

Call for evidence: Part C: Government – A White Paper: Integration and Innovation

1. I am responding to the consultation on behalf of the British Association of Dermatologists (BAD), via its Access to Medicines Working Group and Clinical Services Unit.

2-3. The white paper has key proposals about how the integration and innovation of services will improve health outcomes. However, the need for timely access to medicines and medical devices is paramount to achieving this aim. It is envisioned that improvements in outcomes will be reliant on ease of accessing appropriate medicines and medical devices to help achieve the triple aim of better health and well-being for everyone, better quality of health for all individuals and sustainable use of NHS resources. Indeed, access to medicines and medical devices should be embedded in the White Paper to address how these will be commissioned and also to make sure there will be access throughout the UK to abolish postcode lotteries.

4-13. The proposals set out the formation of the new Integrated Care Systems (ICS). These will hopefully help to reduce bureaucracy and improve access locally, helping to tackle local needs by encouraging integration of the different layers of health and social care such as primary, intermediate, secondary, and tertiary.

There should be completely separate, clear, and concise protocols for commissioning of devices; the standards for this should be as rigorous and robust as they are for commissioning of medicines. At present, there is a significant lack of knowledge about procurement of devices, especially on artificial intelligence (AI), amongst clinicians and managers – and a tendency to accept a much lower standard of evidence base before commissioning which could risk patient safety.

The new ICS will also help to make sure commissioning decisions are made by taking into account the views of a wide variety of stakeholders. However, at a national level, this may still lead to difficulties accessing medicines and medical devices in certain areas due to differing commissioning decisions at local levels. Therefore, an overarching system to ensure there is flexibility to allow local needs to be taken into consideration in commissioning by ICS, but also to maintain national standards of access to medicines and medical devices needed by specific groups of patients.

National formularies could be helpful in this regard, but all too often local formularies may result in obstructions that prevent patients getting access to the care they need, leading to increasing bureaucracy for patients and healthcare professionals trying to access specific medicines and medical devices for their patients with specific

conditions. Integrated primary and secondary care formularies, including a traffic light system to identify those drugs that 1) are designated for initiated in secondary care only, 2) can be started in primary care and 3) needing initiation in secondary care but can be continued in primary care, will help patients access their medication and also help to get more care delivered in the community preventing unneeded hospital appointments. However, these should be comparable across the UK and hence there should not be a large variation in these between areas to prevent problems if a patient relocated. Indeed, this continued access when relocating should be included as a statutory duty for the new ICS and should not be disincentivised, e.g. by altered/removal of tariffs or the need for financial balance.

For licensed and unlicensed medicines and medical devices, access should be at the point of need, so should be based on a needs' analysis of local the population and regularly reassessed to pick up changes in the requirements of medicines and medical devices locally. However, the routes to get access to specific medicines and medical devices for those with rare conditions should not be onerous so as to act as a barrier to prevent patients getting the care they need. Therefore, local commissioning pathways should be streamlined to help get access in a timely manner. Indeed this was seen recently with COVID-19 and the need to get specific medications to help manage patients with severe COVID-19 requiring ITU. There were shortages of medications and the White Paper should aim to help prevent problems like this from occurring again in the future.

14-18. To maximise innovation, it is important to involve all stakeholders in the future of how care is delivered, including research bodies and the life science industries. Whilst some barriers may constrain innovation, it is important to make sure that there is adequate safety assessment for new medications and medical devices such as well performed clinical trial and post-marketing surveillance, to keep the public safe and help to pick up new dangers as soon as possible to prevent further harm. However, there should be mechanisms to quickly assess these to also provide reassurance if the worries are unfounded.

Current barriers include a lack of recognition of this work when done by NHS clinicians – difficulties accessing national funding to support this, difficulties accessing the right advice from R&D (even in well-established Trusts with a track record for research), duplication of effort to undertake very similar studies across different disciplines (lack of cross-talk), unrealistic expectations from Trusts/government about the time taken, and resources needed to support this to ensure robust research takes place.

Post-market surveillance for devices, and for AI in particular, needs to be considered separately; with the continual update and improvements of algorithms, the current strategies used for drugs will not be fit-for-purpose for AI to ensure that safety and efficacy is maintained over time.

Setting up registries with mandated imputing of information, to make sure important information is not missed, would be helpful in allowing informed decisions about the use of medicines or medical devices which are new or where there were concerns. However, the collaboration should be as wide as possible, including other international bodies as well as private providers, and a sharing of data would allow for even quicker safety signals to be picked up as part of post-marketing surveillance.

19-21. The formation of new bodies in the White Paper may lead to more red tape and rationalising them or having a clear delineation of their individual roles/remits would be helpful in allowing patients and their healthcare professionals access to medicines and medical devices when needed. Without this clarity they may prevent rather than help patients and healthcare professionals get access to what is needed.

22-26. Overall, the White Paper focuses us on the recent threats to our national health but as well as looking at this, the paper should also be trying to prepare us, as a nation, for the next (public) health threat. To some extent it does this by the reorganisation of powers, formation of new bodies, and the ability by the MHRA to set up registries. However, one of the learning points of COVID-19 is the need to move rapidly to deal with a threat, mobilising resources for frontline staff, and make sure that new and novel treatments can be assessed in a timely manner to help protect public health. All of this was demonstrated by the response to COVID-19 but needs to be built on further.

There also should be wider powers for the MHRA to look at those products that focus on well-being and also to act on and assess products that are being brought into the UK without a licence and sold as natural remedies. From examples in the past, some of these products have had medical ingredients added to them which have not been declared and should have been licensed, e.g. topical corticosteroids in Wau Wa cream and Etin Skin Solution. The MHRA should have greater powers to tackle this to protect patients who would be unaware of the risks from these products.

In addition, MHRA should extend regulation of dermal filler devices, which are often traded as cosmetic devices. However, these injectable products can have life-ruining and long-term side effects. The CE mark requires minimal safety or efficacy data, and the status of these injectable devices should be upgraded to prescription-only. The same goes for digital apps; many apps claim to be regulated by the MHRA with a CE

class 1 marking and there is no oversight of this category. Furthermore, it is easy to not even have that if an app classifies itself as for well-being. However, many of these apps will collect patient data and will provide healthcare advice, and more clarity is needed.

The paper also needs to do more to safeguard the ability to manufacture medicines or medical devices in the UK where there is a shortage or difficulty importing in sufficient quantities. This is important for most medicines that can have occasional difficulties in supply chains but is especially important if facing another pandemic-level threat.

Ingredients are becoming scarce or more expensive internationally and this means some medicines are being discontinued. Medicines also may become financially not-profitable to manufacture due to other factors resulting in high costs but are niche products for certain patients, e.g. Calmurid for ichthyosis. There should be mechanisms in place to tackle shortages when they occur or have the ability to manufacture alternatives to these medications in a timely manner. At present, licensing may adversely affect this, and reformulation of a new product will take time, impacting on patient care. Removing barriers from this process would help to maintain stocks of important medication and improve access resulting in benefits for patient health.

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