

Ms. Éilis Fallon
Committee Secretariat
Committee of Public Accounts
Leinster House
Dublin 2

March 13 2019

RE: Single Public Service Pension Scheme

Dear Ms. Fallon,

Thank you for your letter of February 27 last concerning recent discussions at the Committee of Public Accounts on the Single Public Service pension scheme (Single Scheme), and specifically the provision of employer contributions. At the outset, I would like to thank the Committee for this opportunity to clarify how the HPRA is dealing with this matter, the implications for the HPRA cost base and potential impact on services. I would also like to clearly state that we welcome the introduction of the Single Scheme and we are currently making both employee and employer contributions to DPER.

As you may be aware, the Health Products Regulatory Authority (HPRA) is both a fee and exchequer funded organisation. Fees are charged to the pharmaceutical industry for licensing, authorisation and other regulatory activities performed by the HPRA.

The circular in relation to employer contributions under the Single Scheme was raised with us by the Department of Health in January 2018. As a responsible financial organisation we immediately started the process of financial planning to implement this new requirement. This involved revising our fee model and related statutory instruments to fund the significant payroll increases involved. The proposed new fees were subject to a public consultation, which among other matters outlined the new pension liability arising from the Single Scheme. In December, the new fees were implemented by statutory instrument with effect from January 1 2019. On that date, we also commenced paying the employer contributions to DPER.

The HPRA prides itself on both financial transparency and financial planning and accordingly we have clear, transparent procedures (outlined below) on how we fund our costs. In these circumstances, where a circular was not issued to us, we were not informed of or asked for the funds and, as the provision is discretionary, we do not consider that a retrospective liability exists.

The impact of the employer contributions for the HPRA as an organisation, where payroll accounts for 70% of our cost base, is very substantial. The increase in cost can be up to 17% per employee on the scheme. Unfortunately, this increase will be exponential for us, as staff turnover tends to replace employees on the local government superannuation scheme (LGSS) with those on the Single Scheme.

As such, we will continue to see our cost base increase disproportionately over the next 10 years. This will have to be reflected in further increases to fees to the industry, which may have significant negative impacts and most acutely on medicines availability. The majority of companies which provide fees to the HPRA supply generic medicines to our market, and these operate on relatively small margins. It is a particularly challenging time for them and all pharmaceutical companies as Brexit will significantly increase the cost of supplying medicines on the Irish market. Companies, in response to

the increases required for 2019, have already said that it will be uneconomical to keep some medicines on the Irish market. The situation may only worsen as we are forced to increase our fees year on year to fund the Single Scheme. The consequences of such actions could be negative for our health system, patients and public in terms of both medicines availability and increased costs.

The HPRA also receives fee income for regulatory activities we perform on behalf of the European Medicines Agency (EMA). Our staff compliment incorporates additional resources to enable us to contribute to these European regulatory activities. This forms part of our payroll costs. However, given that fees for European regulatory activities are set by the EU and paid to us by the EMA, we have no ability to increase them to support the making of employer pension contributions for our staff.

The manner in which the HPRA funds its non-exchequer activities is also pertinent. Each June we start budgeting for the following year and, based on projected costs, revise our fee model (both upwards and downwards). Based on those projections we publish two fees consultations (for human and veterinary medicines) on our website. The industry is aware of this process and makes submissions which we consider before finalising the fees. These fees which are then proposed to our parent department, are signed into law in a number of ways. The majority of fees are either included in an SI signed by the Minister for Health or approved by the Minister for Agriculture and DPER. Our fee process is transparent, clear in what the fees are funding, and is agreed on an annual basis. Consequently, retrospectively looking at a cost that was not included in this process is not appropriate nor would it match the standards of transparency, corporate governance and fiscal planning that the HPRA adheres to.

In conclusion, for the reasons outlined above, I do not consider that there is a liability in relation to the retrospective Single Scheme employer contributions. As a final point, it is also worth noting that the HPRA had been instructed to impose a fee freeze over that same period as a result of the economic crisis. This is relevant as a retrospective liability, which was envisaged in the Circular, and is one that arises in the past. Yet at the same time we were prohibited from increasing fees, and this is the only action we could have taken had we been informed that we were obliged to pay an employer contribution.

I would like to thank the Committee for this opportunity to provide clarification on this matter. I am very happy to expand on any of these points if that would be of assistance.

Yours sincerely,



Lorraine Nolan

Chief Executive