HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2025

Veterinary Medicinal Products

OCTOBER 2024

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 2024, the HPRA operating environment stabilised after a number of challenging years following the COVID-19 pandemic. Hybrid working is established within the organisation, enabling 400 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.

2024 was a busy year where the activity levels reached or exceeded pre pandemic levels. Volumes of transactions were high across all areas of the organisation, and this was combined with significant project work such as the new website.

Overall, while veterinary medicine income remains at expected levels, the income mix has shown significant change and volatility.

The implementation of Regulation (EU) 2019/6, (the New Veterinary Regulation (NVR)), continues to be a significant challenge in 2024 for the Veterinary Sciences department. While some aspects of the regulation are becoming 'business as usual' the EMA's Union Product Database (UPD),

[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.

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 2025, authorisation and volumes are expected to be consistent with 2024 and costs are expected to increase. Payroll costs were significantly less than planned in 2024 as full employment in the market, resource constraints and delays in approvals meant that positions were unfilled for part of the year. However, while the number of staff was less than budgeted, the Government pay deal for the public sector increased the staff cost. We expect significant increases in the cost of payroll in 2025. This is related both to increases in staff numbers and the balance of pay increases under the pay deal. In 2024, we had an external review of the resource requirements in the Veterinary Sciences Department, considering the volume of work undertaken and in particular, the HPRA role as one of the leading European agencies for centralised and MRP and DCP assessment. This report recommended an uplift in staff numbers, which will impact costs in 2025 and 2026. Big projects such as website upgrading and contributing to the review of national veterinary medicines legislation were also undertaken. Costs in 2024 increased in line with inflation. General inflation has stabilised and is expected to be between 2% and 3% in 2025 although wage inflation remains significantly higher.

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, particularly in the area of judicial review and personal injury claims. While the HPRA's Veterinary Science department successfully defended a judicial review running over a number of years, the result of this is increased costs and resources dedicated solely to work which delivers nothing under our animal health remit.

2.1 Regulation (EU) 2019/6 (NVR)

There continued to be significant work on the NVR and extensive consultation with the Department of Agriculture, Food and the Marine (DAFM) in 2024. A challenge from the NVR is the number of Commission implementing and delegated acts which are still being drafted and implemented. HPRA staff have been actively involved in a number of expert groups tasked by the Committee for Veterinary Medicinal Products 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 2024. The HPRA has also engaged with DAFM in relation to the development of the new national legislation on veterinary medicines. Once all planned new national legislation is available, the HPRA will have to amend several work processes and associated guidelines and application forms in 2024/2025. There has also been some volatility in the number of decentralised and mutual recognition procedures being submitted. While Ireland continues to play a leading role in their assessment in the EU, a 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 will be implemented by 2025.

Another very challenging issue arising from Regulation (EU) 2019/6 is the 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 more complicated and resource intensive than envisaged and will continue into 2025. 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 the NVR 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

identified the themes and activities which we believe are most relevant to the development of our regulatory activities. 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)

In 2025, our key objectives related to veterinary medicines under the strategic plan include:

General
- Develop, agree and sign off the next iteration of the HPRA's strategic plan for the period 2026 to 2028 (3 years).
- Cross-organisational readiness and engagement with the BEMA V assessment in March 2025.

Strategic goal 1
- Strengthen and increase the scientific animal protection inspections programme, enhancing the role the HPRA as an advocate for the 3R principles.

Strategic goal 2
- Continue preparations to support Ireland holding the 2026 EU Presidency.
- Continue implementation of the NVR

Strategic goal 3
- Continue the communications and engagement strategy implementation.

Strategic goal 4
- Implement additional innovation supports at an EU and national level.

Strategic goal 5
- Deliver the new HPRA website.
- Continue to work on initiatives to support the People Strategy, especially focusing on the career and capability framework project.
- Continue the implementation of the Digital Transformation Strategy, including:
  - Progression of an organisation wide 'time recording' project

  - Delivering further Eolas implementation projects and determining an approach for the assessment of Eolas future direction options
  - Developing a future data approach and enhancing our skills and use of automation.
- Progress building enhancements and other energy efficiency initiatives based on the HPRA climate action roadmap, including the move of Compliance to the main HPRA building.

4 THE OUTLOOK FOR 2025

Financial outturn for 2024
While inflation has stabilised the volume of work has increased and the need for additional resources has resulted in a challenging operating environment.

Financial impacts on 2025
It is expected that there will be a substantial increase in costs, particularly payroll, reflecting the filling of unfilled vacancies and the implementation of a planned uplift in our assessment capability. The pay deal outline below also continues to affect the costs base. While inflation has stabilised, nonetheless costs have increased between 2-3% in 2024 and are likely to be at a similar level in 2025.

Payroll

The key driver of payroll increases in 2025 will be the impact of the new pay deal which was finalised in January 2024 and resulted in pay awards in 2024 and 2025 as follows:

Year 2024
- 2.5% or €1,125 whichever is higher in January 2024
- 1% in June 2024
- 1% or €500 whichever is higher to be paid in October 2024

Year 2025
- 2% or €1,000 whichever is higher to be paid in March 2025
- 1% to be paid in August 2025
- 1% to be paid in September 2025 (local bargaining)

The increases in 2024 were not included in costings for 2024 and will be in place for a full year in 2025. There will also be additional staff numbers related to expanded functions, increased levels of work and 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 2024 and will have a knock-on impact in 2025 although there

is evidence of steadying energy costs. While inflation (which has been running as high as 6.3% in 2023), has reduced to 2.6% in 2024, it will still impact on projected costs.

4.1 Risks and uncertainties in relation to the fee model

The introduction of the NVR means there is continued uncertainty in relation to 2025. The fee proposal outlined below is based on the volumes and patterns of submissions seen in the first seven months of 2024. 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 2025 and further amend the fees and fee structure, if required for 2026.

5 PROPOSED FEES

In 2024, the HPRA increased the fees by only 1.5% notwithstanding the level of inflation experienced in 2023 and the pay deal that was implemented in 2024. The cost base of the HPRA will increase in 2025, and to reflect this, the HPRA propose to impose a general increase of 5% in 2025 which is significantly less than the combined payroll and inflationary increases and equates to 3.25% p.a. over the last two years.

5.1 General change to fees

As outlined above there will be a 5% adjustment to fees for the year 2025.

5.2 Other proposed adjustment to fees – Veterinary medicines

5.2.1 Group variations

It is proposed for group MR VRA-S variations where Ireland is the RMS, that the RMS supplement fee (fee code 621 - €430) is applied to each high-level variation classification category (F, G, H or I) included in a group variation application.

With the implementation of the NVR, restrictions on variations that can be grouped together were lifted and it is now possible to group any variations. Unrelated grouped variations are generally more complex and therefore more assessors and work is required.

5.2.2 Variation category – G.I.15z changes to the labelling or the package leaflet which are not connected with the SPC

It is proposed to charge a reduced fee of €210 for the above variation category where the variation relates to labelling and package leaflets for new products.

5.2.3 Veterinary Clinical Trials

The HPRA has reviewed the resource needs for veterinary clinical trials considering fee returns over recent years. Accordingly, it is proposed to increase the clinical trials to commensurate with resources required. However, the overall effect of these fees on the animal health sector will be small as few clinical trials are conducted in Ireland.

Fee code	Description	Current fee	Proposed fee
903	Variation of a current research trial licence	275	375
904	Research trial for an IVP unauthorised in the EU for use in a major species	1,100	1,250
905	Research trial for an IVP unauthorised in the EU for use in a minor species	745	850
906	Research trial for an VMP unauthorised in the EU for use in a major species	745	950
907	Research trial for an VMP unauthorised in the EU for use in a minor species	415	550

6 CONSULTATION

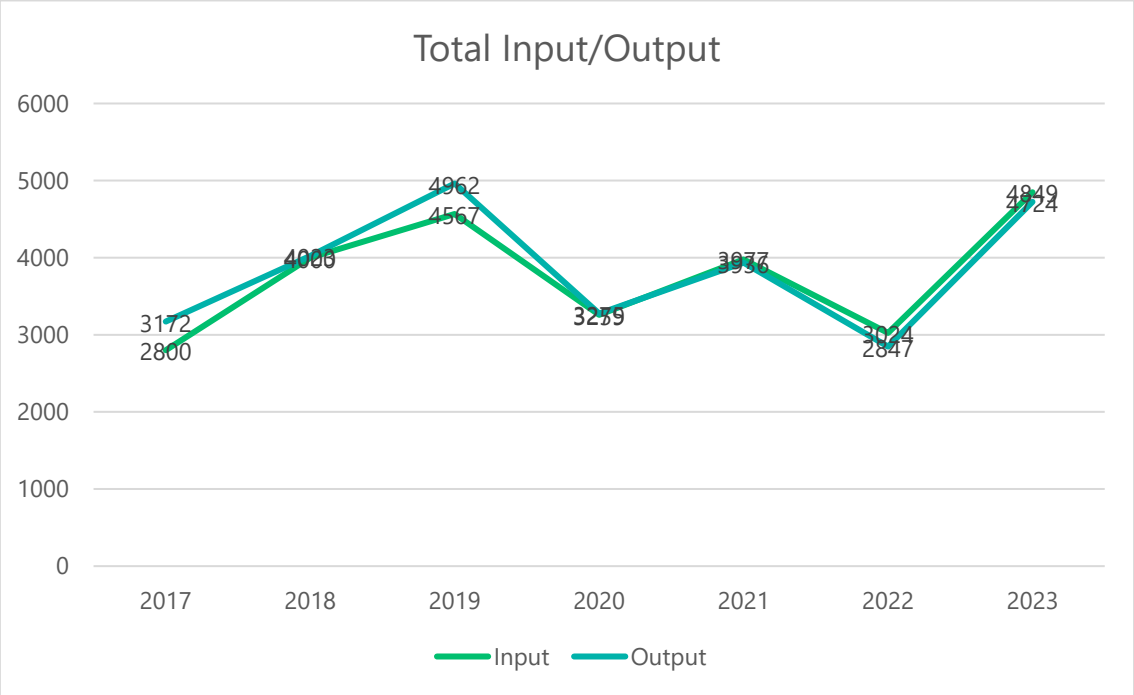
The HPRA welcomes comments on this proposal and invites respondents to comment.

Contributions to the consultation on this proposal may be provided to the HPRA by 30 October 2024. Contributions should be sent by email to feesconsultation@hpra.ie.

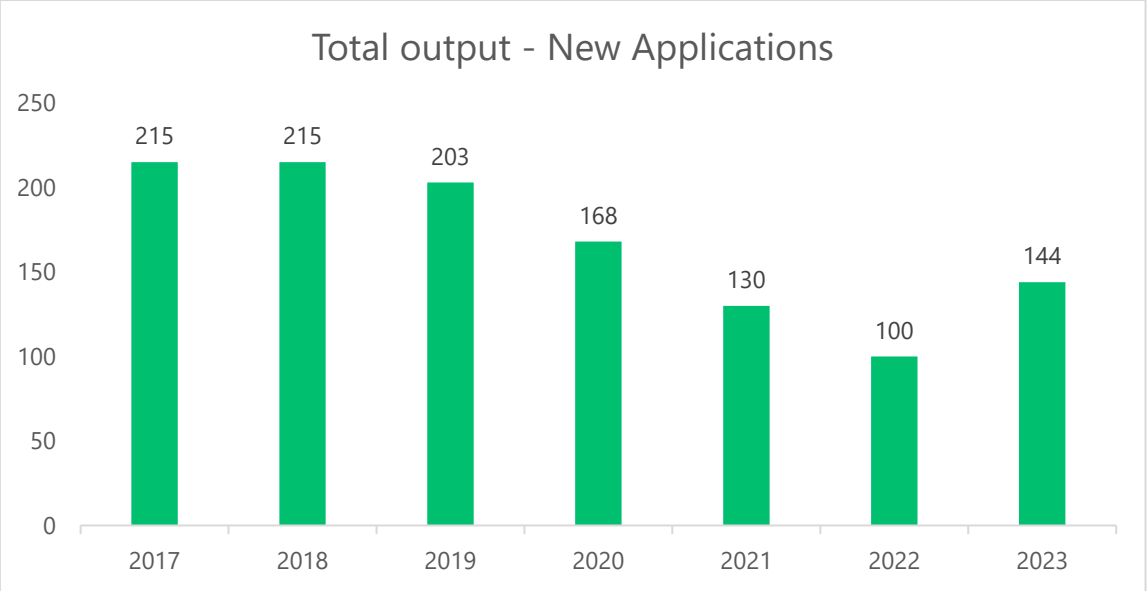
APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2023.

The graph below indicates all applications received through both Eolas and Nimbus and the total cases closed out on both systems. Figures are extracted from 'work in progress' reports.



The graph below indicates all new applications (MR, national, DCP, SRP, centralised, clinical trial, homeopathic, Article 5(6)) received in Eolas. Figures are extracted from 'work in progress' reports.



The graph below indicates all variations (MR, national, centralised) received in Eolas. Figures are extracted from 'work in progress' reports.