HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2021

Veterinary Medicinal Products

09 OCTOBER 2020

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1 INTRODUCTION

The Health Products Regulatory Authority (HPRA), since its establishment in 1996, has successfully run its regulation of veterinary medicines authorisation, manufacturer and wholesaler operations without recourse to exchequer funding and has established sufficient reserves to allow it to fund capital and IT expenditure and deal with unexpected costs as these arise. This is both a requirement under the Irish Medicines Board Act and a stated objective of the Authority[1] of the HPRA. Since 2004, the HPRA has implemented a policy of annual fee reviews following consultation with industry.

As stated in previous consultations, it is a priority for the HPRA to match resources from fee income with current work volumes and to plan for future activity. The second aim, in respect of fee income, is to provide predictability, stable timelines and ability to fund the cost of the regulatory system that we operate.

To ensure that we manage the business properly we have agreed to review our fees on an annual basis to reflect changes to our cost base and service levels. This document summarises the outcome of our review of fees and it also sets out the current operating environment, the service levels and activities and expected changes in service levels and activities for 2021.

2 THE OPERATING ENVIRONMENT

This year has been a challenging year for both the HPRA and the industry. As with all companies, the COVID-19 pandemic has resulted in the HPRA adapting to a different way of working and providing a wide variety of support to the Government and Health Services. Brexit has continued to bring considerable uncertainty to the regulatory framework and both industry and the HPRA have expanded their resources in preparation for Brexit. With the exception of inspection activity and related income, regulatory activity has held up well during the COVID-19 crisis.

Last year saw an increase in some regulatory activities related to Brexit such as transfers and variations. Some of these activities continued into 2020 but not at the levels seen previously. In terms of costs, the Haddington Road salary reductions have been largely re-instated and salaries are subject to general public service pay increases of approximately 2% per annum. General inflation remains low although the COVID-19 crisis has caused uncertainty in relation to costs and income. While the impact of Brexit is unknown, it is becoming clear that regulatory alignment and a free trade agreement are unlikely and 2021 will see the real impact of a hard Brexit.

[1] The term 'Authority' is used to refer to the persons appointed under section 7 of the Irish Medicines Board Act, 1995, and previously referred to as the 'Board' of the IMB.

Due to increased complexity of regulation and enhanced regulatory and public health offerings, staff numbers continue to increase. As noted above, the biggest impact on activities in 2020 was Brexit. Since Brexit was announced, the HPRA committed to the industry that we would work with them to minimise the regulatory burden where possible, to progress Brexit related changes in an expedited manner and to actively work with industry to deliver pragmatic solutions, where possible. In addition, we agreed with a request from industry to accept, if requested, to become Reference Member State (RMS) for any product that the UK previously was RMS and where Ireland was a Concerned Member State (CMS). We are happy that we delivered on and continue to deliver on these commitments, but it obviously had an impact on resources.

As noted previously, Government policy in relation to pensions changed and from 2019 the HPRA was required to make an employer contribution in respect of all staff employed since 2013 under the Single services pension scheme. This will, by its nature, increase exponentially as all new staff are covered by this obligation and this means that as longer serving employees leave they are replaced by a more expensive resource. It is appropriate, in common with all pension schemes, that the employer makes a contribution, but this does have an impact on fees.

A particular area of concern is one of increased litigation, in the areas of both personal injury and judicial review. An unfortunate result of this is increased costs and resources dedicated to work which delivers nothing under our public health remit.

The impact of new veterinary regulation continues to be evaluated in consultation with the Department of Agriculture, Food and the Marine (DAFM) and project plans have been put in place. Implementation plans for the required implementing and delegated acts commenced in 2019 and have continued through out 2020. HPRA staff have been actively involved in a number of expert groups tasked by the CVMP to provide scientific advice on several implementing and delegating acts. The regulatory model is becoming more complex, there are more complex medicines as well as referrals and regulatory action arising from the outcome of these referrals. In addition, detailed requirements for particular topics such as controls on prescribing, use and monitoring of veterinary antibiotics, operation of the new pharmacovigilance system, etc., will have to be elaborated in advance of the January 2022 deadline. The HPRA business model for veterinary medicinal products will be significantly affected by the new legislation, and by further complementary national measures that are foreseen. There is likely to be opportunities for improved efficiency and worksharing in the future, but this will be offset by increased requirements for compliance monitoring, changes to the data requirements, transparency, and further controls. Public scrutiny and the role of the regulator in relation to medicines has increased and compliance activity, particularly outside of Ireland, is also increasing. It is not possible to predict the full effect on the business model currently. Nevertheless, in the short-to-medium term, adapting current systems and creation of new systems to meet the new requirements will be resource intensive. The HPRA expects to hold staff levels at current levels during 2021, but is uncertain about trends thereafter

3 STRATEGIC DIRECTION OF THE HPRA

The HPRA has commenced the process of developing its new strategy for the period 2021 to 2025. We continue to deliver under our current strategic plan for the years 2016 – 2020, which also aligns with the EMA and HMA joint strategic plan. The high-level strategic goals under the current plan are as follows:

- **Access to medicines** (enhancing regulatory support to patient access to medicines)
- **Better informed users** (providing current information to inform choices and decisions made by patients and their healthcare professional)
- **Optimised regulatory system** (keeping pace with product, manufacturing and supply chain developments)
- **Supporting innovation** (providing regulatory support and advice to research and development centres)
- **Internal capabilities** (ensuring strong internal systems, resource and expertise)

The plan for 2021 to 2025 will be published in Q4 2020. Many of the themes from the previous plan will be reflected in the new strategic plan while incorporating changes to the regulatory environment past and future, identified over the last 5 years. While this plan is still going through a consultation, process, key projects for 2021 will include:

- Managing the impact of Brexit across all our strategic initiatives and in particular with our stakeholders, seeking to minimise the impact of Brexit at 31 December 2020
- Dedicated project and resources to manage medicines shortages from a regulatory view point, incorporating both the impact of COVID-19 and Brexit
- Preparing for the implementation of the New Veterinary Regulation (NVR).
- The further development of the innovation office and support for early innovation on a global basis.
- Implementation of the IT strategy to ensure longevity and resilience in the system, as well as compatibility with new IT systems being developed by the EMA to fulfil the requirements of the NVR.
- Facilitating new ways of working resulting from the COVID-19 pandemic.
- European and international projects in pharmacovigilance, crisis management and GMP.
- Increasing our regulatory offering both centrally and in the decentralised system.

All the above initiatives will provide real and tangible benefits to our stakeholders.

4 PROPOSED CHANGES FOR 2021

The HPRA, as outlined above, is operating in a challenging environment, particularly in light of Brexit. As outlined above, we have committed proactively to supporting the industry and to manage its regulatory obligations in Europe following the still unknown outcome of the UK Brexit negotiations.

Overall income and costs have performed well in 2020. While veterinary Income is below budget in most categories, work on centralised activities has meant that overall income has held up despite COVID-19. While we have not seen a particular impact from COVID-19 on income, the timeline for regulatory submissions is such that much of the income to date relates to work that would have been substantially progressed pre COVID-19. The longer-term impact of COVID-19 on the business is unclear and while we recognise that in a health crisis there is an increased demand for certain medicines, this was not the case generally for veterinary medicines. We expect that the effective shutdown of countries at the early stage of COVID-19 may have an impact on regulatory submissions downstream.

While there was still some income related to Brexit compliance activities in 2020, most veterinary companies had made the necessary changes during 2019. Therefore, it is unlikely that there will be Brexit compliance income in 2021 and there will be fee income issues related to products that have failed to make the necessary regulatory changes. In addition, the commercial impact of Brexit on the industry has not yet happened and as such, the impact on regulatory activity and fees is unknown.

Costs, as a result of COVID-19 have not behaved as expected in 2020. The HPRA offices have been closed for five months and consequently many consumables related to a large office building have significantly reduced. Other costs such as travel, training and meetings have also significantly reduced as meetings were cancelled or delivered virtually. Predicted staffing levels are also below expected levels as recruitment was put on hold. While recruitment has recommenced, it is challenging and it will take some time to achieve optimal staffing levels.

Despite the positive impact on costs arising from COVID-19, payroll which accounts for up to 82% of total costs continues to increase, with further increases expected in 2021 for the following reasons:

- The impact of the new Public Service Pay increases will result in pay awards of approximately 2%.
- The HPRA receives no funding for pensioners under the local government superannuation scheme (LGSS). Previously as a 'young' agency, this did not affect the HPRA significantly, but we have seen significant increases in pension costs in the last two years and it now accounts for 4% of payroll.
- Brexit: While the final shape of Brexit is still unknown, it is likely that managing the aftermath of Brexit will still be a significant workload for the HPRA. A longer term effect will be our commitment to taking over a significant amount of work that was previously carried out by the UK. This will affect the mix of work HPRA undertakes with a much greater emphasis on outgoing work.

In addition, the Veterinary Sciences Department will have the key challenge of adapting the business model in 2021 for implementation of the new veterinary regulation in the coming years.

Despite pressures on costs we propose to freeze the fees for 2021. The proposed changes to the fees are as follows:

- No general fee increase for 2021
- Removal of the fee category for classification requests for– products at the same time.
- Amendment of the outgoing MRP supplement where the outgoing MRP is applied for within six months of the national procedure ending to twelve months of the national procedure ending.

Compliance Fees

- Application of the inspection fees to trainee inspectors for productive inspection time

4.1 Risks and uncertainties in relation to the fee model

COVID-19 and Brexit means that there is more uncertainty in relation to 2021 than we have ever experienced in previous years. In addition, the fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2020. The nature of regulatory income is that it is dictated by industry activity, which can change significantly over a period of time.

5 PROPOSED FEES

5.1 General change to fees

As outlined above there will be a freeze on fees for the year 2021.

5.2 Other proposed adjustments to fees – veterinary medicines

5.2.1 New applications

It is proposed to amend the outgoing MRP supplement where the outgoing MRP is applied for within six months of the national procedure ending to 12 months of the national procedure ending in order to bring the fees in line with the Decentralised outgoing fees for new products.

5.2.2 Classifications

It is proposed to remove the reduced fee category relating to the submission of a classification request for other products at the same time. The standard classification request fee will apply per product in the future.

Classification Requests	Current Fee	Proposed Fee
Borderline Products – Classification Request	€270	€270
Borderline Products – Classification Request – other products at same time	€215	€270/product
Borderline Products – Appeal to a Classification	€270	€270

5.3 Other Proposed adjustments to fees – Compliance activities

5.3.1 Fee for inspectors undergoing accreditation

It is proposed to charge the current inspection fees for trainee inspections for productive inspection time.

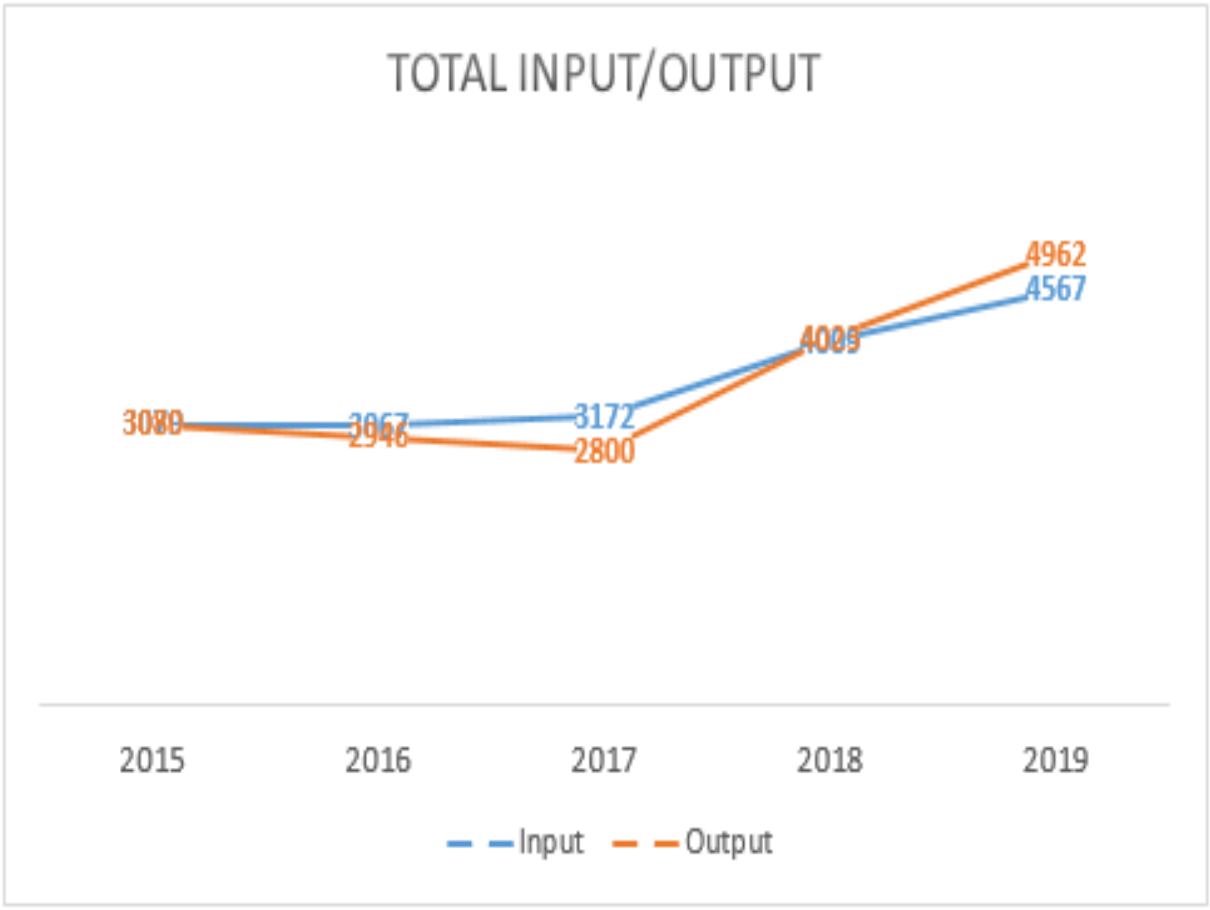
6 CONSULTATION

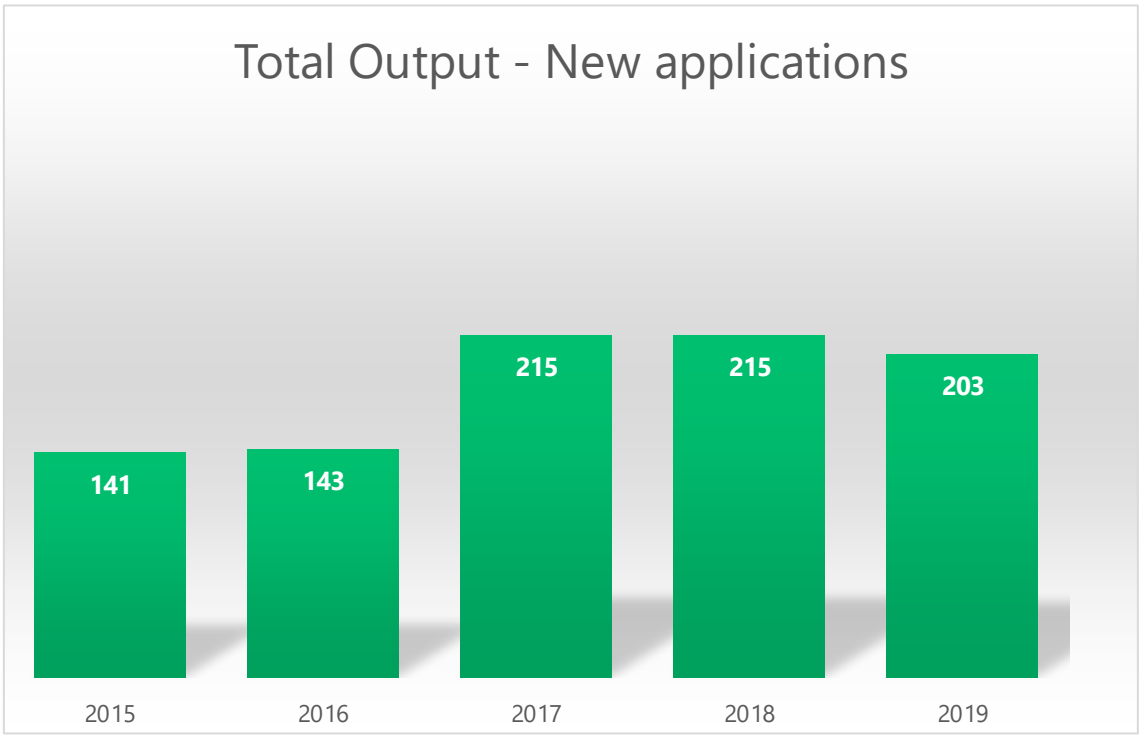
The HPRA welcomes comments on this proposal and invites respondents to comment.

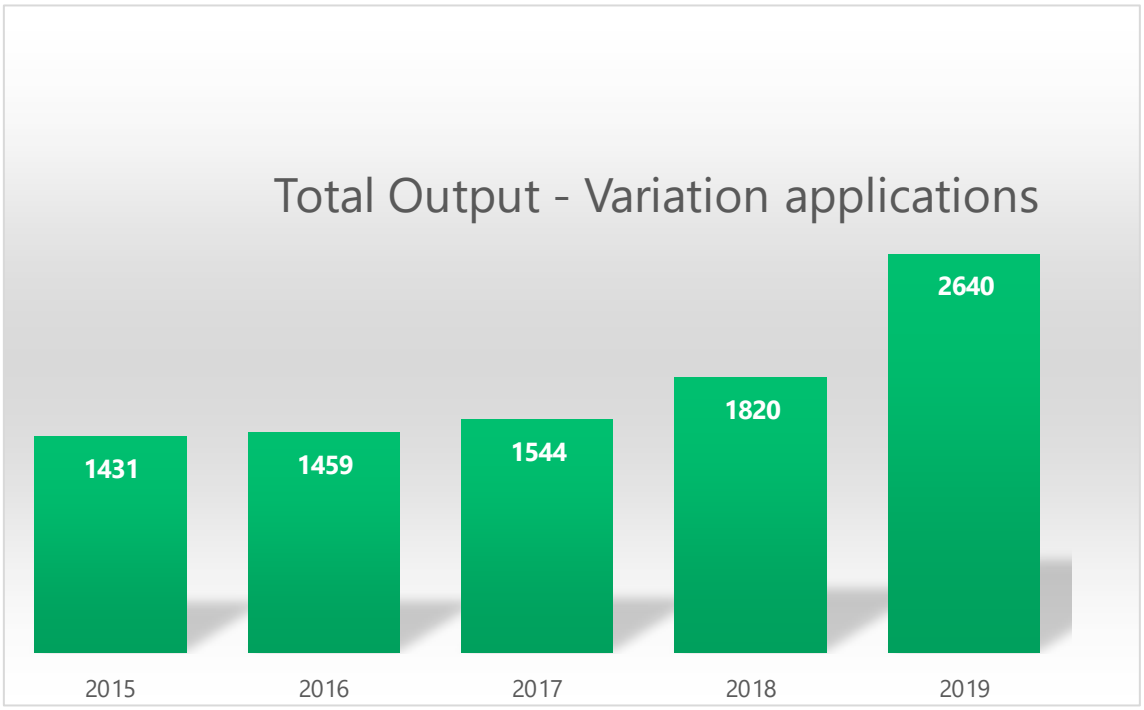
Contributions to the consultation on this proposal may be provided to the HPRA by 31 October 2020. Contributions should be sent by email to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2019.




Total Output - New applications
141
143
215
215
203
2015
2016
2017
2018
2019


Total Output - Variation applications
1431
1459
1544
1820
2640
2015
2016
2017
2018
2019