BIVDA
British In Vitro Diagnostics Association

GMDN Agency
Hampden House
Monument Business Park
Chalgrove
Oxford
OX44 7RW

British In Vitro Diagnostics Association
299 Oxford St
London
W1C 2DZ

29th November 2021

Dear Chinaniso,

Thank you for the opportunity to provide feedback on the proposed scaling back of antibody-specific IVD terms within the GMDN.

BIVDA represents approximately 200 organisations within the IVD industry including start-up companies, SMEs, UK developers and manufacturers as well as subsidiaries of the global IVD corporations. We also represent some distributors and other economic operators. Our response is therefore submitted on behalf of this membership and reflects the general views of companies within the IVD sector.

The responses received from our membership were evenly split in support and opposition to the change.

The comments from those who support the change to a single GMDN code include:

- It can be burdensome to identify the correct GMDN code when there are multiple device types.
- IgG, IgM, IgA and combinations are all similar, so it seems to be logical to group these as one under antibody assays generally.
- Currently, not all pathogen/IgG type combinations are covered by GMDN codes, resulting in new codes being requested often. A reduced or single code would simply this process.
- Combining into a single code allows for products which may fall across multiple codes to be coded correctly and reduces ambiguity.

The comments from those who oppose the change to a single GMDN code include:

- Industry is working to update their technical documentation in line with the EU IVDR, which has included reference to GMDN codes in IVDD and IVDR compliant documentation. Where this coding changes, it will require manufacturers to update all of this information again, a somewhat timely and costly process.
- This does not adapt well to multiplexing; markers on an IVD are confined to a single stream of pathology e.g. a device may simultaneously measure a biochemical, a haematological and a microbial marker and this is not clear from GMDN codes.
- Multiple stakeholders are likely to rely on GMDN for a wide range of uses, including mapping, the Essential Diagnostics List, procurement, reporting of problems, and investigation of problems. Reduction of the list would make this challenging.

BIVDA
British In Vitro Diagnostics Association

We would like to suggest (if it has not already been done) that MHRA also provide comment on this proposal, as it is likely to greatly affect the MHRA registration system.

We are grateful to be given the opportunity to comment on such proposed changes, and BIVDA is available to assist in activity and dialogue into any future changes within the landscape for IVDs in the UK. BIVDA remain at the disposal of GMDN should you require any clarification in relation to our consultation response.

Yours sincerely,

Ashleigh Batchen
Regulatory Affairs Manager
British In Vitro Diagnostics Association (BIVDA)

E ashleigh@bivda.org.uk |T +44 (0)333 3208 823 |M +44 (0)756 4044 133