APPENDIX REPORT

Office of the Committee for Health & Social Care

Medicines Committee

Annual Report 2021

MEDICINES COMMITTEE ANNUAL REPORT 2021

Introduction to the Medicines Committee

The Medicines Committee, and its membership, is established under section 2(1) and 2(3) of the Medicines (Human and Veterinary) (Bailiwick of Guernsey) Law, 2008 ("the Law"). While the Law has been in force since October 2009, the Medicines Committee was only formally established by the Committee *for* Health & Social Care (the C*f*HSC) in September 2020[1]. Prior to this, where specific advice has been required, it has been provided on an extra-statutory basis by the most relevant States of Guernsey officers.

As detailed in the original 2004 Policy Letter, "Medicines (Bailiwick) Law", Article XIV, Billet d'Etat XIV of 2004, the Medicines Committee is designed to bring together experts in their relevant fields to advise the Department on matters relating to medicines and the execution of the Medicines Law. The planned commencement of a COVID-19 vaccination programme necessitated the establishment of the statutory Medicines Committee so that formal advice could be provided on the potential designation of vaccines, building upon the States' direction when considering a mass vaccination programme for COVID-19 (Billet d'État XVIII of 2020), that every step should be taken to ensure robust governance.

In accordance with the Law, the Medicines Committee combines pharmacy, public health, veterinary and nursing expertise. It provides a wide ranging, and robust, evaluation of the scientific evidence available and the associated governance so to make informed recommendations to the C*f*HSC in respect of the use of medicines locally.

Functions of the Committee

Section 3(1) of the Medicines Law states that:

> *The [Medicines] Committee shall advise the Department on matters -*
>
> *(a) relating to the execution of the above Law,*
> *(b) relating to the exercise of any power conferred by or under the above Law, or*
> *(c) otherwise relating to the regulation of medicinal products."*

Section 3(2) also states that it is the duty of the Medicines Committee –

[1] The membership of the Medicines Committee is defined in s.2(2) of the Medicines Law and includes the Chief Pharmacist, the Director of Public Health, the States Veterinarian, a senior nurse, and a senior civil servant.

"(a) to give advice with respect to –

(i) safety, quality and efficacy in relation to medicinal products, and
(ii) local practice regarding the manufacturing, wholesale distribution and dispensing of medicinal products in the Bailiwick,

(b) to promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling the advice in paragraph (a) to be given,

(c) to undertake any other function related to the regulation of medicinal products which may be conferred by this Law or any enactment made thereunder except in so far as those functions may otherwise be assigned to a committee established under section 4 (establishment of sub-committees), and

(d) to advise the regulatory authority in cases where –

i) it is required by the provisions of Part II (Regulatory provisions relating to medicinal products), or by the provisions of any other enactment, to consult the Committee with respect to any matter arising under those provisions, or
(ii) it so requests, in relation to any matter arising under any of the provisions referred to in sub paragraph (i).

Activity of the Medicines Committee

The Medicines Committee has provided advice on the designation of COVID-19 vaccines to the C*f*HSC, as per the agreed process for designating a vaccine authorised for use by the UK Secretary of State for Health and Social Care under Regulation 174 of the Human Medicine Regulations 2012. This process sets out the actions, and their associated governance arrangements, required prior to the C*f*HSC considering the designation of a COVID-19 vaccine for use in the Bailiwick of Guernsey. The 'Process for designating a vaccine for the virus causing COVID-19 in the Bailiwick of Guernsey' can be seen in appendix 1.

By considering the information publicly available - published by the Medicines and Healthcare products Regulatory Agency ("the MHRA") and by the Joint Committee on Vaccination and Immunisation ("the JCVI") – the Medicines Committee was satisfied by

the evidence available that the vaccines were safe, well-tolerated and had a high efficacy.

Accordingly, the Medicines Committee made a recommendation to the C*f*HSC to designate the following vaccines:

- Pfizer/BioNTech Vaccine on 3rd December 2020
- AstraZeneca Vaccine on 4th January 2021
- Moderna Vaccine on 19th January 2021

In recommending the designation of the above vaccines, the Medicines Committee advised the C*f*HSC that it would keep under review any emerging evidence both locally and from other jurisdictions in respect of adverse reactions associated with the vaccine. As with any new medicine, the products have been closely monitored to allow for the quick identification of new safety information and the Medicines Committee has considered the summary information published weekly on the Yellow Card reporting scheme[2] by the MHRA and remains satisfied that the expected benefits of the vaccines in preventing COVID-19 and serious complications associated with COVID-19 far outweigh any currently known side effects.

All vaccines and medicines have some side effects, and the vast majority of suspected adverse reaction reports have been for comparatively minor reactions such as sore arms, or generalised symptoms such as headaches, nausea etc. In the case of the more severe, and extremely rare, potential side effect associated with the AstraZeneca vaccine regarding a specific type of blood clot with low blood platelets, the Medicines Committee is satisfied that the updated advice provided by the UK, and adopted in Guernsey, is appropriate to the risk.

The Medicines Committee noted that in the months following the designation of the three vaccines set out above, the MHRA issued a marketing authorisation with conditions to both the Pfizer BioNTech (re-branded as the Comirnaty vaccine) and Moderna vaccines. This type of authorisation from the regulator is automatically recognised in The Medicines (Human) (Exemptions and Recognition of Marketing Authorisations) (Bailiwick of Guernsey) Regulations, 2009 for the purposes and provisions of the Law and its subordinate legislation.

[2] The UK system for collecting and monitoring information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices. More information is available online at https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/

The Medicines Committee has additionally benefited from the opportunity to discuss amendments to the Law with policy officers supporting the C*f*HSC. Recent experiences have demonstrated the value of ensuring Laws remain reflective of ever-evolving clinical practice and appropriately aligned to equivalent UK provisions. The Medicines Committee fully supports any steps to ensure that the legislative framework locally is responsive and flexible and would be happy to support the C*f*HSC further in this regard.

Looking forward – 2022

The Medicines Committee intends to reconvene early in the new year to:

- Draft the terms of reference for the Committee, establishing the frequency of meetings, quorum, reporting arrangements and secretary responsibilities, among other things;
- Progress arrangements to appoint a lay member;
- Establish a schedule of meetings for the calendar year; and
- Review any learning from its activities during 2021 and make recommendations to the CfHSC, as necessary.

APPENDIX 1:

PROCESS FOR DESIGNATING A VACCINE FOR THE VIRUS CAUSING COVID-19 IN THE BAILIWICK OF GUERNSEY

	Action	Governance
1	The Medicines and Healthcare products Regulatory Agency (MHRA) will recommend a vaccine to the Secretary of State, possibly initially as a temporarily authorised product	The MHRA is an executive agency sponsored by the Department of Health and Social Care which regulates medicines, medical devices and blood components for transfusion in the UK. The MHRA has been actively involved in the Vaccine Taskforce and is responsible for regulatory oversight of vaccine manufacture. It is also involved with vaccine safety surveillance and monitoring. Approval by the Secretary of State will permit a mass vaccination programme to proceed using a vaccine that has a temporary authorisation. In doing so, The Health Protection (Vaccination) Regulations 2009 require the Secretary of State to ensure, so far as is reasonably practicable, that the recommendations of Joint Committee on Vaccination and Immunisation (JCVI)[3] are implemented, and where those recommendations relate to new provisions for vaccination under a national vaccination programme in response to a question referred to the JCVI by the Secretary of State are based on an assessment which demonstrates cost-effectiveness. The JCVI is an independent expert body which advises the UK Government in respect to vaccination and immunisation. The JCVI will take into account all of the clinical evidence relating to efficacy and risks of the proposed vaccine for COVID-19 and will also make recommendations as to the priority cohorts to receive the vaccine.
2	Medicines Committee to convene to provide advice to the C*f*HSC	This will fulfil the statutory duties set out in Sections 2 and 3 of the Medicines Law to advise the C*f*HSC.

[3] https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

		In respect of making regulations to designate a vaccine, the role of the Medicines Committee would be to consider as much information as is available about the safety, quality and efficacy of the proposed vaccine against the virus COVID-19, including the recommendations of the JCVI, before providing advice to the C*f*HSC about the designation of the proposed vaccine in the Bailiwick.
3	Consultation	When considering whether to designate a vaccine, the C*f*HSC must consult with the Policy & Resources Committee, the Policy & Finance Committee of the States of Alderney and the Medical & Emergency Services Committee of the Chief Pleas, Sark. Consideration will be given to consultation with other stakeholders, as appropriate.
4	Consideration by the Committee *for* Health & Social Care	The C*f*HSC will consider the advice of the Medicines Committee when considering whether to designate a named vaccine for use in the Bailiwick. The Committee will be provided with as much information as possible about the safety, efficacy and cost-effectiveness of the vaccine. The Committee will also consider what, if any, measures to mitigate the risks and associated liability are available and practicable. In doing so, the C*f*HSC will take into account feedback received from the consultation in 3 above.
5	Signing and registration of regulations	If approved by the C*f*HSC, regulations to designate a vaccine, exempt the vaccine from various regulatory provisions in the Medicines Law, and make the necessary consequential amendments to a number of existing regulations made under that Law, would be finalised and signed by the President, and lodged at the Greffe.