BRITISH GENERIC MANUFACTURERS ASSOCIATION

Generic industry supply chain resilience post-COVID-19

About us

The BGMA represents the interests of UK based manufacturers and suppliers of generic medicines and promotes the development of the generic medicines industry in the United Kingdom.

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Contents

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1.0 **Summary**

This paper sets out our proposals for enhancing the resilience of the generic and biosimilar medicines supply chain in the light of the experience of the COVID-19 pandemic, and in a way that maximises the economic contribution of the generic and biosimilar medicines industry to the UK.

We set our resilience objective as to have a robust supply chain, able to supply medicines to patients as needed, with flexibility to be efficient at normal and enhanced levels of need. We analyse the strengths and weaknesses of the current arrangements. We argue that greatest resilience is created by ensuring that there are multiple suppliers at all levels of the supply chain; that the supply chain itself holds sufficient volumes to give time to increase production in times of emergency; and that there is sufficient diversity and flexibility in manufacturing and regulation to allow manufacturing to be ramped up or changed to other products quickly in the time bought by those increased volumes in the supply chain.

We conclude that there is no one single measure that delivers this on its own – the answer lies in a number of measures that mitigate the risks and bottlenecks in the existing supply chain, based on categorising medicines according to the supply risk that they present. For this to be effective, there needs to be an industrial strategy for multi-source off-patent medicines. We explain this in the coming pages.

Our proposals are summarised in this chart:

	Category 1 Medicines Low risk products due to indications and supply	**Category 2 Medicines** Higher risk products due to importance and supply risk	**Category 3 Products** Products most likely to come under pressure in pandemic
Increased inventory	Increase hospital trust stock holdings reversing the Carter Reforms	Buffer stocks of finished dosage form product	Medicines reserve of finished dosage form product and API
Pro-resilience procurement	Secondary care procurement policies to reward resilience and ensure plurality of supply		
Regulatory flexibilities & refocusing	BAU regulatory flexibilities to instil supply chain resilience and flexibility of MAH response		
	Off the shelf crisis flexibilities to be agreed and held in reserve for future crises		
	Incentives through regulation and procurement to increase resilience through inspections of foreign API sites and level playing field quality, increased numbers of API and manufacturing sites on MAs, greater focus on the upstream supply chain		
Targeted investment in manufacturing		Targeted investment in manufacturing capacity of defined medicine types (e.g. sterile injectables, oral solid dose, etc), via capital grants, tax credits, etc	
Pro-manufacturing IP policies	Maintenance and extension of the SPC manufacturing waiver to make the UK a more attractive base for generic manufacture for export to non-patent protected markets whilst ensuring UK patent protection		
International cooperation	International cooperation to aid medicines flows in times of crisis and to generate regulatory alignment and a global reference product to make generic registration in the UK more attractive post-Brexit		

2.0 **Overview**

2.1 **Performance of the supply chain**

The COVID-19 pandemic put unparalleled pressure on the generic medicines supply chain with huge surges in demand for medicines used in Intensive Care Units, particularly for patients who needed mechanical ventilation.

Given the extraordinary circumstances, the supply chain held up well, though margins were tight. Cooperation and coordination between industry, government and the NHS ensured that patients received the medicines they needed, though exceptional effort was required to achieve this.

2.2 **Concerns**

Notwithstanding this success, because of the effort needed, concern has been expressed about the potential fragility of the medicines supply chain with focus on issues such as:

i. **UK manufacturing:** The reliance on finished dosage form (FDF) manufacturing capacity outside of the UK, particularly in India and less so in China (though we estimate that 20-25% of generic medicines used by the NHS are manufactured in the UK and perhaps >40% in the European Union).

ii. **Reliance on India and China:** Concentration of active pharmaceutical ingredient (API) production in India and starting materials and intermediates production in China (though there remains significant API production in the EU, particularly in Italy).

iii. **Single sources of supply:** FDF manufacturers being reliant on one source of API and one manufacturing site, undermining flexibility if there were supply or manufacturing issues at those sites.

2.3 **Other considerations**

Though the supply chain coped well, we agree that the Government and industry working together can and should take steps to enhance supply chain resilience for the future. There is no single effective way of achieving this: a multi-layered, balanced approach is needed.

For example:

i. We need to understand and address the reasons for the eastward drift in manufacturing, and market concentration in API supply, rather than simply attempt to change the result in a way which might be economically unsustainable.

ii. Work by management consultancy Kearney for the World Economic Forum showed the inherent conflicts in this sort of analysis, for example between:
   a. The goals of adding dual sourcing to supply chains and reducing complexity.
   b. The ambition to create more nimble or agile local supply chains whilst coordinating across global value chains.

iii. Kearney also highlighted the benefits of relationships with suppliers shifting from the transactional to more committed strategic long-term, value-focused relationships.

2.4 A strategic approach

This demonstrates the need for Government and industry to agree a broad industrial strategy for generic and biosimilar (or off-patent multi-source) medicines which meet 78% of NHS demand, such as the Life Sciences Strategy that exists for the innovative sector which meets 22%.[1]

Structures should be established to agree, implement, and review this strategy at official and political levels.

Such a strategy should encompass:

i. **A strategic medicines reserve and / or buffer stock:** Potentially the simplest and most cost-effective means of dealing with unexpected surges in demand.

ii. **Intellectual property:** The initial eastward drift of manufacturing from the UK was because of the UK adopting a more restrictive approach to intellectual property rights than in other countries. To be an attractive base for the development of generic medicines and manufacturing, it will be critical for the UK at least to maintain the current balance of intellectual property rights and broaden post-Brexit the EU's manufacturing waiver to enable the production of generics for export to non-patent protected countries during the UK patent term. This would not change the balance between originator and generic companies in the UK where the originator's protection would be maintained, but would allow UK based generic manufacturers to compete in export markets that would otherwise be closed to them.

iii. **Procurement:** A focus on price above all else has intensified the eastward drift to lower cost economies to enable suppliers to reduce their own cost base. More weight must be placed on past supplier performance when awarding contracts, along with other factors in accordance with the MEAT principle. Similarly, single award tenders concentrate the number of suppliers, often manufacturing in low cost economies, creating transactional rather than strategic relationships, further reducing resilience and flexibility.

iv. **Regulation:** There are additional regulatory costs for manufacturers in having more than one API supplier on marketing authorisations or more than one manufacturing site. This needs to be reversed, aligning enhanced resilience with intelligent regulation. Additional flexibilities should be introduced both for business as usual (BAU) and to deliver enhanced agility in times of crisis.

v. **The UK manufacturing base:** Against this broader background, we need an evidence based approach to establish what beyond these changes is required for the UK to support the resilience of the supply chain and potentially as an element of industrial or economic policy in a post-Brexit world. This might lead to the development of a targeted investment and development plan.

2.5 Principally a secondary care issue

The UK's competitive, multi-source generic market has worked extremely well, including through the pandemic, particularly in primary care where the UK benefits from the lowest prices in Europe and high levels of supply in comparison with other European markets as a result of high levels of competition between suppliers and low levels of official intervention: this must be maintained and strengthened.

Most measures that we propose below are therefore targeted at enhancing the resilience of supply of hospital medicines. Some of the broader measures we consider would apply to all medicine supplies, but specific more interventionist measures are appropriate to secondary care medicines, and then on a risk assessed basis.

More widespread intervention carries the additional risk of disrupting a well-functioning market to no benefit.

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The crucial importance of generic medicines, sometimes decried as "old", has been seen during the pandemic when they were the critical ITU medicines needed to support mechanical ventilation of the most ill COVID-19 patients.

1 https://www.nhsbsa.nhs.uk/statistical-collections/prescription-cost-analysis-england/prescription-cost-analysis-england-2019

3.0 An industrial strategy for generic and biosimilar medicines

3.1 The need for a strategic approach

It is critical not to look at potential resilience measures in isolation; and that this should not be a one-off review.

The UK, particularly in a post-Brexit world, needs an industrial strategy for the multi-source off-patent medicines that meet four-fifths of British patients' medicine needs in the UK, just as it has one for innovative medicines that meet one fifth of patients' needs.

Whilst recognising and supporting other economic and scientific contributions made by the research based pharmaceutical sector, there also needs to be a patient focussed strategy to promote and encourage the effectiveness and sustainability of the generic and biosimilar sectors that provide access to cost-effective medicines for the majority of patients.

Generic and biosimilar medicines manufacturers can provide established cost-effective treatments for met clinical needs, whilst the research-based sector can focus on creating treatments for unmet clinical need. In this way, the two parts of the industry can be mutually supportive and provide the best value and care for patients and the NHS.

The crucial importance of generic medicines, sometimes decried as "old", has been seen during the pandemic when they were the critical ITU medicines needed to support mechanical ventilation of the most ill COVID-19 patients. And it was, of course, a generic medicine that was the first identified as a treatment for the most seriously ill patients. This re-purposing of generic medicines holds great promise for the cost-effective treatment of many patients with numerous conditions, and the work that we and NHS England & Improvement have been carrying out in this area needs to be accelerated and made more mainstream.

In addition to a focus on a resilient supply chain, an industrial strategy should ensure that the generic and biosimilar medicines industry can best continue to unlock billions of pounds of annual savings in the NHS drugs budget whilst also helping to treat more patients and support the UK's economy.

3.0 An industrial strategy for generic and biosimilar medicines continued

3.2 The location of the manufacturing base

The key resilience objective should be to have a robust supply chain, able to supply medicines to patients as needed, with flexibility to be efficient at normal and enhanced levels of need. There is no one single measure that delivers this on its own – the answer lies in a number of measures that mitigate the risks and bottlenecks in the existing supply chain.

This is particularly true when we do not know the nature of any future pandemic and the possible demands on medicines, or on which medicines. Plans need to be made to deal with different types of shock or emergency. We can envisage different pandemics, viral or bacterial; and supply chains could be disrupted due to trade wars or conflict.

Merely increasing local manufacturing capacity would not be effective in delivering a robust supply chain, or economically viable. There are mutual dependencies at different levels of the supply chain that drive efficiencies. One benefit of the current arrangements for generic and biosimilar medicines is that they invariably lead to there being multiple suppliers of the same medicine, with the ability of other suppliers to fill the gap if one is unable to supply, for whatever reason. This resilience is weakened if those multiple suppliers are themselves dependent on one or limited providers of API or raw materials, or if procurement policies themselves concentrate the number of suppliers.

Concentration of API supply and the supply of intermediates and raw materials is a much greater threat to supply chain resilience than the location of manufacturing sites; and yet the UK and Europe may be less amenable to the creation of chemical plants to manufacture these products for environmental as well as commercial reasons. It is worth noting that supply of API did not become a restraining factor on FDF manufacturing during the pandemic, not least because FDF manufacturers typically hold significant stocks of API, possibly over six months' normal need. They are now working to replenish those stocks.

The complexity and interdependence of the supply chain means that concentrating supply of FDF product, APIs or starting materials in any location, even locally, may undermine resilience. Diversity and flexibility are more important features. This can be driven in significant part by public policy measures or changes.

3.3 Intellectual property

The lack of a so-called 'Bolar' provision in UK intellectual law was key to driving generic R&D and product development out of the UK and Western Europe, and where a product is developed is often where commercial manufacture stays long term. The current concentration of starting materials in China, and API production in India, and the Eastward move of production, has been further driven by procurement and pricing policies that have incentivised lower production costs above resilience. This must change.

Support for UK based manufacturing would be enhanced by maintaining and ultimately enhancing the EU-derived SPC Manufacturing Waiver, enabling the production of medicines in the UK (where exclusivity provisions may be in place) for export to other countries where exclusivity has expired. The waiver could be enhanced to provide a real competitive advantage for UK-based manufacturers (including in comparison with those based in the EU) to produce and then export medicines to global markets without changing the balance between originator and generic companies in the UK.

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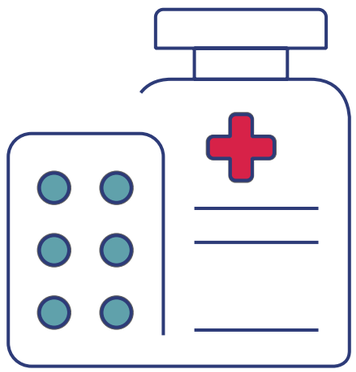
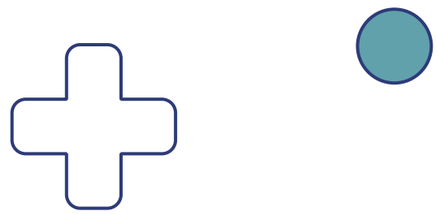


3.4 Overarching approach to resilience

Greatest resilience is created by ensuring that there are multiple suppliers at all levels of the supply chain; that the supply chain itself holds sufficient volumes to give time to increase production in times of emergency; and that there is sufficient diversity and flexibility in manufacturing and regulation to allow manufacturing to be ramped up or changed to other products quickly in the time bought by those increased volumes in the supply chain.

Thus, a multi-layered approach is required to enhance supply chain resilience, including:

i. Creation of buffer stocks and a strategic medicines reserve on a risk-based model that works for government and industry, potentially at different stages of the supply chain.
ii. Adoption of procurement policies particularly for secondary care medicines that incentivise supply chain resilience as well as encourage a plurality of suppliers through appropriate sharing of risk between supplier and purchaser.
iii. Maintenance of regulatory flexibilities to ensure that the industry is more cost-effective and is able more quickly to respond to short term peak demands and change / increase manufacturing; with a second line of flexibilities identified in advance to deal with crises.
iv. Incentives on industry to increase resilience through reversing the trend towards concentration of suppliers of starting materials and APIs, and FDF manufacturing sites.
v. Targeted increase in UK based manufacturing with flexibility to change product production quickly for the most critical medicines if their supply cannot be guaranteed in other ways.
vi. International cooperation through bilateral or multilateral mutual support agreements and measures that support trade in medicines and facilitate efficient regulation.



4.0 A strategic medicines reserve and buffer stocks

4.1 Assessing risk

A reserve of all medicines would be unnecessary, unwieldy, and expensive. Different approaches should be taken for specific medicines based on an assessment of risk. With assistance from industry, the Government should select those products on which it wishes to concentrate. This might be decided, for example, by reference to (i) their importance to healthcare generally and supply risk; and (ii) those medicines that the Government believes are most likely to come under pressure in the face of another pandemic or similar emergency. Annual reviews of the approach involving industry should be undertaken.

Medicines could then be assigned to categories:

i. **Category 1 medicines:** Low risk products where special measures are unnecessary beyond companies' normal risk management plans and the broader elements of a strategic resilience and industrial policy set out here.
ii. **Category 2 medicines:** Higher risk products where routine buffer stocks would be deemed necessary but sufficient, for example high volume solid dose oral products but with limited suppliers and an uncertain upstream supply chain.
iii. **Category 3 medicines:** Critical products where the Government and / or NHS should invest in its own strategic reserve of FDF and / or API outside of the normal supply chain to be called on in emergency, for example where buffer stocks and other measures would be inadequate on their own to deal with the sort of surge in demand that the pandemic created for sterile injectable products.

A reserve of all medicines would be unnecessary, unwieldy, and expensive. Different approaches should be taken for specific medicines based on an assessment of risk. With assistance from industry, the Government should select those products on which it wishes to concentrate.

4.2 Buffer stocks for category 2 medicines

The Government should agree with industry the modalities of creating buffer stocks so that they meet the needs of each. They could be managed in different ways according to these principles:

i. Government purchases stock, but stock is held and may be rotated by manufacturer; or
ii. Government pays a fee to manufacturers to hold a certain level of stock in the UK:
    a. May be rotated by the manufacturer.
    b. Should be subject to audit.
    c. May not be used for other purposes without government permission.
    d. Any stock that is unused, close to the end of its shelf-life or expired would be recompensed by the Government.
iii. Additional stocks should be of a volume that does not distort the normal operation of the market when they are released into the market on rotation, or entrench market shares between competitors. Any resultant reduction in competition could weaken resilience in the longer-term. For similar reasons, these provisions should only apply to medicines that are of agreed higher risk, and not more generally.

Additionally, increased inventory should be held by hospital trusts. The Carter Review of hospital operational productivity in February 2016 proposed a reduction in hospital stock holdings . The "just in time" principle for hospital medicines is not appropriate. Trusts should simply be advised to increase their stock holdings to a determined level of supply measured in time.

We have considered whether additional buffer stocks outside of the NMBS type approach above could be held at the different stages of the supply chain (e.g., retail, wholesale, hospital trusts, and suppliers) driven by financial incentives or regulation. We have concluded that, superficially attractive that this might be, it is impractical or potentially disruptive of the normal and effective operation of the market.

At the distributor level of the supply chain, most stock is held by pre-wholesalers, where title remains with the supplier or manufacturer. We understand that wholesalers have little additional space in their own premises to increase their normal holdings. Assessing and reimbursing the financial impact of a requirement on wholesalers to hold more stock would be difficult, as would agreeing specific volumes to be held given different market shares and demand fluctuations.

We have previously expressed similar concern that any broadly based regulatory requirement on Marketing Authorisation Holders (MAHs) to hold predetermined excess levels of stock would be potentially expensive and impractical, particularly if repeated by multiple countries. It would be difficult to mandate and enforce specific volumes when market shares in the generic sector change frequently and supplies ebb and flow according to supply schedules and changing demand. There is also the risk that, if repeated elsewhere at high volumes, it would unnecessarily tie up stock around the world and make the overall medicines supply situation worse.

4.3 Medicines reserve for category 3 medicines

A strategic reserve held by the Government should apply to a small number of high-risk products and be tendered for, bought and held by the Government. Depending on volumes in the reserve, different arrangements would need to be in place to prevent market disruption, such as transparency on how and when supplies might be released into the market, or agreement that any unused strategic reserve stocks would be written off. The strategic reserve should include FDF and API.

As noted elsewhere, consolidation of API and raw materials supply is much more of a threat to supply chain resilience than the lack of FDF production. To protect against medium-term disruption, a reserve of API should be maintained for Category 3 critical products. APIs typically have a longer and extendable shelf-life than FDF products and are easier to store. They can also be sent to any required location easily and rapidly (e.g., by air) if needed. For example, if India is disrupted by a future pandemic, API stored in the UK could be sent elsewhere for FDF production.

A 12 month supply of API would be sufficient to extend the reserve for long enough to formulate a long-term plan (18 months if the FDF reserve was for six months). Manufacturers typically already hold 6 or more months' supply of API, and this enabled production of medicines to continue during the pandemic when API exports from India (a major source) were disrupted.

Other European countries have begun to stockpile sterile injectable APIs for pharmacy compounding in their hospitals. This is misplaced: hospital-based manufacture is typically much less efficient and able to produce much smaller volumes than dedicated manufacturing plants. However, if an API reserve is to be orchestrated – and we look forward to debating this with the Government – its use and distribution should be based on the normal supply chain and needs to be coupled with regulatory flexibilities.

5.0 **Secondary care procurement policies**

Basing tender awards wholly or mainly on price as has traditionally been the case in the UK incentivises manufacturers to develop a leaner supply chain rather than focus on resilience. This must change.

Purchasing decisions should take into account past performance (as is now the case) and resilience issues such as the number of API suppliers on the product licence, supported by regulatory changes to facilitate this. The number of FDF manufacturing sites could also be a factor but this is less important for resilience than flexibility of API suppliers.

This could be facilitated via a scoring system for award of secondary care contracts using MEAT principles, which could include resilience measures or security of supply criteria as a factor in the award, including track record of supply. This sort of matrix approach is already in use within the NHS for some tenders and could be extended. We should like to discuss and agree with the Government and NHS appropriate measures and weighting.

To support this, the NHSE&I Commercial Medicines Unit (CMU) contracting process should be revised so that at least critical medicines contracts have:

i. A commitment to purchase, possibly with higher penalties for non-supply as a quid pro quo.
ii. Longer lead times.
iii. More accurate demand usage estimates / forecasts.

To encourage plurality of supplier, where the volume is big enough to be supplied by two or more suppliers, the CMU should lot these volumes so that there are always multiple suppliers wherever possible.

Consideration should be given to Trusts purchasing freely available primary care products on the open market rather than using a tendering system. This would build on an effective primary care supply and pricing system, and remove the negative effects of tendering in potentially concentrating the market and removing competition.

All of these measures should apply to the four Home Nations and not just England.

6.0 **Regulatory flexibilities**

The MHRA should retain for BAU those flexibilities shown to aid supply during COVID-19, boost supply chain resilience and promote fast adoption of new manufacturing facilities, including:

i. QP flexibilities.
ii. Remote audit of API manufacturers, product manufacturing sites & extensions (new and existing) by MAHs and regulators to be followed by on the ground audit.
iii. Notification (no pre-approval) of minor changes.
iv. Expediated assessment of new generic applications and supply chain variations for agreed groups of products.
v. Fast track process for API and finished product manufacturing site and laboratory transfers.
vi. Rapid access to MHRA advice.
vii. Lower fees for dormant licenses to disincentivise cancellation of MAs and a fee structure than incentivises rather than disincentives multiple sourcing of API and FDF manufacturing sites.

In addition, the MHRA should agree with industry a range of flexibilities that could be introduced during any future emergency to aid supply of medicines. Though cooperation between regulator and industry during the pandemic was excellent, having agreed additional crisis flexibilities on the shelf in advance would aid efficiency.

In a post-Brexit world, innovative ways of regulating generic and biosimilar medicines must be introduced to make the UK a more attractive location for manufacture and early launch of these follow-on products. Any need to repeat regulatory processes for the UK post-Brexit will act against these objectives, increasing NHS costs, reducing the range of medicines available to British patients, and undermining any attempts to boost UK manufacturing.

In a post-Brexit world, innovative ways of regulating generic and biosimilar medicines must be introduced to make the UK a more attractive location for manufacture and early launch of these follow-on products.

7.0 Incentives to increase resilience

Recognising that concentration of API supply (and that of starting materials) rather than FDF manufacture is the more concerning element of the supply chain, regulators should include API suppliers directly within the medicines regulatory framework thus reducing the burden on FDF manufacturers, with more inspections of API sites, to facilitate fast decisions to add API suppliers to MAHs' licences whilst ensuring that quality is maintained. Driving a common approach to quality internationally will also ensure that suppliers in low cost economies cannot benefit from lower compliance costs creating a level competitive playing field in this regard with Europe.

Regulatory data should extend upstream to include key starting materials suppliers. The MHRA could hold a database to show the full and true extent of MAHs' supply chains for each FDF product, allowing the Government and industry to assess risk, and agree mitigation plans.

In addition, regulators could incentivise some or all of the following:

i. Increased number of API suppliers on the MA.
ii. Increased number of manufacturing sites on the MA.
iii. Vertical integration v CMO manufacture.

However, if the UK acted unilaterally, e.g., to apply a requirement to add additional API suppliers, this would make the UK much less attractive than other markets which did not apply a similar requirement. We are aware that other countries and the European Commission are having similar considerations and the UK should work internationally to promote more resilience this way to avoid the UK becoming a less attractive market for supply and manufacture.

Possible incentives include:

i. A scoring system for award of secondary care contracts, though similar provisions could not be made effective for primary care products.
ii. A higher price or advanced commitment to purchase to enable more resilience, again applying only to secondary care products.
iii. Reduced regulatory cost for multiple API and manufacturing sites on the MA.

8.0 UK based manufacturing and production flexibility

8.1 Current levels

Overall, we estimate that approx 20-25% of UK generics are manufactured in the UK, 40-45% in the EU, and 30-35% in India (with perhaps 5% elsewhere). China is a dominant global source of starting materials and India for active pharmaceutical ingredients (API) (perhaps 50%), though Italy remains a significant source.

8.2 COVID-19 sterile injectables experience

The focus during the global COVID-19 pandemic was on sterile injectable medicines given the nature of the disease, and the call for mechanical ventilation of the most seriously ill patients. A future pandemic or other crisis might be different in nature and require different medicines, so building UK manufacturing capacity solely to meet the needs of the current pandemic could be pointless or even counter-productive for the future.

The sterile injectables market is small in volume, which explains why manufacturing plants are generally multi-national to build scale and why the market is serviced by comparatively few manufacturers, mainly with finished dosage form manufacture in Europe (though there is growth in India which is also a significant source of API).

Manufacture of sterile injectables is comparatively simple, but the manufacturing plants are complex (not least for environmental and employee safety reasons) with very high GMP quality standards, enforced by the regulator, the MHRA. The main barrier to market entry is the capital cost of building / equipment installation and set-up.

Building sufficient capacity in the UK to meet the huge increase in need for sterile injectables to deal with COVID-19 levels of demand would lead to massive excess capacity in normal times such that the economics would not work without huge government subsidy (even recognising that demand may become higher due to NHS capacity building).

Seed-corn funding support for the building and installation cost would be needed, as well as a commitment to purchase the excess production that would be generated as a result, and at prices higher than those offered in the competitive marketplace. Public support for this investment and premium payment may not be sustainable in the future. This scale of increase in UK manufacturing capacity thus seems impractical, though limited, targeted increases may have a place.

8.3 Targeted investment

We believe that the measures outlined above will significantly add resilience to the supply chain. Limited, targeted increase in UK manufacturing capacity and particularly production flexibility might be appropriate if properly focused and as part of an overall package. Given the risk of oversupply and competition from goods manufactured elsewhere, regulatory changes driving manufacturing flexibility , commitment to purchase and long-term underwriting of volume (of API or FDF) are essential to make an increase in manufacturing capacity viable.

Any government support to assist an increase in manufacturing capacity of API or FDF should be provided on a fair and transparent basis and, to the greatest extent possible, not disrupt the normal operation of the market.

The focus should be on a small number of likely critical medicines , to be agreed between industry and government, possibly around some type of "national resilience formulary" and linked to the strategic medicines reserve discussed above.

8.0 **UK based manufacturing and production flexibility** continued

The objectives, which should drive public investment decisions, should be:

i. To invest in more modern & innovative factory designs (automation, continuous manufacture, integrated systems); "pops up" to be brought into production in the case of an emergency; or to upgrade and supplement existing facilities.
ii. To establish an agreed minimum capacity for each type of medicine (sterile injectables, solid dose, controlled substances, biosimilars) under BAU (noting that BAU demands might be higher due to other resilience measures (e.g. increase in ITU capacity)).
iii. To create flexibility within manufacturing sites, e.g. through holding tools to change presentations to meet unanticipated demand for specific medicines and ready to use formats.

Government driven incentives are needed to achieve this, such as:

i. Seed-corn funding for new plants or development of existing ones, with commitment to purchase (volume and price) from them to make them commercially viable.
ii. Capital grants for new manufacturing facilities linked to more flexible lines that can easily be changed to manufacture different products, e.g. by requiring change tools to be provided and held on site as a condition of public investment.
iii. Specific national regulatory requirements or financial incentives to drive this sort of environment.
iv. Reform of state aid rules to provide for security of supply investment.
v. Tax credits for companies making strategic investments.
vi. An intellectual property regime that makes the UK an attractive location for generic and biosimilar medicines development and manufacturing.
vii. Support in the planning system for extended or new facilities by noting their strategically important nature in official Government planning guidance.

Indeed, the historic growth of generic medicines manufacturing in the Republic of Ireland was driven by a mix of planning assistance, capital grants, low Corporation Tax rates and a supportive intellectual property regime from the viewpoint of generic manufacturers, together with membership of the EU providing a large, easily accessed single market for manufacturers based in Ireland.

A clear plan with outcome objectives should be established to give strategic focus.

8.4 **Manufacturing waiver**

We comment in section 3.3 that "Support for UK based manufacturing would be enhanced by maintaining and ultimately enhancing the EU-derived SPC Manufacturing Waiver". Given likely regulatory divergence with the EU, it will be critical to expand the markets available to UK based manufacturers if the UK is to be an attractive manufacturing base outside of the EU single market.

Maintaining the manufacturing waiver will be critical to this; and it should be expanded once the UK is outside of the EU pharmaceutical acquis such that it applies more broadly and not just to Supplementary Protection Certificates issued after July 2019, and the amount of stockpiling that can be undertaken should be expanded.

This would not change the balance between originator and generic companies in the UK where the originator's protection would be maintained, but would allow UK based generic manufacturers to compete in export markets that would otherwise be closed to them.

A clear plan with outcome objectives should be established to give strategic focus.

9.0 **International cooperation**

The Government should embrace a new trade agenda on security of supply, including bilateral or multilateral agreements pledging mutual support and sharing of medicines and associated goods in times of crisis; and agreement not to erect barriers to the cross-border supply of medicines, intermediates and starting materials.

During the pandemic, European manufacturing facilities largely continued in production (not always the case elsewhere) and medicines and their constituents were exempted from border closures. Similar attempts in other countries were not as successful (though there were occasional glitches in Europe), and the UK should promote international agreements on these issues, as it successfully did during the pandemic via the G20.

In a perfect world, there should be an excess of global capacity such that if any one region is disabled, production can continue and worldwide demand be met. This does not mean simply building capacity in the UK: rather there should be a worldwide spread of capacity. If the UK is severely disrupted, it will need medicines from elsewhere and local production may be ineffective.

Consideration could be given to production and trade agreements with politically aligned areas (UK, EU, USA, Canada, Australia, New Zealand, Japan). This can be supported by a wider programme of mutual reliance, including recognition of others' regulatory standards to be given effect through Mutual Recognition Agreements or Free Trade Agreements. Regulatory agreements and convergence with other like-minded countries will be critical to support the industry and its role in the UK post-Brexit.

10.0 **Conclusion**

The proposals in this paper aim to set out a strategy for the generic and biosimilar medicines industry that will:

i. Enhance the resilience of the supply chain through business as usual measures that apply to all off-patent medicines.

ii. Provide for greater resilience of supply measures for medicines deemed to offer greater risk to patients due to their specific characteristics, rather than applying a one size fits all approach.

iii. Maximise the economic benefit to the UK delivered by the generic and biosimilar medicines industry.

iv. Maximise the attractiveness of the UK as a base for development and manufacturing of generic medicines, not least in the light of the loss of many of the benefits of scale due to Brexit.

v. Provide a joint industry / government mechanism for agreeing the strategy and overseeing its implementation.

Together, these proposals form a strategic approach to maintaining the crucial role of the off-patent medicines sector in the UK, strengthening the resilience of their supply chain, and ensuring their continued contribution to reducing NHS costs, increasing patient access, and contributing to the UK economy.

We hope that they make a positive contribution to the Government's thinking and look forward to discussing them with the Government.

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