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29th July 2020

The Rt Hon Alok Sharma, MP
Secretary of State for BEIS

Sent via email to: alok.sharma.mp@parliament.uk

Dear Secretary of State,

Thames Valley Chamber members urge for clarity over UK's new standards regime post BREXIT.

Representatives from the Chambers most senior Business Alliance membership met earlier this month at our Business Manifesto Advisory Group (BMAG) meeting (held 15th July).

The Focus was on "Restart - Rebuild – Renew" – moving towards a new normal for business post COVID-19 and as we move towards 'Exit-day'. In discussion, our membership largely praised your own Department's and Her Majesty's Government (HMG) wider efforts to support the UK economy and business during the COVID-19 pandemic. Our thanks are extended to you once again.

Eyes naturally are returning to issues associated with BREXIT and business raised great frustration with issues relating to the continued lack of clear guidance on the UK scheme to replace the EU's Conformitè Europëenne (CE) health, safety and environmental protection mark.

As you know, the CE marks are essential for legally placing products in EU markets and cover, for example, a vast number of industrial products including perhaps most pertinently the life sciences and healthcare sector where, for example, medical products (like PPE) and devices (like ventilators) would come under this legislation.

HMG has still not published details of how its own planned mark, the UK Conformity Assessed (UKCA), will operate and most recent reports suggest we remain a little way off from Government providing the clarity business really need now, stating: *"the UK has proposed mutual recognition of conformity assessment which would facilitate trade in UK Conformity Assessed (UKCA) and CE marked goods. This is subject to ongoing negotiation and we will provide further details in due course".*

What our businesses are telling us is that HMG is running out of time to design, test and guarantee compliance for a new UK quality assurance scheme to replace the EU's "CE" product labelling system before the end of the BREXIT transition period. They are also gravely concerned that Brexit will

double regulatory burden, adding extra cost to products and making companies less competitive because of HMG policies. They have also told us:

1. Given how close we are to E(xit) day we need a meaningful transition period after any agreed UKCA terms are finally agreed, during which old CE stock can be used up and new stock UKCA ordered. During a recession, asking companies to stop selling stock – i.e. scrap it and take a write off seems completely ridiculous (unless HMG offers full tax relief - and even then, companies would rather have product to sell than tax losses).
2. The lead times for new packaging, let alone certification to new UKCA standards, are almost inevitably going to run beyond E-day. There is therefore a need to build in enough capacity for technical certification. Has the certification capacity needed, both operationally and available skills, being modelled? Will HMG allow non-UK based certification agencies to certify to UKCA? If not, the hold ups already identified could be magnified as prototypes have to be shipped to UK certification facilities and then possibly final product tested again for future conformance.
3. As well as a transition period, there should be clear supportive guidance to Trading Standards (who will, we assume, be enforcing the UKCA marking) for a graduated/phased approach to enforcement. Businesses will be grappling with new supply chains and the last thing they will need is 'heavy handed' enforcement from 1st January 2021.
4. There remain real issues around how highly regulated industries have no real clarity on how the EU will receive UK made products in the future or whether the same standards will be mutually recognised.
    a. Taking the supply of UK made pharmaceuticals to the EU after BREXIT; As part of the EU, UK made medications could be sent to EU without further import testing (as everything was made to the same cGMP standards). HMG has stated that following BREXIT we will still receive EU made drugs, but the EU is yet to state whether they will take UK made medicines (and not subject them to further customs and import release testing).
    b. This situation has the real potential to make already complex and highly regulated supply chains more complicated and expensive. This could mean, yet further, reduction in the attractiveness of UK pharma manufacturing as companies look to relocate EU production onto mainland Europe/EU to circumnavigate this.

Our business our being affected directly. The following are examples of some of the direct impacts being reported most recently:

- *"The most critical issue is that the Government have not yet confirmed that CE marked products can be placed on the UK market after 31st December 2020 …. even though we have no detail on the new UK system and nobody has enough time to change all their packaging, labelling and certification. The cost of this is horrendous too".*
- *"We want Government to urgently update its plans and guidance for the UK scheme or risk interrupting component supplies and our capacity, potentially, to continue to supply cars, motorcycles, marine engines and power equipment to customers in the UK from our manufacturing base in the Thames Valley".*
- *"We chose to change our CE mark, at some cost, due to the opaque nature of progress …".*
- *"At our [manufacturing] company, as a result of the risk associated with CE marking, and the potential for there not to be cross-border recognition, we have transferred our regulatory body office from the*

UK to mainland Europe (Belgium). This has been at a considerable cost and has already taken the best part of a year to complete, due to the vast number of products and packaging items which simply quote the office 4-digit number under the CE mark. Is this part of the 'Brexit dividend' we've heard so much about?"

- *"The uncertainty over the new UK conformity assessment and marking requirements is yet another concern for us in the run up to the end of the Transition Period. It will take months, if not years, to ensure that all our products comply with any new regulations and to update all product, label, website and literature markings. The cost will be considerable, particularly if UK product regulations start to diverge from their EU equivalents. More information is needed urgently."*
- *"On www.gov.uk HMG is saying that, 'after a time-limited period, only the UKCA marking will be recognised for the UK market'. Having changed CE mark to a European one to gain access to Europe does our company now need to plan for a bespoke UK version of our product at further expense and increased stock carrying?"*

May we ask for your response to these concerns and most important issues. This will help, we trust, provide our members with the clarity and answers being raised. Most notably, understanding the options being considered, including a call for the grace period to be reinstated, and details of when the new scheme to be published, immediately come to mind as issues to address.

The implications to business in your own constituency, across the Thames Valley and UK are evidentially clear. The impact on individual businesses will undoubtedly be different but it is likely SME's may well be most affected as suppliers into larger companies and their supply chains.

Finally, may I remind you that you have an open invitation to directly meet our membership, including those within your Reading constituency on this and other related matters.

On behalf of those members and our wider business community we thank you in advance.

Yours sincerely

Paul Britton
Chief Executive

cc: Adam Marshall | Director General | British Chambers of Commerce
Contributing companies