HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – For Financial Year 2019

Veterinary medicinal products

DATE <3rd October 2018>

CONTENTS

1 INTRODUCTION

The HPRA (formerly the Irish Medicines Board (IMB)), since its establishment in 1996, has successfully run its core 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 IMB 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 2019.

2 THE OPERATING ENVIRONMENT

Following the economic crisis, there are signs of recovery and the Irish economy is one of the fastest growing in Europe. However, despite the projected growth in the economy, that growth is not translating into a better economic outlook for the HPRA. Regulatory activity has remained flat during the last number of years while wage inflation/cost pressure have increased. General inflation has been low reflecting prices for food, clothes, alcohol and other consumables. Business expenses such as rent, utilities and IT costs have been increasing beyond the general rate.

Due to increased complexity of regulation and enhanced regulatory and public health offerings, staff numbers have increased without a corresponding increase in income. Brexit has also had a considerable impact on the HPRA. Industry is uncertain of the future while the work related to Brexit has increased significantly. While some of this work is self-financing, much of it is without corresponding income (e.g. work in preparing plans to circumvent shortages etc.).

Government policy in relation to pensions has changed and the HPRA are now being asked to make significant contributions to the pension scheme in 2019 and this has resulted in a disproportionate increase to payroll costs.

[1] The term "Authority" is used to refer to the persons appointed under section 7 of the Irish Medicines Board Act, 1995 as amended, and previously referred to as the "Board" of the IMB.

The impact of new veterinary regulation is currently being assessed. Preparatory implementation plans for the required implementing and delegated acts will commence in 2019. There will be a number of European databases and systems to be developed. 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 Pharmacovigilance system, etc. will have to be elaborated in advance of the January 2022 deadline. 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 worksharing 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 turn, adapting current systems and creation of new systems to meet the new requirements will be resource intensive. The HPRA expects staff levels to increase across all areas in 2019. As noted in previous consultations the HPRA has absorbed the payroll cost resulting from greater regulatory complexity and additional requirements from the changing regulatory and legal environment without increasing its fees.

3 STRATEGIC DIRECTION OF THE HPRA

During 2015 the HPRA developed a new strategic plan for the years 2016 – 2020 which also aligns with the EMA and HMA joint strategic plan. Following extensive consultations, detailed review of the environment within which we operate and management discussions, we have identified the themes and activities which we believe are relevant to the development of our regulatory activities over the next five years. High-level strategic goals have been determined as follows

- **Access to medicines** (enhancing regulatory support to patient access to medicines).
- **Better informed users** (providing current information to inform choices and decisions made by healthcare professional).
- **Optimised regulatory system** (keeping pace with product, manufacturing and supply chain developments).
- **Supporting innovation** (providing regulatory support and advice to research and development centres).
- **Internal capabilities** (ensuring strong internal systems, resource and expertise).

While the strategic plan expands on each of these strategic goals, key projects for 2019 include:

- Managing the impact of Brexit across all our strategic initiatives.

- Dedicated project and resources to manage medicines shortages from a regulatory view point.
- Implementation of the new veterinary regulation.
- The further development of the innovation office and support for early innovation on a global basis.
- The rollout of a new regulatory work flow system 'Eolas' across the entire organisation which will put the HPRA at the cutting edge in Europe in respect of its IT capabilities.
- 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 REVIEW OF THE 2010 TO 2018 FEES

The HPRA last increased fees significantly in 2010. In 2011 and 2012 the HPRA reduced fees and from 2013 to 2017 fees were not increased. In 2018 there was a minor cost of living increase of 2%. In the intervening period, the HPRA has increased payroll numbers from 283 to 360 without recourse to increased fees. Some of these increases relate to increased volumes but much of the staffing is to reflect the greater regulatory offerings, increased support for public health, the implementation of new legislation and the increasing complexity of the work and the development of the agency. The development of the agency has ensured the HPRA is well placed to negotiate the impact of Brexit and the ever changing regulatory environment that we operate in but it comes at a cost. To date these staff increases have been primarily funded through supressed payroll and other costs arising out of the economic crash where all State sector salaries were significantly reduced. These reductions (Haddington Road) are being reversed and we have also seen the reintroduction of cost of living increases. HPRA and the pharmaceutical industry recruit from the same pool of candidates and it is becoming more challenging to retain staff in the light of significantly higher salaries in industry. As outlined below, HPRA will see a substantial increase in payroll costs next year and these increases are set to continue as upward pressure remains on payroll costs, particularly for technical staff.

5 PROPOSED CHANGES FOR 2019

The HPRA, as outlined above, is operating in a difficult economic environment particularly in the light of Brexit. We have committed proactively to supporting the industry and to manage its regulatory obligations in Europe following the outcome of their Brexit negotiations.

Overall income has remained flat for the first 8 months of 2018. Incoming new applications are down by 6% from the previous year suggesting perhaps Brexit related caution. Product withdrawals are significantly higher compared to the same time last year which again may be a reflection of Brexit.

More significantly the HPRA cost base has been increasing. As noted in previous submissions, payroll remains the most significant part of HPRA being up to 78% of total costs. Payroll costs have increased over the last number of years but will increase particularly in 2019 for the following reasons:

- The impact of Haddington road is being reversed resulting in pay awards of nearly 3% at the end of 2018 and 2019.
- Staff numbers and specialty resources have increased to reflect the increasingly complex regulatory environment.
- DPER has requested an employer contribution from fee funded agencies of up to 17% of the salary of those on the single service scheme (SSS). As HPRA have over 130 staff in that scheme, this is the single biggest increase to our payroll.
- HPRA received no funding for pensioners under the local government superannuation scheme (LGSS). Previously as a "young" agency this did not impact significantly but we have seen significant increases in pension costs in the last two years and it now accounts for 4% of payroll.
- Brexit; the impact of Brexit is twofold, in 2018 and into 2019 we will have significant numbers of staff working on Brexit and its impact for the Irish market. In addition, we have committed to take on any of the work currently carried out by the UK. This will impact on the mix of work HPRA undertakes with a much greater emphasis on outgoing work. HPRA's fees for outgoing work are modest compared to other MSs in Europe as our numbers of outgoing work were traditionally low. But this model is not sustainable where outgoing work increases as is planned for 2019. The fees charged do not reflect the time or cost of providing this service.

In addition, the Veterinary department will have the key challenge of introducing the new veterinary regulation in 2019 and 2020.

For these reasons it is proposed that the fees will be increased as follows;

- General fee increase of 8%;
- Increases and alignment of new product application fees.
- Revised fee per additional species.
- Reinstatement of fee for additional CMS (capped).
- A new reduced fee for vaccines will be introduced.

5.1 Risks and uncertainties in relation to the fee model

The fee proposal outlined above is based on the volumes and patterns of submissions seen in the first seven months of 2018. The nature of regulatory income is that it is dictated by industry activity which can change significantly over a period of time. In addition, the uncertainty from Brexit means that forecasting is extremely difficult and subject to change.

The HPRA has been able to freeze fees in previous years with a small increase in 2018 due to the continued management of our cost base. However, as noted above, we are experiencing increased workloads and increased costs due to increased staff levels and a reversal of some of the pay costs that arose during the economic down turn. The HPRA will also be required to pay significant pension contributions to DPER for the first time. Consequently the HPRA is seeking the fee increase outlined above. As with previous years the HPRA commits to review the proposed fees during the planning cycle in 2019 and further amend the fees and fee structure, if required, for 2020.

6 FINANCIAL OUTURN 2018

The financial position in 2018 is as expected and HPRA expect income to cover costs for the year. However as noted above our cost base and in particular salaries are increasing. As outlined in previous submissions we have increased headcount to reflect additional responsibilities and deliverables while absorbing these costs without additional fees. As outlined above, it should also be recognised that the salary cost of the HPRA has been artificially suppressed with substantive pay cuts across all grades for the last five years and with a recovering job market the HPRA is starting to lose key senior members of staff as salaries are falling below the market place. As stated in every consultation for the last number of years the HPRA has an unfunded pension liability which is a cost of the business, but to date has not been reflected in the fee model. If the HPRA is to continue to deliver the service industry requires, we will need to be in a position to recruit staff with the relevant expertise at the appropriate salary level. Although we hope to break even at year-end, we have substantial financial commitments. Following an IT strategic review of the organisation's needs and existing IT framework, we have commenced a very significant IT project 'EOLAS. Our existing workflow systems are now over 10 years old and increasingly more challenging to support. Given the importance of IT in our service delivery we started a four-year programme in 2016 to replace all the internal workflow and stakeholder facing systems to ensured continued provision of a 'best in class' service. The investment in IT and infrastructure has delivered and will continue to deliver long-term savings and efficiencies. The HPRA will also be required to pay significant pension contributions to DPER for the first time in 2019.

7 PROPOSED FEES

7.1 General change to fees

As outlined above there will be a general increase of 8% in HPRA fees in 2019.

7.2 Other proposed adjustments to fees – veterinary medicines

7.2.1 New applications

It is proposed to increase the fees for applications to reflect the actual time involved in these applications. A review of the time input into new applications has shown that we cannot continue to provide a service in this area without aligning the fees with the costs of delivering the service. **Note: these increases are inclusive of the general 8% increase.**

Reduced Dossier Standard	**Current Fee**	**Proposed Fee**	**Change**
National Application	7,499	8,800	1,301
Mutual Recognition – CMS	5,239	6,200	961
Mutual Recognition Supplement - RMS	6,978	8,200	1,222
Decentralised – CMS	7,499	8,800	1,301
Decentralised - RMS	19,584	23,000	3,416

Reduced Dossier Complex	**Current Fee**	**Proposed Fee**	**Change**
National Application	11,094	13,100	2,006
Mutual Recognition – CMS	7,909	9,300	1,391
Mutual Recognition Supplement - RMS	10,734	12,700	1,966
Decentralised – CMS	11,094	13,100	2,006
Decentralised - RMS	29,376	34,600	5,224

Complex Dossier	**Current Fee**	**Proposed Fee**	**Change**
National Application	14,895	17,600	2,705
Mutual Recognition – CMS	10,425	12,300	1,875
Mutual Recognition Supplement - RMS	10,734	12,700	1,966
Decentralised – CMS	14,895	17,600	2,705
Decentralised – RMS	39,168	46,200	7,032

Related fees to each of these categories will increase proportionally as per Appendix II.

7.2.2 New Incoming MR/Decentralised fees - Immunologicals

To recognise the importance of vaccines and other immunologicals, a new fee for these applications will be implemented and the fees will not be increased in 2019.

7.2.3 CMS Supplement - Outgoing MRP & DCP procedures

It is proposed that a supplement of €500 per Concerned Member State will be charged for all decentralised and mutual recognition outgoing procedures. This will be capped at €7,500.

7.2.4 Additional Target Species

As per the current fees, a fee of €2,499 is charged per additional species. The fee is currently capped at €7,350. In 2019 the additional target species fee will apply to all outgoing MRP/Decentralised procedures. The minor species exemption to this fee will continue to apply.

7.2.5 Bulk fees – fee codes 626,630 & 631

It is proposed that the bulk fee will not apply to group complex type II variations as the bulk fee does not cover the assessment time required for type II complex variations.

7.2.6 Veterinary Manufacturing and Inspection fees

It is proposed to increase the veterinary manufacturing inspection fees by 4% in additional to the general overall increase in fees to bring them in line with the fees for human medicines manufacturers.

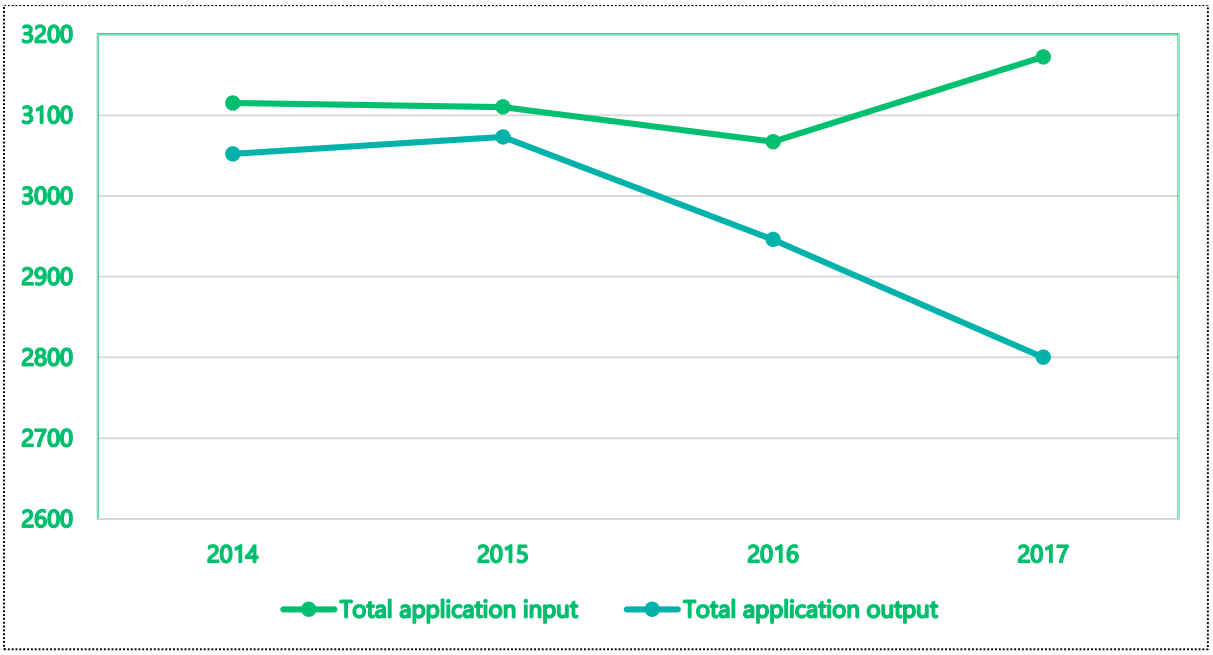
8 CONSULTATION

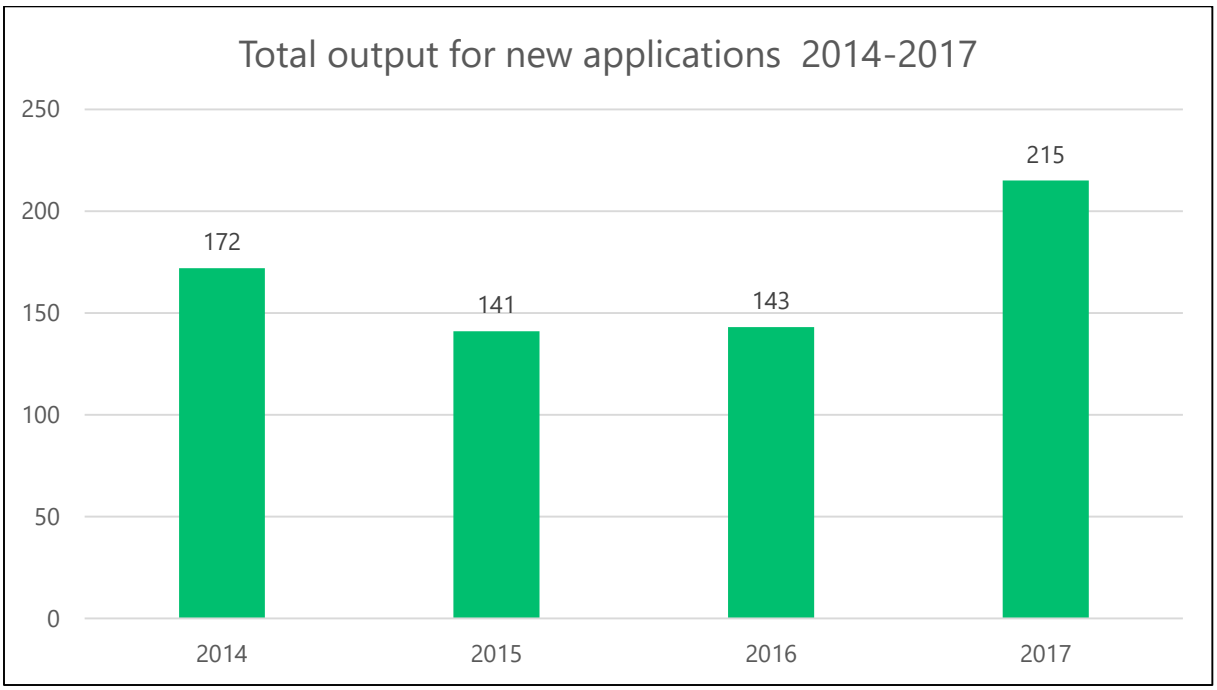
The HPRA welcomes comments on this proposal and invites respondents to comment.

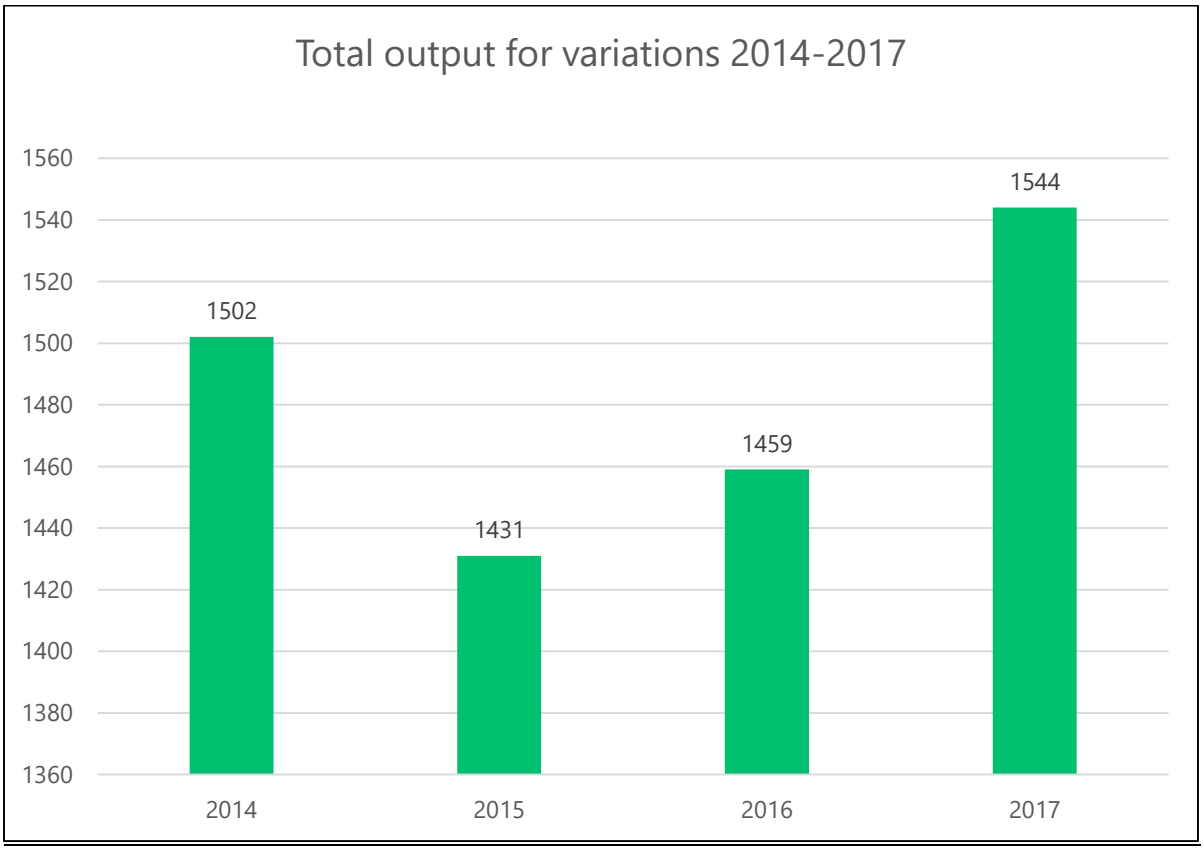
Contributions to the consultation on this proposal may be provided to the HPRA by 31 October 2018. Contributions should be sent by e-mail to feesconsultation@hpra.ie.

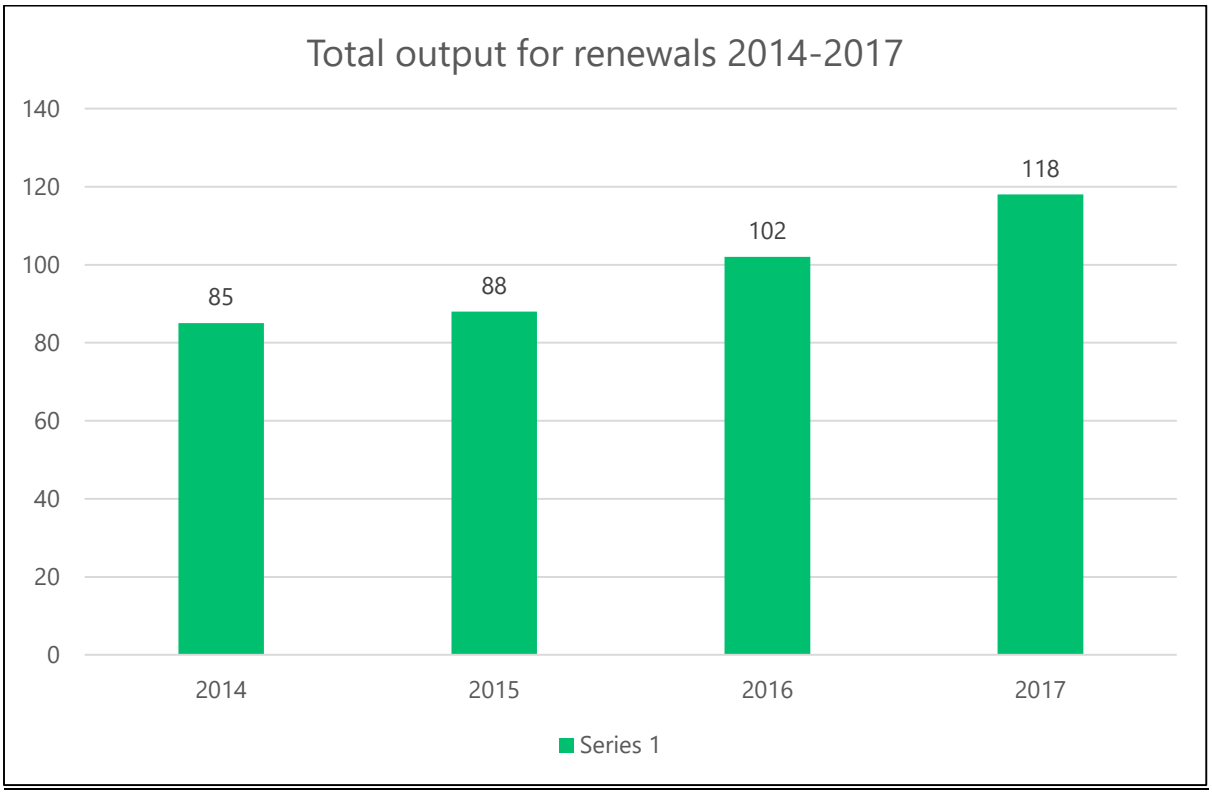
APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2017.






Total output for variations 2014-2017
1560
1540
1520
1500
1480
1460
1440
1420
1400
1380
1360
1502
1431
1459
1544
2014
2015
2016
2017


Total output for renewals 2014-2017
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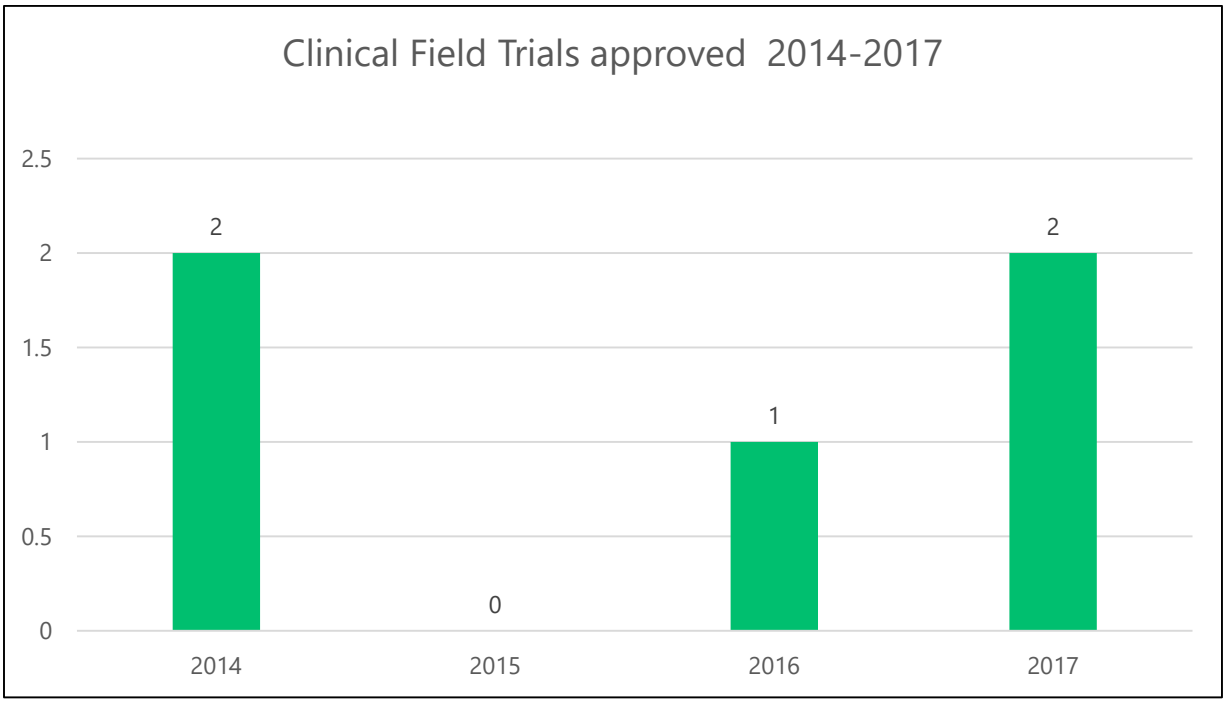
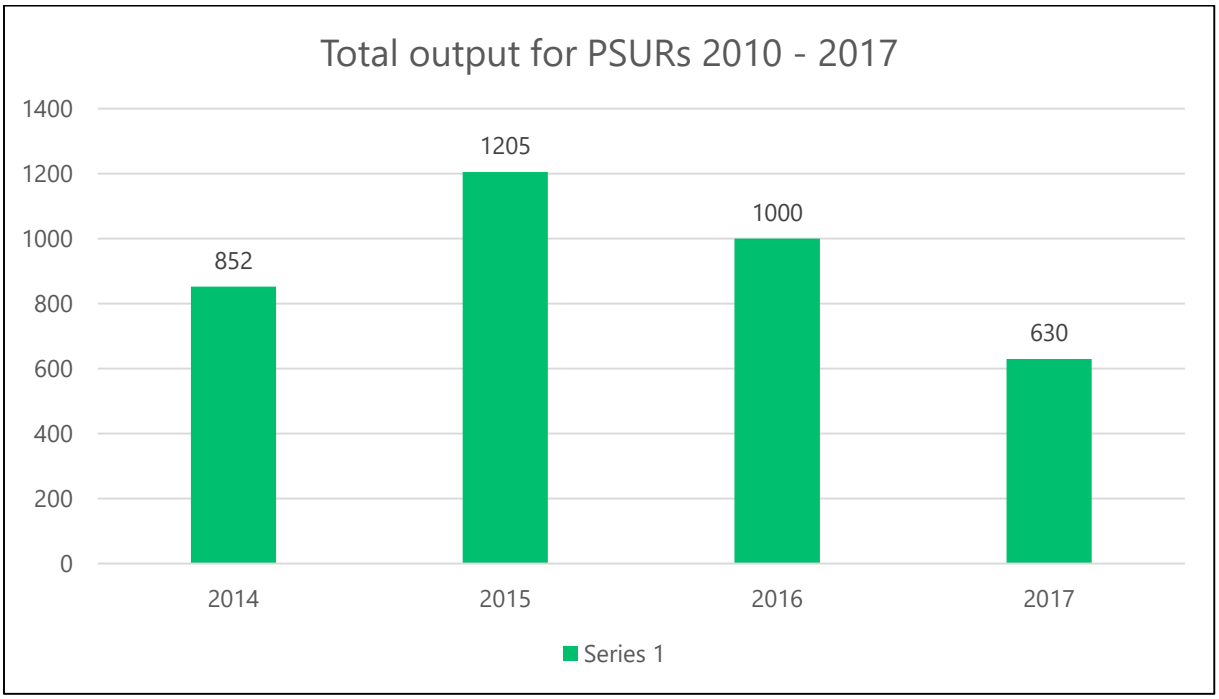
120
100
80
60
40
20
0
85
88
102
118
2014
2015
2016
2017
Series 1


Clinical Field Trials approved 2014-2017
2.5
2
1.5
1
0.5
0
2
0
1
2
2014
2015
2016
2017


Total output for PSURs 2010 - 2017
1400
1200
1000
800
600
400
200
0
852
1205
1000
630
2014
2015
2016
2017
Series 1

APPENDIX II NEW APPLICATION FEES

Reduced Standard Dossier	Current Fee	Proposed Fee	Change
National Application – each additional form	4,984	5,900	916
National Application – each additional strength	643	760	117
Mutual Recognition CMS- each additional form	2,800	3,300	500
Mutual Recognition CMS- each additional strength	643	760	117
Decentralised – each additional form	4,984	5,900	916
Decentralised – each additional strength	643	760	117
Additional DMF submitted	3,183	3,800	617

Reduced Complex Dossier	Current Fee	Proposed Fee	Change
National Application – each additional form	4,984	5,900	916
National Application – each additional strength	643	760	117
Mutual Recognition CMS- each additional form	3,183	3,800	617
Mutual Recognition CMS- each additional strength	643	760	117
Decentralised – each additional form	4,984	5,900	916
Decentralised – each additional strength	643	760	117
Additional DMF submitted	3,183	3,800	617

Complex Dossier	Current Fee	Proposed Fee	Change
National Application – each additional form	4,984	5,900	916
National Application – each additional strength	643	760	117
Mutual Recognition CMS- each additional form	3,584	4,200	616
Mutual Recognition CMS- each additional strength	643	760	117
Decentralised – each additional form	4,984	5,900	916
Decentralised – each additional strength	643	760	117
Additional DMF submitted	3,183	3,800	617

Subsequent Extensions	Current Fee	Proposed Fee	Change
National Application – first additional form	7,499	8,800	1,301
National Application – each additional form	4,984	5,900	916
National Application – first additional strength	2,499	2,900	401
National Application – each additional strength	643	760	117
Mutual Recognition CMS- first additional form	5,239	6,200	961
Mutual Recognition CMS- each additional form	2,800	3,000	200
Mutual Recognition CMS- first additional strength	1,889	2,200	311
Mutual Recognition CMS- each additional strength	643	760	117
Mutual Recognition RMS- each additional form	2,800	3,000	200
Mutual Recognition RMS- each additional strength	643	760	117
Decentralised CMS - first additional form	7,499	8,800	1,301
Decentralised RMS – first additional form	19,584	23,000	3,416
Decentralised – each additional form	4,984	5,900	916
Decentralised – first additional strength	2,699	3,000	301
Decentralised – each additional strength	643	760	117

Other	Current Fee	Proposed Fee	Change
Switching application	4,845	5,100	255
Addition of food producing animal	3,264	3,900	636