HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2023

Veterinary Medicinal Products

OCTOBER 2022

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 the 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 2023.

2 THE OPERATING ENVIRONMENT

2022 has been another 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. In May 2022, the HPRA returned to the office under a hybrid working model. Enabling staff to return to the office while continuing to facilitate home working has brought its own challenges.

The implementation of Regulation (EU) 2019/6, (the New Veterinary Regulation (NVR)), has been the most significant challenge faced during 2022 for the Veterinary Sciences department. Many work processes and their supporting documentation had to be changed to meet the new requirements, while the HPRA had to continue to invest in changes to the IT infrastructure needed to interact with the EMA's Union Product Database (UPD). Moreover, significant resources were spent in cleaning up data underpinning product information so that it could be uploaded to the UPD. More information on this is given later in this document.

[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.

As a public health agency with responsibility for human and veterinary medicines and medical devices, 2022 continued to be impacted by the authorisation and the roll out of the COVID-19 vaccines and vaccine boosters. While the activity did not directly impact the work of the Veterinary Sciences department, the impact of COVID-19 was felt across the organisation. In relation to Brexit, the HPRA worked with Government and the Commission in the development of an EU legislative proposal to implement the Brexit exemptions for human medicines. The Commission communication extended these exemptions for veterinary medicines until the end of 2022. Given the continued difficulties over Brexit and the Northern Ireland protocol, availability of veterinary medicinal products on the island of Ireland remains a significant issue. The position in respect of 2023 is still under review and the HPRA continues to engage with Government and the Commission to urgently explore a solution for veterinary medicines.

In 2021 and 2022, veterinary income fell significantly from prior years and may have reflected uncertainty in relation to the NVR. In the same period and particularly in 2022, costs have been increasing due to inflation. Payroll costs were less than planned in 2022 as full employment in the market and resource constraints meant that vacant positions were unfilled for part of the year. In 2023, we expect significant increases in the cost of payroll as existing vacancies are filled and pay increases being negotiated by Government across the State sector are expected to lead to a gross increase in cost of between approximately 5- 6%. Other costs in 2022 were still below pre COVID-19 levels as the HPRA offices were closed for the early part of the year and travel and other events have not recovered to pre-pandemic levels. However, the indications for the latter part of the year show a significant increase in activity and related costs and we are expecting this increase to be maintained in 2023. General inflation is high and is expected to impact costs for 2023. Additionally, it is expected that fuel costs will increase in 2023 with a knock-on impact for other costs.

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 solely to work which delivers nothing under our public health remit.

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

In 2022, there continued to be 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 continued into

2022. 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 2022 and 2023, with many requiring 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, with more complex medicines as well as referrals and regulatory actions arising from the outcome of these referrals. In addition, detailed requirements for particular topics such as controls on the prescribing, use and monitoring of veterinary antibiotics, operation of new variation and pharmacovigilance systems etc., are still being addressed in 2022. The HPRA has also been engaging with DAFM in relation to the elaboration of new national legislation, as well as in relation to the development of the proposed national e-prescribing system for veterinary medicines. However, as the new national legislation is not yet available, the HPRA will have to further amend several work processes and associated guidelines and application forms again in 2023.

A second very challenging issue arising from Regulation (EU) 2019/6 is the new Union Product Database (UPD), which was 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 it has been a complex and iterative process. The process of uploading the data has been more complicated and resource intensive than envisaged throughout 2022 and will continue into 2023 as the UPD's functionality improves. A key challenge is the data must be in a prescribed format and that the national systems must be capable of handling the initial update and the subsequent operationalisation of the system. This has required a large project to manage data cleansing, develop IT systems and redesign internal business processes.

The HPRA business model for veterinary medicinal products has been affected by the new legislation, and by further foreseen complementary national measures. While Regulation 2019/6 was intended to reduce the administrative burden, including within NCAs, in practice initial experience suggests the opposite is likely. Moreover, there are increased requirements for compliance monitoring, changes to the data requirements and 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 continue to be resource intensive.

3 STRATEGIC DIRECTION OF THE HPRA

During 2020-2021, the HPRA developed a new strategic plan for the period 2021-2025. Following extensive consultations and a 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 and 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 2023 will include:

- For the Veterinary Sciences department, the full implementation of Regulation (EU) 2019/6 will continue to be the biggest strategic project for 2023.
- In addition, the department will be part of the following cross organisational projects:
  - Replacing the existing HPRA website with a new website with greater functionality. This is a major development project with a cross organisational team and external service supplier.
  - Developing plans (including capital investment) to deliver on the Government sustainability plans for 2030
  - 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
  - Assessing and managing the impact of hybrid working.

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

4 PROPOSED CHANGES FOR 2023

The operating environment is expected to be challenging in 2023. Significant cost of living inflation combined with full employment on the Irish market has made staff retention and recruitment challenging. Further increases in costs in Q4 2022 and 2023 will impact on the ability to match income with costs. Hybrid working and changes to standard working hours also provide challenges in the working environment which must be managed. The Veterinary Sciences department is also committed to ensuring that Regulation (EU) 2019/6 operates efficiently and delivers the planned benefits to veterinary regulation and animal health.

4.1 Financial outturn 2022

Veterinary income in 2022 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 it is not unique to Ireland and other EU countries have also experienced a reduction in new applications. One possible reason is that companies are adapting their business models under Regulation (EU) 2019/6, which may have impacted the timelines for submitting new applications. There may also be a residual impact from Brexit. We also consider that the continued impact of COVID-19, and the shutdown experienced at the start may have had an impact on regulatory submissions downstream.

While income was lower than expected in 2022, costs including payroll numbers were also below normal which helped the HPRA absorb some of the increases in payroll that have occurred in 2022. However, the current negotiations in respect to pay may be backdated to February 2022 which will impact the final outturn for 2022. In 2023, it is expected that costs will increase significantly due to national pay awards, the energy crisis and related inflation. Implementing the hybrid model will continue to bring additional costs too.

Payroll

Payroll will increase in 2023 due to:

- The impact of the new pay deal, which has yet to be finalised will result in pay awards in 2022 and 2023 as follows:

  Year 2022

  - 1% backdated to February 2022
  - 3% to be paid October/November backdated to February 2022 (proposed in current negotiations)
  - 1% in October 2022

  Year 2023

  - 2% in March 2023 (proposed in current negotiations)
  - 1.5% in October 2023 (proposed in current negotiations)

  The 3% in October 2022 was not included in costings for 2022 and the other 2022 increases will be in place for a full year in 2023. The net impact of these increases is a 6% uplift from the costs budgeted for in 2022

- 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.

Other costs

While other costs have been below average during lock down, we are seeing significant increases in Q4 2022 and these are expected to continue into 2023. The energy crisis will significantly increase costs in 2023 and the impact on the economy, while uncertain, will result in increased costs. While inflation (which has been running as high as 9% in 2022), is expected to steady in 2023, there is a lag in terms of the impact of inflation on a business like the HPRA where most costs are either service based or related to the office. All contracts that are being renewed for 2023 have increases built into them ranging from 5-15% and energy costs may double or triple this winter and on into 2023.

The HPRA expects that 2023 will be very challenging for the reasons outlined above. We are proposing the following for 2023:

General fee proposal

- A general fee increase of 9% for 2023.
- An increase in the fees for both reduced and standard national variations.
- Alignment of the standard variation supplement fee with the reduced variation supplement fee.
- Alignment with human product fees.

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 2023. In addition, the fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2022. 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 general increase of 9% in HPRA fees in 2023.

5.2 Other proposed adjustments to fees – veterinary medicines

5.2.1 Variations requiring assessment - National

It is proposed to increase the fee for national VRA-R to reflect the increased workload. There is now a requirement to produce an assessment report for VRA-R variations under the new legislation and each variation category is dealt with individually in the report.

It is also proposed to increase the fee for national VRA-S variations to reflect the increased workload relating to the removal of the restrictions on which variations can be grouped which makes them more complex and difficult to manage.

The new regulation (Commission Regulation (EC) No 2019/6) also imposes a new requirement to publish changes to MA's and a requirement to send the SPC and labelling to UPD following variations. Coordination of the SPC changes with changes arising from VNRAs managed in UPD also increases the complexity of all variation cases.

Fee Code	Description	Current Fee	Proposed Fee
591	Variations requiring assessment reduced (VRA R) National	505	545
597	Variations requiring assessment standard (VRA S) National	545	585

5.2.2 Alignment of the Variation requiring assessment standard (VRA-S) supplement fee

It is proposed to align the VRA-S mutual recognition/decentralised RMS supplement fee.

Fee Code	Description	Current Fee	Proposed Fee
621	VRA S – Mutual Recognition/Decentralised RMS supplement	365	370

5.2.3 Alignment with human product fees

Recognising the smaller market size relative to human medicines, the HPRA has kept fees for veterinary product applications below those of human medicines since 2010. In general, the fees are 4-5% less than human fees. However, the regulation for veterinary medicines has added

complexity relative to human medicines because of different target species and in reality, the regulatory costs are equivalent. In order to address the challenges for the business model for veterinary medicines and ensure that the resources are sufficient for the long-term success of the department, it is necessary to revisit this differential between fees for human and veterinary medicines and consider bringing veterinary medicine fees back in line with those of human medicines. In the proposal for 2023, we have brought new application fees and some variation fees to within 96% of those human medicine fees. We will look at overall differences further in the 2024 proposal.

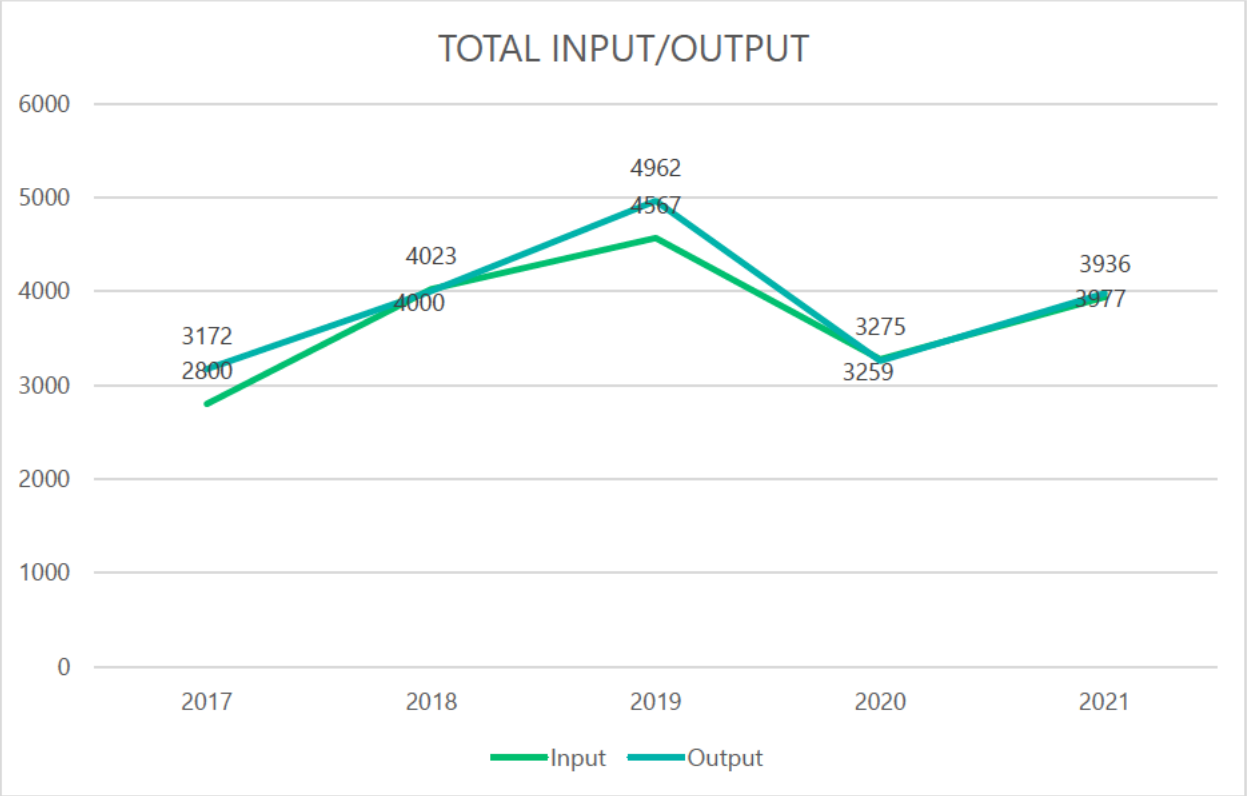
6 CONSULTATION

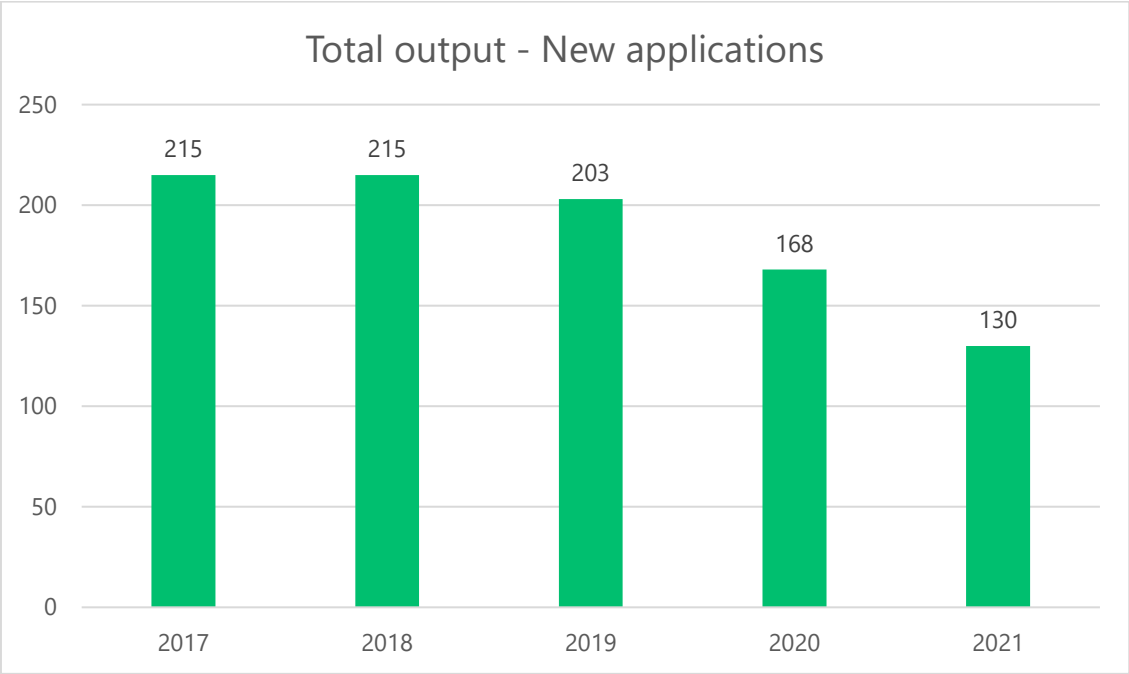
The HPRA welcomes comments on this proposal and invites respondents to comment.

Contributions to the consultation on this proposal may be provided to the HPRA by 29th October 2022. 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 2021.




Total output - New applications
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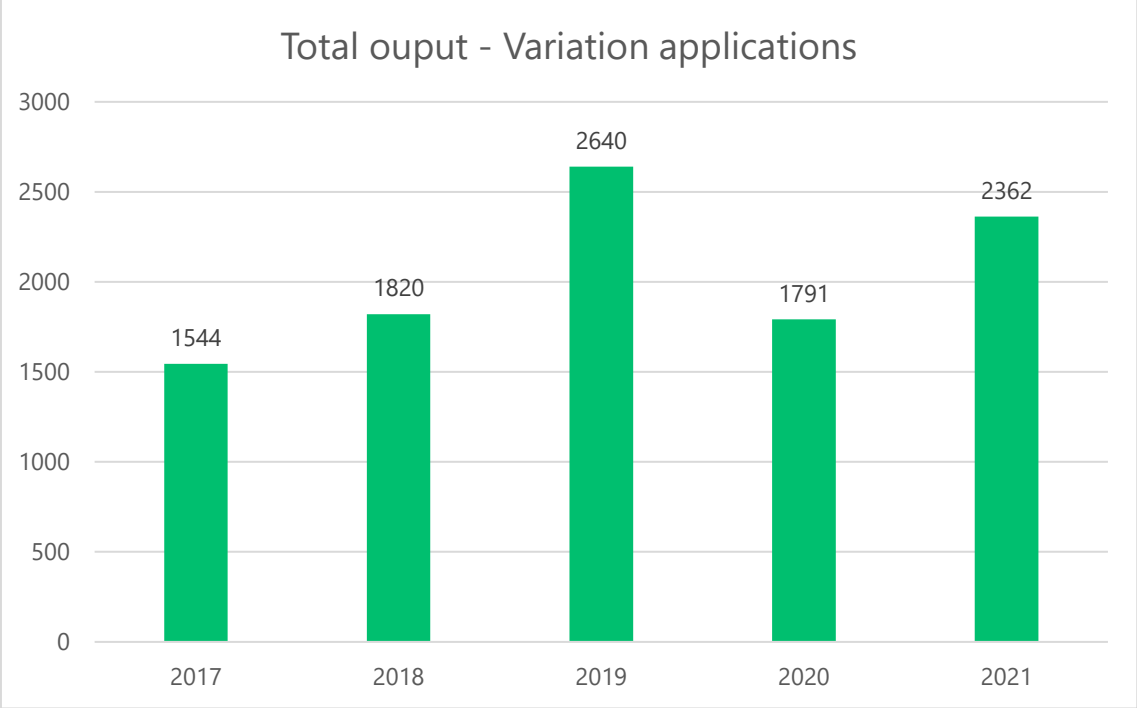
150
100
50
0
215
215
203
168
130
2017
2018
2019
2020
2021


Total ouput - Variation applications
3000
2500
2000
1500
1000
500
0
1544
1820
2640
1791
2362
2017
2018
2019
2020
2021