HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Public Consultation on
Annual Review and Proposal for Fees – Financial Year 2020

Veterinary Medicinal Products

03 OCTOBER 2019

CONTENTS

1 INTRODUCTION

The Health Products Regulatory Authority (HPRA), since its establishment in 1996, has successfully run its regulation of veterinary medicines authorisation, manufacturer and wholesaler 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 2020.

2 THE OPERATING ENVIRONMENT

2019 has been a challenging year for both the HPRA and the industry. Brexit has brought considerable uncertainty to the regulatory framework and both industry and the HPRA have expanded their resources in preparation for Brexit. While there has been an increase in regulatory activity related to Brexit, such as transfers, variations and RMS applications, some of these changes were not subject to additional fees. We have also seen an increase in product withdrawals in 2019. In terms of costs, the government sanctioned Haddington Road reductions and general pay increases for staff have been re-instated. While 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 continue to increase. As noted above, the biggest impact on activities in 2019 was Brexit. The HPRA committed to the industry that we would work with them to minimise the regulatory burden where possible, to progress Brexit related changes in an expedited manner and to actively work with industry to deliver pragmatic solutions, where possible. In addition, we agreed with a request from industry to accept, if requested, to become Reference Member State (RMS) for any product that the UK previously was RMS and

[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.

where Ireland was a Concerned Member State (CMS). We are happy that we delivered on and continue to deliver on these commitments, but it obviously had an impact on resources.

As noted previously, Government policy in relation to pensions changed and from 2019 the HPRA was required to make an employer contribution in respect of all staff employed since 2013 under the singe services pension scheme. This will, by its nature 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 would make a contribution, but this does have an impact on fees.

A particular area of concern is one of increased litigation, both on the personal injury side and judicial review. An unfortunate result of this is increased costs and resources dedicated to work which delivers nothing under our public health remit.

The impact of new veterinary regulation continues to be evaluated in consultation with the Department of Agriculture, Food and the Marine (DAFM) and project plans are being put in place. Implementation plans for the required implementing and delegated acts commenced in 2019. 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, 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 term, 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 2020.

3 STRATEGIC DIRECTION OF THE HPRA

The HPRA has commenced the process of developing its new strategy for the period 2021 to 2025. We continue to deliver under our current strategic plan for the years 2016 – 2020 which also aligns with the EMA and HMA joint strategic plan. The high-level strategic goals under this plan are 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 2020 include:

- Managing the impact of Brexit across all our strategic initiatives.
- Preparing for the implementation of the new veterinary regulation.
- Increasing our regulatory offering both centrally and decentralised (particularly in the light of the UK departure.
- Dedicated project and resources to manage medicines shortages from a regulatory view point.
- The further development of the innovation office and support for early innovation on a global basis.
- The rollout of a new regulatory workflow 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.

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

4 PROPOSED CHANGES FOR 2020

The HPRA, as outlined above, is operating in a challenging environment, particularly in light of Brexit. As outlined above, we have committed proactively to supporting the industry and to manage its regulatory obligations in Europe following the still unknown outcome of the UK Brexit negotiations.

Overall income has remained flat for the first seven months of 2019. There has been an increase in transfers which are once-off Brexit-related income. Product withdrawals are higher than forecast, 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 77% of total costs. Payroll costs have increased over the last number of years but will increase particularly in 2020 for the following reasons:

- The impact of the Public Service Pay and Pensions Act 2017 will result in pay awards of approximately 3%.
- It is estimated in 2020 that an additional 30 staff across the organisation will be subject to the employer contribution in relation to the single scheme.
- HPRA receives 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: While the final shape of Brexit is still unknown, it is likely that managing the aftermath of Brexit will still be a significant workload for the HPRA. A longer term effect will be our commitment to taking over a significant amount of work previously carried out by the UK. This will impact on the mix of work HPRA undertakes with a much greater emphasis on outgoing work.

In addition, the Veterinary Sciences Department will have the key challenge of adapting the business mode in 2020 for implementation in the coming years.

Despite pressures on costs we propose to keep the increase in fees to 3% which is in effect a cost of living increase. The proposed changes to the fees are as follows:

- General fee increase of 3%
- MR/DCP outgoing supplement for Type IA variations.
- Alignment of the fees for combined national and MRP procedures with the DCP fees where the MRP follows the national procedure within six months.
- Revised/increase in veterinary clinical trial fees

4.1 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 2019. 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.

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 are required to pay significant pension contributions to the Irish Government (DPER). 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 2020 and further amend the fees and fee structure, if required, for 2021.

5 PROPOSED FEES

5.1 General change to fees

As outlined above there will be a general increase of 3% in HPRA fees in 2020.

5.2 Other proposed adjustments to fees – veterinary medicines

5.2.1 New applications

It is proposed to introduce the following supplement fees where the MRP is applied for within six months of the national procedure ending, in order to bring the fees in line with Decentralised outgoing fees.

PROCEDURE	FEE
Complex – New Active	€16,375
Complex – Reduced Dossier	€9,065
Standard – Reduced Dossier	€6,180

5.2.2 Type IA – Outgoing Variations - €270

It is proposed to introduce a MRP/DCP outgoing supplement for type IA variations. Ireland has significantly increased the number of products that it acts as reference member state (RMS) and while there is no fee for the assessment of the variation, there is a high administrative cost in bringing these variations through the European process and the HPRA can no longer absorb this cost.

5.2.3 Veterinary Clinical Trials

It is proposed to restructure/increase the following fees for veterinary clinical field trials as the current fees do not reflect the work involved.

CLINICAL FIELD TRIAL	FEE
Research trial for an IVP unauthorised in the EU for use in a major species	€995
Research trial for an IVP unauthorised in the EU for use in a minor species	€675
Research trial for a VMP authorised in the EU for use in a major species	€675
Research trial for a VMP authorised in the EU for use in a minor species	€375

CLINICAL FIELD TRIAL	FEE
Variation of a current research trial licence	€250

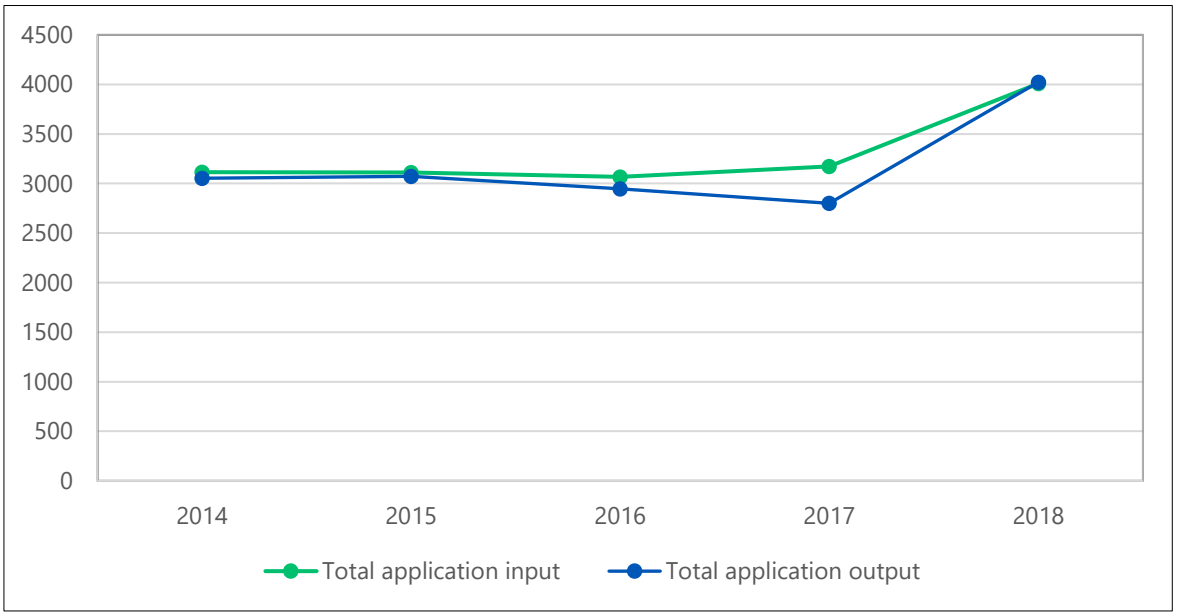
6 CONSULTATION

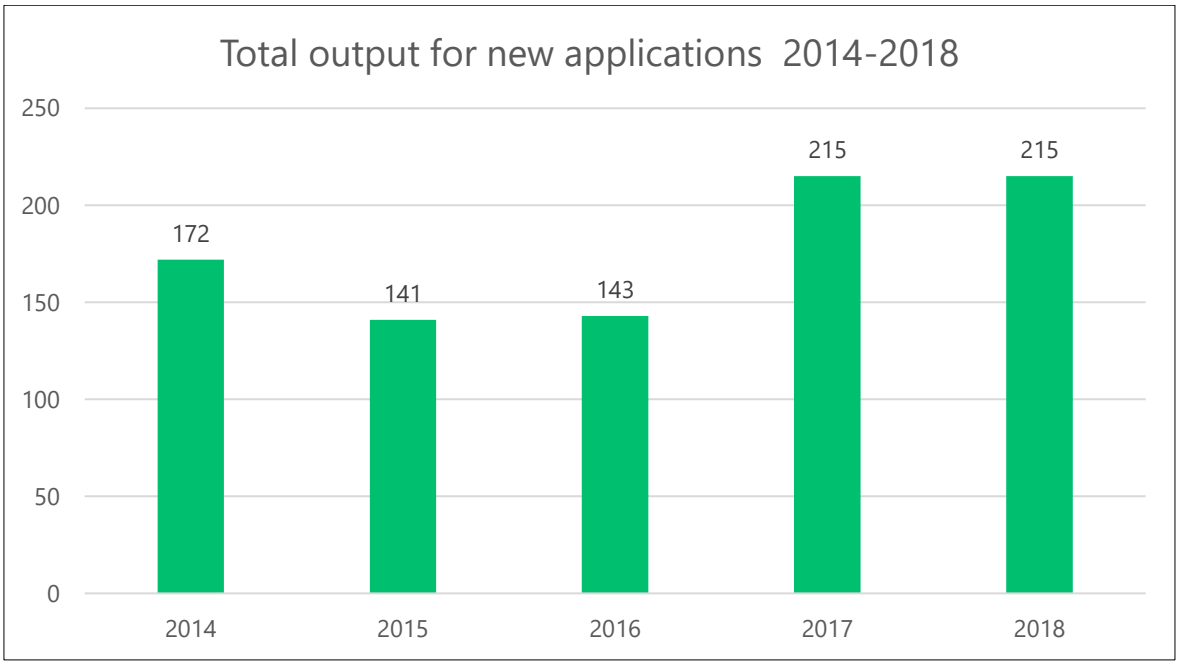
The HPRA welcomes comments on this proposal and invites respondents to comment.

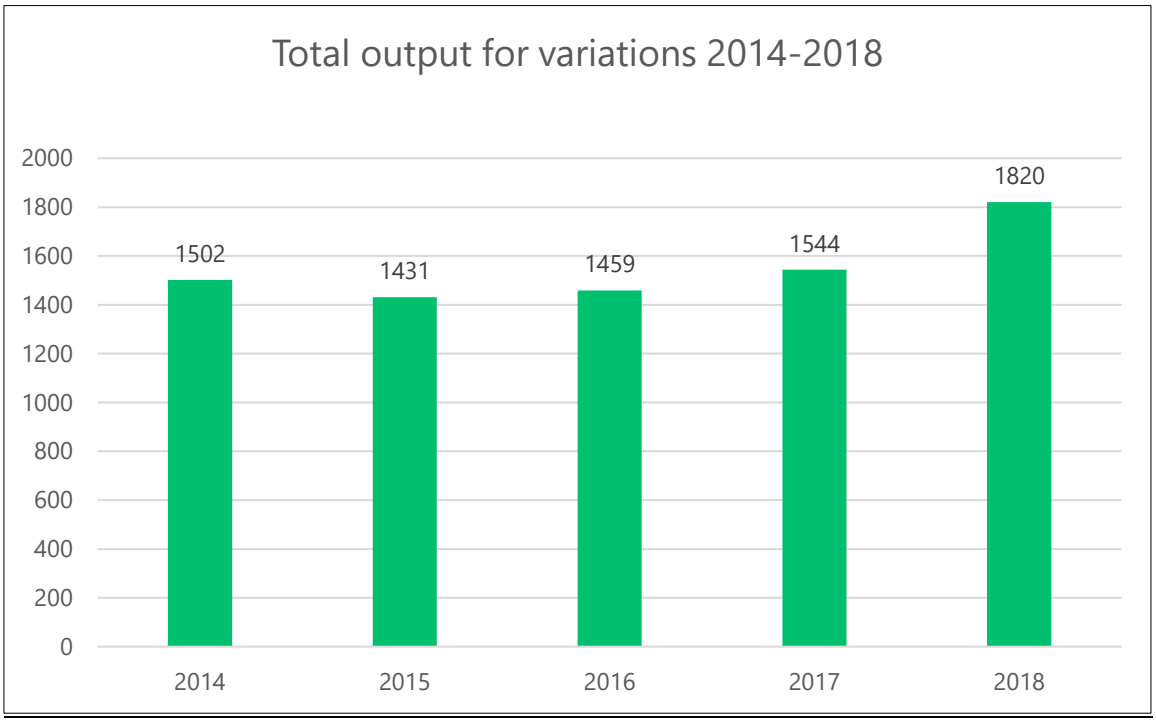
Contributions to the consultation on this proposal may be provided to the HPRA by 31 October 2019. Contributions should be sent by email to feesconsultation@hpra.ie.

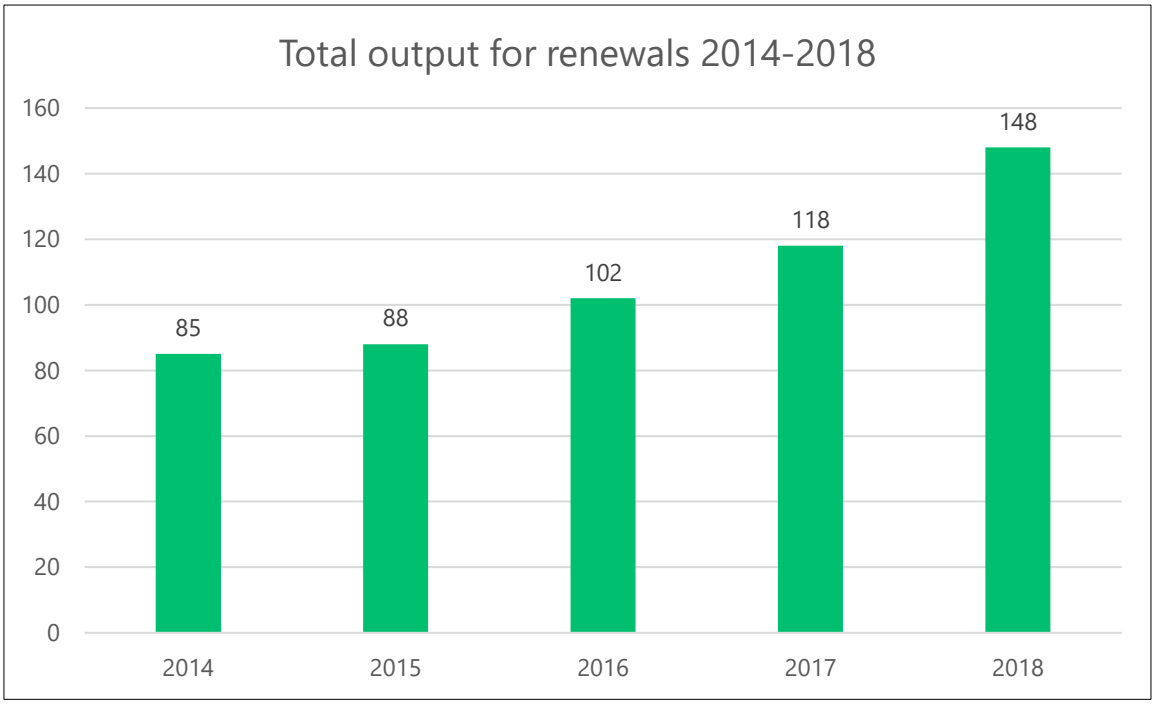
APPENDIX I SERVICE LEVELS

The following graphs outline the output across all application types up to the end of 2018.






Total output for variations 2014-2018
2000
1800
1600
1400
1200
1000
800
600
400
200
0
1502
1431
1459
1544
1820
2014
2015
2016
2017
2018


Total output for renewals 2014-2018
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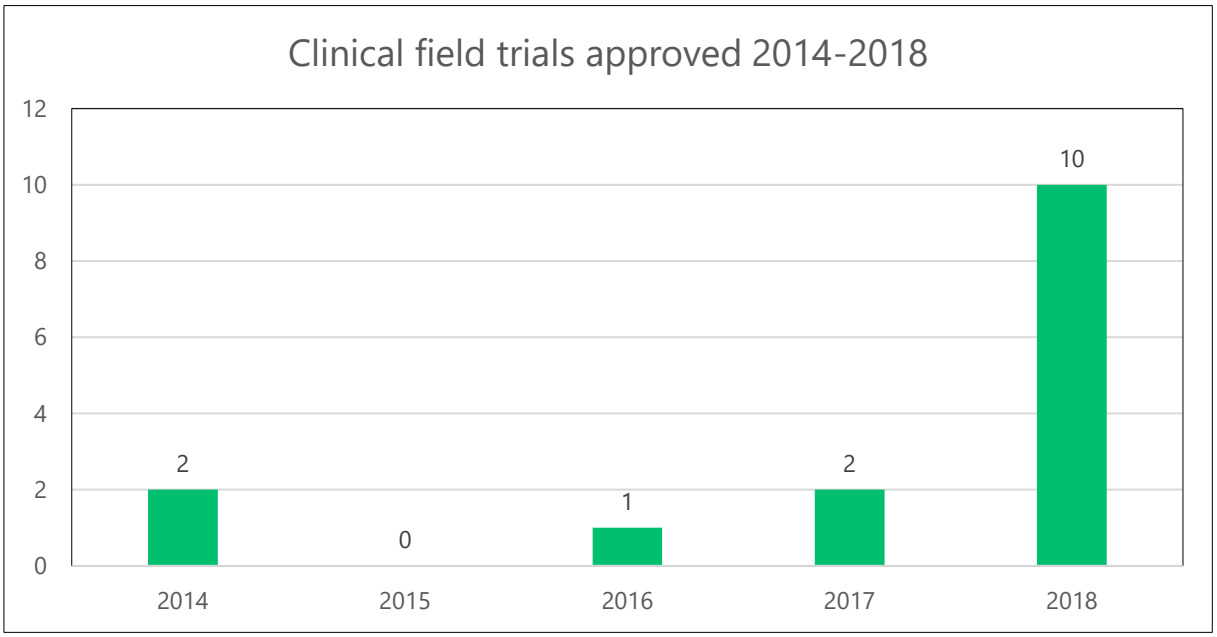
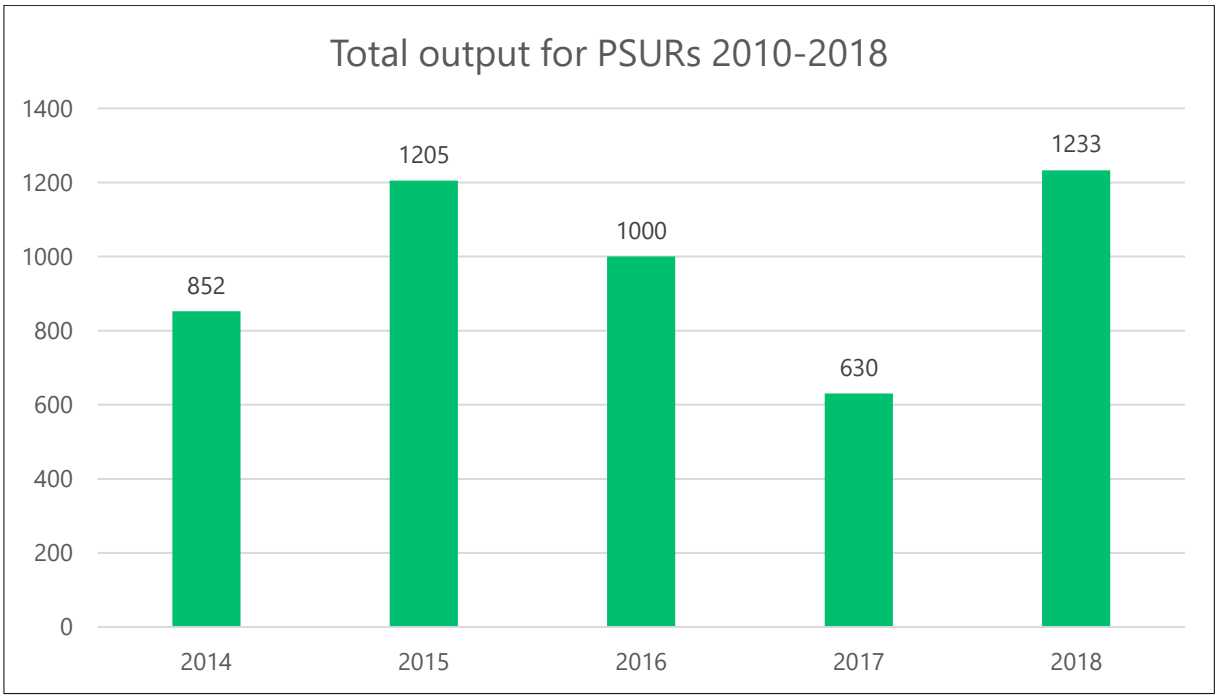
140
120
100
80
60
40
20
0
85
88
102
118
148
2014
2015
2016
2017
2018


Clinical field trials approved 2014-2018
12
10
8
6
4
2
0
2
0
1
2
10
2014
2015
2016
2017
2018


Total output for PSURs 2010-2018
1400
1200
1000
800
600
400
200
0
852
1205
1000
630
1233
2014
2015
2016
2017
2018