REPLY BY THE PRESIDENT OF THE COMMITTEE *FOR* HEALTH & SOCIAL CARE TO QUESTIONS ASKED PURSUANT TO RULE 14 OF THE RULES OF PROCEDURE BY DEPUTY P J ROFFEY

Although these questions have been directed to the Committee for Health & Social Care, they engage aspects of the mandate for Committee for Employment & Social Security and have accordingly be jointly agreed.

1. **Please will the Committee for Health and Social Care confirm the funding status of each of the drugs set out in the separate attachment to this email? In each case please advise if they are available on prescription in Guernsey, under what circumstances, and in those cases where they are not available on prescription explain why not.**

A completed table is attached as Appendix 1. Only medicines which have specifically been requested will have been considered for funding.

The detailed process through which priority setting takes place is detailed in Policy G1033 (which may be found online at https://www.gov.gg/fundingprioritisation). This Policy takes a population based approach to ensure that the Committee *for* Health & Social Care's limited resources are used in a way which maximises the value of care delivered to the population as a whole. This process takes into account all health and care developments and is premised on treating investment decisions about all conditions at all stages of life in the same way so to enable the fairest and most equitable delivery of care.

Recommendations from the Drugs and Therapeutics Committee are considered as part of the overarching prioritisation process where they are considered against other competing priorities. Such prioritisation takes place quarterly, whereby all developments – for example medicines, surgical procedures, screening programmes, medical devises or vaccines – are collectively considered, assessing their cost effectiveness and benefit to the health and wellbeing of the population. From there, considering the Committee *for* Health & Social Care's budgetary position, a decision is made on which, if any, developments should be funded.

Decisions which require the Committee *for* Employment & Social Security to agree to the funding are handled by the Pharmaceutical Benefit Advisory Committee. This Committee make recommendations based on the same overarching principles set out in G1033 and with the same regard for value for money and cost effectiveness.

This means that end of life treatments are subject to the same decision making principles and processes as all other treatments. This approach differs to that used in NHS England, where a differential operates around end of life care when considering cost-effectiveness, and means that those drugs approved by NICE using the end of life premium are less likely to fit within the funding parameters used locally as part of the prioritisation process.

2. **Further will the committee please comment on why Nintedanib is not available in Guernsey for the treatment of idiopathic pulmonary fibrosis when it has been in the EU since 2015 and the UK since January 2016 and is also available in Canada, Switzerland and Japan?**

To date, neither the Committee *for* Health & Social Care nor the Committee *for* Employment & Social Security have received a request from a clinician for the funding of Nintedanib.

NICE guidance on the use of Nintedanib, published in 2017, was issued on a conditional basis, noting that a review was ongoing in respect of another drug, Pirfinidone, which is also used to treat idiopathic pulmonary fibrosis. While this guidance recommended the use of Nintedanib as an option for treating idiopathic pulmonary fibrosis in defined circumstances, it considered that Nintedanib had similar cost effectiveness to Pirfenidone and therefore could only recommend its use for a defined subgroup in which Pirfenidone, when provided with the discount agreed in the patient access scheme, is currently recommended by NICE's technology: those with a percent predicted forced vital capacity - the amount of air which can be forcibly exhaled from the lungs after taking the deepest breath possible – of 50–80%. This guidance recognised that Nintedanib could only be considered cost effective compared with Pirfenidone, Not compared with best supportive care where the use of Nintedanib as a replacement was not considered a cost-effective use of NHS resources.

Further guidance published by NICE earlier this month which further clarifies that Nintedanib is the first choice agent as the Pirfenidone has a better cost effectiveness position compared with best supportive care.

While neither Nintedanib nor Pirfenidone have been requested by local or off-island clinicians in the recent past, where an application to be made, these would be considered in light of the latest published guidance. Were an application to be made in respect of Nintedanib in line with the restricted basis set out in the NICE guidance, it would fall within the normal commissioning policy range, and would be considered in line with the process detailed in question 1.

3. **Further will the committee explain why Ibrutinib is only now being considered for funding for the treatment of blood cancers in Guernsey when it has been NICE approved for use by the NHS for the last 14 months.**

The funding of Ibrutinib for the treatment of blood cancers was first noted by the Pharmaceutical Benefit Advisory Committee (PBAC) in late 2016. At this stage, PBAC deferred consideration pending the publication of NICE guidance. Following the publication of this guidance in January 2017, PBAC considered the funding in Ibrutinib in March of that year, however as the ICER QALY – a measure through which the cost-effectiveness of a health care intervention is considered considering both the quantity and quality of life generated – was at the time in excess of £50,000, it fell outside the normal commissioning parameters.

The funding of Ibrutinib was reconsidered by the PBAC earlier this year, following a re-application, including a request from the visiting haematologist, and the simplification of the pricing structure. PBAC

recommended funding and the Committee *for* Employment & Social Security gave the necessary approval. As part of this process, The Committee *for* Health & Social Care needed to seek reassurances that it would be able to access Ibrutinib at the special rate used by NICE to determine its cost effectiveness – on this occasion it took longer than normal to obtain such reassurances, however this has now been resolved.

4. **Further can the committee please clarify the future funding status of the drug Ruxolitnib for the treatment of blood cancers?**

Ruxolitnib is approved for use in Guernsey by the Committee *for* Employment & Social Security (on their 'white list') for the treatment of disease related enlargement of the spleen or symptoms in adults with myelofibrosis – a relatively rare bone marrow cancer. This approach is in line with NICE TA 386 and its licensed indication. Such approval is based on the ability of the Committee *for* Health & Social Care's pharmacy to access Ruxolitnib at the special discounted rate, which currently it can.

Appendix 1

Glossary

ICER	Incremental Cost Effectiveness Ratio, the extra cost benefit compared with standard commissioned care
QALY	Quality Adjusted Life Year, a measure of the health gain achieved
Discounts/Patient Access Schemes	Discounts on the list price agreed by pharmaceutical companies to bring the ICER QALY within the agreed parameters for a NICE recommendation, or mechanisms by which refunds are made to bring the costs down, can be quite complex to access and apply to the NHS only (Guernsey cannot automatically assume it is able to access them, though it usually can after some discussion with the company)
Routine Care ICER QALY	NICE usually calculates this to be between £20-30k
End of life premium ICER QALY	NICE uses this to cover drugs which extend life for a relatively short period, usually months and is calculated as being between £30-50k.(i.e. 1.7 times routine care)
Affordability	What the health system can afford with the given resources at its disposal. NHS calculated that it is between £12-20k.
Note:	Guernsey in policy G1033 does not treat end of life as 'special' and treats all ages, diseases and stages of life the same.

Funding Committee	Recommending/Advising Committee
Committee *for* Health & Social Care	
	Drugs and Therapeutics Committee (DTC) advises on policy for use of medicines and which medicines are to be used within CHSC. (Approvals have to be in the context of the white list operated by CESS and agreed as part of the prioritisation processes set out in G1033). The DTC is made up of senior clinical, nursing and pharmacy staff, chaired by the Chief Pharmacist.
Committee *for* Employment & Social Security	
	Pharmaceutical Benefit Advisory Committee (PBAC), advises on which medicines are to be funded by CESS for use in the community/people's own homes which includes oral chemotherapy. This list of approved drugs/medicines is commonly known as the White List. PBAC also works in the context and guiding principles set out in G1033 and is made up of representatives from the three primary care practices, Public Health, MSG and pharmacy staff from CHSC chaired by the Prescribing Advisor.

Drug Name	Indications and restrictions	NICE approval	NICE TA End of Life Premium used	Patient Access Scheme for discounted price	Request submitted to DTC or PBAC	Approved in Guernsey for State Funding	Comments	Observations
Afatinib	EGFR mutation positive Non-small cell lung cancer Must Not have had prior TKI therapy.	TA310 April 2014	No	Yes	No	No	Other Tyrosine Kinase Inhibitors used, which have equal effectiveness, No plausible ICER QALY could be calculated but assumed equal to other products in the class	£2,023 per 28 x 50mg tablets, one month's supply (access to discount scheme reduces this)
Axitinib	For advanced renal cell carcinoma when other TKI's or cytokines have Not worked.	TA333 February 2015	Yes	Yes	No	No	Only for use after failure with first-line Sunitinib or a cytokine. ICER is above the range usually considered to be a cost-effective use of NHS resources in NICE technology appraisals (between £20,000 and £30,000 per QALY gained), approval therefore only based on end of life premium	

Enzalutamide	Metastatic hormone-relapsed prostate cancer.	TA377 January 2016	No	Yes	No	No	Most plausible ICER for Enzalutamide compared with best supportive care was nearer to £31,600 than to £34,800 per QALY gained.	
Olaparib	Relapsed platinum sensitive ovarian, fallopian tube or peritoneal cancer who have BRCA 1 or 2 mutations.	TA381 January 2016	Yes	Yes	No	No	NICE identified sub set of patients, end-of-life criteria for the subgroup of patients with relapsed BRCA mutation-positive, platinum-sensitive ovarian cancer who have received 3 or more previous lines of platinum-based chemotherapy the drug cost of Olaparib for people who remain on treatment after 15 months will be met by the company	
Panobinostat	To treat myeloma after at least 2 prior treatments.	TA380 January 2016	No	Yes	No	No	Concluded that the ICER was likely to be no higher than £25,000 per QALY gained and therefore within the range that would normally be considered a cost-effective use of NHS resources	

Radium 223 dichloride	Advanced metastatic prostate cancer after treatment with Docetaxel.	TA376 January 2016	Yes	Yes	No	No	Not a technology used locally No application has been made from secondary centres or local clinicians	
Cabazitaxel	For hormone-relapsed metastatic prostate cancer after Docetaxel chemotherapy.	TA391 May 2016	Yes	Yes	No	No	Changes in the patient access scheme reduced the QALY from over £80k to £45k, when combined with updated outcome data, mean gain of life expectancy about 0.25 yrs.	
Radium-223	Recommended as an option for treating hormone-relapsed prostate cancer, symptomatic bone metastases and No known visceral metastases, if they have had prior Docetaxel.	TA412 September 2016	Yes	Yes	No	No	Not a technology deliverable locally , No application received from a tertiary centre or local clinicians	

Crizotinib	For untreated ALK-positive advanced Non-small cell lung cancer.	TA406 September 2016	Yes	Yes	No	No		
Nivolumab	For previously treated advanced renal cell carcinoma.	TA417 November 2016	Yes	Yes	No	No	This has been approved for use in 2016 for malignant melanoma and in combination with Ipilimumab	Extends life by median of 5.4 months at a cost of £15-20k, ICER QALY estimated at under £50k
Pertuzumab	Pertuzumab, in combination with Trastuzumab and chemotherapy, for neo-adjuvant treatment of patients with Her2 positive breast cancer.	TA424 December 2016	No	Yes	No	No	High degree of uncertainty over exact value of ICER QALY	

Eribulin	For locally advanced or metastatic breast cancer after treatment with 2 or more prior chemotherapy regimens.	TA250 December 2016	No	No	No	No	NOT APPROVED BY NICE	
Everolimus	Everolimus, in combination with Exemestane for Her2 negative, ER positive advanced breast cancer.	TA421 December 2016	No	Yes	Yes	Yes	Agreed for NICE TA421 approved by CESS	Approved for use in Guernsey
Pomalidomide	For treating myeloma at third or subsequent relapse.	TA427 January 2017	Yes	Yes	No	No	ICER QALY below £50k and approved with end of life criteria for 3 months extra survival	
Everolimus	For advanced renal cell carcinoma after previous treatment.	TA432 February 2017	No	Yes	Yes	Yes	Local agreement for NICE TA421 approved by CESS for specialist use only	Approved for use in Guernsey

Pembrolizumab	For PD-L1 positive metastatic Non-small cell lung cancer. **(Cancer Drugs Fund).**	TA428 January 2017	Yes	Yes	No	No	Certainty about the use of these checkpoint inhibitors will only become clear in the next 2 yrs. guidance due for review in 2019 ICER QALY £45k-60k for 2 yrs. treatment	Pembrolizumab is recommended as an option for treating locally advanced or metastatic PD-L1-positive Non-small-cell lung cancer in adults who have had at least one chemotherapy (and targeted treatment if they have an epidermal growth factor receptor [EGFR]- or anaplastic lymphoma kinase [ALK]-positive tumour).
Trastuzumab emtansine	For Her2 positive advanced breast cancer previously treated.	TA458 July 2017	Yes	Yes	No	No	Survival estimated to be around 24 months following treatment which lasts around 14.5 months at a cost of just under £60k (full price £92k)	Treatment may be toxicity limited
Carfilzomib	For myeloma.	TA457 July 2017	No	No	No	No	As a third line the most plausible ICER was uncertain but very likely to be in a range above	

							the company's estimate of £41,429 per QALY gained and could be substantially higher. As a second line agent the most plausible ICER is £27,629 per QALY gained	
Cabozantinib	For previously treated advanced renal cell carcinoma.	TA463 August 2017	Yes	Yes	No	No	ICER QALY estimated to be below £50k, costs £5143 per month of treatment (unless purchased through special scheme)	Has more toxicity than other treatments such as Everolimus, but more effective. Gain of approximately 5.0 months considered a 4th line treatment
Sorafenib	For treating advanced hepatocellular carcinoma.	TA474 September 2017	Yes	Yes	No	No	ICER QALY estimated to be below £50k, £3576 per 112 tablets of 200mg a month's supply (unless purchased through special scheme)	Option for treating advanced hepatocellular carcinoma only for people with Child-Pugh grade A liver impairment

Regorafenib	For treating unresectable or metastatic GIST after prior treatments.	TA488 November 2017	No	Yes	Yes	Yes	Very special discount offered so patients could participate in long term study offered through Oxford, brought QALY within Normal commissioning levels, decision made prior to the NICE TA being released.	£3744 for 84 x 40mg tablets a months supply, without special discount (which is above 25%)
Venetoclax	For certain specific types of chronic lymphocytic leukaemia. (Cancer Drugs Fund).Previously treated Non-squamous Non-small cell lung cancer that is PD-L1 positive.	TA487 November 2017	Yes	Yes	No	No	Venetoclax is recommended for use within the Cancer Drugs Fund, within its marketing authorisation, as an option for treating chronic lymphocytic leukaemia (CLL) in adults:	£4789/112 tablets which is a month's supply (Patient access scheme reduces this significantly)
Nivolumab	Previously treated Non-squamous Non-small cell lung cancer that is PD-L1 positive.	TA483 November 2017 **(Cancer Drugs Fund).**	Yes	Yes	Yes	No	Met the criteria to be considered a life-extending, end-of-life treatment, and concluded that the ICER of £60,882 per QALY gained was not within the range usually considered a cost-effective use of NHS resources even taking into account additional	

							weights applied to QALY benefits for a life-extending treatment at the end of life. It therefore did not recommend Nivolumab for treating locally advanced or metastatic squamous NSCLC after chemotherapy in routine commissioning.	
Palbociclib	Metastatic ER positive Her2 negative breast cancer.	TA495 December 2017	No	Yes	Yes only for private patient use	No		
Atezolizumab	First line treatment of bladder carcinoma when cisplatin not suitable. **(Cancer Drugs Fund).**	TA492 December 2017	No	Yes	No	No	Without a 17p deletion or TP53 mutation, and whose disease has progressed after both chemo-immunotherapy and a B-cell receptor pathway inhibitor.	
Lenvatinib	Lenvatinib with everolimus for previously treated advanced renal cell carcinoma.	TA498 January 2018	No	No	No	No	Second line agent to be used in patients who have an ECOG score of 0 or 1 As those more ill would be unlikely to tolerate its side effects.	

Ixazomib	Treatment of relapsed myeloma, with Lenalidomide and dexamethasone . **(Cancer Drugs Fund).**	TA505 February 2018	NO	Yes for cancer drugs fund	No	No	Recommended only for use in the context of the cancer drugs fund, to further evaluate its cost effectiveness and survival data	