HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2024

Veterinary Medicinal Products

OCTOBER 2023

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 2024.

2 THE OPERATING ENVIRONMENT

In 2023 the operating environment, following the difficulties during and after COVID-19, stabilised in HPRA. Hybrid working is established within the organisation, enabling 350 staff to return to the office while continuing to facilitate homeworking. While the hybrid model continues to be reviewed, the organisation is adapting to the new way of working.

During 2023, the pandemic officially ended and, it has become business as usual. However, 2023 was a busy year as work that had been put on hold during the pandemic years restarted. In relation to Brexit, the HPRA successfully engaged with the EU Commission leading to agreement on the extension of the expiry for the Brexit exemptions until the end of 2025. Nevertheless, the HPRA continues to work to mitigate the effects of Brexit including the impact on joint UK/Ireland labelled medicines. This is a resource intensive exercise which is being continued in the interests of availability, notwithstanding that there are significant challenges ahead. Overall, while veterinary medicine income remains at expected levels, the income mix has shown significant change and volatility.

[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.

Implementation of Regulation (EU) 2019/6, (the New Veterinary Regulation (NVR)), has again been the most significant challenge faced during 2023 for the Veterinary Sciences department. The EMA's Union Product Database (UPD), which underpins many of EU work processes, continues to absorb significant resources, particularly for Reference Member States (RMS). In this regard, given its historic leadership place as RMS in the EU, Ireland has had the largest share of work amongst member states in shouldering this burden. Moreover, significant resources were spent in processing G.I.18 variations to update product information to meet the requirements of the NVR.

In 2024, authorisation and inspection volumes are expected to be consistent with 2023 and costs are expected to increase. Payroll costs were significantly less than planned in 2023 as full employment in the market, resource constraints and delays in approvals meant that positions were unfilled for part of the year. In 2024 we expect significant increases in the cost of payroll related both to increases in staff numbers and pay increases, although the latter have not yet been agreed. Big projects such as web site upgrading and contributing to the review of national veterinary medicines legislation were also undertaken. Costs in 2023 increased in line with inflation. General inflation remains high and is expected to impact costs for 2024.

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 (NVR)

In 2023 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 challenge from Regulation (EU) 2019/6 is the number of Commission implementing and delegated acts which are still in the process of being drafted. HPRA staff have been actively involved in a number of expert groups tasked by the Committee for Veterinary Medicinal Products (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 2023. The HPRA has also been engaged with DAFM in relation to the elaboration of the new Act on veterinary medicinal products, as well as planned national legislation affecting veterinary medicines that will be

elaborated before the end of 2023. Once all planned new national legislation is available, the HPRA will have to further amend several work processes and associated guidelines and application forms in 2024. Another issue is that there has been a decline in the number of applications being submitted to the decentralised and mutual recognition procedures. While Ireland continues to play a leading role in their assessment in the EU, the reduction in overall numbers mean that this source of revenue has declined. While the HPRA is well positioned to pivot to centralised applications, the full effect of the change in legislation on veterinary medicines is still being internalised by the animal health industry and might yet change again due to the impact of the EMA fees review which is expected to be implemented by 2025.

A second very challenging issue arising from Regulation (EU) 2019/6 is the new Union Product Database (UPD), which is critical to the operation of the regulation. The iterative nature of the development of the UPD has meant that it has been a complex process requiring continual adaptation of processes with an associated increase in workload. The process of uploading HPRA data from our national database was expected to be an automatic one, that would allow seamless updates from variations processed nationally to be carried through to the UPD. However, given the problems encountered, we have had to settle for a semi-automatic batch upload system, with additional checks needed to confirm correct data has been uploaded to the UPD. This work around is therefore more complicated and resource intensive than envisaged and will continue into 2024. The HPRA remains hopeful that a fully automatic solution can be found once UPD functionality improves. Nevertheless, our resource needs continue to be greater than that originally envisaged.

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 national competent authorities, in practice the opposite has been our experience. Moreover, changes to the method of supply designation in national legislation will also require consequential changes to product information which must be implemented by way of variations. While the HPRA has adapted our risk assessment policies to focus on changes that have most impact, there will be a need for increased compliance monitoring in the years ahead. 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 2024 will include:

- For the Veterinary Sciences department, the full implementation of Regulation (EU) 2019/6 will continue to be the biggest strategic project for 2024. The HPRA is currently reviewing the impact of the NVR on our strategic plan and the operation of the business model.
- 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.
  - Implementation of the new people strategy.
  - Assessing and managing the impact of hybrid working.

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

4 THE OUTLOOK FOR 2024

Financial outturn for 2023
In a period of high inflation, the operating environment remains challenging. The outturn for 2023 will be break-even. This reflects the income levels operating as expected and significantly lower costs, principally in the area of payroll caused by the inability to bring expected levels of staff on Board in the first half of 2023.

Financial impacts on 2024
It is expected that there will be a substantial increase in costs for 2024. This reflects the high level of recruitment in Q3/Q4, planned additional staff in 2024 and a continuing increase to costs reflecting the continuing high levels of inflation. Income levels are expected to hold in 2024.

Payroll

The key drivers of payroll increases in 2024 will be:

- Additional staff numbers related to expanded functions, increased levels of work.
- The impact of the 1.5% increase from October.
- Pay increases 2024 (not yet known but under negotiation).
- Increased pension costs.

Other costs

Other costs continue to increase as activity levels are returning to pre-pandemic levels. The energy crisis significantly increased costs in 2023 and will have a knock-on impact in 2024 although there is evidence of steadying energy costs. While inflation (which has been running as high as 9% in 2022), has reduced to 6% in 2023, it will still have a significant impact on projected costs.

The HPRA expects that 2024 will be another challenging year in managing costs for the reasons outlined above.

4.1 Risks and uncertainties in relation to the fee model

The introduction of the NVR means that there is continued uncertainty in relation to 2024. In addition, the fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2023. The nature of regulatory income is that it is dictated by industry activity, which can change significantly over a period of time.

As with previous years, the HPRA commits to review the proposed fees during the planning cycle in 2024 and further amend the fees and fee structure, if required for 2025.

5 PROPOSED FEES

While the cost base of the HPRA will increase in 2024, the HPRA acknowledge that the costs, in particular payroll, were below budget in 2023 and this resulted in a positive financial outcome. To reflect this, and taking the two years together, the HPRA propose to impose only a minor inflationary adjustment of 1.5% in 2024. This 1.5% is only intended to cover the agreed payroll increase in October 2023 and which will be in place for all of 2024. It will not cover other cost increases which will be reviewed as part of the 2025 fees.

5.1 General change to fees

As outlined above there will be a minor 1.5% adjustment to fees for the year 2024.

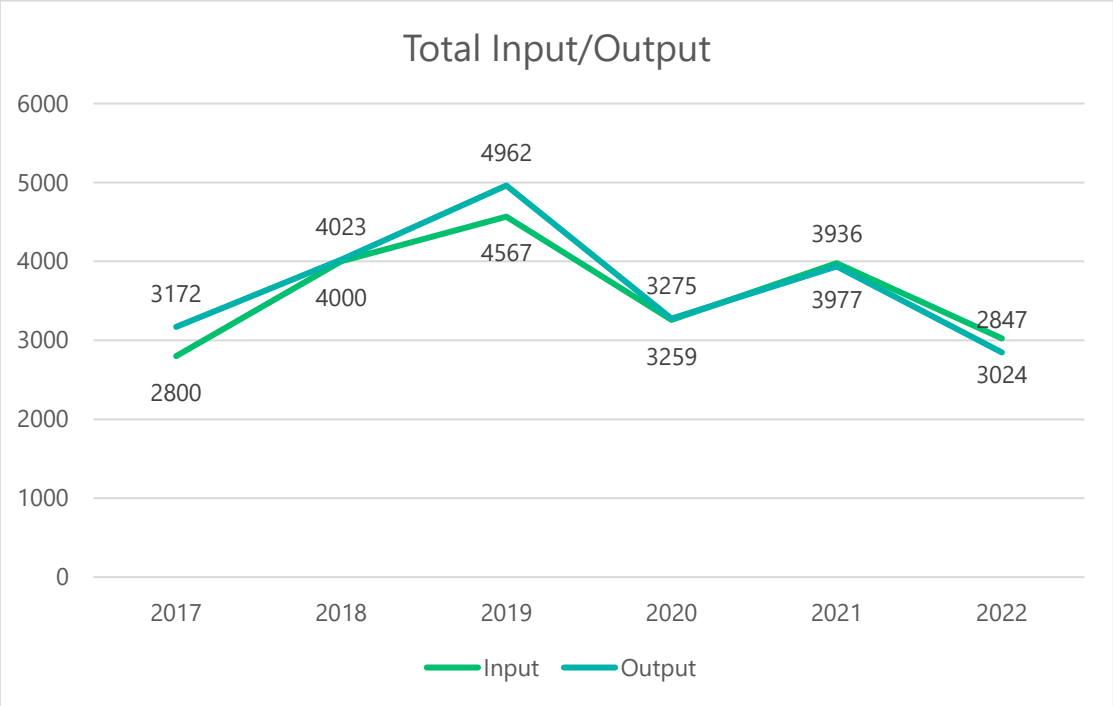
6 CONSULTATION

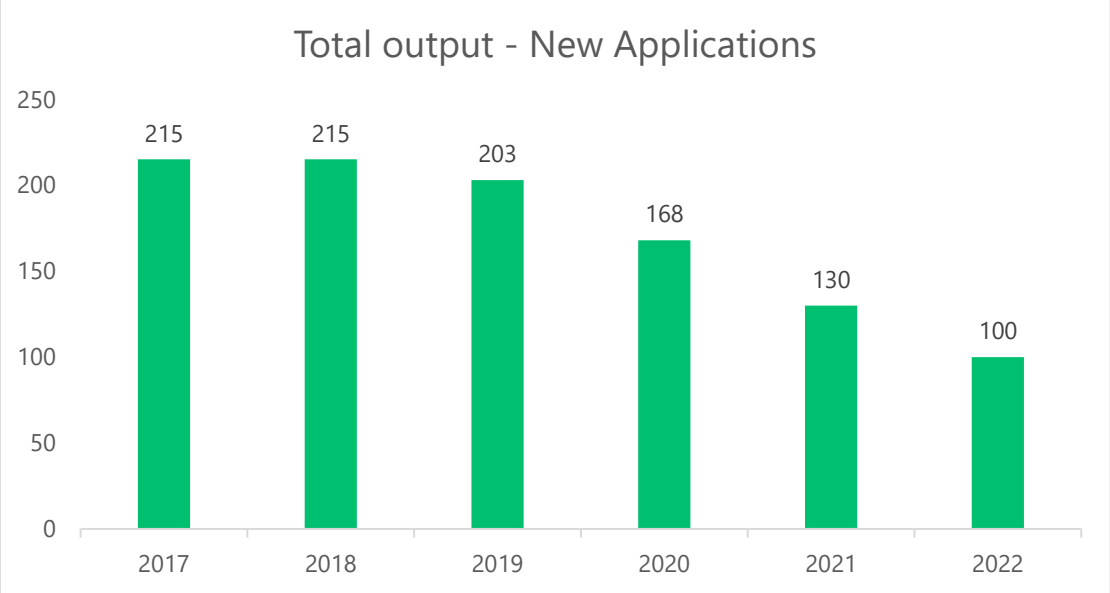
The HPRA welcomes comments on this proposal and invites respondents to comment.

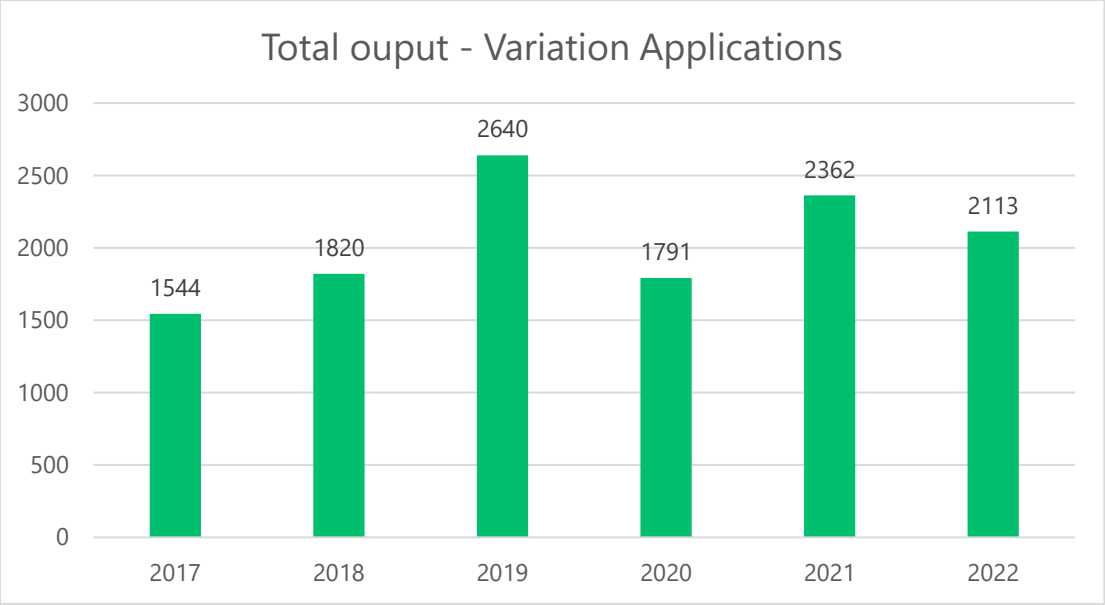
Contributions to the consultation on this proposal may be provided to the HPRA by 27 October 2023. Contributions should be sent by email to feesconsultation@hpra.ie.

APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2022.






Total ouput - Variation Applications
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1500
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500
0
1544
1820
2640
1791
2362
2113
2017
2018
2019
2020
2021
2022