, thank you. I work for the Nuffield Trust, which is an independent health and social care think tank that is based in London but works across the UK, funded by a charitable endowment. I led our work on leaving the European Union, including all the different implications of that in terms of divergence, rest of world trade and the UK internal market.

I am very conscious that I certainly do not have the level of expertise in public health issues that either Julie or Ian have, but I would assume that, in line with our usual areas of work, we would be involved in the working of this common framework, for example, by being asked through a formal consultation or behind the scenes to comment or advise on any changes that were suggested and whether they pose any concerns, particularly if that became a political or policy issue.

To some extent, as you have described, this intersects with issues relating to the Northern Ireland protocol, which I think will be a priority for our research in the future across this and many other areas of healthcare that involve people or supplies, objects, crossing borders for healthcare. The issues in that respect are somewhat similar for medicines.

The Chair: That is very helpful. We can draw on your expertise as we go through with your background on the European legislation. Finally, can I ask Ian to give us the MHRA perspective?

Ian Rees: Thank you very much, Chair. The MHRA, and its little tricky acronym, is part of the Department of Health. We are sponsored by the Department of Health and Social Care, as is the Human Tissue Authority, which is relevant to today's discussion. We regulate medicines, devices and blood for transfusion. We have regulated blood for transfusion since the 1990s and, as you mention, our role there is primarily operational; it is the inspection of the various activities across the blood sector, from blood donation to how the blood is processed and how it is transferred to hospital blood banks and facilities for their storage and deployment.

All these have the common thread that patient safety is absolutely key, so in this case it is the recipient of the transfusion, but it also goes all the way back to the donor of the blood.

As in many things, we are not just there for the nasty things in life. We do regulation, absolutely, but we are there to engage and support the community, as we do with medicines and devices. We have various mechanisms to engage with them. We have the Blood Consultative Committee and there is a liaison group. We link with the various other expert groups in this area such as SaBTO, which is the advisory group for Ministers, and the JPAC, the joint professional advisory committee.

A lot of our work is operational, but we occasionally have some direct contacts with the devolved Administrations, and there is an excellent example from the Covid work: the collection and study of convalescent plasma. Although the studies show that this work had no real benefit, that regulatory support, which was ongoing and immediate, helped to increase the collection capacity and so on, and that work has continued. It has pivoted into a collection of UK plasma for fractionation, so that is an ongoing and new piece of work.

Perhaps just for context, when we were part of the European Union we were very heavily involved in all sorts of sectors, but particularly medicines and blood, so we were a very active part in all sorts of working groups at the EMA on medicines. For transfusions, we also attended the blood competent authority meetings, which were either two per year or three per year, looking at all sorts of areas of regulation, including things like how the disease pattern changes, the epidemiology, and hemovigilance—the vigilance aspect for blood.

Perhaps also relevant to today's meeting are the changes that were initiated on the blood and tissues legislation. In fact, I chaired one of the stakeholder meetings a few years ago in Brussels, and there are further pieces of work. It is called a joint action, which is a way of harmonising and improving the assessment of blood components, so that may be useful to the committee.

The Chair: It is indeed. It gives us a real sense of the depth of engagement and the spread of issues that you have been dealing with, so it is absolutely useful to us. Thank you very much indeed, each of you, for that. A very good start. I will turn to my colleagues, Baroness Crawley and Lord Bruce, to ask about co-operation.

Q105 **Baroness Crawley:** Thank you to our witnesses for being with us. It is very important for us. When we were looking at these frameworks we felt that we needed some specialist input to influence our debates and our thinking on them.

As we go forward with our work on health common frameworks, in co-operation across the four Administrations, perhaps I could pick up the last part of Ian's presentation. Could you say a bit more about how co-operation was managed between the four Administrations before Brexit,

and how important European rules and regulations were for that co-operation? Ian, I know that you spent some time in Brussels working particularly on blood products, so perhaps you could compare and contrast how things were before and how things are now, and what the challenges are. Perhaps we could start with Ian and then Mark and Julie can come in if they wish.

Ian Rees: Thank you for those questions. The primary legislation that we worked on from Europe, which has been transposed into UK national law and which provides the legal framework for the regulation, was focused on the quality and safety of the blood for transfusion and how it is supplied for use to be manufactured, for example, in medicines. Although that is outside the scope of today, it is important. There is the expression, "You can't make a silk purse out of a sow's ear"; you have to have good quality and safe material to start with.

I think the legislation has been quite successful. As we know, the infected blood inquiry was a large part of the stimulus to create a European framework for the safety and quality of blood and its counterpart on tissues and cells. That has not only enabled us to work across the UK in the four areas but given us the authority to inspect the collection of blood: how donors are managed, how the blood is processed, how it is stored, how it is distributed and how testing is done to make sure that it gets to the right person in the hospital.

That has worked very well. As I say, our primary links are with those blood establishments. There are about 11 of them across the UK, including the Welsh blood service, the Northern Ireland blood service, the Scottish national blood service and NHSBT. It has worked extremely well both at that formal level, that operational level, and at an informal level.

I know that a lot of people are concerned about contacting the regulator but, as I mentioned, we are also here to help if, for example, changes are being made in Scotland, which consolidated a lot. Because of the geographic spread in Scotland, they brought a lot of the processing units together into one. We worked with them to make sure that there was continuity, certainty and clarity in the regulatory requirements so that they were right first time, and we did the same for the consolidation into a Bristol unit. That has worked very well, and I hope that it will continue. Perhaps I am an optimist. I think there are good relations and good working relationships.

There is a balance that we have to strike. As a regulator, we have to have a certain distance to avoid a conflict of interest, but there is a balance between the regulation and taking action where necessary, as we do and as we have done. We also need to be approachable in any contact about queries, including major infrastructure changes that they could be making. I hope that, whatever happens in the future, that spirit of co-operation will continue so that we all move together, which is the intent of the framework.

Mark Dayan: There are many ways in which the four health services of the UK co-operate, in particular—beyond what we are discussing today—on medicines and the professional registers of staff, both of which are handled largely at a UK level.

During the period of our membership of the EU, the situation, as Ian described, was that the underlying laws existed essentially at the EU level for medicines, medical devices, and the substances of human origin that we are discussing.

These common frameworks, as you will all be aware and have seen with other common frameworks, have come about essentially because, with the removal of EU law, these are in fact de jure devolved powers and are not listed as reserved powers alongside medicines and devices in the Scotland Act 1998 and the other ones with it. I think that creates a set of challenges for which these common frameworks—well, two of the three of them—become relevant, essentially because in many ways it makes sense to continue to regulate them at a UK level, as Ian has described colleagues doing.

It is certainly desirable that systems—for example, traceability—should keep working at a UK level so that there are consistent ways to trace who has given blood or who has given an organ and to ensure that the safety of that can be upheld and any events can be notified. At the same time, by the letter of the law it is completely within the power of any one of the four UK countries to change its rules in a way that might make that harder to continue with. That is one of the key impacts of Brexit on these modes of co-operation in this area, and that is the kind of context here, if that makes sense.

Dr Julie Cavanagh: Because of the structure of the faculty and the fact that all our members are employed by a wide range of organisations, we have a very different way of engaging in all this. Over years, our basic philosophy has been about co-operation on the definition and wide range of public health to which we operate, which covers everything from the air we breathe, the water we drink, the education we give our children, the early start we give our children, through to our access to and use of harmful substances, so pretty much every aspect of our lives.

We have always sought to be involved in policy at the earliest point at which it can be influenced, because it is a very broad policy area and it traverses very many areas of specialism. We have done that up to now mostly through different aspects of professional co-operation. We have tried hard to maintain those. We have had regular conferencing with five nations—the four nations of the UK and the Republic of Ireland—to make sure that at least in close environs we have policies that understand each other.

Also, public health has an ever-changing agenda, so it is very important that we learn from the experience of colleagues on the ground in different places, because invariably what happens in one place will happen in another patch at some point in the future. So we have that co-operation.

We try to use that to build up formal scientific evidence to help us formulate policy in association with each other. We also work through the WHO European region. That is another example of how we do it.

Probably the most obvious example of EU rules and regulations in relation to the faculty is the standards for specialists that we have had to operate. In many decades in public health working with these standards, we have always been very proud of the UK standards, but we find it very useful to have an understanding of what standards regulated specialists other countries are operating to, so that we can understand the value of what different people are telling us, what that is based on and what weight to put on it.

The Chair: Thank you very much, Julie. That is very helpful. Witnesses, we have a lot to get through. Can we have short answers? We are getting terrific amounts of information from you, which is wonderful, but I am very conscious of time as well.

Q106 **Lord Bruce of Bennachie:** Thank you for coming. I would normally be speaking to you from Aberdeenshire, but I am speaking to you from London at the moment for the first time in 14 months, which is an indication of the times we live in.

You have touched on the fact that we are emerging from an umbrella under the EU, which had co-operation, but there was an overarching framework that has been lifted. How do you feel that will affect divergence in the future? Are there opportunities in that for improving co-operation, or is there a danger that we will have divergence for the sake of it?

From the patients' point of view, it seems to me that all they want to know is that the standards are good. Speed, safety and all those things are what matters, and we have seen during the pandemic—this affects the public health sector—different decisions that are not always clearly understood, such as the relaxation of the Covid rules. In England and Wales, two households of any size can meet. In Scotland, six people from three households can meet, so two families cannot meet. There is no rationale behind that that has been explained.

How do you feel this will emerge? Also, will the co-operation across the four nations require co-operation with the EU so that what you have done over the last 40 years is not lost? I would be interested to hear what you feel are the worries or opportunities of those changes.

Mark Dayan: Those are good questions. In terms of the scope for divergence, we can talk about two types of divergence here. One is the UK in some sense diverging from how the EU does things. The other is divergence within the UK between its component parts.

I will set aside Northern Ireland here, because Northern Ireland in many ways now has diverged very much from the UK and has remained aligned with the EU. There are scenarios where you can imagine a legitimate case for different approaches in some of these areas, whether that is because a certain part of the UK might have a particular problem that might affect

people donating blood or organs more than others, or because of different levels of reliance on products coming in from outside. But this is unlike in areas like medicines and devices, where new products constantly come up, and there is always a trade-off to be made between innovation and making it easier for companies to do new things, and protecting safety.

When we are talking about substances of human origin, safety is reasonably to the forefront, and the existing system is generally viewed as having done a fairly good job of upholding that. There would be a bit of a barrier to clear in terms of divergence within the UK, so that whatever changes were made justified any potential disruption to the ability to safely monitor things moving around the four countries.

Again, a case could be made for divergence of the UK from the EU, but it is not as obvious a case as perhaps some people would like to see for medicines or devices regulation change now that we have left the European Union. I hope that makes sense.

Lord Bruce of Bennachie: Thank you. Is that your view, Ian?

Ian Rees: Let me perhaps say a bit about divergence. Absolutely, there are those two dimensions from the EU and within the UK. At the core, even if we have a change of legislative framework, as long as the core principles are the same we can assure the safety and quality of blood. That also means that we can move those components around more easily. It is particularly important with blood, probably more important than medicines because of the very short shelf-life of some of these things. You cannot stock build.

There are two illustrations of this. One is that a lot of the details of what we call good practice—how you train staff at the blood establishments, how you look after donors—is now with the Council of Europe. The EU links into the Council of Europe, which we are still part of, so there is continuity there.

Perhaps there is an example that I can draw from medicines and the phrase "mutual recognition". Currently we have internal mutual recognition across Europe and within the UK, and we have agreements with countries with very different legislative frameworks, such as Japan, the US and Canada on medicines and so on, but the core principles are the same. If, for example, a medicine has to be sterile, it still has to be sterile in whatever jurisdiction, so I am hopeful that those core principles will be the same, even though the legislative apparatus may be different. If administratively there are problems, the core thing is that the materials are safe and continue to be available.

I agree with the previous speaker that there is a slight dichotomy with innovations. You want this to happen, because science and technology continues to progress. The Commission has been working on the amendment to blood and tissue legislation to make it more innovation-friendly, but it is putting a mechanism in for robust assessments so that

these things cannot just come in and so that patients are assured of the continued quality and safety of them. I am perhaps slightly in the optimistic camp here.

Dr Julie Cavanagh: I agree broadly with the ideas on divergence. One of the things that the Covid pandemic has taught us, if we did not know it before, is that viruses know no boundaries and diverge the way they diverge, if you see what I mean. Basically, my landscape for the control of Covid is much broader than Europe, although some sort of co-operation across Europe to pool information and get all our data in comparative datasets is essential. That is not quite as refined as we would like it to be, even now. There is some UK data missing from some of the European comparisons at the moment, which is unfortunate. I will leave it at that.

Divergence in public health is something we welcome if it is about implementing a local solution. Convergence is necessary at the level of certain floor policies, such as the common framework, but there is a need to allow a lot of divergence so that there is local implementation, one being useless without the other.

Lord Bruce of Bennachie: Yes, I think you are speaking to the converted on this committee on that.

Dr Julie Cavanagh: I hope so.

Q107 **Baroness Redfern:** Good morning, Mark and Ian, and again to you, Julie. Thank you very much for coming today. My question is about these three important frameworks. Could you tell me a bit about your awareness of them and if you have been consulted as part of their development? It is very important to note that there might be a platform—and you might agree with this—to build the regulatory regime even further with the intention of maintaining a strong existing collaboration between the four nations, while respecting that the policy is the responsibility of each of the Governments across the UK. Ian, as an ex-blood donor—and I know you have been speaking about blood donations—can I go to you then first and then Julie and then to Mark?

Ian Rees: Thank you for that. I suppose there is always scope for more involvement in the development of frameworks, and, as you say, the policy lead is the Department of Health and other Administrations. I mentioned that we have liaison groups, formal groups like the blood liaison group, which will meet formally with the department and flag this framework for us and ask for our comments. In general, because they are looking at higher-level activities, there is not much operational difference for us as yet. The sort of comments we have had are that, if there are changes, we should be part of the change process to evaluate the risk assessments, should any be initiated by the different Administrations.

I think all four regions are agreed that collaboration is important, particularly in blood, for example because of capacity and geographic

availability. Obviously there are a lot more people in England than there are in Wales, Northern Ireland and Scotland. If, for example, you are looking for a rare group or if there is an emergency—some crash or something like that—they will need to be supplied from within those other regions, so they recognise that that continued collaboration is important. Singing from the same hymn sheet is key to that, and MHRA stands ready to evaluate any changes to make sure that at an operational level that quality, safety and availability are continued.

Dr Julie Cavanagh: In relation to the three frameworks, the one that would be most relevant to us is the one for public health protection and health security. For obvious reasons that have been discussed, we have had nothing resembling the level of involvement that we would prefer. We are taking some of this forward ourselves, and in Scotland we will have a workshop with experts to help inform our position on what we think should be involved.

Another framework that we would expect some of our specific experts to be involved in is blood products. We have various experts who are involved in different capacities in the public health aspect of products and organs. There are a couple of examples, which are pretty obvious. One is infection in blood and organs. We have experts such as Professor David Goldberg, who will hopefully have been involved, although again he has been very tied up with Covid. Is that enough information?

Baroness Redfern: Yes, and I think you said earlier that you are facing very challenging times, particularly in health protection as such.

Dr Julie Cavanagh: Yes. We are all working in health protection at the moment. Normally we would try to spread our public health work between a much broader range of issues and try to concentrate on other things, like drug deaths and drug misuse and screening, but we are all deployed in health protection for a lot of the time at the moment.

Baroness Redfern: Yes. Thank you very much, Julie.

Q108 **Lord McInnes of Kilwinning:** Good morning, everyone. I want to look more at your own opinion and observations about co-operation. At the heart of the idea of the common frameworks programme is co-operation and coming to agreement between the four Administrations. I would like to know your own observations, as important stakeholders, on the transparency of that co-operation. Does it tend to be done behind closed doors and you then hear about whether it is working or not? Or is it through the discussion of any policy framework that you feel you have a good handle on how that co-operation is going and how it is moving forward? I will ask Mark first for his overall view, and then maybe Ian and Julie can talk briefly about their own experiences in their areas.

Mark Dayan: I would absolutely endorse the importance of co-operation in this area, if by "this area" we mean substances of human origin and infectious diseases in particular. That is for the reasons that Ian laid out, which are that, when you have aligned systems for dealing with blood

and organs, you can move things more quickly because you do not need things like special supplier contracts—as I think you do to move between the UK and the EU—and you can move them more safely if you have compatible systems for tracing, notifying and so on.

The common frameworks process itself has shown some relatively promising signs of being transparent, and of course any change that would come up as relevant to this would involve at least secondary and probably primary legislation in one of the four countries, so there would be a visible and open process there. There have been elements of the process that have perhaps been less ideal. The non-publication of the health security common framework is obviously not very transparent.

As the Institute for Government and others have said, the internal market Act process last year suffered quite badly from a lack of transparency about its aims, its implications and the process behind it. That chapter is now somewhat closed, but there are still processes in that legislation that are somewhat non-transparent in the way they interact with common frameworks, but on the more consensus-based common frameworks approach it has been reasonably transparent.

Ian Rees: Yes, I am sure there is always room for more transparency and engagement. Certainly we were consulted on this and we provided comments. I am sure that as the framework continues to develop and move into an operational phase we will have more comments to provide and we stand ready to do that. Absolutely, the earlier something is put in, the easier it is to get it accepted, and then hopefully changes are more finessing as we get operational experience.

I can also speak on behalf of the Human Tissue Authority. I have been in touch with them, and its level of experience has been similar to ours in that it has been consulted. Yes, there is always a balance to strike between overburdening somebody and not engaging enough, but I think the two regulators are on a similar page.

Dr Julie Cavanagh: Some of the consultation we have had has been through our membership of the medical royal colleges. They are consulted on many policy issues. Just as in my speciality in particular, the royal colleges in general have been somewhat diverted by Covid in the last year, and at our weekly meetings we do not have an awful lot of time in the way we would in years gone by for discussing such consultation issues in the depth we would like to.

The biggest issue for us is the health protection framework, and we would like a lot more involvement in that. Certain specified experts have had some input, but it has not been the sort of professional consultative process—or consultation with professionals, I should say—that we all would have preferred it to have been.

Lord McInnes of Kilwinning: Beyond following up on that particular framework, and beyond being a consultee, do you feel that you have oversight of the co-operation between the four Administrations, or does

your consultation response basically go into a machine and out pops a result and you are not aware of what happens within?

Dr Julie Cavanagh: We are not particularly involved in informing in the process, certainly not at the level we would like to be. As I say, specific individuals with expertise may have a chance to be involved in one piece, but not overall as the speciality delivering on the ground.

Lord McInnes of Kilwinning: That is very helpful. Thank you.

Q109 **Lord Garnier:** Thank you, all three of you, for coming. It is pretty clear from the answers you have given, to Lord McInnes and to Lady Redfern, what your concerns may be about the three frameworks, not least the last one. Can I focus very narrowly on the issue of risk assessment? Have you had a moment to consider whether sufficient risk assessment has been built into the creation of these three frameworks—well, certainly the two that you have been able to look at? Perhaps we could start with Ian.

Ian Rees: Certainly when I looked at the common framework my view was that although the MHRA is mentioned, it is not called out specifically enough and the focus is more at the policy level of making changes rather than what the implications may be at the operational level. This is key for our work and key for the availability and ease of movement and so on.

I would suggest, and I fed this back to the department, that our role and that of the Human Tissue Authority be made clearer in the risk assessment so that there is an engagement loop there and we provide our feedback to make sure there are no significant divergences or any issues that would cause a lack of availability.

The Chair: Julie, is that your experience?

Dr Julie Cavanagh: I do not have any more to say on the first two frameworks. I think you can probably surmise my answer to the last framework, although I would like to subject that framework to our processes, which are a health impact assessment to look at how it is covering the public health determinants of health in the way that we feel it should. We have some concerns about a narrow biosecurity approach and would like to have been reassured on the risk we anticipate now, which obviously we cannot be at the moment.

Lord Garnier: Thank you. Mark, how about you?

Mark Dayan: There are two levels of risk assessment, one of which may be what Julie was speaking about, which is the risk assessment of having a common framework in the first place. It seems to me that, for the two we have seen, that is reasonably straightforward, because to a considerable extent they are about keeping—or at least keeping within bounds—the status quo of alignment that we had within the EU rather than bringing in particularly a change. It is certainly possible that that will contain something a bit more than simply maintaining things as they were.

The way the common frameworks set out how risk assessment will happen seems to me superficially to be quite reasonable. If there were changes to the way that, say, organs or blood are regulated, that would need to be risk assessed as a new measure, as something that might impact health through the process. I am sure Ian is right when he says that there could be more operational consideration there, but overall that does seem to me to be the right point at which to assess risks.

Lord Garnier: Thank you. If there are further points, I am sure they could be followed up in writing later as we get more vision on the final framework.

The Chair: Thank you very much. That was a very important question.

Q110 **Baroness Randerson:** Mark just referred to the risk assessment needing the common framework in the first place. The DHSC identified five policy areas with its remit that it later went on to decide did not require frameworks: clinical trials, additional products, elements of tobacco regulation, good laboratory practice, medicine prices and medicine products for human use. Given that these are devolved and there might well be areas of policy difference from one area to another, were you concerned at all that there was a need for a framework? Were you at all surprised by the decision in any case?

In asking that question, I draw your attention to the fact that medicine product prices in Northern Ireland have already created controversy and are clearly being affected by the protocol. Since Mark made the reference to start with, shall we start with him?

Mark Dayan: That is an excellent question. You can break the areas that it was decided did not require a common framework into a few different categories. Three of them, as you suggest, all relate to medicines, for which only Northern Ireland has devolved powers. They are reserved in respect of Scotland and Wales. I would think that a common framework is not being put into place there largely because of the bringing into existence of the revised Northern Ireland protocol. That does not mean that Northern Ireland essentially has those powers to diverge in a devolved sense; rather, that Northern Ireland must continue to follow EU rules.

A common framework is about devolved countries with control over something coming together to make sure that they do it in an aligned way, where that is helpful. So I can understand the logic that instituting a common framework is perhaps not that relevant to medicine issues concerning Northern Ireland. In fact, it does not in effect have control over those things, and for the rest of the UK it continues as a unit.

One of the other frameworks dealt with tobacco control. There is a complex argument to be made here, but I think there is a case for that simply remaining a devolved competency. We have seen some quite good examples in the past of different UK countries in effect experimenting with new and different ways to regulate tobacco, for example. Scotland, for example, was the first to ban smoking in pubs and the like. Up to a

point, that may fall within an area where it is legitimate for devolved Governments to experiment, to try different things and maybe to diverge to some extent without that necessarily having problematic implications.

The last framework, which I am not very well across, relates to good laboratory practice. I suspect the view here may have been that these are relatively standardised processes and do not require further co-ordination. It may be interesting to look into that one further. For the others, I think there are good reasons why those decisions will have been made.

Baroness Randerson: Julie, you might want to comment about tobacco products.

Dr Julie Cavanagh: Absolutely. I will start with tobacco. Basically we would welcome some common framework for tobacco, because we feel that the EU standards are the floor, the minimum. Sure, we would like to be able to experiment with different methods of improving on that, but we are quite concerned too that it is not part of a common framework. We are not completely sure what the consequences of that will be, but there is an expressed level of concern in the profession for the quartet, as we call them: alcohol, food with high salt, sugar, and gambling. We also feel the same about those.

Were we surprised that things were not in? I do not think we considered that question, so I could not say whether we were surprised. We are a bit concerned about what is considered not to need a common framework and whether or not that will lead us to need to press for secondary legislation. The sorts of examples I have include the transport of radiological dangerous goods. I have a big long list that I will put in written evidence, if that helps you, but there are various issues that are highly important in public health, such as water quality and maritime and port directives. Flood risk management is part of public health and emergency—

The Chair: Anything you can put in evidence would be wonderful, Julie. Thank you.

Ian Rees: Perhaps I will start with GLP—good laboratory practice. This covers medicines and a range of other areas that are outside the main regulatory remit of MHRA, such as agricultural chemicals, although our inspectorate looks at this. The main rules come from the OECD, and obviously we are still there. There is also EU legislation, but through the ambit of the OECD there should continue to be a common framework, so to that extent I am content.

Tobacco I am less familiar with, but I know that there is tobacco and related products regulation. The role of MHRA here is specifically on e-cigarettes and control—I am not directly involved in that—so there is some legislative framework there that we touch on. Medicines and clinical trials of medicines are absolutely mainstream MHRA territory. You are

probably aware of the Medicines and Medical Devices Act, which allows continued changes there that we have left the EU.

There is work to make changes under this new legislation, and I hope that that work—I am certainly involved in it—will continue to move that forward to make the UK an attractive place to manufacture and supply medicines, so I am reasonably content that those are not within a common framework. Certainly our experience of regulating these areas across the four Administrations has been very positive.

Baroness Randerson: Thank you very much to everyone.

Q111 **Lord Murphy of Torfaen:** A very simple question: how might you expect policy to change in the future in these areas now that European Union rules no longer apply?

Mark Dayan: That is a very good question. As I said earlier—Ian will likely know more about this than I do—there is not necessarily a very busy agenda for divergence from EU rules on substances of human origin—blood, organs, tissues and cells—compared, for example, to medicines regulation, where there is a great deal of policy interest in the UK, for us to do things differently.

The most interesting common framework in this respect may be the one that we have not seen on public health notification and data sharing in particular, which is trying to replicate the European Centre for Disease Prevention and Control. The UK will no doubt want to rebuild a set of relations—as it has to some extent through the trade and co-operation agreement with the EU last year—with public health agencies in Europe, in different countries, and with international bodies like the WHO, on systems for notifying and being notified of public health risks, issuing guidance and working on things like that. That will now have to be done more at a freestanding UK level rather than working through the European Centre for Disease Control.

Unfortunately we have not seen that common framework. However, I imagine that one of the issues it will need to handle is that Public Health England has long dealt with international relations to some extent on behalf of the public health agencies in each country. Its task in doing that will change somewhat as a result of Brexit, becoming more difficult in the sense of not having full access to ECDC but potentially fostering interest in working with others more deeply. The common framework will presumably set out how that will be co-ordinated with the powers that each UK country independently holds.

The Chair: Ian, did you say you did not have anything to add to that?

Ian Rees: No, it was an apology. I talked across Julie there. Very briefly, we are not aware of any significant appetite for policy change. The underlying and fundamental core is to maintain those equivalent quality and safety standards so that product is safe and available for patients. So provided that this is protected and our link with the Council of Europe and the EDQM continues to provide the detail that is important in this area, I

do not get any sense of an appetite for policy change. I mentioned earlier the experience of working with Covid, with convalescent plasma and then more recently with plasma for fractionation, which has continued to be harmonised. I may be wrong, but I do not see a big appetite for change in policy.

Q112 **Lord Thomas of Cwmgiedd:** Again, my question is probably susceptible to a yes or no answer. Do you expect the different Administrations of the UK to take different approaches on any of these issues? If the answer is no, that is the end of it. If you do, could you identify in what areas you think they will be changed and which Administration might wish to see divergence?

Dr Julie Cavanagh: Sadly, my answer is yes and no. Briefly, there is some divergence. The Public Health etc. (Scotland) Act 2008 has allowed us to give more support to people who self-isolate, which has been useful in helping people to self-isolate. That is a specific power under that Act, which is a divergence from others, so some aspects of divergence are very useful.

On the other hand, our whole principle is to try to work at an even wider level than the UK, because all the evidence across the world is relevant to our judgments and to balance in the scientific basis for different decisions in a complex setting. I cannot remember whether my answer was yes or no, but it is about convergence there. Is that helpful? I am sorry. I have good examples that I can include in my written evidence.

Lord Thomas of Cwmgiedd: Could you put that in writing to us? That would be helpful.

Mark Dayan: My answer is basically no, if we are talking about the specific areas covered by these three common frameworks. I am not aware of any active agenda for divergence, with the exception that Northern Ireland will be doing things quite differently because it effectively remains under EU law on several of those.

Ian Rees: I am with Mark there, absolutely. I am not aware of any changes that are going on in Ireland. I mentioned earlier that the EU is changing both the European blood legislation and the tissue and cells legislation. It could do something significantly different, such as bringing things together in a single piece of legislation and so on. That is something they will have to accept, provided that the core principles and the good practice are maintained. Hopefully we can manage that and the differences will be more administrative—issuing different licences and so on. At an operational level, it should be no different.

Lord Thomas of Cwmgiedd: Thank you very much for your very brief answers.

The Chair: Equally brief, I hope, will be Lord Caine. I will call the Irish protocol question next, because I know you are under pressure of time this morning, so please put your question with Lady Ritchie's, if you would like.

Q113 **Lord Caine:** Thank you, Chair. Good morning to all the witnesses. Very briefly, because you have touched on the protocol and have probably answered a number of the points I was going to make, and very specifically, given the heavy reliance of Northern Ireland on the rest of the UK for organ donations and on England for blood supplies, what will be the practical impact or effect of regulatory divergence between Great Britain and Northern Ireland as a result of the protocol? Should people in Northern Ireland be concerned? This question is probably more for Mark in the first instance.

Mark Dayan: It is an excellent question. There are two different issues here because, as Ian very rightly says, it is not that Northern Ireland is diverging from rest of the UK. The core principles and the way these things work remain the same. None the less, even with essentially no substantive divergence, I believe there are additional barriers to circulating, for example, organs between Great Britain and Northern Ireland because Northern Ireland now is effectively in the space of importing those products into the European single market from the UK, which is outside them. I believe that will mean that import licences and supply contracts are required where they would not have been before, which adds a bureaucratic hurdle for those processes.

If the UK were to diverge from some of the core principles that Ian has spoken about, it could make things considerably more difficult, because to bring blood into Northern Ireland from the UK, I believe, traceability and notification are required to be done in a similar way. If they were not, the barriers would be more considerable. However, as it is, it is not so much a question of divergence but of having to do extra paperwork to show the convergence, because it is not being guaranteed by European law in the same way.

Ian Rees: Certainly from my perspective there is an administrative challenge, as there is with medicines, licences and so on. There is also an opportunity here. Something I have discussed with the department is the creation of mutual recognition agreements. We have that in medicines. Medicines can flow relatively freely between the UK and the seven other areas that have this mutual recognition agreement, so it facilitates that. That could be put in place, or I would counsel putting it on the radar to consider if there is that sort of legislative difference. It would facilitate rapid movement. As mentioned, when tissues, cells and blood need to move, they need to move quickly.

Q114 **Baroness Ritchie of Downpatrick:** My question is more to do with north-south co-operation on health between the two jurisdictions on the island of Ireland. In your view, how important is cross-border co-operation and cross-border healthcare co-operation between Ireland and Northern Ireland? As somebody who lives in Northern Ireland, I am fully aware that if people need urgent surgeries they can have them in Dublin through a mutual agreement for payment purposes between both health services.

Mark Dayan: It is important, and I suspect it will grow in importance. It happens in several different ways, including some planned services such as cancer; Derry effectively serves populations on both sides of the border. Some highly specialised care is increasingly done once for the island of Ireland; paediatric heart surgery, for example, being moved simply to Dublin.

There are also areas where northern Irish emergency services will typically cross the border to help people in the republic, because there are many areas where the biggest urban centre around is on the Northern Irish side of the border. It is important, and obviously in some of those cases moving human tissues will become relevant.

As we have discussed, under the protocol Northern Ireland is staying in close alignment with the Republic on those issues. We have spoken about some of the difficulties with the Northern Ireland protocol, but its original purpose was to prevent the need for checks and obstruction at the Republic-Northern Ireland border, and it should achieve that.

Ian Rees: Yes, I agree that the free flow of blood components, tissue and cells components is important. It is not a massive traffic. It is not like the large quantity of medicines moving backwards and forwards. However, when it does happen, it needs to happen quickly, because it is urgent. You cannot stockpile these things because of the short shelf life. So maintaining that ease of movement and, as we discussed in the previous question, reducing those barriers and bureaucratic requirements is important.

Baroness Ritchie of Downpatrick: Julie, is there a Scottish perspective here? I presume not.

Dr Julie Cavanagh: Not specifically. There are lots of shared services. I have a reasonable list of them here, which makes me think that it is pretty critical that we have a very clear arrangement for that to continue.

For us in public health, it is more that in the north of Ireland we have standards for professional public health that we share with the Republic of Ireland. We have interchangeability of professional exams and things like that, which we would need to look at to make sure that that was maintained for standards.

The Chair: Thank you very much. We have two final questions, both of which are very important.

Q115 **Lord Foulkes of Cumnock:** Thank you, all three of you, for your evidence. It is very impressive. You certainly know your stuff. I have a very easy question for you. The public health protection and health security framework has not been published. The Government say that this is because much has changed since it was written in December, and because of the pandemic, and that it would not be appropriate to do so. Do you accept that is a good reason for not publishing it?

Ian Rees: Certainly when I have asked the department about this it has clarified that it is largely for stakeholders like Public Health England and its equivalents. We certainly will be involved. Yes, it would be nice, as I mentioned earlier, to have a bit of an earlier sight of it so that we can say whether there is an impact on us from an operational perspective. Certainly I will get text on that, so we will be able to provide comment.

Lord Foulkes of Cumnock: Do you think they are right? Do you think it is reasonable that they have not published it yet?

Ian Rees: From what I understand—obviously I have not seen it—things are changing rapidly. It would be nice for us to provide comment and see it first hand, that is for sure.

Lord Foulkes of Cumnock: Mark, do you agree with that?

Mark Dayan: I do think it would be good to have seen it, yes. There is a slight element of circularity here in that it has not been published earlier and so now cannot be published because it is out of date. I am sure it is out of date by now. Some of the things that will have changed, which I understand will need to be updated, such as Public Health England being split into two parts and the signing of the trade and co-operation agreement, do not affect fundamental questions like which forms of data this common framework will cover. As Julie said, does it cover non-infectious disease issues or not? It would be helpful to see some detail on that, yes.

Lord Foulkes of Cumnock: What about you, Julie? Are you worried about its non-publication?

Dr Julie Cavanagh: Yes, I am very concerned about it. I can understand that you might not want to have something published on the web that is sensitive, as it might be at this time. However, we would have liked to have seen some trust and faith and a more profession-wide discussion of what is in there. Obviously it majorly affects my speciality and my area of practice. More importantly, we have a huge amount of expertise to bring to bear on it and vast experience that could help to develop it.

Lord Foulkes of Cumnock: That appears to be the view of all three of you, so guilty as charged, as Lord Hope would say.

The Chair: Thank you, Lord Foulkes. That was a very interesting and helpful question. Can we move to Lord Hope for the final question?

Q116 **Lord Hope of Craighead:** Thank you very much. My question is about the supply by commercial bodies of substances of human origin and the interaction between their activity and the mutual recognition provisions in the internal market Act, which as they stand will prevent any divergence in the activities of these commercial bodies. To Ian to begin with, how much are commercial bodies likely to be involved, or indeed are involved, in the supply of these substances?

Ian Rees: To a large extent the underlying principles of the supply of blood, tissues and cells is voluntary and unpaid donation. Certainly there are commercial organisations involved to the extent that they are providing specific services to the NHS, for example. They might irradiate blood or something like on that on its behalf, which they have to be paid for. Obviously those commercial organisations need to cover their costs.

There are other commercial organisations, or commercial transactions, involved. One example is supplying plasma for transfusion, which is getting less now as the risk of variant CJD diminishes, and supplying plasma for fractionation, which traditionally comes from the US but will come increasingly from the UK. Clearly that is not the entire solution. There are commercial arrangements, if you like. It is quite different from medicines, where it is a private entity that manufactures and supplies something. It is more a reimbursement.

The opportunity for big commercial involvement is probably more limited—or less appetising, if I can put it like that. Certainly we see some, and we regulate them, so our coverage goes back to those.

Lord Hope of Craighead: Do you see divergence being an issue here, or can one discount that as a problem in this case?

Ian Rees: I think it is less likely to be a problem if the core principles of voluntary and unpaid donation remain in place and that there is, if you like, limited commercial opportunity. It is certainly an important element of the supply network, but is not as predominant as it is in medicines and devices, for example. From my perspective it is limited.

Lord Hope of Craighead: Thank you very much. Mark, do you have a comment on that?

Mark Dayan: That is essentially right. If you stack up a few hypotheticals, you could conceive of a situation whereby, say, Wales ceased to purchase supplies of plasma from the US in the same way and changed its rules so that they were not permitted. A company could then notionally object to that under the mutual recognition principle. You would have gone quite a long way down the route of divergence then, which might have brought up its own issues.

It is worth saying that there are a couple of sections in the internal market Act that might create an exclusion for this. There is one about stopping the spread of infectious agents, which might apply in my hypothetical example if Wales was trying to stop the spread of something in particular. Then there is a sort of exemption, which is not very clear, for things that have been agreed through common frameworks. Had it been agreed between the four UK countries that the risks of that divergence were manageable, that might create an exception of this nature. There is a very hypothetical scenario in which it could come into play.

Lord Hope of Craighead: Thank you. Julie, do you have any comment?

No, that is perfectly fair. Thank you, all three of you, very much indeed.

The Chair: Thank you, Lord Hope. Let me thank the witnesses very much indeed. We have had a fascinating range of experience today. It has been rather nice that we have even had Wales and Scotland represented alongside England. That always pleases us no end.

You have brought a degree of professionalism, deep knowledge and experience that has been fascinating in the way the questions expanded themselves almost by definition so that you were able to pick up on breadth and depth. It is very important for us to hear those perspectives. They enable us to make sense of the more abstract materials that we get when we look at the frameworks. I am extremely grateful to you.

If there is anything you want to add by way of written evidence, or indeed if you want to get back in touch with us about anything, please feel free. We will be absolutely delighted to hear from you. Thank you very much indeed. At this point I will now formally end the meeting.