HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2022

Veterinary Medicinal Products

06 OCTOBER 2021

CONTENTS

1 INTRODUCTION

The Health Products Regulatory Authority (HPRA), since its establishment in 1996, has successfully run its regulation of veterinary medicines authorisation and manufacturer 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 2022.

2 THE OPERATING ENVIRONMENT

2021 has been a challenging year for both the HPRA and the industry. As with all companies, the COVID-19 pandemic continues to require the HPRA to work in a different way. As a health agency with responsibility for medicines and medical devices, 2021 has been particularly challenging with the authorisation and the roll out of the COVID-19 vaccines. HPRA has provided a wide variety of support to the Government and Health Services across a range of activities. In addition, there was a unique challenge in managing the post authorisation supervision of the vaccines following the very successful and largest vaccine campaign in the history of the State. In relation to Brexit, while Ireland benefited from Commission regulatory exemptions, the start of 2021 brought a new set of challenges as companies' negotiated issues in relation to supplying the Irish market following the end of the transition period and the actual departure of the UK from the EU. The HPRA dedicated resources to Brexit and continued in 2021 to work with stakeholders to minimise the impact of Brexit and to ensure continued supply of medicines to the Irish market. With the exception of inspection activity and related income, regulatory activity has continued at expected levels during the COVID-19 crisis.

[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.

In the Veterinary Sciences department, preparing for Regulation (EU) 2019/6, (the New Veterinary Regulation (NVR)), managing the impact of Brexit and engaging on antiparasitics have been the main challenges in 2021. See section on the NVR below for more information.

In 2021 veterinary income fell and is expected to be significantly less than the previous year while costs have increased in 2021. Payroll costs increased, reflecting an increase in staff numbers due to managing the NVR, pension costs and the reversal of Haddington road pay agreement / cost of living increases. Other costs however have remained at previous levels or at below normal levels due to working from home. General inflation remains low although the COVID-19 crisis has caused uncertainty in relation to costs and income and there is expectation that fuel costs will increase in 2022 with a knock on impact for other costs.

Due to increased complexity of regulation and enhanced regulatory and public and animal health offerings, staff numbers continue to increase.

As noted previously, since 2019, the HPRA makes an employer contribution in respect of staff employed since 2013, under the single service scheme. This contribution is up to 17% of the payroll cost of those employees. By its nature, it will 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 and we have flagged in previous fee consultations the long-term impact of an unfunded pension scheme. This pension liability continues to impact on fees.

A particular area of concern is 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.

2.1 Regulation (EU) 2019/6 (The New Veterinary Regulation (NVR))

In 2021 there was significant work on Regulation (EU) 2019/6 and extensive consultation with the Department of Agriculture, Food and the Marine (DAFM). A HPRA NVR project to manage the transition to the NVR has been in place since 2019 and was fully operational in 2021. A challenge from Regulation (EU) 2019/6 is the number of Commission implementing and delegated acts which are still in the process of being drafted in 2021, and many require implementation plans at MS/NCA level. 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 variation and pharmacovigilance systems, etc., will have to be elaborated in advance of the January 2022 deadline.

A second very challenging issue arising from Regulation (EU) 2019/6 is the new Union Product Database (UPD), which is due to be operational by the implementation date and is critical to the operation of the regulation. This database requires that the NCA transfer significant data in relation to all products licensed nationally. Delays in relation to the development of the UPD has meant that the process of uploading the data is only starting to happen access Europe. A key challenge is the data must be in a prescribed format and that the national systems must be capable of being able to handle the initial update and the subsequent operationalisation of the system. This has involved a huge project around data cleansing, IT systems development and redesigning business processes.

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 work-sharing 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 2022, but is uncertain about trends thereafter.

3 STRATEGIC DIRECTION OF THE HPRA

During 2020-2021, the HPRA has developed a new strategic plan for the period 2021 to 2025. Following extensive consultations, detailed review of the environment within which we operate, we have identified the themes and activities which we believe are relevant to the development of our regulatory activities over the next five years. The high-level strategic goals under the current plan are as follows:

- **Health System Partnerships** (strengthening our collaborations across all areas of the health system)
- **Progressive Regulation** (increasing our use of proportionate and adaptive approaches for better patient outcomes)
- **Communication & Engagement** (improving our models of engagement to strengthen public trust and confidence)
- **Enabling Innovation** (enhancing our supports for innovation from discovery through to regulatory approval)
- **Great people, Great Processes** (developing our organisation and people to successfully achieve our goals)

The key projects for 2022 will include:

- For the veterinary sciences department, the implementation of Regulation (EU) 2019/6 will be the biggest strategic project for 2022.
- Managing the continued impact of COVID-19 as vaccines and therapeutics are authorised/ rolled out.
- Maintaining the post-authorisation systems in response to any COVID-19 vaccines.
- 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. Including facilitating new ways of working resulting from the COVID-19 pandemic.
- Managing the return to office based work.
- 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 2022

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 outcome of the UK Brexit negotiations. The Veterinary Sciences department is also committed to ensuring that we are in a position to implement Regulation (EU) 2019/6 on time, although recognising that some aspects of the implementation are outside of our remit/control.

4.1 Financial outturn 2021

Veterinary income in 2021 is below budget in most categories, the exception being centralised income which remains at expected levels. The reason for the decrease in income is unclear although the evidence is that is not unique to Ireland and other EU countries have also experienced a reduction in new applications. One possible reason is that companies are waiting for Regulation (EU) 2019/6 to be implemented before submitting new applications and there may also be a residual impact from Brexit. We also consider that the effective shutdown of countries at the early stage of COVID-19 may have an impact on regulatory submissions downstream.

The HPRA offices have been substantially closed for 2021 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.

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

- The impact of the new pay deal (Building Momentum) will result in pay awards of approximately 1%.
- 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, we are still managing the impact from the 1 January 2021 exit by the UK. A longer term impact 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 2022 for implementation of Regulation (EU) 2019/6 in the coming years.

As outlined above, the significant work in implementing the NVR combined with a fall in income, albeit off set to a certain extent by reduced costs, is both worrying and challenging for the HPRA. We have however, taken a decision to substantially maintain fees at the current levels for 2022 so that we can understand the impact of the NVR before deciding whether the fees need a more substantial change for 2023. We hope that the current decrease in applications is temporary and normal levels will return in 2022.

On this basis, we are proposing the following for 2022:

- No general fee increase for 2022.
- Removal of the fee for outgoing Type IA variations and the renaming of variation categories in line with the NVR.
- Subsequent Extensions are now classified as variations and no changes to the fees are proposed.
- Removal of fees for outgoing renewals and parallel imports where the originator is not on the Irish market.
- Introduction of fees for SPC Harmonisation.
- Introduction of fees for applications under Article 5(6).

Compliance Fees

- Fees for Active Substance Registrations.
- Removal of inspection booking fee and introduction of an inspection cancellation/rescheduling fee.
- Application of a fee to expedited variations to Annex 3 & 4 for Vet MIA's.

4.2 Risks and uncertainties in relation to the fee model

COVID-19 and the introduction of the NVR means that there is continued uncertainty in relation to 2022. In addition, the fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2021. 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 2022.

5.2 Other proposed adjustments to fees – veterinary medicines

5.2.1 Type IA Variations

In accordance with Regulation (EU) 2019/6, Type IA variations will no longer exist and therefore there will no fee for outgoing Type IA variations. Former Type IA variations are now classified as variations not requiring assessment (VNRA) and will be processed in the Union Product Database.

5.2.2 Renaming of the following variation classifications

In accordance with Regulation (EU) 2019/6, the following current variation classifications will be renamed. The fees will remain the same:

CURRENT CLASSIFICATION	NEW CLASSIFICATION
Type IB Variation	Variation requiring assessment reduced (VRA R)
*Type II Variation	Variation requiring assessment standard or extended (VRA S or VRA E)

* Some of these variations will continue to be subject to a complex fee

5.2.3 Subsequent Extensions

In accordance with Regulation (EU) 2019/6, procedures previously known as extensions are now classified as variations. These are now detailed in Chapter I of the *Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU)*

2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations. The fees for these former extensions remain unchanged.

5.2.4 Renewals

In accordance with Regulation (EU) 2019/6 renewals will no longer exist and therefore no fees will be required under the regulation.

5.2.5 Parallel Imports

Parallel Imports where the originator is not on the Irish market will no longer be allowed and therefore the current fee (code **654**) will be removed.

5.2.6 SPC Harmonisation

SPC harmonisation is a new procedure under Regulation (EU) 2019/6. It is proposed to introduce fees in the range of €2,500 to €15,000 for SPC Harmonisation. The fee applied will depend on the role of the HPRA, the complexity of the assessment and the trigger for harmonisation procedure.

5.2.7 Applications under Article 5 (6)

It is proposed to introduce the following two fees for applications under Article 5(6):

FEE TYPE	PROPOSED FEE
Registration under Article 5 (6)	300
Maintenance for medicines under Article 5(6) (Annual fee)	100

5.3 Other Proposed adjustments to fees – Compliance activities

5.3.1 Fees for Active Substance Registration's

It is proposed to apply the following fees to veterinary active substance registrations:

FEE TYPE	PROPOSED FEE
Registration fee, per activity – importers, distributors	270
Registration fee, per activity - manufacturers	475
Immediate notification of a change which may have impact on the quality or safety of the Active Substance	830
Notification of an administrative change to the active substance register	150
Annual fee – Active substance distributor	270
Annual fee – Active substance importer	540
Annual fee – Active substance manufacturer	1,080

5.3.2 Inspections – cancellation/rescheduling fee

It is proposed to remove the inspection booking fee (€1,000) and introduce an inspection cancellation fee. The cancellation/rescheduling fee (€500) will apply to companies who give less than 3 weeks cancellation notice.

5.3.3 Expedited variations to Annex 3 and 4 – Veterinary MIA's

It is proposed to charge a fee of €1,225 to expedited variations to Annex 3 and 4 for Human and Veterinary MIA's. Only one expedited fee would apply to applications where the same change is made to a number of authorisations.

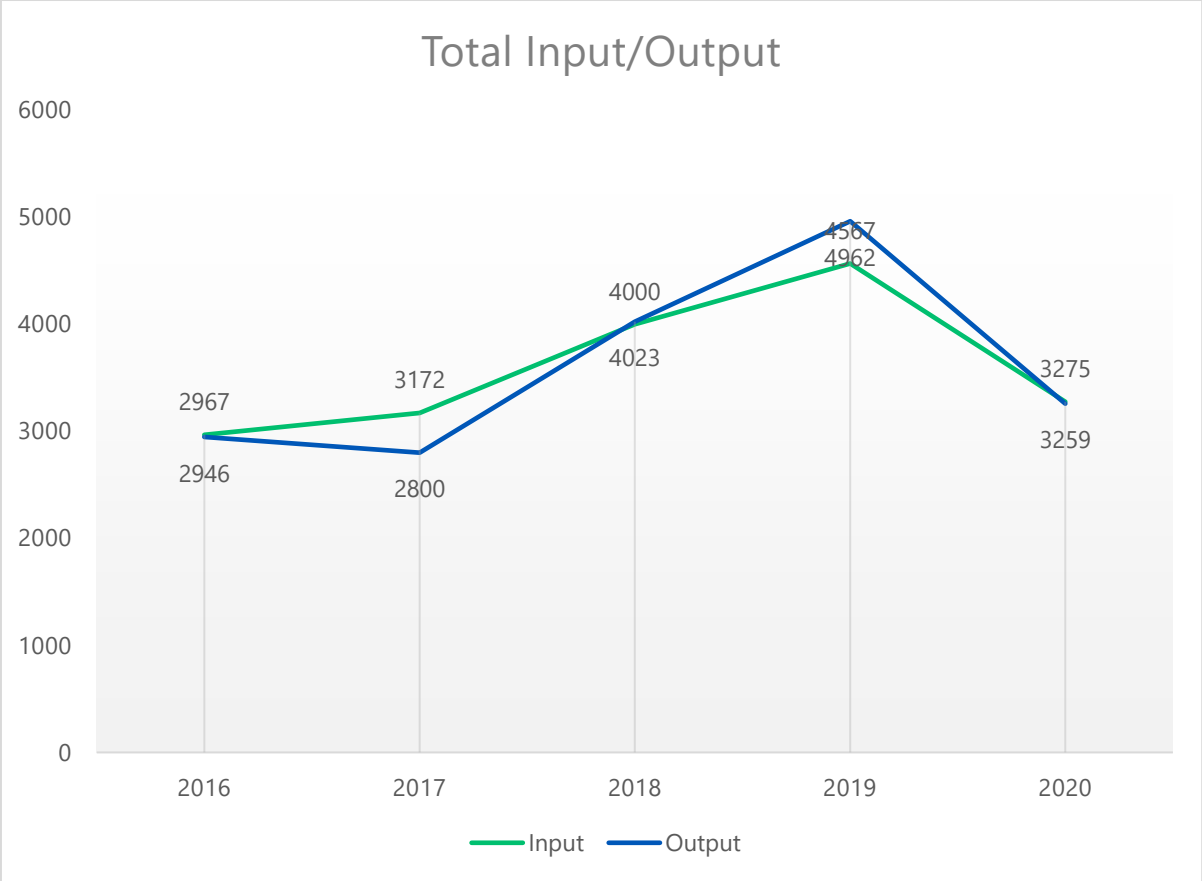
6 CONSULTATION

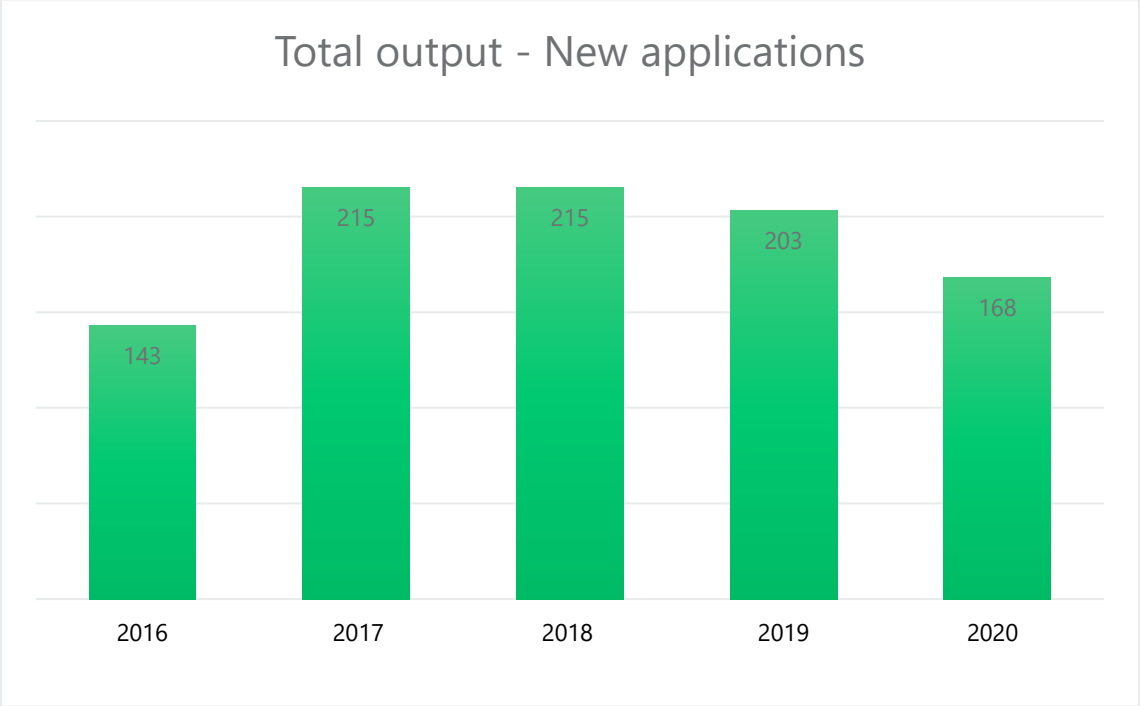
The HPRA welcomes comments on this proposal and invites respondents to comment.

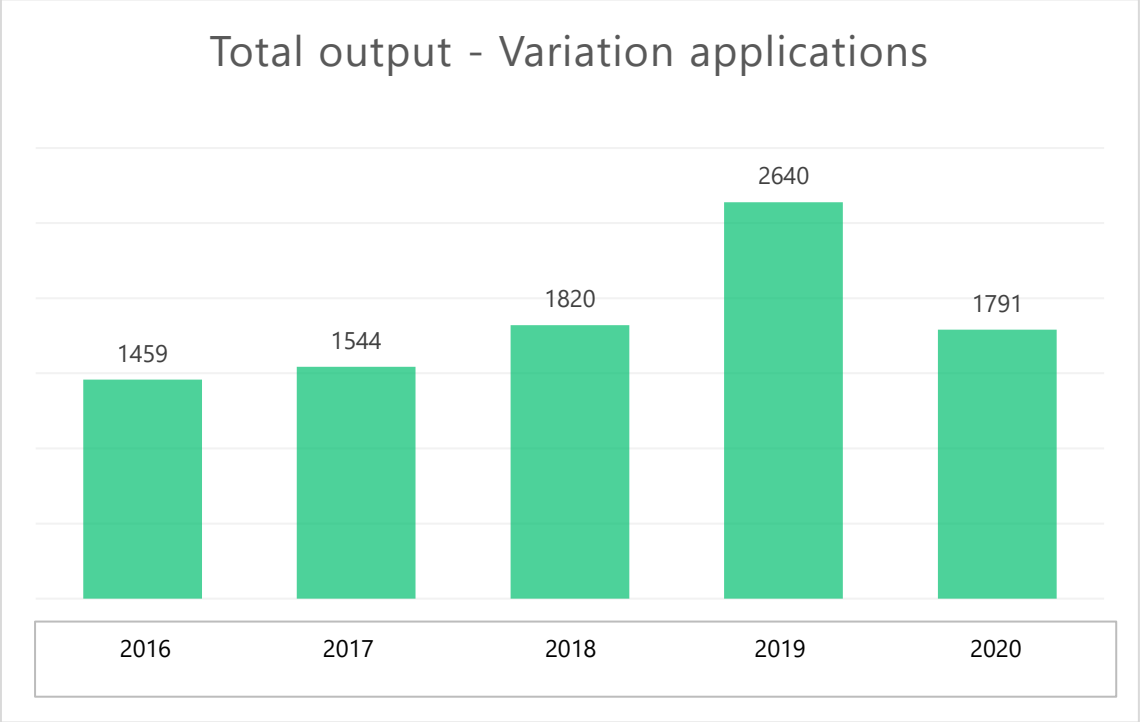
Contributions to the consultation on this proposal may be provided to the HPRA by 5 November 2021. Contributions should be sent by email to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2020:




Total output - New applications
143
215
215
203
168
2016
2017
2018
2019
2020


Total output - Variation applications
1459
1544
1820
2640
1791
2016
2017
2018
2019
2020