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# Drug Tariff Part IX Annual Review 2019-2020

## 1. Summary

During 2019-20, 197 new applications for products to be considered for inclusion in Part IX of the NHS England and Wales Drug Tariff have been received. This represents a decrease of 46% compared with 2018-19. The percentage of applications for unique products is 11% of all applications received, for 'me-too' type products is 75%, and the percentage of line extensions is 14% of all applications. A significant proportion of the "me-too"/ "line extensions" involved requests for listings with higher prices compared with similar products already in the Drug Tariff. Applications of this type require more information from applicants to meet the cost-effectiveness criterion with associated correspondence and data analysis.

The majority of applications received are subsequently approved. The main reasons for a delay in the process are:

- CE documents are either missing or incorrect;
- Samples missing/ incorrect;
- Insufficient information for cost-effectiveness assessment

The most common reason for applications remaining in the pending state for an extended period of time is due to the delay resulting from applicants needing time to compile additional information to support the cost effectiveness of their product.

During 2019-20, there was an 11% increase in the number of price increases requested through the price increase mechanism compared with 2018-19. The price increases for July account for 41% of the amount that were implemented in the whole period of 2019-20. No requests for exceptional price increases were received.

Leading up to the declaration of the Covid-19 pandemic, NHS Prescription Services were already noting a sharp reduction in the number of applications for a listing in Part IX from December 2019 onwards. This may have been due to uncertainties over Brexit, or difficulties obtaining products from the Far East before the pandemic took hold more widely.

## **2. Introduction**

The legislative basis for Part IX of the Drug Tariff is sections 126 and 164 of the National Health Service Act 2006 and regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) regulations 2013. The Drug Tariff is compiled and published on a monthly basis by NHS Prescription Services on behalf of the Secretary of State for Health and Social Care (Health Secretary), as provided for by these legislative provisions. Part IX of the Drug Tariff is the list of appliances and chemical reagents approved on behalf of the Secretary of State and which may be prescribed at NHS expense by an appropriate prescriber.

Responsibility for administration of Part IX of the Drug Tariff is shared between the Department of Health and Social Care (DHSC) and NHS Prescription Services of the NHS Business Services Authority. The DHSC has responsibility on all aspects of policy. NHS Prescription Services has responsibility for approval of the lists of appliances and chemical reagents on behalf of the Secretary of State for the purposes of the 2006 Act, to determine the prices on the basis of which the payment for such appliances and chemical reagents is to be calculated and to remove products from Part IX when NHS Prescription Services is notified that they are no longer available.

This paper reviews the activity of NHS Prescription Services between April 2019 and March 2020 with regards to the administration of the application process for listing in Part IX, the Part IX price increase mechanism, any applications for an exceptional price increase and the Part IX Appeal process.

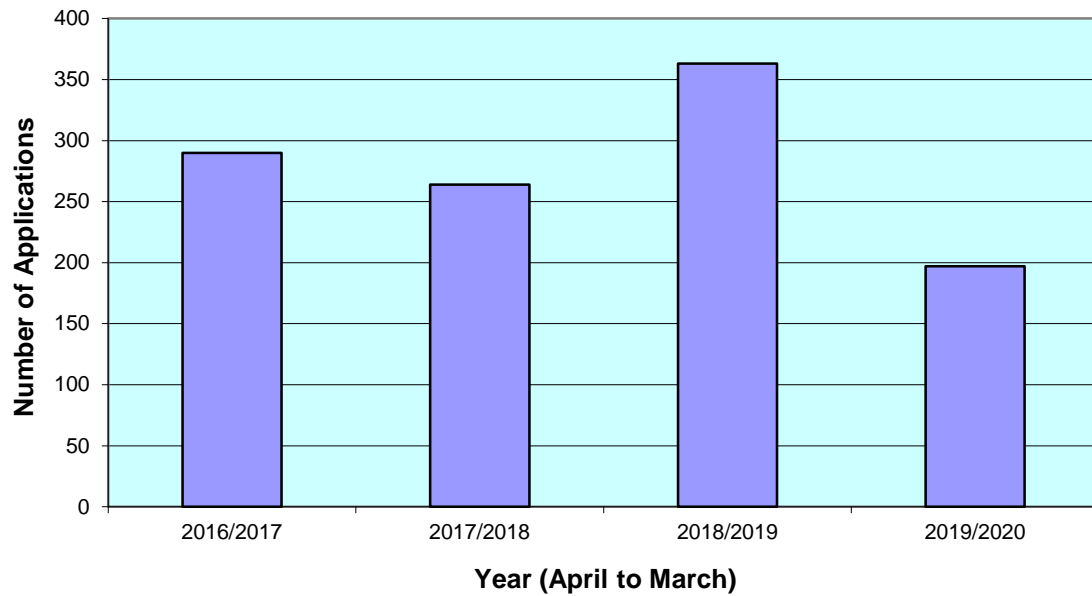
## **3. Applications for inclusion in Part IX**

The application procedure for products to be listed in Drug Tariff Part IX is set out in the Drug Tariff Guidance Notes. There are three criteria that an application must satisfy in order to be approved for listing in Part IX which are:

- i. The products are safe and of good quality;
- ii. They are appropriate for prescribing in primary care;
- iii. They are cost effective.

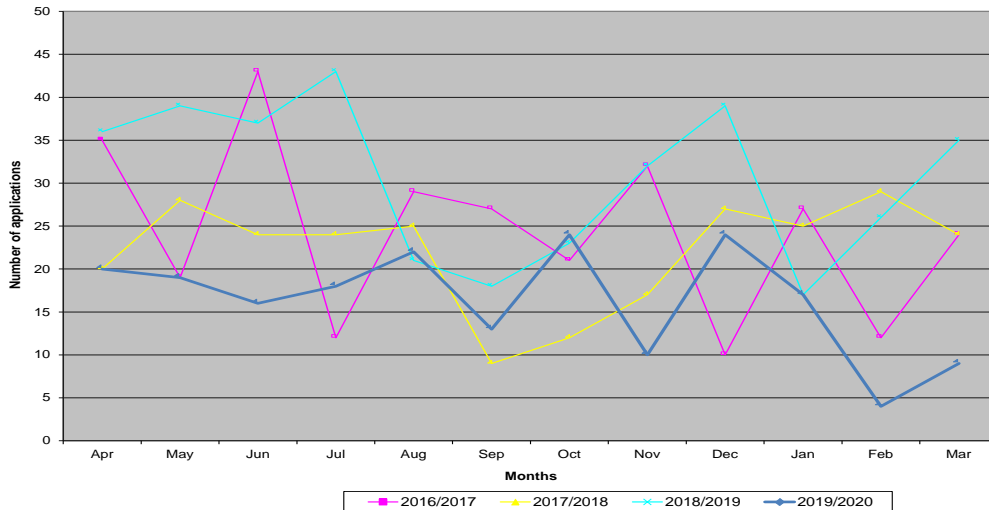
Between April 2019 and March 2020, a total of 197 new applications for products to be considered for inclusion in Part IX were received. This represents a 46% decrease in the number of applications made compared to the year 2018-19 when 363 were received. Figure 1 illustrates the total number of applications received over the previous four financial

years. The average number of applications received per year over the four year period was 279.



**Figure 1.** Number of Part IX applications received over the previous four financial years.

The number of applications received each month continues to fluctuate throughout the year. Figure 2 shows the numbers of applications received month-by-month and makes comparison with the data from previous financial years. During 2019-2020, the average number of applications received per month was 16 which was lower than last year when the average was 30 applications per month.



**Figure 2.** Number of Part IX applications received each month over the previous four financial years.

Table 1 shows a breakdown of the types of applications received during 2019-2020 compared to the previous year. The percentage of the total applications for “new” products has increased to 11% from 8% last year. The percentage of “me-too” products has increased from 74% to 75% and the percentage of “line extension” products has decreased from 18% to 14% compared with 2018-2019. The evaluation of “new” products is often more complex and time consuming than applications for line extensions or products where similar products are already listed (“me-too” products). These can require prolonged correspondence with the applicant as the necessary information is collated. Increased workload is also associated with a “me-too” product where the applicant requests a higher price for similar items currently listed in Part IX. This increased cost request has to be justified by the applicant resulting in the application being more complex due to increased negotiation. These factors need to be considered alongside the total number of applications received in order to fully consider the workload associated with the application process for 2019-2020.

Application type	Applications received 2016-2017	Applications received 2017-2018	Applications received 2018-2019	Applications received 2019-2020
“New” products	26(9%)	15(6%)	30(8%)	22(11%)
Line extensions	74(26%)	71(27%)	64(18%)	28(14%)
“Me too” products	190(65%)	178(67%)	269(74%)	147(75%)

**Table 1.** Summary of the types of applications received during 2019-2020 compared with the previous three years. (“New” products are those where no similar products have been listed in the Drug Tariff before; Line extensions are extensions to existing ranges in the Drug Tariff; “Me-too” products are products where similar products are already listed in the Drug Tariff)

A summary of the status of all applications received and processed in 2019-2020 is provided in Table 2.

<b>APPLICATIONS RECEIVED 2019-2020</b>	<b>197*</b>
Approved	212**
Rejected	3**
Withdrawn by company	9**
Pending / On Hold	85***

**Table 2.** Summary of applications received approved, pending and rejected in 2019-20

(\* the applications received refer to those logged between 1st April 2019 and 31st March 2020; \*\* the figures for approved, rejected and withdrawn refer to all applications processed between 1st April 2019 and 31st March 2020, which includes some carried over from the previous financial year. Therefore the sum of the approved, rejected, withdrawn and pending does not equal the total applications received in 2019-2020; \*\*\* the number of pending/on-hold applications is correct as of the 31st March 2020)

The number of applications withdrawn by the applicant during 2019-2020 has decreased compared with last year. NHS Prescription Services continues to review applications where no response has been received from the applicant for 3 to 6 months (depending on workload) to ensure that all applications are current. Three applications were rejected during 2019-2020.

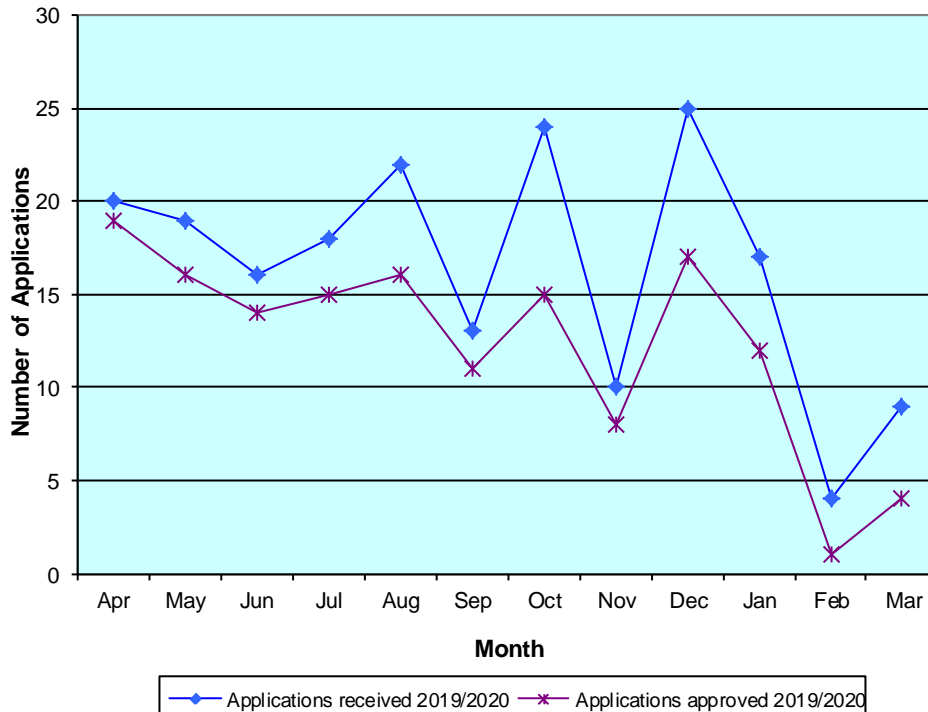
There were 87 applications pending or on hold as of 31 March 2020. On average 66% of “me-too” /line extensions could be processed first time, without requesting further information from the applicant. This has increased from 52% last year. Of the applications that could not be assessed first time insufficient information to support cost effectiveness is

the main area where an applicant needs to be contacted and accounts for 56% of requests. Incorrect certificates account for 21% of referrals back to the applicant.

Of the total number of referrals back to the applicants:

- 70% related to the 'declaration of conformity' certificate not being provided
- 5% were due to applicants not providing confirmation as to which member state of Europe the product is registered in
- 25% were due to no or incorrect notified body certificates
- 56% of "me-too"/ line extensions required additional information to support a premium price. This also still remains the main reason that applications remain pending for a long period of time
- 22% related to problems with the samples of the products. Most commonly applicants either do not provide the correct sample of the product or they do not provide the packaging/ label of each of the variants they are applying for (e.g. each different size of dressing)

NHS Prescription Services approved 212 applications for products to be listed in Drug Tariff Part IX during 2019-2020. Figure 3 shows the number of applications received in each month and those which were subsequently approved. The gap between the lines represents those that have been withdrawn or that are pending or on-hold.

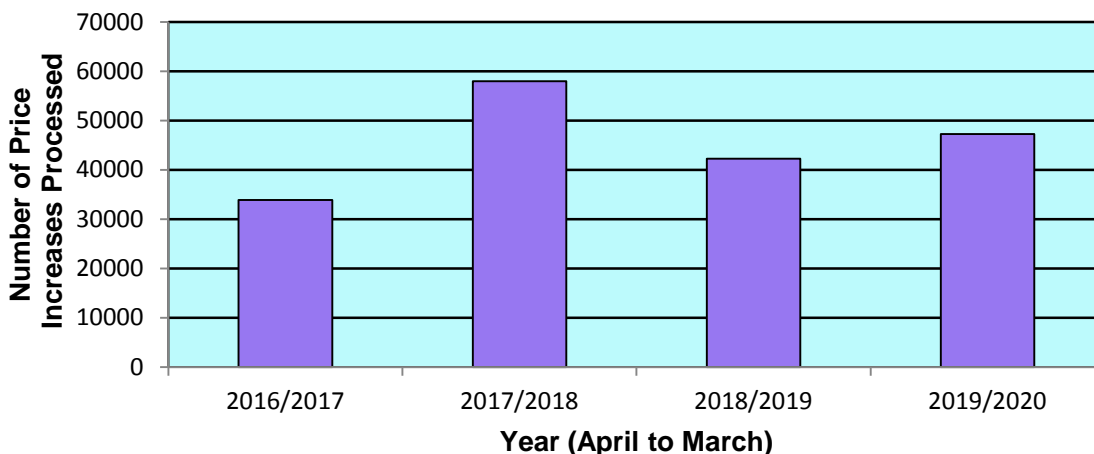


**Figure 3.** Number of Part IX applications received during 2019-2020 vs. those that have subsequently been approved.

## 4. Part IX Prices

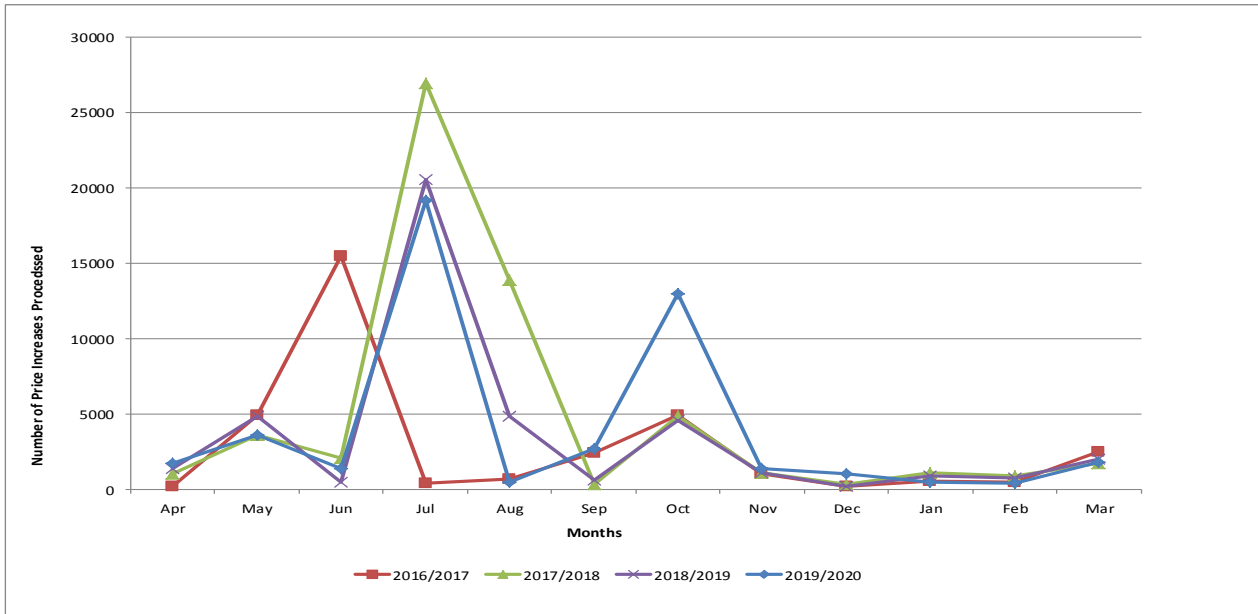
The mechanism to allow annual price rises to products listed in Part IX is set out in Annex D to the Drug Tariff Part IX Guidance Notes and is an agreement between the DHSC and the Drug Tariff Part IX Forum. Manufacturers are required to give two months' notice before the publication deadline of the Drug Tariff in which the price rise will take effect, and a formula related to the Gross Domestic Product (GDP) forecast is applied to all requests. Requests for a price increase greater than that permitted by the pricing mechanism can only be approved if special circumstances prevail (and this follows a separate procedure for exceptional price increase requests). There were no enquiries regarding exceptional price increases for the period April 2019 to March 2020.

Figure 4 illustrates the change in the number of price increase requests that have been processed for Part IX products. In total 91 manufacturers submitted 187 price change requests resulting in a total of 47,256 price changes in the period April 2019 to March 2020. This is an 11% increase on the previous year. Figure 5 shows the number of price increases processed for each edition of the Drug Tariff. The figure for July was the highest at 19,177 price increases, then October at 12,983 and May the third highest at 3,645. The price rises for July account for 41 % of those price increases implemented in the whole period of 2019-20; and were predominantly for ranges of lymphoedema garments.



**Figure 4.** Number of price increases processed for Part IX appliances and chemical reagents for the previous four financial years.





**Figure 5.** Number of Part IX price increases processed for each Drug Tariff edition over the previous four financial years.

## 5. Covid-19

Leading up to the declaration of the Covid-19 pandemic, NHS Prescription Services were already noting a sharp reduction in the number of applications for a listing in Part IX from December 2019 onwards. This may have been due to uncertainties over Brexit, or difficulties obtaining products from the Far East before the pandemic took hold more widely.

On March 31, in response to the Covid 19 pandemic, the DHSC instructed NHS Prescription Services to temporarily suspend the assessment of new and pending applications for the listing of medical devices in Part IX with immediate effect. This was to help us manage staff resource during the current Covid-19 pandemic, and was initially for a period of 3 months. All manufacturers who had applications with us were contacted individually; the Secretariat of the Part IX Drug Tariff Forum was asked to contact members; and a statement was placed on the website. All those applications which had been approved for listing were honoured, as were any routine annual price increase requests.

At the time of writing this suspension is still in place, but is expected to be reviewed soon with a decision pending. The impact will be reported in the annual report for April 2020 to March 2021.