HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2026

Veterinary Medicinal Products

OCTOBER 2025

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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 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 2026.

2 THE OPERATING ENVIRONMENT

In 2025, the HPRA operating environment stabilised after a number of challenging years following the COVID-19 pandemic. Hybrid working is established within the organisation, enabling nearly 500 staff to return to the office while continuing to facilitate homeworking. While the hybrid model continues to be reviewed, the organisation has adapted to the new way of working.

2025 was a busy year where the activity levels reached or exceeded the previous year. Volumes of transactions were high across all areas of the organisation, and this was combined with significant project work and the preparation for the expiry of the Brexit exemptions.

Overall, while veterinary medicine income is preforming well, 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.

The implementation of Regulation (EU) 2019/6, (the New Veterinary Regulation (NVR)), continues to be a challenge in 2025 for the Veterinary Sciences department. While some aspects of the regulation are becoming 'business as usual' 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 continue to be spent in processing G.I.18 variations to update product information to meet the requirements of the NVR.

In 2026, licensing volumes are expected to be consistent with 2025 and costs are expected to increase. Payroll costs were significantly less than planned in 2025 due to delays in approvals which meant that positions were unfilled for a large part of the year. However, in 2025 we experienced significant payroll costs arising out of the Government pay deal for the public sector which will also impact 2026. We expect significant increases in the cost of payroll in 2026 due to increases in staff numbers. Increased staff numbers reflect delays in recruiting in 2025 and further staff requirements. 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 on a phased basis during 2025 and 2026, which will impact costs in 2025 and 2026. General inflation has stabilised and is expected to be around 1.9% in 2026 but we are experiencing increases closer to 3% reflecting cost of living increases and wage inflation is 3.5% in 2025.

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 2025, and this will continue into 2026.

Detailed requirements for particular topics such as controls on the prescribing, use and monitoring of veterinary antibiotics, operation of new variation and pharmacovigilance systems, approach to SPC harmonisation, etc., are still being addressed in 2025. As requirements are being clarified and processes refined, the HPRA has to amend internal work processes and associated guidelines and application forms – this work will continue into 2026.

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. This may be due to a shift in new marketing authorisation applications by the animal health industry from DCP/MRP to the centralised system (associated with the 'optional' scope of the centralised system provided for in the NVR). 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.

The regulatory model is becoming more complex, with more complex medicines. Linked with this we have seen an increase in the number of regulatory and/or technical queries from applicants/MAHs, many requiring significant resource input either in writing or in the context of one-to-one meetings. This is an important service to the animal health industry and is linked with one of the main objectives of the NVR which is to support innovation/new product development.

Another of the principal objectives of the NVR is to increase availability of veterinary medicinal products, which is particularly important for Ireland, a small EU market. To address availability needs, the HPRA has committed substantial resources to pursuing initiatives such as promoting joint (with the UK, UK/NI) or multilingual labelling, identifying therapeutic gaps and communicating on VMP shortages.

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. In addition, the HPRA continues to experience data quality/completeness issues in UPD that hamper transfer of product information from the HPRA case management system to UPD requiring significant resource input in the form of investigation and/or workarounds. 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 and will continue into 2026.

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. 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

The HPRA has commenced the process of developing its new strategy for the period 2026 to 2028. We continue to deliver under our current strategic plan for the years 2021-2025. The new strategic plan is in draft and reflects extensive stakeholder engagement. As it has not yet been approved by the Minister, we cannot include it in this fee consultation but the high-level strategic goals from the current plan will be reflected in the new strategic goals.

The Strategic plan for 2026-2028 will be published in Q4 2025. Projects for 2026 will include:

Animal Health Priorities

- Pursue initiatives that will safeguard/improve product availability such as: promoting common/multilingual labelling; promoting SPC harmonisation; proactive engagement with MAHs on product information update variation submissions (G.I.18) to ensure market compliance by Jan 2027.
- In collaboration with other MS competent authorities, pursue initiatives to address therapeutic gaps.
- Contribute to managing the threat of antimicrobial resistance and optimising One Health by ensuring timely updates to the conditions of use of authorised antimicrobials to reflect new scientific knowledge and/or ensure compliance with the NVR.

Regulatory Priorities

- Ensure that the NVR continues to be fully implemented across the transitional period.
- Continue to update procedures/processes based on experience since application of the NVR, with a view to optimise.
- Ensure regulatory preparedness and successful implementation for new legislation, e.g. NIS2, the EU AI Act, SoHO, CER-D.

Engagement and Collaboration Priorities

- Support the Department of Health and Permanent Representation in Brussels in relation to hosting the Presidency of the Council of the EU and prepare for hosting the 22 plus meetings (which includes three veterinary meetings) in the regulatory network under the EU presidency.
- Host information campaigns and events to continue to promote the HPRA's visibility and value to the animal health sector.

- Provide appropriate regulatory support for the animal health industry, in particular around new product development.

Business Priorities
- Continue to work on initiatives to support the People Strategy, especially focusing on the career and capability framework project, implementation of the L&D roadmap to enhance organisational capabilities, succession planning and an updated PDP process.
- Complete the onboarding of processes and data to Eolas and assess options for the upgrade or migration to an enhanced enterprise platform.
- Review IT system needs and deliver an organisation wide 'time recording' solution.
- Advance an organisational data strategy focusing on data optimisation and its utility linked to opportunities for identification of sources of risk. Pilot the conversion of HPRA's unstructured data records to structured data sets using AI technologies.

4 THE OUTLOOK FOR 2026

Financial outturn for 2025
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 2026
It is expected that there will be a substantial increase in costs in 2026, particularly payroll. This reflects the high level of recruitment in Q3/Q4, planned additional staff in 2026, and a continued increase to costs reflecting the increased workloads. Income levels are expected to be similar to those in 2026.

Payroll

The key driver of payroll increases in 2026 will be the impact of the new pay deal which was finalised in January 2024 and resulted in pay awards in 2024, 2025 and 2026 as follows:

Year 2024
- 2.25% 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)

Year 2026

- 1% of €500 whichever is higher to be paid in February 2026
- 1% in June 2026

The impact of these pay increases is to increase payroll by 3% in 2026

There will also be additional staff numbers related to expanded functions, increased levels of work and increased pension costs.

Other costs

Inflation is running at 1.9% and we broadly expect other costs to increase by a similar amount. The HPRA expects that 2026 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 there is continued uncertainty in relation to 2026. The fee proposal outlined below is based on the volumes and patterns of submissions seen in the first seven months of 2025. 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 2026 and further amend the fees and fee structure, if required for 2027.

5 PROPOSED FEES

The HPRA proposed to increase fees by 2.5% to reflect wage and general inflation.

5.1 General change to fees

As outlined above there will be a 2.5% adjustment to fees for the year 2026.

5.2 Other proposed adjustment to fees – Veterinary medicines

5.2.1 Variations - Reference member state (RMS) supplement fees

There is no differential in fees between the VRA-S/E and VRA-R RMS variation supplements. To reflect the difference in complexity, it is proposed for realign and increase the fees for VRA-S variations and VRA-R supplements and to also bring them in line with the human fees.

Fee code	Description	Current fee	Proposed fee
593	VRA R Mutual recognition/Decentralised supplement	430	460
621	VRA S/ VRA E Mutual recognition/Decentralised supplement	430	490

5.2.2 Annual Maintenance Fees

It is proposed to increase the veterinary annual fees by €100 per product to cover an increase in costs and payroll within the department.

5.2.3 SPC Harmonisation

It is proposed to increase the SPC Harmonisation fees as the fees do not reflect the time it takes to carry this procedure.

Fee code	Description	Current fee	Proposed fee
656	SPC Harmonisation as RMS	5,805	11,610
657	SPC Harmonisation as CMS	2,905	5,810

5.2.4 New Product Applications

The HPRA are considering applying a single fee for new product applications. A single fee will apply to an application for a marketing authorisation and the fee will cover all strengths and pharmaceutical forms. The proposed combined fees have been restructured on a cost neutral basis. In other words, we have taken the average income received per application for all strengths and pharmaceutical forms and have proposed a single fee to reflect this new approach. The benefit for both the industry and HPRA is that it simplifies the application process and gives certainty on the fee. It will result in lower or higher fees depending on the number of line extensions, but over time should be cost neutral, but also allows companies to add additional strengths at no additional cost.

Complex Dossier – New Active Substance

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
511	National Application	22,750	24,000
512	Each additional form (at the same time)	7,960	0
513	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Concerned Member State		
515	Mutual Recognition - CMS	15,930	16,800
514	Mutual Recognition – CMS (Immunologicals)	12,355	13,000
516	Each additional form (at the same time)	5,685	0
517	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Reference Member State		
518	Mutual Recognition – RMS Supplement	17,065	17,065
526	Mutual Recognition – RMS Supplement – within 12mths of national application	17,065	17,935
	Decentralised Concerned Member State		
525	Decentralised CMS	22,750	24,000
520	Decentralised CMS (Immunologicals)	17,650	18,500
523	Each additional form (at the same time)	7,960	0
524	Each additional strength (at the same time)	1,135	0
	Decentralised Reference Member State		
527	Decentralised RMS	56,875	59,000
523	Each additional form (at the same time)	7,960	0
524	Each additional strength (at the same time)	1,135	0

Reduced Dossier - Complex

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
531	National Application	17,065	18,000
532	Each additional form (at the same time)	7,960	0
533	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Concerned Member State		

Fee code	Description	Current HPRA fee	Proposed fee
535	Mutual Recognition - CMS	11,375	12,000
536	Each additional form (at the same time)	5,685	0
537	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Reference Member State		
538	Mutual Recognition – RMS Supplement	17,065	17,065
534	Mutual Recognition – RMS Supplement – within 12mths of national application	11,375	11,935
	Decentralised Concerned Member State		
545	Decentralised CMS	17,065	18,000
543	Each additional form (at the same time)	7,960	0
544	Each additional strength (at the same time)	1,135	0
	Decentralised Reference Member State		
547	Decentralised RMS	45,500	47,000
543	Each additional form (at the same time)	7,960	0
544	Each additional strength (at the same time)	1,135	0

Reduced Dossier - Standard

Fee code	Description	Current HPRA fee	Proposed fee
	National Applications		
551	National Application	11,375	12,200
552	Each additional form (at the same time)	7,960	0
553	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Concerned Member State		
555	Mutual Recognition - CMS	7,960	8,500
556	Each additional form (at the same time)	4,550	0
557	Each additional strength (at the same time)	1,135	0
	Mutual Recognition – Reference Member State		
558	Mutual Recognition – RMS Supplement	11,375	11,375
554	Mutual Recognition – RMS Supplement – within 12mths of national application	6,820	7,225
	Decentralised Concerned Member State		

Fee code	Description	Current HPRA fee	Proposed fee
565	Decentralised CMS	11,375	12,000
563	Each additional form (at the same time)	7,960	0
564	Each additional strength (at the same time)	1,135	0
	Decentralised Reference Member State		
567	Decentralised RMS	29,575	30,800
563	Each additional form (at the same time)	7,960	0
564	Each additional strength (at the same time)	1,135	0

The overall general increase in fees will be applied to the proposed fees stated above.

6 CONSULTATION

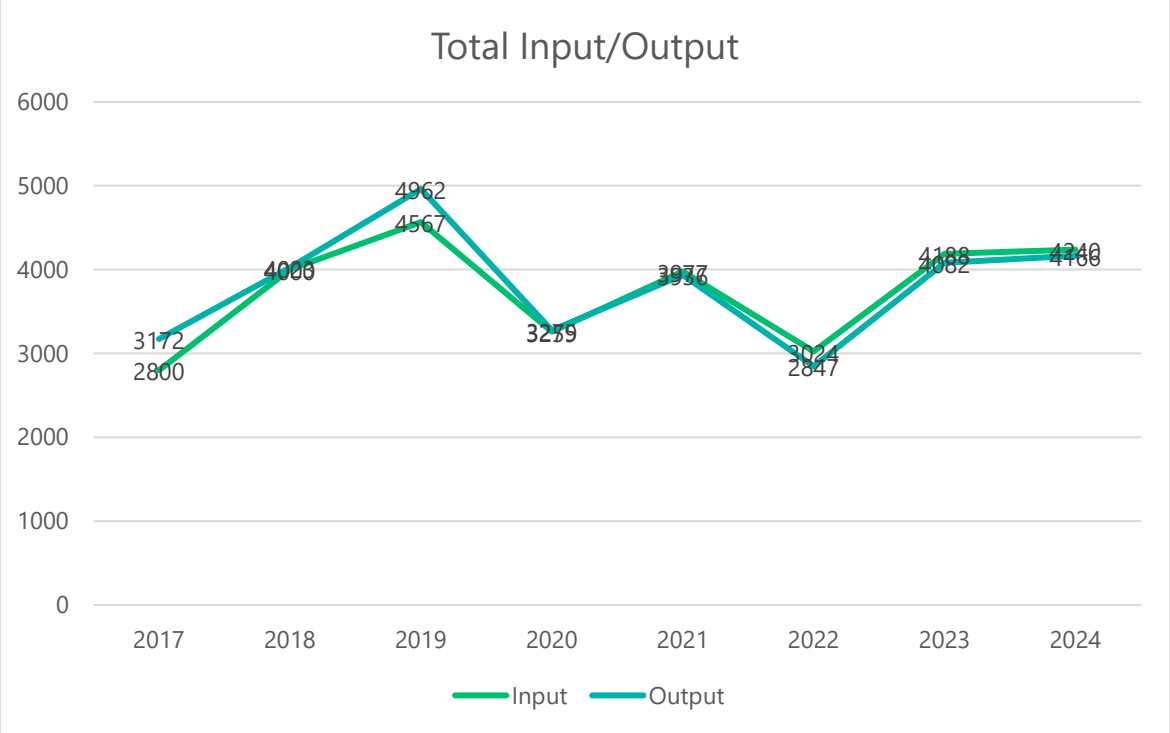
The HPRA welcomes comments on this proposal and invites respondents to comment.

Contributions to the consultation on this proposal may be provided to the HPRA by 31 October 2025. Contributions should be sent by email to feesconsultation@hpra.ie.

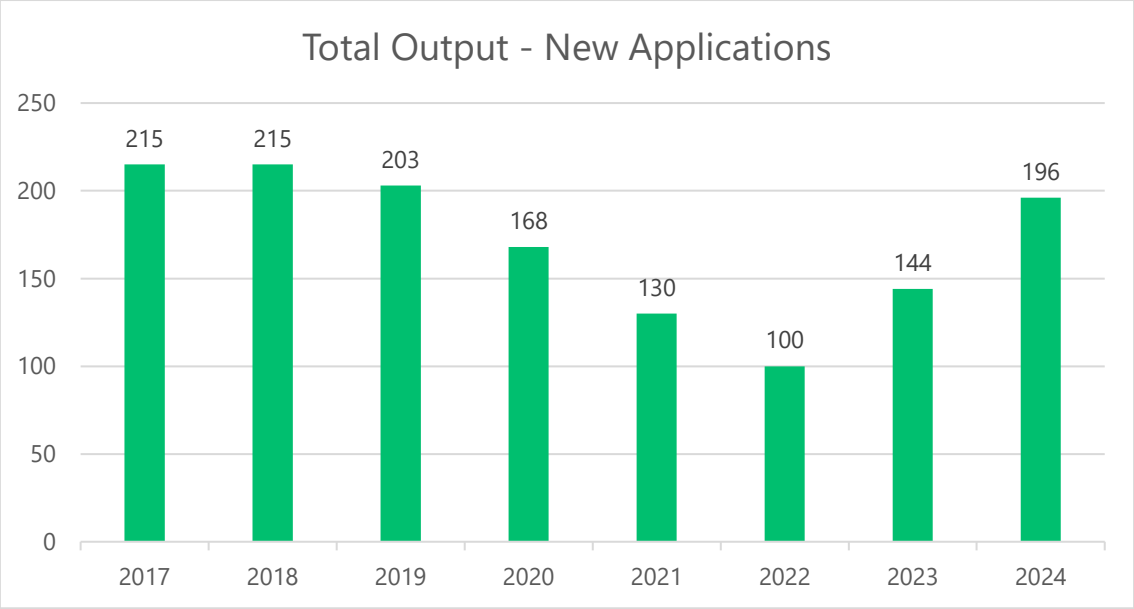
APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2024.

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.