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6th December 2019.

Dear Sir/Madam,

RE: Review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia- CONSULTATION RESPONSE.

The TGA is seeking feedback on whether the Excluded Purpose Specification is fit for purpose and the potential impact that remaking the Excluded Purposes Specification would have on affected stakeholders. Submissions should include information relevant to the questions raised in the paper which are also summarised below:

Following evaluation by the TGA to determine their safety and performance, and considering the experience with HIV self-testing, should:

– self-tests for other infectious diseases be able to be legally supplied in Australia subject to evaluation and approval by the TGA with appropriate risk mitigation strategies?

–Are there any particular tests that should not be available in Australia as a self-test? Please provide reasons why not.

–Do you have any suggestions on how potential risks to consumers could be mitigated? .

GSKCHA Response.

GlaxoSmithKline Consumer Healthcare Australia Pty Ltd (GSKCHA) would specifically like to comment and provide feedback on – *self-tests for other infectious diseases including notifiable infectious diseases (Influenza Virus).* We support the remaking, of the excluded purposes specification as highlighted below (**proposed specification**). We believe as it stands the specification is not fit for purpose and that self-tests for influenza virus should be exempt as this would have a strong individual and social impact on disease identification and aid in effective and efficient flu diagnosis.

– self-tests for other infectious diseases including notifiable infectious diseases (Influenza Virus);

Proposed Excluded Purposes Specification
The Excluded Purposes Specification specifies the following self-testing IVDs are excluded from supply:

(a) Tests for the presence of, or exposure to, pathogenic organisms or transmissible agents (other than the Human Immunodeficiency Virus and **Influenza Virus**), including agents that cause notifiable infectious diseases.

GSKCHA agrees with the following points highlighted in the review. Technological developments in recent years have made IVDs for self-testing less expensive and more readily available. There is also a growing desire by consumers to have more say in their healthcare decisions. Therefore considerations around the remaking of the excluded purpose specification should be considered.

GSKCHA supports the proposal on greater flexibility on self-testing and greater access for consumers for self-diagnosis. However, we understand that appropriate TGA evaluation to demonstrate the products performance and safety is critical. There are clear benefits to wider availability of IVDs for self-testing which outweigh the risks associated with their use depending on the steps that can be taken to mitigate concerns. HIV self-tests illustrate this point with clear risk mitigation measures. In the case of influenza virus IVDs, by exemption for the excluded purposes specification, this would in fact stop consumers from importing non-TGA registered devices by allowing appropriate registration routes in Australia and appropriate consumer access after effective TGA review and risk mitigation.

While laboratory tests remain the 'gold standard' for diagnosing and confirming infectious diseases there are many advantages arising from rapid screening at the point of care or in the home. Self-testing devices for influenza virus may allow for early screening and intervention if required. It may also make testing accessible to consumers who would not otherwise be tested. This would include individuals who are not comfortable accessing current health services or do not have ready access to health services; e.g. people in remote communities. In general Australia is well served in major cities and large regional centres.

Viral infections such as influenza which have seasonal peaks can lead to overwhelming demand on healthcare services particularly Emergency Departments (EDs) and general practitioners (GPs). The demands on EDs and GPs during these seasonal peaks could be reduced if reliable self-testing devices that screen for influenza could be legally supplied in Australia, allowing consumers to access kits directly and promptly and to be tested outside of clinics. Earlier use of rapid screening for influenza could also reduce the severity of the disease by allowing for earlier treatment with antiviral drugs and or avoid potential for increased transmission. Further, the availability of real time testing results via the invitro flu diagnostic device is an additional benefit. It is clear early intervention can limit the progression of the disease and lead to many other health benefits accordingly.

GSKCHA understand and support the identified risk mitigation proposals for any additional infectious disease self-tests proposed for exemption, including influenza virus IVDs.

These mitigations could and may include ensuring:

- instructions for use and sample collection and test procedures are straightforward and easy to perform and are clear and straightforward;
- the test kit or device is robust and stable under a range of environmental conditions;
- that the sensitivity and specificity of the test is suitable to minimise the risk of false negative and false positive results;
- the interpretation of test results is clear and unambiguous and appropriate advice is available about follow up actions required and support services.

Restrictions on advertising of therapeutic goods.

As self-testing IVDs are likely to be advertised to the general public in some manner there maybe risks of inappropriate use if consumers are confused or misinformed as to the utility of the devices.

GSKCHA agree and understand that advertisements to the public for self-testing IVDs (as therapeutic goods) are subject to the Therapeutic Goods Advertising Code (the Advertising Code) . The promotion of self-testing IVDs must therefore comply with the requirements of the Advertising Code.

GSKCHA also understand that point of care IVDs which involve intervention with a Healthcare Professional is not in scope of this consultation.

In conclusion GSKCHA supports consideration of remaking the excluded purposes specification to exclude self-tests for notifiable infectious diseases specifically, influenza virus.

Please do not hesitate to contact the undersigned by telephone on [redacted] or by fax on [redacted] should you have any queries or clarifications on this response to consultation.

Yours Sincerely,

[redacted]

[redacted]