



Cynulliad Cenedlaethol Cymru **The National Assembly for Wales**

Y Pwyllgor Iechyd a Gofal Cymdeithasol **The Health and Social Care Committee**

Dydd Mercher, 22 Ionawr 2014
Wednesday, 22 January 2014

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Motion under Standing Order 17.42 to Resolve to Exclude the Public from the Meeting for
the Following Business: Item 6 on Today's Agenda and from the Meeting on the Morning of
30 January 2014

Cofnodir y trafodion yn yr iaith y llefarwyd hwy ynddi yn y pwyllgor. Yn ogystal, cynhwysir trawsgrifiad o'r cyfieithu ar y pryd.

The proceedings are reported in the language in which they were spoken in the committee. In addition, a transcription of the simultaneous interpretation is included.

Aelodau'r pwyllgor yn bresennol
Committee members in attendance

Leighton Andrews	Llafur Labour
Rebecca Evans	Llafur Labour
William Graham	Ceidwadwyr Cymreig Welsh Conservatives
Elin Jones	Plaid Cymru The Party of Wales
Darren Millar	Ceidwadwyr Cymreig Welsh Conservatives
Lynne Neagle	Llafur Labour
Gwyn R. Price	Llafur Labour
David Rees	Llafur (Cadeirydd y Pwyllgor) Labour (Committee Chair)
Lindsay Whittle	Plaid Cymru The Party of Wales
Kirsty Williams	Democratiaid Rhyddfrydol Cymru Welsh Liberal Democrats

Eraill yn bresennol
Others in attendance

Joanne Ferris	Swyddog Gweithredol Polisi a Phrosiect, Cymdeithas Diwydiant Fferyllol Prydain Policy & Project Executive Association of the British Pharmaceutical Industry (ABPI)
Dr Richard Greville	Cyfarwyddwr, Cymdeithas Diwydiant Fferyllol Prydain Director, Association of the British Pharmaceutical Industry (ABPI)
Karen Samuels	Pennaeth Arfarnu Technoleg Iechyd a Rheoli Meddyginiaethau, Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan Head of HTA & Medicines Management, All Wales Therapeutics & Toxicology Centre

Swyddogion Cynulliad Cenedlaethol Cymru yn bresennol
National Assembly for Wales officials in attendance

Chloe Davies	Dirprwy Glerc Deputy Clerk
Llinos Madeley	Clerc Clerk
Philippa Watkins	Y Gwasanaeth Ymchwil Research Service

*Dechreuodd y cyfarfod am 09:30
The meeting began at 09:30*

Cyflwyniad, Ymddiheuriadau a Dirprwyon Introductions, Apologies and Substitutions

[1] **David Rees:** Good morning. I welcome members of the committee to this morning's meeting of the Health and Social Care Committee in which we will hold our first public session into the inquiry into access to medical technologies in Wales. The meeting is bilingual, and headphones can be used for simultaneous translation from Welsh to English on channel 1, or for amplification of the sound on channel 0. I remind people to turn off their mobile phones or any other equipment that may interfere with the broadcasting equipment. There are no scheduled fire alarms, so, in the event of a fire alarm sounding, please follow the ushers. We have received no apologies for absence this morning. Therefore, we will move on.

09:31

Ymchwiliad i'r Mynediad at Dechnolegau Meddygol yng Nghymru—Sesiwn Dystiolaeth 1: Grŵp Strategaeth Meddyginiaethau Cymru Gyfan Inquiry into Access to Medical Technologies in Wales—Evidence Session 1: All Wales Medicines Strategy Group

[2] **David Rees:** I welcome Karen Samuels, head of healthcare technology appraisal and medicines management at the All Wales Therapeutics and Toxicology Centre on behalf of the All Wales Medicines Strategy Group. Good morning and welcome. Thank you for the written evidence that we have received to date. Obviously, Members will have some questions based upon that. However, perhaps you would like to give an introduction as to the role of the AWMSG and how it may be applied to medical technologies.

[3] **Ms Samuels:** Okay. Thank you very much indeed. Good morning. I suppose that the main issues that I would like to raise about the All Wales Medicines Strategy Group are basically the remit and why it exists. We are there to provide evidence on the clinical and cost-effectiveness of new and existing medicines to the Minister for Health and Social Services in an efficient and transparent manner, with the main aim of benefiting the patients within NHS Wales and improving equitable access to those medicines that are deemed to be proven both cost and clinically effective. We feel that the manner in which we actually conduct the process is very important. The basis behind that is because it is open and transparent, and it is inclusive because we utilise an expert panel, which is made up of NHS clinicians, pharmacists, academics, health economists, and both industry and patient representatives, to come together with a consensus view on new medicines and policies, basically promoting the best use of those medicines for the patients within NHS Wales. The other issue I would like to point out is the fact that this process has recently received recognition from the National Institute for Health and Care Excellence accreditation programme for NICE evidence for the robust processes that have been involved.

[4] **David Rees:** Before I ask Members to ask you questions, could you just clarify the relationship between AWMSG and NICE?

[5] **Ms Samuels:** Okay. Basically, the relationship between AWMSG and NICE goes back quite a long way. It started with our current chair of AWMSG, Professor Philip Routledge, who was on the original NICE panel when it appraised its first technology. Both he and Sir Mike Rawlins go back a long way and have been friends and colleagues for over 40 years. *[Inaudible.]* We work to a memorandum of understanding with NICE, so, we are very mindful of its policies and procedures and try to emulate, to the best of our ability, the

policies and procedures that it applies. We have representation on a number of its committees. I and some other senior colleagues sit on NICE committees, so there is a lot of cross-fertilization there, and we have a very good working relationship with it. Basically, I can pick up the phone to a board member on NICE to clarify any issues on process. Would you like me to go into how it affects our work programme?

[6] **David Rees:** That may come up in questions.

[7] **Ms Samuels:** Okay.

[8] **David Rees:** Gwyn, do you want to start?

[9] **Gwyn R. Price:** Yes. Good morning. What, in your view, is needed to ensure that a more strategic co-ordinated approach is taken to the introduction of new medical technologies in Wales?

[10] **Ms Samuels:** Well, I suppose what I can talk about is my experience with medicines and the advantages that I think that that has offered Welsh patients in improving safety and equity of access and, therefore, the overall benefit for the NHS, in effect. There are similarities, I think, to the processes that we apply, or that are applied by the All Wales Medicines Strategy Group, and those could be transcribed across to medical technologies. I think that the most important part is the transparency of the process insofar as all of the information that we use is available on the website and the meeting is public. The other major benefit is the timeliness of our advice because we are there, really, to expedite access to cost-effective and clinically effective medicines for patients within NHS Wales. So, we are very keen to ensure that that is done in a very timely fashion. I know that Professor Phil Routledge is often quoted as saying that delay is the deadliest form of denial, and that is basically something that we have in our mindset to make sure that a decision is made, because the absence of a decision is sometimes more harmful than a decision.

[11] **Rebecca Evans:** To pick up on what you said about taking an inclusive approach—and you mentioned your expert panel—I was wondering whether you look only to Wales for expertise or whether you take a wider look. I particularly have an interest in rare diseases. When looking at medicines for rare conditions, do you go worldwide? How does that work?

[12] **Ms Samuels:** That is a very valid question because our first port of call is obviously Welsh expertise, because the advice is going to be applicable within NHS Wales. So, because of that and because the availability of services within NHS Wales may differ from that across the border, the expertise and views of local clinicians are our first port of call and our main aim to receive. Having said that, a number of services are not available within NHS Wales and patients do need to go to England for expert treatment. In those instances, we have approached experts from other areas of the UK. From recollection, I do not think that we have gone outside the UK yet. We have certainly used written evidence from outside the UK, but we have not approached individual experts from outside the UK. We are certainly not restricted to Wales, but it would be our first port of call.

[13] **Rebecca Evans:** Okay. Following on from Gwyn's question, how would you respond to the suggestion that your group could be expanded to also take on medical technologies?

[14] **Ms Samuels:** Right, well, I could see that there would be benefits in—. Right, let me just think about this one very carefully. There would be benefits from a replication or modification of some of the processes that we use. I think that we have very good experience and track record from the past 12 years. There could be benefits from focusing the expertise with regard to critical appraisal skills within one unit—health economics input, for example. I think that, so far, we have very good links with clinicians. The policies and the processes

used, I believe, could be replicated, with modification. I suppose that it is for the committee to decide whether or not it would be appropriate to have one route of advice to the Welsh Government. I think that there is potential for significant overlap, so should that not be within AWMSC's widened remit, but within another body's remit, whichever body it would be, we would have to work very closely with it, because of the way that new technologies are developing.

[15] **David Rees:** Out of curiosity, we have had some evidence stating that perhaps a regional rather than an all-Wales approach would be better, particularly for technologies, because they tend to be focused on clinicians' individual specialities. What is your view on that?

[16] **Ms Samuels:** In all honesty, we are straying into the use of devices here, which is not my area of expertise, although I am aware that, with the use of devices, there is a larger element of user preference, if that makes sense. They have to insert it or use it, so there is the question of the physical usability of the product, which is not necessarily the same as for a medicine. There are some similarities, for example, with the use of inhalers, and some patients find certain things easier to use, so we could extrapolate from that, maybe, in relation to the clinicians who would have to use the devices. I think that there are benefits to having one authoritative view within NHS Wales, such as the fact that, to a large extent, the clinical and cost-effectiveness evidence would be the same and would be considered by different areas. There would be a need to balance that with ownership of the ensuing decision.

[17] **David Rees:** Thank you. Lindsay is next.

[18] **Lindsay Whittle:** Thank you, Chair. Good morning. Do you have any evidence that medicines and technologies are available, but are not NICE-approved, and that people are therefore being asked to pay for that treatment? They can have the treatment, but because the health boards and NICE have not approved it, people have to pay.

[19] **Ms Samuels:** I believe that you are talking about medical top-ups; is that correct?

[20] **Lindsay Whittle:** Yes.

[21] **Ms Samuels:** I believe that that does occur. The perspective that we would take is that it is the patient and clinician choice to go down that route, should a medicine have been considered neither clinically effective nor cost-effective, and therefore not the best use of NHS resources.

[22] **Lindsay Whittle:** I see. Okay, thank you for that.

[23] **Kirsty Williams:** May I take us a step back to medicines that are approved either by NICE or by yourselves? In your evidence, you state that, even though that might have been achieved, that,

[24] 'does not automatically result in timely adoption of the medicine by NHS Wales.'

[25] Could you give us an understanding of why that is and who is responsible for ensuring that there is a timely uptake of those medicines? I note that the support unit was established in 2010 to monitor uptake. Have you been able to establish whether the creation of that unit has resulted in a quicker uptake of medicine than previously, and are you able to supply us with any data that that unit has collected with regard to the timeliness of take-up?

[26] **Ms Samuels:** Right, there was a number of questions there. The first question, I believe, was—

[27] **Kirsty Williams:** Why?

[28] **Ms Samuels:** —why products, maybe, are not adopted. If we can start with the fact that if a medicine has a positive appraisal, either by NICE or by AWMSG, it is the obligation of the health board to make that medicine available, should it be prescribed. So, therein lies the first divergence. By a medicine being deemed both clinically effective and cost-effective, there is no obligation that it must be prescribed.

09:45

[29] It should only be prescribed if it is deemed clinically appropriate by the clinician looking after that patient. It does not say that it is better or worse than other medicines that are currently available. It is there as an option, and that is the terminology that is used a large amount of the time—that a medicine is available as ‘an option’. So, that is the first question as to why they are not necessarily all used. On the potential for the perceived delay, the first thing is that, because it is an obligation on the health boards to make it available, should it be requested, there could be a gap, because you actually have, with prescribers, what we call ‘early adopters’. That is human personality; some people want to try something new and others are quite comfortable with their current armamentarium and would try something new if everything else had failed, and would therefore use it when they deem it appropriate.

[30] **David Rees:** So, that is the clinician’s decision.

[31] **Ms Samuels:** That is the clinician’s decision. The main issue with having the advice being made mandatory by the Minister is the fact that that takes away the financial constraint, so it is an individual clinician’s decision to decide whether it is appropriate for that patient.

[32] **Kirsty Williams:** So, whose job is it to disseminate the information to individual prescribers that this new treatment is available, and has been deemed suitable by either of the processes? Whose job is it to disseminate that information to both the health boards and then to individual clinicians? Who does that?

[33] **Ms Samuels:** NICE does its own dissemination. Once any piece of advice is cleared by the Minister, basically, AWMSG disseminates that, as well, to a vast communication list within the NHS, namely, all the senior members, all the clinicians, all the finance directors and all the pharmacists. That is disseminated on receipt of ratification by the Minister.

[34] **Kirsty Williams:** Since the establishment of your support unit, has that unit been more successful in ensuring a timely uptake, or not? Has it made a difference?

[35] **Ms Samuels:** Yes, it most definitely has made a difference. The unit has monitored both the uptake of positive and negative appraisals to actually see what is happening out there in the service. Those papers have been presented to AWMSG and are available on the website. I can forward those to the committee should that be of any benefit. What one also needs to realise is that it is not only the individual clinician’s decision as to whether it is appropriate, but sometimes the services are not being provided in that locality, because you have tertiary care and some treatments are not provided in some of the more regional hospitals. So, you would not necessarily have all of the specialties in those hospitals. You may see that some products are taken up more in Cardiff than maybe in Glangwili, for example, because patients are referred there for specialist treatments.

[36] **David Rees:** Because of the clinician’s location.

[37] **Ms Samuels:** Yes, because of the clinician’s location. The other issue is the fact that

a lot of medicines have more than one indication. So, because of the information technology, it is possible to see this being used, but it is not possible to see what it is being used for.

[38] **Darren Millar:** I just have some follow-up questions to those that have been asked by Kirsty, really. As I understand it, there are a number of formularies across Wales that health boards use, and if a health board receives advice from the Minister after he has ratified a decision by AWMSG, it is up to the health board then to add the medicine, technology, or whatever it might be, to the local formulary. Is there a case for a national formulary in order to prevent a potential barrier to access for patients?

[39] **Ms Samuels:** There is definitely a case for a national list. The term ‘formulary’ is being used for different purposes in the health boards. The health boards sometimes use a formulary as an educational tool for their more junior medics to try to direct what their first, second or third line choice would be. If there is a new product for a specialist treatment and, to use my example of Glangwili, there is no facility for that medicine to be used there, to actually go and put it on the formulary as a matter of course would perhaps not benefit patients in that region. However, I take your point that there is probably a benefit to having a national list.

[40] **Darren Millar:** Okay, but there is not a national list as it stands at present.

[41] **Ms Samuels:** At the moment, the health boards adopt them on to their local formularies.

[42] **Darren Millar:** However, you are suggesting that there should be a national list of medicines that allows for, ‘This should be the first medicine that might be allocated to a patient with a particular condition and this should be the second choice’, and, should all else fail, ‘These are perhaps other choices of medicines for you to be able to prescribe, should it be clinically appropriate’. That should be on some sort of national list.

[43] **Ms Samuels:** I think that what you are talking about is a list and a prioritisation, and they are slightly different.

[44] **Darren Millar:** Okay.

[45] **Ms Samuels:** To have a list of what has been approved or not approved is appropriate, and that is available on our website and on the National Institute for Health and Care Excellence’s website.

[46] **Darren Millar:** It is just that you mentioned earlier the need for equity and I assumed that you meant equity within Wales, in all parts of Wales, so that when a decision is made, the availability of a particular medicine to prescribers is consistent across the whole country.

[47] **Ms Samuels:** Yes.

[48] **Darren Millar:** You have identified in your own evidence that that is not the case, and we touched on some of the barriers in Kirsty’s evidence. However, do you perceive—I suppose that is the straight question—the fact that there are local formularies as opposed to a national one as a potential barrier?

[49] **Ms Samuels:** No, I do not.

[50] **Darren Millar:** You do not.

[51] **Ms Samuels:** No, I do not. I perceive—

[52] **Darren Millar:** Even though you may get the majority of health boards putting things on their local formularies—. If it is not on a formulary, as I understand it, it cannot be prescribed. Tell me if I am wrong.

[53] **Ms Samuels:** That is not my understanding. I am not based in a health board. I was previously, before taking up this post. As I said, the use of the formularies within the health boards is very different. Some health boards have a very extensive list; others use it as an educational tool to direct prescribing. That is very different from saying that if a product is not on a formulary, it is not available. A lot of the medicines that have been approved are very expensive and you would not necessarily want them to be prescribed by your junior house officer who has just qualified, potentially. However, you would want it to be prescribed by a senior consultant who has expertise in that area. That, I believe, is reflected in a number of the formularies.

[54] **Darren Millar:** Let us talk about senior consultants, then. There are many people in some parts of Wales, particularly north and mid Wales, who receive treatment from clinicians at tertiary centres in England. One of the things that patients come to me with in my constituency office is that, very often, clinicians will feel it appropriate to prescribe a medicine for an individual who is a Welsh patient and be prevented from doing so because a medical technology is not available for prescription to Welsh patients because of the commissioning arrangements from health boards. That is very frustrating for clinicians and patients. In terms of the equity argument that you made earlier, do you think that there needs to be greater equity between England and Wales in terms of access to some of the medicines that are available, for example, through the English cancer drugs fund?

[55] **Elin Jones:** I knew that that was bound to come up.

[56] **David Rees:** You have strayed off into a particular area, but we want to focus upon—

[57] **Darren Millar:** Chair, this is about patients in Wales being treated at tertiary centres in England.

[58] **David Rees:** I want to focus on processes and what we can learn from the processes. We will take the question that was raised: what can we learn to ensure that, if the processes provide two technologies, we can ensure that there is greater benefit across Wales as a whole?

[59] **Darren Millar:** I think that your question is slightly different, Chair. Lots of Welsh patients are treated at tertiary centres in England. There is a perception that there is significant difference in equity, which is noted in the minutes of the AWMSG's November meeting. I know that it is something that concerns the AWMSG. How might that lack of equity be addressed in the future? Do you have any ideas or suggestions?

[60] **Ms Samuels:** I am happy to answer the question if the Chair wishes me to do so.

[61] **David Rees:** Okay.

[62] **Ms Samuels:** We have put a proposal forward, because we share your concerns that it causes issues. At the end of the day, it is the patients who are disadvantaged when a situation is deemed to seem unfair. The situation arises, as you quite rightly pointed out, because of the different commissioning situations in NHS England. The medicines that you refer to have, by and large, received negative technology appraisals via NICE. The large majority of them have had a 'no' from NICE, but have subsequently been made available through different funding streams—you mentioned the cancer drugs fund. We are aware that that has a disproportionate effect on NHS Wales's patients, because those patients in England, for whatever reason, may

have access to that treatment.

[63] **So, we have put a proposal forward that the manufacturers of those medicines can engage with AWMSG on the proviso that they submit a Welsh patient access scheme. It would provide an opportunity for the manufacturers to give a more cost-effective medicine, and therefore for it to be made available to patients within NHS Wales, potentially, once it had gone through the appraisal process.**

[64] **David Rees:** Do manufacturers currently engage with AWMSG?

[65] **Ms Samuels:** Yes, they do, directly.

[66] **Darren Millar:** So, that would affect the cost-benefit appraisal if a manufacturer said, for example, 'If you make it available in Wales, we will halve the price from the original appraisal', or whatever it might be.

[67] **Ms Samuels:** Yes, exactly.

[68] **Darren Millar:** I see. That is very good news; I am very pleased to hear that. What do you do as AWMSG, or what do you think health boards might do, to communicate with clinicians at tertiary centres outside Wales about the availability of drugs that have been appraised by AWMSG as being things that should be available to Welsh patients, should they be clinically appropriate?

[69] **Ms Samuels:** That is something that we are going to have to take into that pot, once we get that process running.

[70] **Darren Millar:** However, even now, there will be drugs that you have appraised as being of benefit that should be available to Welsh patients. How do clinicians in English hospitals know whether you have made a decision about the availability of a new medicine if they are treating Welsh patients?

[71] **Ms Samuels:** I believe that that is part of the commissioning arrangement that the individual health boards have when they refer their patients. Basically, they are referring their patients for a clinical opinion. This is straying slightly outside of my area of expertise; I am a pharmacist, and my expertise is health technology appraisals for AWMSG.

[72] **Darren Millar:** Presumably, the Welsh analytical support unit would monitor the communication with English clinicians to make sure that they were implementing whatever the guidance was from AWMSG. Perhaps it is more appropriate that we ask them the questions.

[73] **David Rees:** I think the question is: are you aware of that activity at this point in time?

[74] **Ms Samuels:** Am I aware of what, sorry?

[75] **David Rees:** Of the ability to communicate with clinicians in England who treat Welsh patients.

[76] **Ms Samuels:** We do not do that directly, because that would be via the health boards that are referring their patients for care.

[77] **Darren Millar:** I have just one final question, Chair, and it is about the role of the Minister. You said that the Minister has to clear the decisions that have been made by

AWMSG, or ratify them—

[78] **Ms Samuels:** He ratifies them. That is the terminology.

[79] **Darren Millar:** Okay; he ratifies the decisions. Does the same situation exist with NICE-appraised medicines and technologies in England, or are they automatically available?

10:00

[80] **Ms Samuels:** My understanding is that they do not go through the Minister in England.

[81] **Darren Millar:** Right. Are you aware of any reason why the Minister likes to clear these things in Wales, once a decision or a recommendation has been made?

[82] **Ms Samuels:** I do not think that I am the best person to answer that question.

[83] **David Rees:** We could ask the Minister when he appears before us.

[84] **Darren Millar:** I am simply asking whether Karen Samuels is aware of any particular rationale for that.

[85] **Ms Samuels:** I am not aware, but I do think that it provides a significant benefit to the implementation of the decisions once they are ratified.

[86] **Darren Millar:** So, you think that it is a good thing that the Minister has to ratify decisions.

[87] **Ms Samuels:** I think that the fact that they need to be available within the health boards three months after the ministerial ratification is a very positive step.

[88] **Darren Millar:** What are the delays between your recommendation and the Minister's ratification? How long is the average delay?

[89] **Kirsty Williams:** There is nothing there, Darren. I know that you are desperate.

[90] **Darren Millar:** I am just wondering. I assume that that is something that the AWMSG would have some information on. How long does it usually take from the time when the AWMSG has made a recommendation to the ratification by the Minister? That is a potential delay that can be significant for a patient outcome, I would assume.

[91] **Ms Samuels:** That is not something that we have monitored.

[92] **Darren Millar:** It is not something that you have monitored. Okay, thank you.

[93] **David Rees:** Thank you. Kirsty?

[94] **Kirsty Williams:** While I have a great deal of sympathy with what Darren has said about the cancer drugs fund, the reality is that the vast majority of cancer patients actually need better access to other forms of technology—not necessarily drugs. That is one of the reasons why we are looking at this, because the inequity for most people lies in the lack of up-to-date technologies. What can we learn from the medicines process that could allow us to ensure that there is not an inequity in the future, for instance, in the latest radiotherapy treatments or other techniques that would perhaps be available in other parts of the world and considered best practice, that we do not adopt in Wales in a timely fashion? What lessons can

we learn from medicines to take over to a better system for non-pharmaceutical intervention?

[95] **Ms Samuels:** I think that one of the most important factors is the area of what we term ‘horizon scanning’. That is the phase before a medicine is licensed. Due to the refinement of the pharmaceutical industry, and the process that medicines need to go through in their development, there is already quite a lot of evidence that they need to collate before they go to licence. There are some timescales attached to that. On a UK-wide basis, there is currently a joint venture between the Department of Health and the Association of the British Pharmaceutical Industry in the development of a database called UK PharmaScan. The devolved nations also contribute a limited amount, and we have representation on that committee. Essentially, it is a database that is populated, so that we know what is likely to come up in the next three, six or 12 months, and maybe a little further on than that, but the closer to licence they are, the more accurate the data become. Essentially, not only do we know what is likely to hit availability, but what sort of area it is in and we have some idea of the cost, or at least the cost bandings. We know within tens of thousands or whatever, whether is it going to be cheap, middle-range or high-cost. That has proved particularly useful, not only from our perspective of appraising those medicines once they are available, but also to feed into the service provision for those sorts of treatments.

[96] **Kirsty Williams:** Could—

[97] **David Rees:** No, I am going to ask William because he asked the last question on horizon scanning.

[98] **William Graham:** I will go on to the evidence base if I may. In your evidence, you suggest how you assess the cost effectiveness of new medicines. Could you give us some idea of how that happens?

[99] **Ms Samuels:** Certainly. Do you want me to focus on cost effectiveness?

[100] **William Graham:** Yes, please.

[101] **Ms Samuels:** Okay. There are different types of models that can be used for cost effectiveness: there is a cost utility analysis, and there is also a cost minimisation analysis. A large amount of those data is provided by the pharmaceutical industry in its submission to us. Our team then does an independent literature search, because independence is particularly important to us, to see what other information is out there, and we do our own analysis, plus we critique the submission that the company has provided. A large amount of that analysis is dependent on the input into the model—the cost-effectiveness or cost-utility model—which is really dependent upon the clinical outcomes. You cannot really divorce the two. So, you may come up with a figure, but what you have surrounding that figure is the level of uncertainty that that figure is correct. For example, if a product may cost £20,000 per colleague, per cost utility or life year gained, and if you were 98% sure that it would cost that, your likelihood would be a positive outcome. However, if the likelihood is that it would be £20,000, but between a range of perhaps £15,000 and £70,000, you are less likely to come out with a positive recommendation. So, it is not only an absolute figure, but it is the parameters and the certainty around the figure that comes out.

[102] **William Graham:** Does your group have any influence on procurement?

[103] **Ms Samuels:** The procurement of—

[104] **William Graham:** The procurement of medicines generally.

[105] **Ms Samuels:** No. I actually think that it is very important that we do not.

[106] **William Graham:** Yes. I understand.

[107] **Ms Samuels:** I think that it is really important that the committee that comes up with the recommendation or the advice to the Minister is independent of providing that service. It is a matter of clear water.

[108] **William Graham:** Are you able to tell us anything about the yellow card centre? Do you have knowledge of that?

[109] **Ms Samuels:** Yes, I do. The yellow card centre Wales is hosted within the all-Wales therapeutics and toxicology centre. It is extremely successful for such a small unit within NHS Wales. The reporting rates are much higher than within the rest of the UK. One of the reasons for that may be that there has been a drive for education through the centre, highlighting the importance of patient safety. It also recently promoted the use of what are called yellow card champions. So, in each health board, there is a designated individual whose focus—or part of their job—is to promote the use of that alerting system.

[110] **Kirsty Williams:** Just to go back quickly to the horizon scanning, you said that that has been a very useful process, enabling people to plan. You said that it gave you a lot of information about the potential cost. Does it also allow you to make an approximation of how many patients will present and would be suitable for prescribing that drug? Is that possible?

[111] **Ms Samuels:** It gives you a view on what the manufacturers think could be the patient population in which it would be suitable. The information there is confidential by the manufacturers. I am not quite sure that their anticipation is always borne out in practice. It does give us an indication of what they anticipate.

[112] **Darren Millar:** In terms of the prioritisation, I would assume that most people might want to appraise new drugs that may be of benefit to larger numbers of people, potentially, rather than those that are perhaps for rare disease treatment—the so-called orphan drugs. How do you prioritise to make sure that you can get the balance right at AWMSG?

[113] **Ms Samuels:** We have been very fortunate, in a way, insofar as we have not yet needed to prioritise, because there is no backlog, and there never has been. We appraise medicines on receipt of a submission from the manufacturers. So, the manufacturers are essentially the first step to the provision of that information. Should they not provide it within three months of their licence being granted, we would issue a statement of advice, which, again, would be ratified by the Minister, stating that, unfortunately, due to a non-submission, the medicine is not available for use within NHS Wales. So, there is no loophole there, but we do have prioritisation criteria ready to go should we be faced with a scenario of overcapacity for our meetings, and they are based on, largely, unmet need: the medicine is aimed at a disease for which there is no alternative treatment, basically. So, unmet need within that patient population and clinician and/or patient demand are the three main areas, really. The potential impact that that product would have on patient care would be at the forefront of our prioritisation.

[114] **Darren Millar:** Just in terms of your capacity, do you think that the new Welsh patient access schemes might have an impact on the number of manufacturers that might be making requests and putting demands on the AWMSG agendas in future? What sort of contingency arrangements do you have to be able to deal with any extra capacity issues that might present?

[115] **Ms Samuels:** The number of medicines coming to licence will not differ. The number of medicines coming to licence will be consistent. Whether the manufacturer decides to

provide a patient access scheme for consideration is within its remit. I think that, provided the patient access schemes are not complex schemes or outcome-based schemes but perhaps more simple discounts, we have the capacity to accommodate that.

[116] **David Rees:** May I clarify something? How does the AWMSG become aware of patient or clinician demand?

[117] **Ms Samuels:** We have extremely good links with our clinical networks. We have representations from our clinicians on our steering committees, our new medicines group and our AWMSG, and we are in dialogue with the cardiac, cancer and diabetes networks, for example—the three quite large areas. So, we send them a list of medicines that we are aware are coming through the horizon scanning process, and we tell them in advance that this is what is likely to come. We ask what they have any particular interest in, and they feed that information back to us. So, it is a two-way process for their perceived interest in those medicines, which is not necessarily the same as patient demand—I appreciate that. With patients, we have PAPIG—the patient and public involvement group—which is a patient interest group that has been recently developed over the past 12 months. We are working on proactively getting information from it. We have a patient-specific section on our website. Basically, patient groups and representatives are also heavily involved in the appraisal process. They submit information that they consider portrays the patient perspective, which is extremely important for the appraisal of medicines. So, that avenue is available.

[118] **David Rees:** I know that this is not your area of expertise, but, given that technology may be focused more on a smaller number of clinicians, specialisations and areas, would that process be applicable to technologies as well?

[119] **Ms Samuels:** I think that it is extremely important to get a feel for what clinicians are waiting to use or are keen to use—they have been to international conferences, they are aware of what is coming out. So, I think that steps would need to be taken to ensure that that sort of network of advice was received. On the feasibility of it, I am not sure whether the existence of those groups applies. Presumably, many of the clinicians would be the same as those using medicines but there will be different specialities as well.

10:15

[120] **Elin Jones:** My question was along the same lines, really, in terms of the applicability of the current processes that you have for medicines and how applicable those relationships are for the clinical networks. The kind of horizon scanning that you do with pharmaceutical companies is a well-established route, but the companies involved in the development of medical technologies are not necessarily large, well-resourced companies; they may be quite small, expert companies, or spin-off companies from universities. There is all of that kind of make-up of involvement and some clinicians may have a relationship with some of those companies and others will not know of their existence. So, how practical do you think it would be to have that kind of horizon-scanning relationship with medical technology developers, which tend to be smaller, more innovative kind of companies?

[121] **Ms Samuels:** I think that the challenges would be more diverse. We would need to go from the fact that the principles are sound, and that, in order to have a good process, the manufacturers can actually see the merit and the benefit in giving that advance notice to appraisers so that we know what is coming and the NHS knows what is coming. I think that they are fully supportive of the benefits. There may be a case to be made to explain to the providers of the technologies that, in the end, subscription or engagement with such a process could benefit their product and ensure that it has far smoother, rapid access to the patients. I am not saying that it would be straightforward to do that.

[122] **Elin Jones:** I just want to question you on the Welsh Health Specialised Services Committee, to which you refer in your paper, and the fair and equitable access to specialised services throughout Wales. What is that committee and how does it work with you to ensure that equitable access to medicines and medical technology application throughout Wales?

[123] **Mr Samuels:** WHSSC is a commissioning body; it commissions specialised services. We work closely with it insofar as it is a key body to provide intelligence and advice on what is needed and on prioritisation. It has a seat at the steering committee, it has a seat at our new medicines group and at the All Wales Medicines Strategy Group. So, we have good links already with that organisation.

[124] **Elin Jones:** Thanks; I know what it is now.

[125] **Kirsty Williams:** The new watchword for the NHS is ‘prudence’ and spending the money that we have in the best possible way. I notice that you said that, when you make an appraisal of a new drug, you do not say whether it is better or worse than existing technology; it is just that you can prescribe this. So, who has the role of establishing whether new medicines in the long run are more cost-effective than perhaps old prescribing practices? They might be more cost-effective and have better patient outcomes. Whose job is it to advise clinicians and health boards on what clinicians should be prescribing? I appreciate that they are independent people and that they cannot be told what to do, and even if they are told what to do, they do not necessarily do it. So, whose job is it to do that?

[126] **Ms Samuels:** I think that maybe what you are talking about is clinical pathways—when patient A or B presents, what is the appropriate route for them to go down? I think that that is done largely at health board level, and they do that using the knowledge of what armamentarium is available for them and based on the services that are there. Also, if you think about drawing a line in the sand, you know that any medicines after AWMSG or NICE are deemed clinically effective and cost-effective. So, you know that anything coming out now has that sort of evidence base behind it. With time, there will be more of those than what is behind that other line, basically.

[127] **Kirsty Williams:** So, do you not see that there is a role for your organisation in giving that guidance? I will give you a fictitious case. Patient A needs drugs to regulate atrial fibrillation. Perhaps the traditional treatment would have been warfarin-type treatment, but we know that there are new drugs that have been approved that are better for the patient. They do not need such close monitoring, et cetera. That patient knows about these and says to the GP, ‘What about these?’ However, the GP says, ‘Oh no, you do not want those, dear. What you want is what I have prescribed for the last 20 years.’ Do you not see that there is a role for you in saying, ‘This new drug is cost-effective and should perhaps be prioritised over some of the older stuff’?

[128] **Ms Samuels:** Okay, I think I now understand. Basically, AWMSG has a dual role. Health technology appraisal is one of them, and providing advice on medicines management and prescribing guidance is another. We produce prescribing guidance for specific problem areas, and we have produced guidance on atrial fibrillation, for example, which gives guidance on where those new products would be best focused. We do not produce guidance for absolutely every medicine as it comes out. One needs to realise that experience with a medicine’s use needs to be gained in clinical practice before a guideline can be developed. So, we have produced a number of clinical guidelines in difficult areas.

[129] **David Rees:** However, this is still a clinician’s decision.

[130] **Ms Samuels:** It is most definitely a clinician’s decision, as an individual practitioner.

[131] **Kirsty Williams:** Would you recommend that, if we were to set up a new system of doing non-pharmaceutical technologies, that kind of usage guidance should go hand in hand with the appraisal process?

[132] **Ms Samuels:** This is about the benefit that we have had from the development of the Welsh Analytical Prescribing Support Unit, for example, and I will bring in some of the prescribing indicators that it has used. Through prescribing indicators, we have promoted the best use of non-steroidals and proton-pump inhibitors, and we have reported that at a health board level. We have reported variation in that, and we have fed that back. That, I think, is the most powerful tool for clinicians to question variation: is it for a good reason, or is it maybe for reasons of current practice or services? People need to delve down as to the reasons behind that. The feeding in of usage and how things are put into practice is a very powerful tool for clinicians. They would then evaluate their practice against their peers.

[133] **Kirsty Williams:** That is helpful.

[134] **David Rees:** Before I bring in Elin, I will ask something. Clearly, we are looking at technologies. As a consequence, we are talking about medicine and we are looking at processes and at whether we can learn from them. There has been a more common move towards combination where devices are required to work with new medicines. Are those guidelines that you are talking about also applicable in those circumstances?

[135] **Ms Samuels:** For a combination situation, such as HER2, which is a diagnostic test that would need to be used before the appraisal of a breast cancer treatment, it would be best to look at those two things. Looking at them in isolation would not be correct. Moving forward, we would need to be cognisant of the availability and cost of those tests. There needs to be some overlap or conjoined working in those specific areas.

[136] **David Rees:** Okay. We now have questions from Elin and then Rebecca.

[137] **Rebecca Evans:** I think that my question has been answered.

[138] **Elin Jones:** Mine is along the same lines. Ms Samuels, would there need to be more proactivity with clinicians in providing advice and support to them to adopt medical technologies, as compared with new medicines, because there may be a reluctance to adopt new technologies by individual clinicians? Also, is it even more challenging with technologies than it is with prescribing medicines?

[139] **Ms Samuels:** Any change in practice can be perceived as being a careful step that practitioners would need to make. I go back to my original point about doctors and more traditional uptake. If it involves a change in procedure, for example, and not just using a different device, I would imagine that there are other factors that would come into play as well over and above their choice of medicine. I am probably not the best person to answer that.

[140] **David Rees:** Okay; we will ask NICE. I think it is important to understand because, as you say, as devices come in, procedures may also change as a consequence of that. In medical and medicine terms, does that ever happen? Do procedures change as a consequence of a medicine coming in or is it just purely the medicine?

[141] **Ms Samuels:** No, the choice of a medicine will or can affect the process and procedures that patients undertake. You touched on the use of warfarin, for example, and some of the new anticoagulants that have recently been made available. They have the potential to affect the way that anticoagulant services are run. So, it has an impact.

[142] **David Rees:** Do you look at those issues when you evaluate the medicine?

[143] **Ms Samuels:** Yes, definitely.

[144] **David Rees:** Do any other Members have questions? I see that there are no more questions. Thank you, Karen, for coming today. We appreciate that your expertise is in medicine, but it is important for us to understand the processes that are currently operational so that we can see whether they are or could be applicable to technologies. Thank you for your time today.

[145] **Ms Samuels:** Diolch yn fawr.

*Gohiriwyd y cyfarfod rhwng 10:27 a 10:44.
The meeting adjourned between 10:27 and 10:44.*

**Ymchwiliad i'r Mynediad at Dechnolegau Meddygol yng Nghymru—Sesiwn
Dystiolaeth 2: Cymdeithas Diwydiant Fferyllol Prydain
Inquiry into Access to Medical Technologies in Wales—Evidence Session 2:
Association of the British Pharmaceutical Industry**

[146] **David Rees:** Welcome back to the second evidence session in the inquiry into access to medical technologies. I welcome Dr Richard Greville and Joanne Ferris from the ABPI. Good morning, and thank you for your written evidence to the committee on this inquiry. Do you wish to make an opening statement before we start?

[147] **Dr Greville:** Yes, I am happy to do that, Chair. Initially, I would like to thank the committee for the invite to come along today. Hopefully, the evidence will be useful in your ongoing thinking.

10:45

[148] It is clear to us, or was clear to us, that medicines fall outside the scope of your work currently, and we appreciate that the intention is for you to maintain focus in the area of medical technologies. However, we have been involved in this inquiry for some time and, in fact, had initial conversations with a previous Chair. The reason for that is that the pharmaceutical industry is heading into an area of medicines development very much aligned with the development of diagnostics and devices, so-called 'companion diagnostics'. It is a critical area for the pharmaceutical industry and, as such, a critical area for the Association of the British Pharmaceutical Industry.

[149] To give you a rough idea as to the numbers, of the medicines in the development pipeline currently, about 60% are what would be termed speciality medicines. Most of those medicines, in some way or another, would benefit from diagnostics and the devices associated with them. So, the ABPI, the trade association for branded pharmaceutical medicines in the UK, has had an active presence in Wales for the last 10 years. Our membership includes about 150 or so small, medium and large pharmaceutical companies that are concerned with the development of these new medicines. Our members spend about £10 million a day in terms of developing these medicines in the UK, and, as I mentioned, the link to companion diagnostics is a critical one for us, hence our interest in this area.

[150] **David Rees:** Thank you for that. I can reassure you that access to medicines is outside the focus of this inquiry, but, as you rightly pointed out, the companion devices with medicines are important, as are the processes that medicines follow, for us to see whether we can learn lessons from that. That is the focus of this morning's session. William, would you

like to start?

[151] **William Graham:** Yes, thank you. Forgive my ignorance, but could you illuminate the committee a bit more about companion diagnostics?

[152] **Dr Greville:** Indeed. In terms of developing technologies in this area, you will be very aware of advancing knowledge within genomic definition et cetera, for example. It is increasingly likely that, in the future, not only will the medicine be available for a range of therapies, perhaps, and disease areas, but, with these advancing technological advances, it will be possible to specify which type of patient would respond best to the medicines being considered. Again, that has enormous advantages in terms of efficiency, minimised adverse drug reactions, et cetera. There are a whole host of advantages aligned with companion diagnostics alongside medicines.

[153] **William Graham:** Thank you. The cross-party group, I notice, highlighted that cost savings could be seen from a stratified medicines approach. Would you agree with that?

[154] **Dr Greville:** Yes, indeed. As mentioned, there are efficiency gains, obviously, and there are patient benefits through minimised adverse reactions and associated benefits. In fact, adherence might also be better as patient confidence increases in the science behind medicine specifically for them as individual patients.

[155] **David Rees:** Gwyn Price is next.

[156] **Gwyn R. Price:** Good morning, all. What then, in your opinion, is needed to ensure a more strategic, co-ordinated approach to the introduction of new medical technologies in Wales?

[157] **Dr Greville:** Again, the co-ordinated approach is very important from our point of view. As I think was mentioned in the earlier session, aligning and co-ordinating the assessment of both the companion diagnostic and the medicine is very important. That is something that we would certainly encourage. In terms of a strategic approach, again, that is very useful, I think, in terms of the lessons learned from the assessment of medicines. Transparency is a critical area; again, I know that you touched on that a bit earlier. Also, the robust nature of the assessment itself is critical. So, those are certainly advantages of a strategic approach, and, again, those would apply as much to the assessment of medical technologies as to a smaller sub-set, which is the medicines.

[158] **David Rees:** Rebecca is next, then Leighton.

[159] **Rebecca Evans:** In terms of the practicalities of that strategic approach, clearly it is not there at the moment, so what mechanisms or procedures could be put in place? Would it be a case of expanding the role of the All Wales Medicines Strategy Group, or recommending a shadow group, or a sister group, to deal with medical technologies? What would we need to do get that strategic approach?

[160] **Dr Greville:** I suppose that the approach might be, 'build it and they will come'. So, again, if there is a strategic approach and a clear process for medical technology companies to engage in Wales, that might well be an appropriate way. As to whether it falls within the remit of AWMSG, or an associated group, perhaps your inquiry will come to a decision on that. However, certainly, our view is that having a centralised process avoids the fragmentation of any local decision making, and, in fact, it is critical to the implementation of the assessment, whatever the outcome of the assessment is later on. We have found that, in instances where there is local decision making in the area of medicines—I suppose that the classic area would be individual patient funding requests—that, in itself, adds a level of

complexity, which would be avoided by a more holistic, strategic approach.

[161] **Rebecca Evans:** You work across Britain, so are there things that we could learn from other parts of Britain, or the UK, in this regard?

[162] **Dr Greville:** I am sure that there are. In fact, I was fortunate enough earlier this week to listen to Adrian Newland, who is the chair of NICE's diagnostics advisory committee. He was presenting at a meeting sponsored by the ABPI and the equivalent for the diagnostics industry, the British In Vitro Diagnostics Association, BIVDA. I do not know whether Adrian will be down to speak to you at a later time, but he obviously has great experience of what NICE does and how it does it in England. Again, the applicability of that to Wales might be very useful.

[163] I picked up two points from a lot of technical jargon and other discussions. One of them was the frustrations that he and his committee have about the lack of mandatory funding for companion diagnostics. So, again, a strategic approach in Wales might be beneficial against that. Also, I noticed earlier that there was a discussion about the uncertainties involved in the assessment of medical technologies and medicines, and he made it clear that the way that his committee treated that level of uncertainty was to get good, strong clinical expertise around the committee discussion at the time of assessment. I think that that is a useful lesson, which could not only perhaps influence the way that medical technologies are assessed in Wales, but might also retrofit into the way that medicines are assessed in Wales. I know that one of the recommendations made by the orphan and ultra-orphan drugs review group, for example, was to increase the level of clinical involvement around the decision-making table to avoid the inevitable difficulties for medical technologies that the evidence base is going to be somewhat lighter than for medicine assessments.

[164] **David Rees:** We have questions now from Leighton and then Kirsty.

[165] **Leighton Andrews:** What percentage of your member companies' UK research and development budgets is spent in Wales?

[166] **Dr Greville:** The percentage is probably relatively small—the investment, currently. However, the model is, in itself, changing. *[Interruption.]* Oh, a new microphone—that is the first time that I have ever been not loud enough. *[Laughter.]*

[167] It is a model that is changing. The current model is based on quite large significant research and development centres, and most of those are in England. So, most of the straightforward investment in terms of developing medicines happens around the golden triangle of London, Oxford and Cambridge. However, because of that evolving model, it is increasingly likely that the investment in terms of development will be outsourced to other areas of excellence. This is a critical area for Wales, not necessarily in terms of medical technologies, but certainly in the development of pharmaceuticals. It is something that we are working on very closely with both the departments of economic development and of health, to be honest, in terms of ensuring that Wales has the ability to wave a flag for excellence in a range of clinical areas, which will attract the interest of inward investment in research and development.

[168] **Leighton Andrews:** Can you point to collaborations between your member companies and research institutes in Wales in the sphere of medical technologies?

[169] **Dr Greville:** In terms of medical technologies, not so much, because it is slightly outside of my remit. However, there is a well-documented partnership arrangement between Merck Serono, Cardiff University and Cancer Research UK. That is a partnership that has been developed over the past five years, and a classic example of where inward investment

into Wales can happen without the necessity for bricks and mortar per se, because it is the clinical and academic excellence that drives the vast majority of research and development for pharmaceuticals.

[170] **Kirsty Williams:** I will move to the issue of take-up. It seems that you can have the best evaluation process in the world, but, if that does not translate into actual take-up, its value is lost. From your experience in the field of pharmaceuticals, has the establishment of WAPSU made a difference in terms of take-up? Given the non-mandatory nature of the NICE process for approving technologies, what lessons can we learn from that, and what approaches do you think that we should employ if we move to a different system of evaluation for technologies in Wales? Could some of that then be retrofitted to the pharmaceuticals process?

[171] **Dr Greville:** Yes. Uptake is a critical issue for the UK in terms of medicines. To be honest, I am not close enough to medical technologies to be able to feed in, but, if I relate to you what happens in terms of the area of medicines, perhaps you can enquire further later on in your work. In terms of the uptake of new medicines, the UK is the poor relation across Europe. The expectation of uptake of new medicines in the UK is no greater than in many of the eastern European countries. The reasons for that are probably many and varied. They are probably to do with a degree of clinician conservatism. It may well be to do with the infrastructure within the NHS itself; it may be to do with local barriers or obstacles to the uptake of medicines; and it may be to do with undue concerns about the cost of medicines. You also talked earlier about horizon scanning, and it may also be the inability to plan, or the difficulties involved in planning, for the availability of these new medicines. So, in terms of UK PharmaScan, for example, the industry buy-in to the co-sponsorship of that was very much to do with the issue of whether, if there were a better process of planning in place, the uptake of medicines in the UK would actually improve on the back of that. It is too early days to know whether that has had a profound effect as yet.

[172] In terms of the affordability angle, you may well be aware that, over the past 18 months or so, the ABPI has been in negotiations with the UK Government about the pricing of branded medicines.

11:00

[173] The outcome of those discussions and negotiations has been a commitment from the branded pharmaceutical industry to underwrite any growth in the cost of branded medicines in the UK, again with the intention of supporting improved uptake of medicines in the UK. Again, it is too early to know whether that will make a difference, but the initial responses received suggest that that may well be a step change or will lead to the step change in the uptake of branded medicines in the UK.

[174] You asked about monitoring systems, the importance of monitoring systems and WAPSU. Of course, we view monitoring systems as being absolutely critical because what is not seen is not monitored and is not challenged. So, we see the development of WAPSU as being very, very positive. Again, we accept that it is a complex area, as Karen Samuels mentioned earlier. It is not an easy field; it is a complex field. They are trying to look at the similar areas in England through the innovation scorecard. We would hope that, through collaboration between WAPSU and the innovation scorecard, a process that is acceptable to all will be developed in the very near future. Again, it is too early, I suppose, to know whether that will actually have a significant impact on the uptake of medicines. So, my answer in terms of medical technologies is, 'Well, they're all important, but will they contribute to the improved uptake of medical technologies? Well, the jury is probably still out'.

[175] **David Rees:** Okay. On the question of companion devices, clearly, we have already had clarification. However, you have identified that they are for more specified targets,

effectively, at this point in time. Is that therefore a difficulty you see facing the medicine world, in the sense that we have a device that has to be approved that may not be mandatory and we have a medicine that could become mandatory? How do we balance that side of things?

[176] **Dr Greville:** Yes, again, it is important from our side that, in an ideal world, these would be assessed together, in parallel, by, if not the same body, certainly bodies that had close discussions and communications with one another. That would be the ideal world. Inevitably, for diagnostics more than devices—because I think that devices would inevitably be co-evolved and developed—academic centres will develop their diagnostic skills in isolation from medicines. The only thing that I would suggest in those instances would be that diagnosis or the diagnostic facility should be supported only if the medicine that it related to was also available in the UK or in Wales. To progress the assessment of a diagnostic without identifying the specific treatment that that diagnosis would apply to would be disjointed thinking. So, there would need to be a clear identification as to the treatment before the diagnosis itself was deemed to be cost-effective.

[177] **David Rees:** In relation, therefore, to the evaluation of the cost-effectiveness of medicines at this point in time, clearly, we are aware that the process is wider for medicines. How do you see a similar process working for technologies?

[178] **Dr Greville:** Again, I hate bringing complexity to the table, but, inevitably, that is the nature of the beast. I suppose that, if the ambition was to develop one assessment process for the range of medical technologies, again, that would be wishful thinking. We have found that through the evolution of medicines assessment. We have found that, in practice, you need to modify your approach; you need to modify your methodology, dependent on the medicines concerned. The classic example, I suppose, would be the need for the ongoing evolution of any assessment processes. Evolution, revolution, reform and ongoing updates are absolutely critical. There are examples of that already in this system. There are examples specifically in Wales and there are other examples in England through NICE. So, there are what are termed 'modifiers' being added to the assessment of medicines in the area of ultra-orphans, for example, and for end-of-life criteria. So, there is recognition that the initial methodology for the assessment of medicine does not cover the range of medicines that is available.

[179] The other area would be, I suppose, oncology medicines, and there have been large discussions in terms of the suitability of HTA for the assessment of oncology medicines. I think that you touched on it earlier, but in terms of the figures, NICE assessed 17 oncology medicines in 2013 and approved only one of them. So, you can take it from that that perhaps the methodology that was being used in those instances was not fully compatible with the benefits that those medicines would bring to the table.

[180] The orphan and ultra-orphan review in Wales is another classic example of the recognition that there is a need to assess and tweak the assessment process on an ongoing basis. I would say that the same will probably hold true for medical technologies. It will not be one assessment process, it will probably be a range of assessment processes, but, critically, the principles need to be firm and consistent. So, the principles of transparency and robustness, for example, are critical on an ongoing basis. Consistency can be brought through a consistent approach to the principles, not necessarily the specific methodology involved.

[181] **David Rees:** Thank you. I have another question for you, in that case. We talked about the relationship between ABPI members and the research side of things, but, a lot of the advice is produced by SMEs, small businesses or organisations. What relationship do you have with them, particularly when it comes to the companion devices? Do you support them at this current time and in the process of going through approval?

[182] **Dr Greville:** Again, they are a critical area. They are the sources of excellence for the pharmaceutical industry to engage with in the area of companion diagnostics. You will note that many of our members have either formal or informal arrangements with a whole host of SMEs, because the excellence and expertise rests with the SMEs. We are back to the new model of developing medicines. It is not a UK new model; in fact, it is a global new model. The pharmaceutical industry has learnt over recent years that it cannot do everything in-house, and it is not efficient to try to do everything in-house. So, it engages with a whole range of partners, which would include academics, SMEs, spin-out companies, et cetera. There should not be any limit in terms of the engagement that the pharmaceutical industry has with a whole range of potential partners.

[183] **David Rees:** Therefore, do you have experience of going through the NICE health technologies process? Clearly, NICE has set up one to do that, which is not mandatory, but it does provide the guidance as a consequence.

[184] **Dr Greville:** I do not have any specific experience, other than listening to the chair earlier this week. So, my remit does not extend to that and the experience would probably be very limited within the ABPI, but we would be happy to bring that experience to the table or, certainly, to act as a conduit if the committee was interested.

[185] **David Rees:** Kirsty, do you want to come in?

[186] **Kirsty Williams:** Coming back to the issue of take-up, I am just wondering how valuable you felt that the work of the All Wales Medicines Strategy Group was, as outlined earlier, with regard to guidance around prescribing, and this issue of it not making a judgment as to whether the product would be better or worse than what is already available, but actually that take-up of that new product could be more cost-effective to the NHS in the long run, or deliver better patient outcomes. We heard earlier that there is a second stream of work that goes around giving advice on that, on very specific medicines. Could you give us your evaluation of whether that process is helpful, and should be one of the building blocks that we should put into any system that may or may not be developed in Wales around other technologies?

[187] **Dr Greville:** It is important to try to understand where the potential obstacles lie. I think I heard frustrations earlier, and I can certainly share the frustrations from the pharmaceutical industry to have gone through a process of development, licensing and assessment, and then to find that the medicines, particularly in the UK, are not particularly well used, or are not used to the level of the expectation of our members. That is a frustration, for certain. In Wales, we have equal frustrations and, in fact, we have commissioned some work recently from the University of South Wales to better understand what the local obstacles are to the implementation of assessments for medicines. That piece of work will be available, and if they follow the contract, available before Easter. We will certainly be very happy to share that with you. Alongside that, but entirely separately—embarrassingly for me, in some ways—the Office of Health Economics is also investigating this area of local adoption of NICE and AWMSG guidance. It is taking a look at the planning challenges, again linked up to the horizon scanning that you had a discussion about earlier, but also the challenges involved in the planning for these new medicines. Again, on any learns from that, the timelines for publication would be very similar, so we would hope to be able to share those learns with you, certainly before Easter, if that fits alongside your timelines.

[188] **Kirsty Williams:** You have said a number of times this morning that the UK has particular difficulty, for whatever reasons, in terms of take-up. Within the UK, is Wales any better or any worse than the other constituent NHS departments in the other nations?

[189] **Dr Greville:** I suppose the honest truth is that it varies. There are certainly some

areas where Wales seems to lag behind in terms of uptake of medicines, and there are other areas where Wales perhaps uses more of those medicines than some parts of England. There is not a consistency, which is perhaps in itself an important issue.

[190] **Kirsty Williams:** Could you give us those examples of where we are doing very well and where we are lagging behind?

[191] **Dr Greville:** In terms of some work that I am aware of with a European hat on, Wales—and you mentioned the area of anti-coagulant therapies—

[192] **Kirsty Williams:** That was just off the top of my head. I have not got a specific problem with anti-coagulants.

[193] **Dr Greville:** It so happens that the uptake of anti-coagulants in Wales seems to lag behind some other parts of the UK, and certainly the UK lags significantly behind most of Europe in this area. That would be a specific example. I am very happy to share with you some figures, if that is of use, specifically.

[194] **Kirsty Williams:** What about the things that we are better at—things that we are good at?

[195] **Dr Greville:** They are more difficult to identify, but, again, we can make some enquiries.

[196] **David Rees:** Just to clarify, because you did talk about medicines not used, we are talking about medicines that have been approved by NICE or AWMSC.

[197] **Kirsty Williams:** Yes, that is what I am interested in.

[198] **David Rees:** So, it is a question of clinicians as well, in that case.

[199] **Dr Greville:** Absolutely, as I mentioned, the reasons for it need a lot more investigation, to be honest.

[200] **David Rees:** I just wanted to make that clear.

[201] **Kirsty Williams:** Yes, sorry—I should have said ‘approved medicines’.

[202] **David Rees:** Does any other Member have a question?

[203] **William Graham:** Do you have any influence on procurement?

[204] **Dr Greville:** Our members, obviously, engage in responding to tenders and procurement, so, yes, our members would be involved. Competition would negate any involvement of the ABPI in this area. However, again, our members would be involved.

11:15

[205] **William Graham:** So, would you agree that procurement should be better influenced by clinicians?

[206] **Dr Greville:** It is probably important that procurement takes into account the wishes, needs and expectations of clinicians in this area, as well as respecting the expectations of patients and the citizens of Wales.

[207] **David Rees:** I would like to come back to the question relating to clinical trials. We have heard various evidence indicating that some of the technology approaches are based upon take-up by clinicians. Do you see that as being the right way of getting benefits from that? Should we be pushing more clinical trials through clinicians accepting and taking up a new technology, because, obviously, clinical trials in technology will differ from clinical trials for medicines? Is there anything that we can look at to improve the approach to clinical trials in technology?

[208] **Dr Greville:** Again, I do not have direct experience in this area, Chair. However, referring back to the presentation that I heard earlier this week from the chair of the NICE committee, he made it clear that his committee very often gives a provisional 'yes', recognising the need for additional research in the area and in the use of the diagnostic or the device itself. So, again, it is an area in which it recognises that the evidence base, inevitably, is very rarely as strong as the evidence base that has been developed for medicines. I touched upon the way in which it handles that uncertainty earlier, namely by seeking the greater involvement of clinicians, and then having a route to approve a medical technology with the acceptance that more research is done and made in this area. Exactly how it follows up on the outcomes of that developing research, I am a bit unclear. However, that may be an area on which you can get clarity.

[209] **David Rees:** If there are no other questions from Members, I thank you both for coming this morning and for your written evidence. You will receive a copy of the transcript to check for accuracy and to make any corrections. Thank you once again, we very much appreciate your role and the report that you submitted to us.

11:18

Papurau i'w Nodi Papers to Note

[210] **David Rees:** We have three papers to note. First, we have the letter from the chief dental officer, which is a follow-up to the session that we had with him in December and responds to some of the points raised. Secondly, we have correspondence from Hywel Dda Local Health Board and, thirdly, we have correspondence from me to Hywel Dda regarding service provision. Are Members happy to note those? I see that you are. Thank you very much.

Cynnig o dan Reol Sefydlog 17.42 (vi) i Benderfynu Gwahardd y Cyhoedd ar gyfer Eitem 6 ar Agenda Heddiw ac o'r Cyfarfod Fore 30 Ionawr 2014 Motion under Standing Order 17.42 to Resolve to Exclude the Public from the Meeting for the Following Business: Item 6 on Today's Agenda and from the Meeting on the Morning of 30 January 2014

[211] **David Rees:** I move that

the committee resolves to exclude the public from the remainder of today's meeting and the meeting on 30 January in accordance with Standing Order 17.42(vi).

[212] Are Members content with that? I see that you are. Thank you.

*Derbyniwyd y cynnig.
Motion agreed.*

Daeth rhan gyhoeddus y cyfarfod i ben am 11:19.

The public part of the meeting ended at 11:19.