HORIZON SCANNING AND PLANNING FOR THE FUTURE: NEW MEDICINES AND NHS WALES

Report

for ABPI Cymru

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December 2017

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Prifysgol De Cymru

CONTENTS

1. INTRODUCTION AND CONTEXT 2

BACKGROUND TO THE STUDY 2

WHERE ARE WE IN WALES? 3

SCOTTISH MEDICINES CONSORTIUM AND *FORWARD LOOK* 5

2. FINDINGS – STAKEHOLDER PERSPECTIVES 7

ISSUES RAISED AND DISCUSSED 7

3. CONCLUSION 11

THE OFFER 11

QUESTIONS TO BE CONSIDERED 14

1. INTRODUCTION AND CONTEXT

PROJECT SUMMARY

The Welsh Institute for Health and Social Care, University of South Wales was commissioned by the Association of the British Pharmaceutical Industry (ABPI) to explore issues around horizon scanning in Wales and elsewhere.

The study focused on engaging with how different nations undertake horizon scanning, largely through interviews with key informants. The outcome of these discussions is presented below, and was discussed at a workshop in mid-November focusing on the situation In Wales. The workshop brought together the quartet of stakeholders who are all interested in improving horizon scanning: representatives of the pharmaceutical industry, NHS Wales, Welsh Government and the All Wales Therapeutics and Toxicology Centre (AWTCC).

BACKGROUND TO THE STUDY

In 2013-14, WIHSC conducted some work for ABPI Cymru Wales exploring the processes associated with the implementation of new NICE/AWMSG-approved medicines in NHS Wales[1]. In particular, the work considered:

- How stakeholders perceive the benefits and costs of new medicines
- The barriers to optimal adoption of NICE/AWMSG medicines
- Which barriers could be reduced or removed
- How might the NHS, pharmaceutical industry and others reduce such barriers

Subsequently, it was agreed that a workshop, bringing together some of the key stakeholders, might offer a useful opportunity to capitalise on these discussion and identify some 'easy wins' in improving the processes described. A half-day workshop was therefore held on 8th March 2016, drawing together a good range of highly-experienced participants from the various relevant perspectives[2].

Discussion at the 2016 workshop consequently focused on the following areas:

> **Discussion Area 1** – *How could Health Boards and Trusts develop and apply more rigorous processes in the rational management of the introduction of new medicines?*
>
> **Discussion Area 2** – *How could the pharmaceutical industry and national NHS agencies improve the quality and nature of the evidence available?*
>
> **Discussion Area 3** – *How could the pharmaceutical industry promote new medicines within the context of approved care pathways and constructive collaboration with Health Boards and Trusts?*

The workshop closed with a summary of key findings and suggestions. In relation to the three discussion areas:

[1] Available at http://wihsc.southwales.ac.uk/media/files/documents/2014-05-28/NEW_MEDICINES_AND_THE_NHS_IN_WALES_FINAL_REPORT_06-05-14_docx.pdf

[2] Available at http://wihsc.southwales.ac.uk/media/files/documents/2016-05-16/ABPI_New_Medicines_Workshop_Report_May_2016.pdf

1. Medium-term horizon scanning, typically to a 2 year horizon, could be significantly improved through greater sharing of timely information, to the benefit of both NHS and industry. One early, practical step would be for NHS bodies to identify appropriate points of contact for industry in the short and medium-term. AWMSG might wish to coordinate this process, and also to explore the further development of central long-term horizon scanning.
2. Identification and realisation of 'real world' patient and service benefits from medicines is currently underdeveloped and needs a joint investment by NHS and industry. The practical implications of this now require discussion at an all-Wales level.
3. The industry, with NHS support, might consider how best to harness its contribution within the context of existing and new patient pathways.

Following on from this discussion, a long-standing issue of effective horizon scanning has been commented on by the Cabinet Secretary – how can we in Wales anticipate the arrival of new medicines, and therefore model future services and financial impact in good time? This is particularly important where new medicines might enable new approaches to care, change patient pathways, or have significant resource implications.

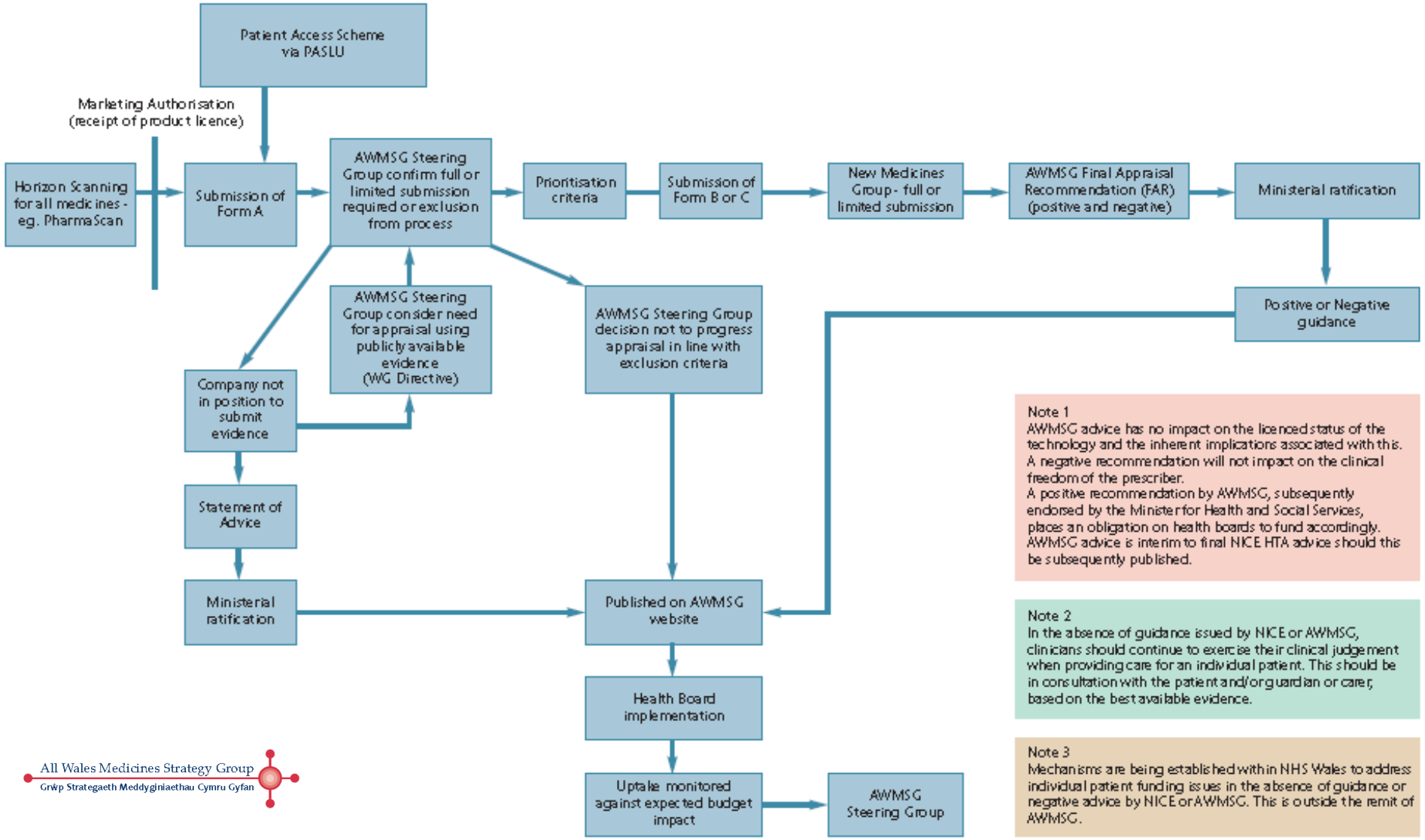
WHERE ARE WE IN WALES?

AWTTC horizon scanning process gathers intelligence on new medicines through a *number* of sources, including UK PharmaScan. PharmaScan aims to provide comprehensive information on technologies that are in the pipeline and expected to receive market authorisation within 3 years, or are in phase III development. AWTCC/AWMSG can access UKMi's NDO publications which provides comprehensive information on upcoming technologies. Companies can also submit Horizon Scanning data directly to AWTCC. According to the AWMSG website '*The onus for engagement with AWMSG appraisal process currently lies with the applicant company, although the horizon scanning process also identifies medicines prior to marketing authorisation'.* Figure 1 below outlines the AWMSG appraisal process for new medicines.

In January 2017 Welsh Government announced a New Treatment Fund. The fund provides additional support of £16 million annually for five years to help health boards in Wales speed up access to medicines recommended by NICE and AWMSG. The fund is ring-fenced to ensure it is used for the intended purpose of supporting health boards to make all new medicines recommended by NICE and AWMSG available faster and more consistently across Wales. The fund aims to help ease the financial pressures that can be associated with the introduction of new medicines, providing health boards with the time to plan to invest in future years. Under the new system, all health boards in Wales are required to make a NICE or AWMSG recommended medicine available no later than two months from the date the final guidance is published, shortening the maximum amount of time before which a health board must make a treatment available by a third.

In respect of NICE recommendations, health boards are expected to introduce medicines recommended by NICE at the first publication of the final guidance, rather than waiting for the final Technology Appraisal guidance published after the appeal period. In combination this means in future all NICE and AWMSG recommended medicines will be available up to eight weeks earlier. As of 9th June, there were 17 applicable medicines available under the New Treatment Fund. All 17 medicines are now available across all health boards in Wales. Data on usage to support measuring compliance to the fund is being drawn

Figure 1 · A flow chart outlining the AWMSG appraisal principles and process[3]



[3] http://www.awmsg.org/docs/awmsg/appraisaldocs/inforandforms/AWMSG%20appraisal%20principles%20and%20process%20flowchart.pdf

from health board and trust formulary data and the NWIS Medusa system which collates data from hospital pharmacy systems.

SCOTTISH MEDICINES CONSORTIUM AND *FORWARD LOOK*

All horizon scanning organisations in the UK can access UK PharmaScan. Approximately 60% of medicines in development are included, which are entered into the database by pharmaceutical companies. The Scottish Medicines Consortium (SMC) in Scotland produce an annual *Forward Look* report, which is split into two sections:

- Impact profiles on drugs expected to be associated with moderate to high net drug budget impact and/or major service implications
- Tabulated information on all new drugs likely to be launched in the UK in the following calendar year

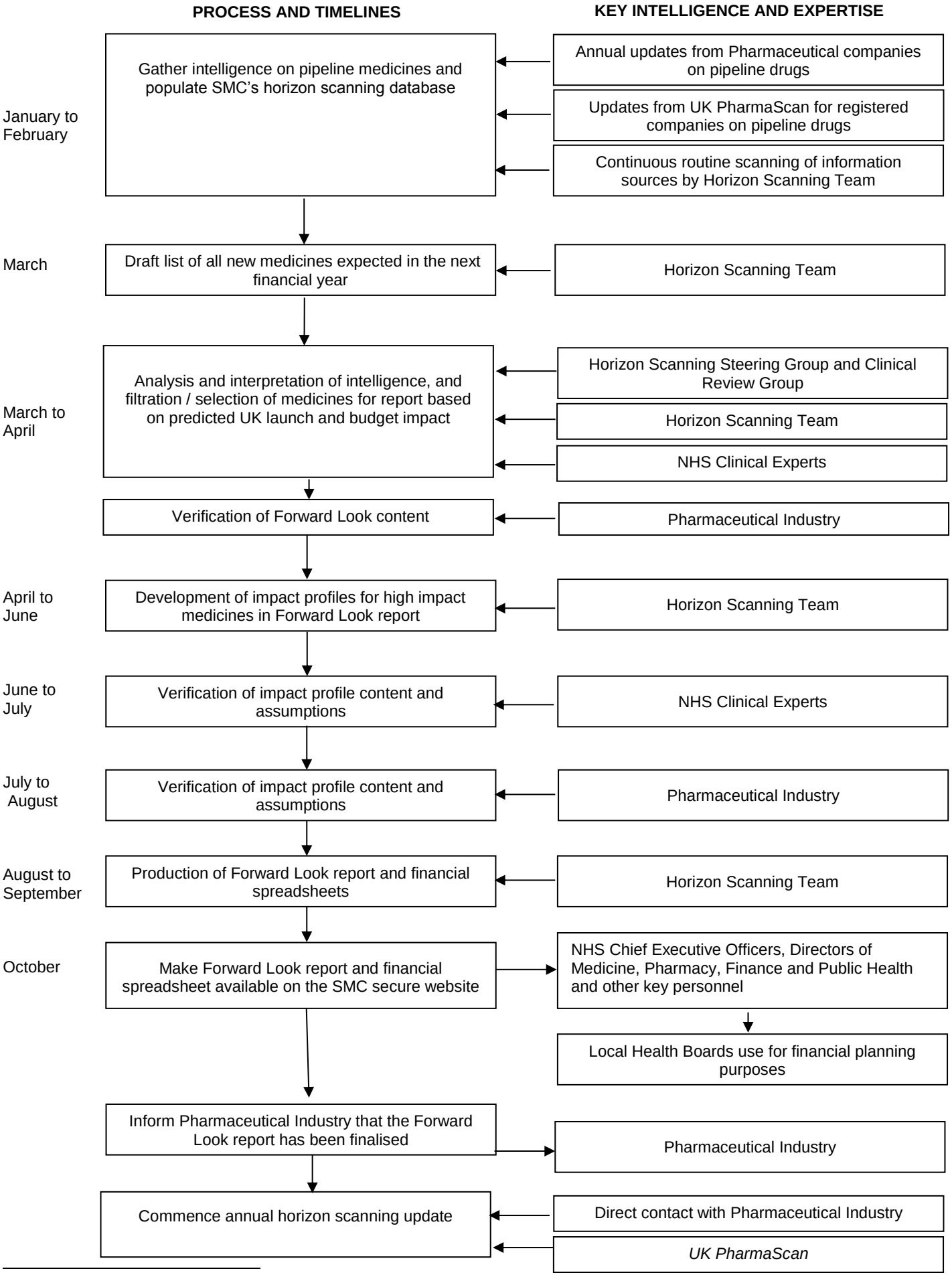
The SMC and Health Boards recognize that figures in the *Forward Look* report may represent a 'worst case scenario' given that some of the new drugs listed may not reach the UK market within the predicted time frame or not at all due to abortion of development or negative reimbursement appraisal from SMC. Financial spreadsheets summarize the estimated incremental net drug budget impact of each significant new drug by geographical area and by individual NHS board. Spreadsheets are categorised in cancer and non-cancer drugs. Spreadsheets include data on:

- Annual net cost of treatment per patient
- Estimated eligible population
- Estimated uptake figures in year 1 and steady state
- Estimated total costs of each new drug in year 1 and at steady state per area
- Service implications – to detect potential additional costs or available savings (e.g. medicine registration can be more/less complex)

The *Forward Look* financial spreadsheets have been developed to allow this ongoing, dynamic in-year adjustment by Health Boards. An update is produced four times a year to highlight significant developments or a change in information on drugs included in the main report. The first update of the year (January) shares information about all drugs, the other three updates only share information on high-impact drugs – see Figure 2 for SMC Forward Look process flow diagram.

The SMC Horizon Scanning team works closely with expert clinicians practicing within the NHS Scotland. For rare conditions, only one or two (instead of five or six) relevant clinicians are available in the SMC expert panel. In these circumstances, additional efforts are made to identify further relevant clinical experts, for example via requests to Scottish Area Drug and Therapeutics Committees (ADTC) or identification of relevant clinicians practicing within the NHS in England, Wales or Northern Ireland.

Figure 2 · SMC *Forward Look* Production Process[4]



[4] https://www.scottishmedicines.org.uk/About_SMC/What_we_do/Horizon_Scanning/Guidance_on_Horizon_Scanning

2. FINDINGS – STAKEHOLDER PERSPECTIVES

The following section represents the issues that came from the 17 interviews with the representatives from the quartet of stakeholders: Government (n=3), horizon scanning agencies (AWTTC and SMC) (n=5), NHS (including finance and pharmacy specialist, drawn from both Wales and Scotland) (n=3), and participants from the pharmaceutical industry (n=6). Interviews lasted typically for 30-45 minutes, the majority of which were undertaken over the telephone between August and November 2017. The findings from the interviews were then presented and discussed at a workshop in mid-November (at which 30 delegates from the quartet of stakeholders were present) and feedback from that event is integrated into the section below.

ISSUES RAISED AND DISCUSSED

The following list of the key issues that were raised and discussed is presented in no particular order.

1 Participants recognised that there is a difference between lengths of horizon. There is a near horizon – defined as being 12 months and less – and a further horizon – which is defined as being longer than 12 months from product launch. There was almost universal consensus that we should seek to cap the further horizon at 24 months ahead of launch in the first instance. Trying to extend the horizon beyond 24 months is just too speculative at the moment in the view of respondents.

2 There is no quick fix here, and there may be value in thinking about these new developments in respect of horizon scanning taking until the end of the Assembly term (May 2021) to be fully implemented at the least.

3 It is important to note that Wales is not alone in trying to think this through and come to a sensible arrangement about horizon scanning. Ultimately though, it doesn't make any sense to have different horizon scanning systems operating across the UK (even though there are clear differences between the four UK nations), as PharmaScan is the UK-wide repository of information and data from industry.

4 Scotland has focused much of its work in recent years focusing on the near horizon and trying to work with health boards to standardise the uptake of new medicines across the whole of the country. The *Forward Look* process and document is well regarded universally, and is considered to be an improvement on the current situation in Wales. Where the near horizon is being extended beyond 12 months, this is down to the actions of individual companies who are providing additional data and information in the form of Advanced Notification Documents to health boards through their extant relationships and networks. In practice, these notifications represent an 'informal' extension of the horizon.

5 Whilst it was the case that people understood why the questions about extending the horizon were being asked, some colleagues in Wales feel that extending the horizon at this stage is the wrong priority. Instead we should be absolutely focused on providing much more accurate detail about the near horizon – this problem, it was suggested, needs to be resolved as the first priority, before thinking about the further horizon. It was acknowledged that there is a risk in

doing this, as there is a danger in missing out on important data and information about medicines already in the pipeline, but there is also a significant risk in not having robust enough processes and procedures in place to financially plan for the near horizon.

6 In these discussions about horizon scanning, the role of information and data was universally acknowledged as being of paramount importance. There is a perceived need to sort out the 'central mailbox' problem which has consistently been identified by industry – that there is no standardised process for distributing information to all of the key people within the NHS at agreed times in the process. There also needs to be issued a set of ongoing assurances about the confidentiality around data and where it is hosted to build confidence for all partners.

7 Horizon scanning is thought of a little like a Trojan Horse – it carries within a huge potential increase in cost, but at the same time potential therapeutic benefits. Finding the right balance between the benefits and the cost is not easy, but overall respondents felt that having more information and better information earlier could only help to improve planning processes.

8 There is real variation in the quality, sufficiency and appropriateness of information being provided to PharmaScan – some companies are providing data up to 30 months ahead of market authorisation, others are providing nothing or very little until the last several months. There is a 'sweet spot' in this process when enough appropriate, high quality information has been provided such that planners and finance colleagues are able to come to sensible determinations about the likely budgetary impact. The time at which this point is reached will vary, but there was agreement that a move to formalising a process for the further horizon would help significantly in this regard.

9 Confidentiality is king in this process, but it was suggested that more people from health boards (with the right oversight and safeguards) could be given access to PharmaScan? It was certainly felt that issues around confidentiality were less of a problem in Wales than they had been in other parts of the UK. This is not beyond the gift of the quartet of stakeholders to resolve, but a new compact would need to be established. As part of this, and trying to future proof the process, there is also a need to review PharmaScan, identifying what is crucial and what might be redundant in the current process. Optimising the quality, quantity and appropriateness of data in PharmaScan and making it increasingly fit for purpose will support all of the other areas of improvement noted – it currently underpins all of the key elements on which all of this needs to be built.

10 There is a need to consider both the transformational and transactional elements of horizon scanning as these discussions proceed, and there are obviously both transactional and transformational elements to both the near and further horizons. Transactionally, there will continue to be a whole host of 'marginal gain' new medicines in both horizons, and transformationally there are the 'game-changers', many of which will be in the further horizon. These different types of medicines will bring different types of challenges in respect of horizon scanning.

11 'Game-changers' are by definition exactly that as they are working to provide solutions in areas of huge unmet need. Just knowing that they are coming won't do anything to reduce the burden when they arrive if a further horizon isn't accompanied by a serious and concerted effort to

discuss the service delivery implications, in order to bottom out the costs, benefits and outcomes here. It was suggested that a change in mindset towards 'invest to save' (over perhaps 5, 10 or 20 years) could help to unglue some of these discussions.

12 It was suggested that the difficulty with 'game-changers' is the likely impact of the change, both therapeutically, financially and in terms of service delivery. Unless you know that a new medicine is absolutely coming, you aren't able to commit to redesigning services – and when do you get to the 'sweet spot' when you definitely know and can then design services? Whilst the long-term 'invest to save' argument is relevant and crucial, it's a pretty hard one to make in the current financial climate. The result is inertia, and improving horizon scanning to an 18-month or 24-month period should help.

13 It was however recognised that there's a need to start the difficult conversations about service redesign much earlier. It takes huge amounts of time and effort to re-engineer services and one of the ways to get a bit more headroom is to start the planning process earlier, which better horizon scanning can help facilitate. The trick will be in finding the time in the process when there is sufficient clarity (from all sides) on the likelihood and size of impact that planners can then act with certainty.

14 Behaviour and trust are fundamental to all of the processes discussed, and will take time to change and amend. 'Bringing the village together' to discuss matters of significant import (like around 'game-changers' with significant service redesign implications) and having time around the table to build relationships is core. Further, it is important to recognise that industry and the service have very good relationships in place, but not everywhere. Much depends on the quality of relationships, knowing and trusting the right people, and developing the right sorts of relationships.

15 'Informal' advanced notification led by industry (whether company by company, or health board by health board) can in effect help to extend the horizon – it augments and complements the current system by adding information on a case by case basis. It was suggested by participants that as part of discussions in Wales about extending the horizon, we could think about formalising this and establish something that might be called a 'Welsh Advanced Notification' process that would be absolutely fit for purpose and confidential, and designed to do the job that PharmaScan and the NICE processes do not? This could be aligned with working closer with Scotland's processes, and would need be based on data being pushed proactively out from industry, and received by AWTTC – in the same way that industry pushes such information to the health boards with whom they have extant relationships. The absolute key to this is that it would have to be a 'once for Wales' process and not duplicate the work that is currently done in Wales, and ideally would be aligned with other processes across the UK.

16 As part of these new developments, it is sensible to think through the way in which lengthening the horizon could adopt the 'safe harbour' meeting approach run by the EMA and latterly by the NICE Office for Market Access. In Wales, developments from AWTTC in respect of 'the vault' could be very useful in helping to secure confidentiality and support the building of trust.

17 Current processes allow for the 'overall' budget figure to be about right, but line by line the current horizon processes often lead to inaccuracies. These figures are impacted upon by Patient

Access Schemes (PAS). The problem arises when health board finance officers are trying to lever money out of budgets to spend on service redesign because a new medicine requires that to happen (perhaps on an 'invest to save' basis). If they think the budget is 'X', and they remove 'Y' from it for service redesign purposes that is a good thing. However if a PAS then saves 'Z' additional money from that budget, it is often too late to invest that in service redesign initiatives. In effect this 'Z' money is money that can't be proactively invested. Whilst it was acknowledged that this is somewhat of a side issue, it was suggested that it does say something about the environment that's being created for dialogue, especially between industry and the health boards.

18 Whatever is decided about horizon scanning, it was acknowledged that there will be some organisations within the quartet of stakeholders – whether individual companies or health boards – who will want to take a lead on this, whilst others will be reticent. It was not felt however that this was a reason for not pursuing this further.

19 On the more negative side, it was repeatedly suggested that uncertain data in will lead to uncertain data out. There are so many variables involved in horizon scanning that a number of respondents struggled to see how the process could be made to be more precise given the growing complexity, unless there is a new and more proactive provision of data in a timely, accurate and appropriate manner – hence suggestions of the WAN. It was felt that extending the horizon was never going to be a panacea, but overall it was felt to be well worth the effort, especially if there is an accompanying shift away from considering individual medicines towards disease areas and therapeutic groups.

20 A majority of respondents felt that there was significant merit in Wales being more aligned with Scotland, and some agreed that Wales would do very well to 'adopt' *Forward Look* for the near horizon, with a view to then potentially realigning itself to prioritise the further horizon, or work (especially with Scotland) in a close, reciprocal fashion. It was felt that doing this might release sufficient resource to take forward both the further horizon in partnership, but also to build on the conversations already going on between Wales and Scotland in respect of closer working. It was noted that there would need to be a Welsh 'translation' and wrap-around of *Forward Look* if this were to happen. On simple advantage of such adoption would be that the 'distribution list' of *Forward Look* is perceived to be excellent, and if repeated here would be a clear advantage for Wales of adopting the system.

3. CONCLUSION

The previous chapter provided a series of insights from stakeholders, and this chapter brings these together with the current context in Wales. This has led us to conclude that there is a consensus within the quartet of stakeholders that extending and improving horizon scanning in Wales could lead to a win, win, win, win situation. This will require significant discussion about the detail.

As a first contribution, Figure 3 provides a diagrammatic representation of the 'offer' that would need to be made of all of the four stakeholders to progress this work. Further information about these points is provided, and we tentatively suggest that these could form the basis of an implementation plan should the quartet agree that this work merits further consideration.

THE OFFER

The following high-level statements are written in response to the question: what is the offer that all stakeholders would need to make in order to improve and extend the horizon in Wales?

WELSH GOVERNMENT

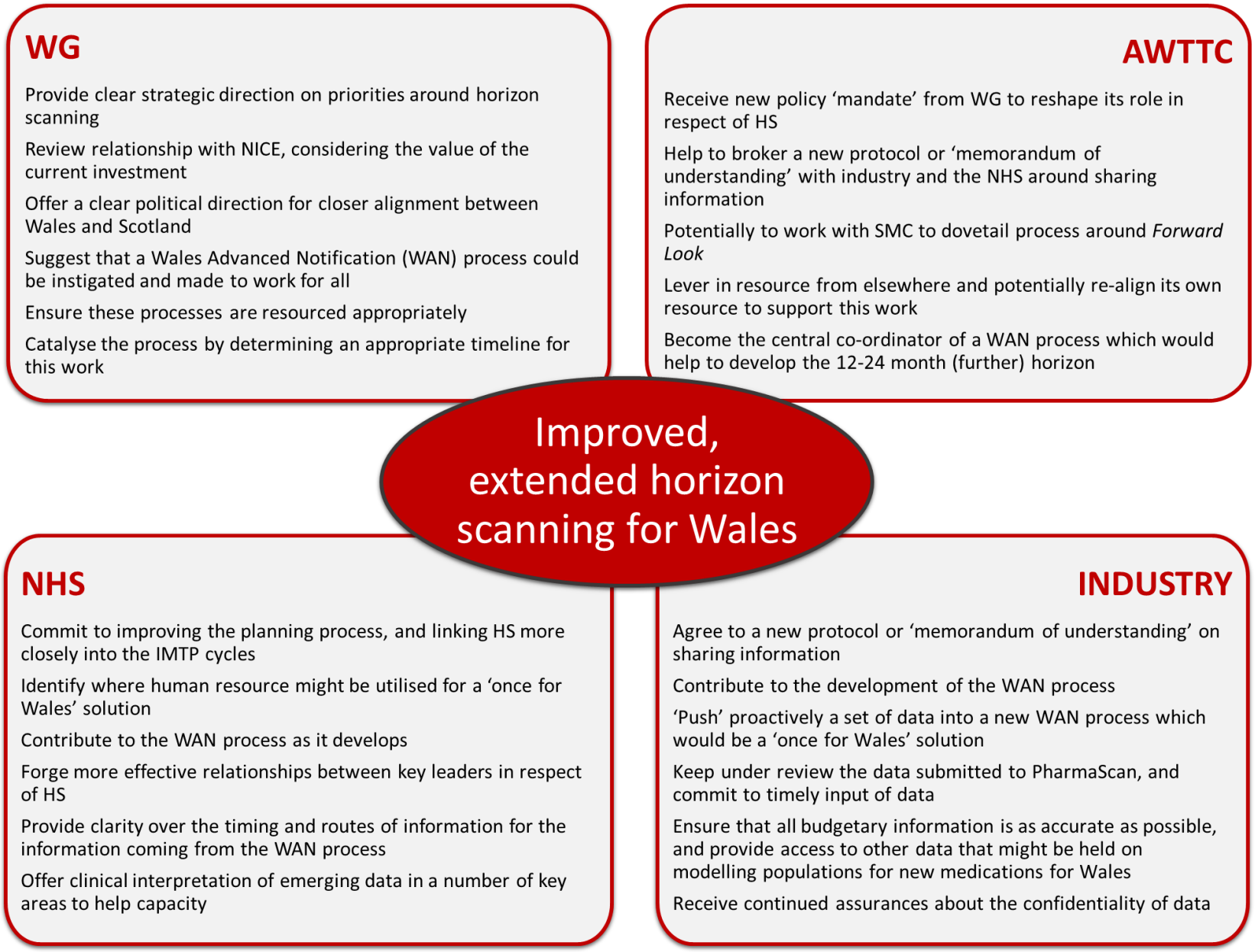
The Welsh Government might choose to:

- Undertake a review of the current relationship with NICE, in order to think through the value of the investment that is made to them, and whether Welsh interests are being well served in the way things are working;
- Provide clear strategic direction on horizon scanning and indicate its relative level of priority compared with the other important issues in this area. This could go so far as thinking about formalising AWTTC's role in respect of horizon scanning, in part depending on the discussion with NICE;
- Give due consideration to the nature of the collaboration between Wales and Scotland. Offering political direction for a closer alignment between Wales and Scotland (should this be determined as an appropriate 'next step') could culminate in the two nations working more closely and reciprocally to mutual benefit. This might mean Wales adopts *Forward Look* subject to a range of caveats as expressed below;
- Suggest that a Wales Advanced Notification (WAN) process could be instigated and made to work for the benefit of the quartet. There is much detail to be worked up in this respect which would need to be led by others, but it is important to ensure that this process (if it were to be taken forward) includes all new medicines in order to minimise the risk of duplicating processes; and
- Ensure that these processes are resourced appropriately, whether with new or existing money, and catalyse the process by determining an appropriate timeline for this work.

AWTTC

Subject to the choices and action of Welsh Government, AWTTC might be tasked or choose to:

Figure 3 · Potential future roles of the quartet in improving and extending horizon scanning for Wales



- Receive new policy 'mandate' from Welsh Government to reshape its role in respect of horizon scanning, especially if this requires closer alignment and the development of a reciprocal relationship with the SMC as part of Healthcare Improvement Scotland;
- Help to broker a new protocol or 'memorandum of understanding' with industry and the NHS around what information can be shared, by whom, to whom and when – possibly through a 'safe harbour' (whether physical or virtual) or the 'vault';
- Think about the new relationship with Healthcare Improvement Scotland – of which SMC is part. Both HIS and AWTTC have broad remits and so exploring wouldn't necessarily have to be limited to horizon scanning – for example, there may be other resources that AWTTC produces that would be of value to HIS, and *vice versa*. There are good grounds for thinking that HIS would be open to exploring a mutually beneficial arrangement although this would need to be discussed and confirmed. This may result in Wales adopting *Forward Look* with an appropriate Welsh 'wrap-around';
- Lever in resource from elsewhere (whether human and/or financial) – possibly from NHS Wales or Welsh Government – and potentially re-align its own resource to support the development of this work; and
- Become the central co-ordinator of the new 'Welsh Advanced Notification' process (once determined and specified) which would help to develop the 12-24 month (further) horizon, and serve to disseminate information from industry which has been 'pushed' to it.

NHS WALES

Further to the choices and action of Welsh Government and AWTTC, NHS Wales might be tasked or choose to:

- Commit to improving the health board planning process, by linking horizon scanning more closely into the extant IMTP cycles;
- Identify where human resource might be utilised for a 'once for Wales' solution, rather than have small teams or individuals duplicating certain horizon scanning tasks multiple times;
- Contribute to the potential new 'WAN' process through being clear about what health boards will want in terms of output from this. Having input from senior managers and clinicians will improve the process and ensure that what is produced is aligned with what these stakeholders need by way of an outcome;
- Help forge more effective relationships between Directors of Finance, Chief Pharmacists and Directors of Planning in respect of horizon scanning. This may well be a natural outcome of the new 'WAN' process;
- Provide clarity over the timing and routes of information for the information coming into health boards from the 'WAN' process. This would standardise the way in which data is shared with senior leaders in the NHS, such that the quartet of stakeholders know what information has been shared with whom and when. This will provide an assurance that health boards will have access to critical information to support financial planning for significant new medicines at as early a stage as possible; and

- Offer clinical interpretation of emerging data in a number of key areas to help identify capacity challenges and support service planning in relevant areas – for example on diagnostic testing, service redesign etc.

INDUSTRY

Colleagues from the pharmaceutical industry might choose to:

- Agree to a new protocol or 'memorandum of understanding' on sharing information, especially as part of 'safe harbours' or the 'vault' as this will offer assurances about sharing information with the service, confidentiality and alignment with the code of practice, which are all essential;
- Contribute to the development of the 'WAN' process as it emerges. Specifically this might result in proactively 'pushing' a set of data into the new process (potentially which could be aligned to *Forward Look*) on the basis that this would be a 'once for Wales' approach, and not create duplication and an unnecessary burden on companies;
- Keep under review the data submitted to PharmaScan, seek to review and optimise the way in which it operates, and commit to the timely input of data; and
- Ensure that all budgetary information is as accurate as possible when provided. This might include supplying (subject to the assurances described above) access to other data that might be held – like on modelling populations for new medications for Wales (should this be available) for example.

QUESTIONS TO BE CONSIDERED

This report concludes not with a series of recommendations, but rather a checklist of questions. The reason for that is that given there is much detail to work through, we have sought to ensure there is sufficient flexibility when it comes to implementation. That said, the evidence collected in this study does point towards the fact that improving the near, and extending the further, horizon in Wales enjoys support from the quartet of stakeholders and accordingly work to achieve this end should now be undertaken.

The quartet might like to consider the following questions as this project moves forward:

- What is the best way of Wales benefitting from better, earlier, confidential information to the benefit of all four stakeholders?
- How could the existing relationship with NICE be optimised? Or can't it?
- How should Wales take forward its relationship with Healthcare Improvement Scotland, the SMC and *Forward Look*?
- How can we effectively build upon the work that's beginning in Wales around the Horizon Scanning and Forecasting Group, and the ongoing Therapeutic Development Assessment Partnership Group? How might these be brought closer together?
- Where does the additional resource come from to facilitate this? How could it be levered out from existing organisations?
- Could this be a win-win-win-win? And does the 'offer' described above provide the best way to make this so?

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