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Mr Diarmaid McDonald  
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Our ref: 2018/0014483  
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Dear Mr McDonald,

Thank you for your letter of 13 April to the First Minister, on behalf of *Just Treatment*, which you copied to myself, requesting that the Scottish Government issue a Crown Use Licence for pertuzumab for the treatment of breast cancer.

As you will be aware, the regulation of pricing of medicines is a matter reserved to the UK Government. It is a decision for each manufacturer as to how much to charge for their medicines. In the UK prices charged by pharmaceutical companies and wholesalers for drugs are generally competitive and the NHS in Scotland relies on competition in the market to keep prices down.

My officials most recently met with representatives from Roche on 4 May. Roche has also held discussions with NHS NSS National Procurement and I expect that dialogue to continue in order that Roche can bring forward a new submission to the Scottish Medicines Consortium for their consideration.

While the Scottish Government has the legislative power to pursue a Crown Use Licence, we do not consider that invoking this power would provide an affordable solution to providing this medicine for patients in Scotland. This is due to the time and expense it would take an alternative manufacturer to obtain regulatory approval from either the Medicines and Healthcare products Regulatory Agency (MHRA) or the European Medicines Agency (EMA) and then to make a submission to the Scottish Medicines Consortium (SMC) to have the medicine considered for routine availability on the NHS in Scotland. Therefore, it would be better for a fair and transparent price to be agreed for patients in Scotland.

Meantime, clinicians are still able to request access to medicines for their patients on an individual case by case basis where they feel there would be significant clinical benefit to the patient. Decisions on whether to prescribe any medicine are based on individual patient

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need and are a matter for the clinical judgment of the patient's doctor in consultation with the patient, informed by advice and guidance about the drug.

I hope you find this information useful.

Yours sincerely,  
Shona Robison

**SHONA ROBISON**

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