Cross-Party Group on Life Sciences
Minute of the meeting: Tuesday 27th March 2018
Committee Room 4, Scottish Parliament

Attendance

MSP's: Kenneth Gibson (Convener); John Scott (Vice Convener); Graham Simpson (Vice Convener); Tom Mason; Clare Adamson; Paul Wheelhouse.

Guests: Sandra Auld, Healthcare Public Affairs; Michael Barrett, Scottish Universities Life Sciences Alliance; Tracey Bowden, Pfizer; Jo Broomfield, Boehringer-Ingelheim; Marion Butchart, Novartis; Susanne Cameron-Nielson, Royal Pharmaceutical Society in Scotland; Maggie Clark, Novartis; Robert Crawford, Novartis; Damien Crombie, AstraZeneca; George Davidson, GSK; Andrew Dempsey, Celgene; Rory Duncan, Institute of Biological Chemistry, Biophysics & Bioengineering; David Eadie, Novo Nordisk, Jane Ferguson, Ettrickburn; Fiona Flemming, NRS; Susan Fletcher, Medtronic Diabetes; Yasmin Fraser, Biogen; David Gleghorn, UCB Pharma; Kathleen Grieve, MSD; Fiona Hamill, Janssen; Claire Headspeath, ABPI; Matthew Hilferty, Alliance; Sally Hughes, Teva UK; Nicola Johnson, Daiichi Sankyo; Philip Jones, Dundee University; Marnie Lawrie, Intercept Pharma; Harriet Lewis, Cheisi; John Mackenzie, Roslin Innovation Centre and Roslin BioCentre; Marie Claire MacPherson, Pfizer; Lindsay McClure, NHS National Services Scotland; Andrew McGuigan, Janssen; Colin McInnes, Moredun Research Institute; Dr Catriona McMahon, Consulting Pharmaceutical Physician; Dr Brian Montgomery, NHS National Services Scotland; Ronnie Palin, Life and Chemical Sciences; Rose Marie Parr, Scottish Government; Lorna Patrick, Bristol-Myers Squibb; Marilyn Robertson, Realise Solutions Ltd; Jonathan Roden, Cancer Research UK; Daphne Stewart, Orion; Jennifer Stewart, Amgen; Alison Strath, Scottish Government; Ellys Wakeman, Ipsen.

Presenters: Alpana Mair, Head of Effective Prescribing and Therapeutics, Scottish Government; Vicky Carmichael, Effective Prescribing and Therapeutics, Scottish Government; Simon Hurding, Effective Prescribing and Therapeutics, Scottish Government; Linda McGlynn, Diabetes UK Scotland; Mike Thompson, Chief Executive, ABPI; Professor Frank Gunn-Moore, The Scottish Universities Life Science Alliance; Steven Burke, Industry Liaison Manager at NHS Research Scotland; Professor Roma Maguire, Strathclyde University; Dr Barbara Blaney, Senior Incubation Manager at MediCity Scotland; Jennifer Nairn, Chemical Engineering Apprenticeship GSK.

1.Welcome from Kenneth Gibson MSP.

The Convenor set the scene for the second meeting of CPG on Life Sciences by acknowledging that this would be a packed agenda of three sections rather than the usual two and that, due to its importance, an additional section was added on the Single National Formulary.

2. **Minutes from previous meeting proposed and seconded**

- Proposed - Alison Culpan, Director ABPI Scotland

- Seconded – Graham Simpson MSP

3. Single National Formulary

The Convener introduced the speakers for the three sub- sections covering SNF and asked that questions be reserved until the end of these presentations.

3.1 Proposed SNF – Alpana Mair, Vicky Carmichael and Simon Hurding from the SNF development team presented on rationale, governance, methodology, process and progress to date**.**

Alpana Mair thanked the group for the opportunity to discuss the SNF. She explained that the objective was to support the various health policy frameworks by

"*Aligning to the priorities of Realistic Medicine, through a 'Once for Scotland' approach, the Single National Formulary aims to reduce unwarranted medicine variation, reduce harm, increase patient safety while ensuring a person-centred approach".*

This was

"In d*evelopment by Scottish Government, Effective Prescribing and Therapeutics Branch in collaboration with NHS Scotland, pharmaceutical and patient representatives".*

A Governance Board with wide representation, including industry, chaired by Dr Iain Wallace, had been set up to ensure due process would be followed. There had been a series of stakeholder events over 6-9 months previously to get feedback and opinion on the chapter development draft process and the final draft was put out for consultation receiving 58 responses.

This will be an interactive, collaborative 4 stage process: Preparation, Development, Peer Review and Adoption. The finalised process and terms of reference will be taken to governance board in May. *Decision focus will be on Efficacy, Safety and value with cost considered in this context.*

Options papers are being prepared on the future administrative 'home' of the SNF and on how SMC-accepted decisions are reflected in the formulary by the Project Team and Health Improvement Scotland respectively. They are also focusing on how SNF can support innovation, use of Real World Evidence and maintaining ongoing communication with 6-weekly meetings programme scheduled with stakeholders.

3.2. Impact on Patients – Diabetes UK

Linda McGlynn from Diabetes UK Scotland said that from a patient's perspective this was all "quite confused".

Linda explained that Diabetes UK had not been involved at all and that they had found out by chance from the National MCN. Linda questioned the rationale and asked what exactly are the aims and objectives? If the main aim is to avoid variation and deliver effective access, is this not in place already through existing frameworks (Prescriptions for Excellence, Effective Prescribing Group: Diabetes Review, SMC) as well as the multiple algorithms, pathways and protocols (SIGN) at national and HB level? Will this make diabetes treatment better? She suggested improved clinical education was needed and the lack of this has a greater impact on why patient outcomes were not improving. As Diabetes UK Scotland had not been involved in the work this could result in unnecessary duplication. Suggesting a formulary which focuses on 80% of medicines which are commonly prescribed was counter-intuitive for diabetes care and not patient-centred. Innovation in diabetes is moving fast, how, she asked, will SNF keep up with changing algorithms?

There was a series of concerns and questions Diabetes UK Scotland wanted answered:

- Personal choice – What if the patient did not want to switch to an SNF medicine?
- NHSScotland is still not hitting diabetes targets – is this more about cost savings than patient-centred care?
- If changing policies, will patients be given suitable medication plans in partnership with their HCPs?

She added:

- SNF project team should be listening and responding to people using the healthcare services;
- Not enough information has been supplied to Diabetes UK Scotland. SNF lacks transparency and they need more information to sell to diabetes patients.

3.3 Current Concerns – ABPI

Mike Thompson, ABPI Chief Executive, held up a map of the Health Boards in Scotland showing commonality/variation of prescribing. He suggested what we need is an "end to end" view from initial discovery to patient access. There were two main issues which needed to be dealt with, he said:

- Variation in Access,
- Affordability.

The Pharmaceutical Prescribing Regulation System (PPRS) has reduced overall medicines spend, and growth in medicines, to 0.4% per year. This scheme will be renegotiated in the New Year and the affordability envelope will be agreed nationally. He suggested that PPRS was a more effective way of dealing with this than the SNF.

He suggested that an SNF will have limited impact on variation, and there would be unintended consequences, above all in reduced investment from Life Sciences and Pharmaceutical companies into Scotland.

Mike explained that a patent for a new drug entity lasts 20 years. A medicine is in the research phase for 10 years before it is licensed and reaches the patient. Usually there are competitors within 2-3 years and after 10 years the drug loses exclusivity and generics become available. The company has limited time to recoup R&D costs plus if they cannot get the drug used the business model fails and there is no incentive to carry out research, launch or market innovation in Scotland.

Does the system (SNF) allow innovative medicines to get to patients? Looking at the biggest selling medicines 80% overlap at HB level and restricting options is not the way to improve innovation uptake.

Mike Thompson then explained that all of these concerns had been raised with the Cabinet Secretary at a meeting that day.

There are more and more precision medicines in development which target smaller populations of patients. Anything which restricts the access to these medicines and technologies runs counter to medical science.

So often there are unintended consequences of good intensions There is a risk that the impact that a SNF will have on life sciences in Scotland may be a significant reduction in inward investment from global companies.

The Convener opened the meeting to questions:

Paul Wheelhouse MSP, **Minister for Business, Innovation & Energy**

He acknowledged that the investment, access to innovation and unintended consequences was the key question that needed to be answered with regards to SNF implementation.

David Eadie – Novo Nordisk

Is patient-centred care the focus of the SNF? How many patients will find themselves receiving off-formulary products and what impact/cost will that have to the health service?

Simon Hurding – SNF Project Team

There are 11HB formulary and 75% commonality, so SNF is reflecting what is already happening. There will be no great surprises but will improve patient variation between NHS Boards. New patients will start on preferred formulary choice and patients on other therapy will have opportunity to switch to preferred.

David Eadie

Looking at Diabetes and all areas. If you look at the Fife formulary, 15,000 patients would not be on a formulary product, which is 9% of patients which extrapolate to 60,000 patients nationally. If these patients are to be switched or reviewed, logistically that would have a massive impact on healthcare services. What is the cost of this compared to the cost of the saving made?

Simon – SNF Project Team

Aimed initially at new patients and the cost of switching a patient is £37. This is factored into decision to switch.

Alpana Mair – SNF Project Team

Health Boards are having these discussions with the Group to have an informed debate. The Group is not taking one formulary and using as template or super imposing on the other formularies.

Linda – Diabetes UK Scotland

Are you just looking at newly diagnosed patients? Is this correct? What about Patient Centred Care? What happens if patients cannot take, or do not want to take, some of the medicines on formulary? Diabetes is a complex disease and requires regular monitoring, patient education and properly trained staff. You are still going to have a huge bill. You need to look at the whole model of care and pathway.

Simon – SNF Project Team

It's not just new patients. The Quality Diabetes Prescribing Strategy will be at the centre of Chapter development.

Brian Montgomery – Healthcare Consultant/ Former Medical Director of NHS Fife

He explained that the driver in Fife was that no additional benefit could be seen for the above average high spend on diabetes drugs. There was no shortage of guidance but low numbers of patients on optimal care. In his opinion SNF will optimise patient care, provide a decision support tool taking account of clinical and cost effectiveness and gives the patient best care.

Mary Ellis – Ipsen

SMC is already doing this. What changes when SNF is live?

Brian Montgomery

The SMC does not provide advice on the pecking order of the drugs. This results in variation at Health Board level.

Sandra Auld – Healthcare Consultant

The SNF can increase the possibility of Scotland becoming less attractive for R&D as the NHS will not be using gold standard comparators for trials

Simon Hurding

We are concentrating on the most popular/volume areas and SNF could provide an opportunity

Paul Wheelhouse MSP

What will the impact on innovation be? Feels he needs to ask his health colleagues their intent in the hierarchy of efficacy versus cost. Both are important but SNF needs to remain person centred and there needs to transparency around balance in decision making.

4. Collaboration in Life Sciences

4.1 Academic R&D - Professor Frank Gunn- Moore (SULSA)

Scotland punches above its weight in life sciences research and innovation. The Scottish Universities Life Science Alliance is a network of 9 universities who work collaboratively and without duplication. SULSA universities employ 10,000 people in Scotland.

•Enable collaborative partnerships and build more competitive consortia;

•Develop collaborative arrangements with industries;

•Position Scotland as a single research site when it makes good sense to do so;

•Support early career researchers to develop their independent research career;

•Build on existing life sciences facilities in Scottish Universities.

There is nothing similar elsewhere, and they leverage more than £400m funding. They have 3 public /private research initiatives with exemplar of success being The European Lead Factory (EU funded and one of largest collaborative drug discovery initiatives with 30 partners and 2 spin-out SMEs), National Phenotypic Screening Centre and Drug Discovery Unit Dundee.

SULSA facilitate R&D collaboration and innovation, and provides the interface for "*working together to solve problems"…"This is where innovative medicines come from and we must keep Scotland competitive or they will go elsewhere."*

4.2 Clinical Trials in Scotland – Steven Burke (Industry Liaison Manager at National Research Scotland)

Steven presented an overview of the role of National Research Scotland in facilitating medicines research from discovery, development to post marketing stages, from basic research to preclinical/clinical trials and real-world evidence. A recognition that "*Economic Growth and NHS Improvement can be driven by research and Innovation".* Success is built on multiple partners and collaboration, a streamlined process with all round the same table working to the same agenda, robust research infrastructure and support systems, Scotland-wide strategic partnerships with commercial organisations and a diverse portfolio of over 1000 trials ongoing at any given time. In summary:

•Research is a priority for the NHS in Scotland;

•Commercial research is core business for NHS;

•Partnerships and collaborations, centre of strategy;

•Joined-up approach stimulates collaboration;

•Integral part of the UK research landscape.

4.3 Real World Evidence – Professor Roma Maguire

Roma provided an overview of the benefits and growing importance of collecting real world evidence to inform the improvement of patient centred services and outcomes. Co-morbidities, aging population, affordability and a need for more evidence to show effectiveness and value in the real world means data is required to enable NHS to get right treatment to the right patient. Real World Evidence can be used to compliment clinical trials. Examples of where e -health and digital systems can facilitate Patient Related Outcomes Measures were presented e.g. The Advanced Symptom Management System,5 countries across Europe are partaking in this study. The University of Strathclyde is the only site in the UK. This system is scalable and can be used for evaluation across multiple health economies.

Linda – Diabetes Scotland

What sort of linkage is there with NHS Platforms in diabetes. How will PROMS fit in with this?

Roma

The data needs to become an electronic health register which has not been done yet. We would want to do this and embed with data linkage.

Mike Barratt – SULSA

We have special situation in Scotland for co-operation and collaboration. What is needed to make companies decide to come and do clinical trials and build a major pharma industry in Scotland?

Mike Thompson – ABPI

Scotland has a real opportunity in terms of connectivity. Community is collaborative but requires investment in the data side of things to link data outcomes to genomics etc. that would be transformative.

Graham Simpson MSP

Question to Steven. Do all universities cooperate on Life Sciences. IF money is coming from commercial how do they allocate this? Is there any collaboration between universities and NHS?

Steven

There is a need for NHS to work closely with academics which they are currently already doing so it is almost seamless and no longer thought about. They divide the monies on who ever applies for it. It is an open pool but there must be joint universities going for it. There are equal voting rights at SULSA.

George Davidson – GSK

Observed that it was encouraging to hear that Real-World Evidence, data platform and rapid access to innovation is coming together. How do we maintain enthusiasm? Are we at our peak? How can we keep momentum going?

Steven

Pull together a commercial strategy- key drivers, bring NHS & patients into this and support industry.

Roma

Keep generating evidence … that is key to all of this. Improve technology that is user friendly for the elderly.

Question for Steven … how does NRS support RWE

Steven

300 new trials last year /330 this year.

5. Women In Science

5.1 Opportunities in Life Sciences – Dr Barbara Blaney (Senior Incubation Manager at Medicity Scotland)

Personal view of her journey within sciences, what motivated her to choose this as her passion and the opportunities that this has presented to her in a wide and varied career. Showcased that there is much more to science and STEM careers out with a traditional laboratory job.

5.2 Motivations to Follow a Science Career – Jennifer Nairn (Chemical Engineering Apprentice GSK)

Innate curiosity about how things worked, science questions everything to come up with an answer. Chose an apprenticeship over traditional study pathway as she would rather develop skills and learn in the work place. There are many different types of apprenticeships, but little awareness and it is a male dominated environment, so this could also be a reason why girls do not apply.

5.3 Opportunities in Life Sciences for Girls - Prof Roma Maguire (Strathclyde University)

Explained her personal journey and rationale for her varied career. The corner stone of this was the need to have a job that had a caring nurturing side as well as the science and hence she started off as a nurse and was able to look after and use science to make people's lives better.

Kenneth Gibson, Convenor, thanked everyone for contributions and asked if there were any last questions.

Paul Wheelhouse MSP

To Barbara: Was there something lacking in schools that girls did not consider a career in science?

Barbara Blaney

Career advice in school back then was not very good, kids nowadays have much more access to information and exposure through social media. They are more inquisitive.

Paul Wheelhouse

He sees many women in these types of jobs in public and private sectors, but their stories are not getting out there. Life Sciences are still perceived as being male dominated.

Claire Adamson MSP

To All Presenters; What keeps them in their roles?

Roma – mentors supported her through hard times plus flexible working

Barbara – If you have a passion it does not feel like a chore. Your environment is important also.

Jennifer – My job is never the same, mixture of responsibilities keeps me interested.

Graham Simpson MSP

No one told his daughter who is doing a PHD of other opportunities which were not lab-based. Commended Barbara for linking up with local schools and inspiring young boys and girls.

Kenneth Gibson MSP, Convenor

Thanked all the speakers, the Minister and members for attending and brought meeting to a close.

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