

Evaluation of procurement quality and prices in Ukraine for

Programme 3 – “Chemotherapeutic agents, radiopharmaceuticals and support drugs for cancer patients”

managed by Crown Agents in 2019

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BACKGROUND AND NOMENCLATURE

The present report analyses the prices of oncology drugs in Ukraine under the procurement Programme 3 “Chemotherapeutic agents, radiopharmaceuticals and support drugs for cancer patients” managed by Crown Agents in 2019, in comparison with prices paid in previous years and compared to international benchmarks.

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2019 compared to previous years where pricing data is available (2018 and 2015).

A note on nomenclature

Every medicine has a brand name, which is given by the pharmaceutical company that markets the drug, and a generic name, the drug’s ‘active ingredient’ that makes it work.

When a medicine with a new active ingredient first appears, it is protected by a patent for several years. The patent is designed to allow the company to make enough profits to recover the money it spent developing the medicine, or on buying the rights to market it.

While the medicine is covered by patent, other companies cannot sell a similar medicine containing the protected active ingredient.

After the patent expires, other companies are allowed to develop medicines based on the active ingredient. These are known as ‘generic’ medicines. There may be several of them with different brand names, but the same active ingredient as the original.

Throughout this report we will use the following terms as here explained:

Medicine: it is the generic name, including the active ingredient denomination but also the specific quantity of active ingredient and the packaging details. This corresponds to the column “*Name (item description, generic name)*” in the file provided by Crown Agents. For the same active ingredient we may have more than one Medicine as here intended; for example “*Bosutinib 100 mg tablet, capsule, pill*” and “*Bosutinib 500 mg tablet, capsule, pill*” are here considered as two separate Medicines and are analysed as two separate lines.

Brand Drug: it is the specific name that each pharmaceutical company has given to a Medicine. This corresponds to the column “*Brand name*” in the file provided by Crown Agents and may also include details on the packaging, volume of solutions, weight of the pills, etc.. Using the same example as above, the Medicine “*Bosutinib 100 mg tablet, capsule, pill*” corresponds to the Brand Drug “*Bosulif® 100 mg - film-coated tablets bosutinib - 28 tablets per pack № 28 (14x2)*”. The same Medicine may correspond to more than one Brand Drug, as is the case of Medicine “*Calcium Folate 50 mg ampoule, vial, syringe*” that was purchased from two different companies with Brand Drugs “*LEUCOVORIN-TEVA - solution for injection, 10 mg/ml - 5 ml in vial; 1 vial in cardboard pack*” (from TEVA) and “*CALCIUM FOLINATE, solution for injection, 10 mg/ml - 5 ml in ampoule; № 5 (5x1)*” (from PJSC Lekhim-Kharkiv).

Note: For 2018 we have a list of prices for each Medicine with one to one correspondence with the Medicines purchased by Crown Agents in 2019. The procurement in 2018 was not managed by Crown Agents, therefore we do not have any details regarding the Brand Drugs for each Medicine, however the coverage of most Medicines makes this comparison very significant. For 2015, the procurement was managed by Crown Agents, therefore we have the detailed list of Medicines procured including all Brand Drugs details; the correspondence with 2019 is not complete, but a significant number of Medicines correspond, so we could perform a significant analysis also in this case. No data has been made available for years 2017 and 2016.

We analysed these aspects:

- **Price variations:** this analysis included two important aspects
 - o Variation of the price per item 2015->2019 and 2018->2019 for each Medicine (% increase or decrease)
 - o Improvement of the overall spending comparing the “Supplier value” for 2019 to the cost Crown Agents would have incurred to purchase the same quantities of each item at 2018 and 2015 prices.
- **Quality:** for each Brand Drug purchased by Crown Agents in 2019 we have searched for an official approval by drug regulatory authorities (SRA-Stringent Regulatory Authority). For the Brand Drugs where we could not find an SRA record, we have searched for GMP (Good Manufacturing Practices) reports for the corresponding manufacturer. This was done to provide an assessment of the quality of Brand Drugs procured in 2019 by Crown Agents.
- **Price benchmarking:** we have collected international price references for all Medicines included in the Programme. We have considered several publicly available sources from different countries, including national databases of approved drugs from regulatory agencies and actual prices paid by purchasers (procurement agencies, regional group purchase organizations, individual hospitals). Whenever possible we have included the benchmark pricing for exactly the same Brand Drug purchased by Crown Agents in 2019; where this was not possible, we have included the benchmarking price for the lowest priced corresponding Medicine we could find.

About ECRI Institute

ECRI Institute, a totally independent and not-for-profit organisation, dedicates itself to bringing the discipline of applied scientific research in healthcare to uncover the best approaches to improving patient care. As pioneers in this science for over 50 years, ECRI Institute marries experience and independence with the objectivity of evidence-based research

More than 5,000 healthcare organisations worldwide rely on ECRI Institute’s expertise in patient safety improvement, risk and quality management, healthcare processes, medical device evaluation, procedures, and drug technology.

Established in 1968 as the Emergency Care Research Institute in Plymouth Meeting, Pennsylvania, ECRI Institute opened its European Office in UK in May 1995 with the goal of serving the particular needs of international healthcare organisations.

All of ECRI Institute's products and services are available through the European Office, but at the same time addressing the special requirements of the region. For example, consulting services to the NHS, accident and forensic investigations, conferences, exhibitions, reports and research, are all supported by our European Office staff. Utilising some of the world's largest health related databases, assistance, support and guidance can be given to our international clients at local level.

<https://www.ecri.org/>

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EXECUTIVE SUMMARY

The present report analyses the prices of oncology drugs in Ukraine under the procurement Programme 3 “Chemotherapeutic agents, radiopharmaceuticals and support drugs for cancer patients” managed by Crown Agents in 2019, in comparison with prices paid in previous years and compared to international benchmarks.

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2019 compared to previous years where price data are available (2018 and 2015).

We have collected evidence of the extreme variability of the prices of cancer drugs in different countries and over the course of time, with very limited correlation with input prices or other common factors, and in line with the literature retrieved **we could not establish any clear link between the variation of prices paid by Crown Agents in 2019 compared to the prices paid in 2018 and 2015, and possible contributing factors such as the variation of currency exchange rates and the change in input prices (API price trends).**

Instead, we see that **elements such as the selection of new suppliers providing a different Brand Drug for the same Medicine (e.g. with the availability of alternative generics and biosimilars) and the procurement of higher volumes of drugs, can lead to significant efficiencies in procurement and overall cost reductions.**

PRICE VARIATION OF INDIVIDUAL ITEMS

We have received all pricing information regarding the Medicines purchased by Crown Agents in 2019. For 2018, we have a list of prices for each Medicine with one to one correspondence with the Medicines purchased by Crown Agents in 2019. The procurement in 2018 was not managed by Crown Agents, therefore we do not have any details regarding the Brand Drugs for each Medicine, however the coverage of most Medicines makes this comparison very significant. For 2015, the procurement was managed by Crown Agents, therefore we have the detailed list of Medicines procured including all Brand Drugs details; the correspondence with 2019 is not complete, but a significant number of Medicines correspond, so we could perform a significant analysis also in this case. No data has been made available for years 2017 and 2016. We have therefore considered the Medicines purchased in years 2019, 2018 and 2015.

The variation of prices from 2018 to 2019 for individual Medicines show that for 61 of the 85 Medicines considered (71.8%) the price has remained stable or has decreased. Most of the Medicines had a variation between -20% and +10%, although there were some individual extreme variations.

The variation of prices from 2015 to 2019 for individual Medicines show that for 47 of the 56 Medicines considered (83.9%) the price has decreased.

This can be explained in terms of the high dynamics of the pricing of cancer drugs in international markets, with the development of new drugs, the expiration of patents and the availability of new generics and biosimilars.

The price variations from 2015 to 2019 were not strictly linked to the variations in the quantities purchased (no information on quantities is available for 2018).

TOTAL SAVINGS

Only considering the % increase or decrease of the price per unit for individual items could lead to wrong conclusions because improving the procurement efficacy for high volume/high cost items is much more important than achieving efficacy for low volume/low cost items and vice versa. It's therefore necessary to also consider the total volume of purchased items. To do so we calculated the improvement of the overall spending comparing the "Supplier value" for 2019 to the cost Crown Agents would have incurred to purchase the same number of each item at 2018 and 2015 prices.

The savings in 2019 for the 85 Medicines analysed in relation to 2018 have been \$3,945,963.84; an improvement of 10.48% relative to 2018 prices.

The savings in 2019 for the 56 Medicines analysed in relation to 2015 have been \$62,413,545.62; an improvement of 70.61% relative to 2015 prices.

The quantities purchased in 2015 were much lower for almost all Medicines than those purchased in 2019, but these data are very significant to show the improvement in procurement efficacy achieved in 2019. Purchasing the same quantities of cancer Medicines at 2015 prices would have costed an extra budget of more than \$60M, with a significant impact on the actual possibility to purchase these Medicines for the people of Ukraine.

The main explanation for this big improvement is the selection of different Brand Drugs made available thanks to the availability of new generics and biosimilars, and the price decrease from some of the same Brand Drugs due to improved negotiations, more volumes and the presence of competing alternatives on the market.

QUALITY

We have examined if the selected products can also be found in international markets and if they received an official approval by drug regulatory authorities (SRA-Stringent Regulatory Authority). For the Brand Drugs where we could not find an SRA record, we have searched for GMP (Good Manufacturing Practices) certificates for the corresponding manufacturer. We have focused this analysis on the Top 30 Medicines in terms of overall expenditure (sum of column "Supplier value").

The vast majority of the Brand Drugs purchased in 2019 by Crown Agents are SRA approved or come from manufacturers with GMP certification (86.6%).

There is clearly no evidence to suggest that prices have decreased due to sourcing from manufacturers with lower quality standards.

PRICE BENCHMARKING

We have explored many international sources of drug prices and found available information from the following:

- **Public price lists approved by ministries of health/national drug authorities** for: Czech Republic, Slovak Republic, Moldova, Saudi Arabia, Brazil, Italy
- **Publicly available procurement data** from WHO MSH International Medical Products Price Guide (ed. 2015)
- **Public tenders awarding** documents in Italy

The public price lists from national drug authorities are usually higher than actual procurement prices, but for most countries is the only publicly available source of data. The WHO MSH and Italian public tenders are more realistic data points to consider (for both of these we considered the median of the available price points collected). In order to provide a comparison of the prices paid by Crown Agents in 2019 with the international prices for the same Medicines, we have focused this analysis on the Top 30 Medicines in terms of overall expenditure.

The results of the international benchmark of prices for the Medicines we have analysed show that Crown Agents in 2019 got better prices for the vast majority of Medicines purchased.

Overall, the procurement activity by Crown Agents in 2019 compared to 2016 and 2015 proved effective, with significant cost savings, good quality products selected from reliable manufacturers and a price benchmark better than the international prices we considered for reference.

GENERAL CONSIDERATIONS

Information received and pre-processing of the data

We have based our analysis on the procurement data provided by Crown Agents. We have received two spreadsheets:

- *2019 Adult Oncology Ukraine Data V3.xlsx* (including full data for 2019 and a single column with the prices for 2018)
- *2015 Adult Oncology Ukraine Data.xlsx*

The information available for 2019 are:

- *Name (Item description, Generic name)*
- *Brand name*
- *Manufacture*
- *Supplier*
- *Pack size*
- *Est delivery (according to contract)*
- *Shelf life*
- *Date of delivery*
- *Quantity 100%*
- *Quantity quota*
- *Quantity contract*
- *Price per unit (supplier)*
- *Supplier Value*
- *CA Fee (%)*
- *CA Fee per unit (\$)*
- *UMP Fee (%) for ACT*

The “Supplier value” is calculated considering the “Price per unit (supplier)” into the “Quantity contract”, therefore in our analysis we have considered the “Quantity contract” as the reference to evaluate the savings in 2019 compared to 2018 and 2015 prices.

For 2018 we have a list of prices for each Medicine with one to one correspondence with the Medicines purchased by Crown Agents in 2019. The procurement in 2018 was not managed by Crown Agents, therefore we do not have any details regarding the Brand Drugs for each Medicine, however the coverage of most Medicines makes this comparison very significant.

For 2015, the procurement was managed by Crown Agents, therefore we have the detailed list of Medicines procured including all Brand Drugs details; the correspondence with 2019 is not complete, but a significant number of Medicines correspond, so we could perform a significant

analysis also in this case. The information available in the spreadsheet for 2015 are very similar to those available in the spreadsheet for 2019.

All these data needed to be re-organized in order to highlight the item-by-item and overall performance of 2019 in terms of comparison to 2015 and 2018 procurement. We have therefore prepared a separate spreadsheet and included the following data:

- Medicine – corresponding to *Name (Item description, Generic name)*
- Brand Drug – corresponding to *Brand name*
- Manufacture
- Supplier
- Pack size
- Quantity contract 2019
- Price per unit 2019
- Supplier value 2019
- Price per unit 2018
- Value quant 2019 price 2018
- Price per unit 2015
- Value quant 2019 price 2015

Since in the original file there were multiple lines for the same Medicines/Brand Drugs (corresponding to more purchases for the same product during the year), we have grouped these together to highlight the total quantities and expenditures, and obtain a file without duplicated lines.

We have obtained a list of **90 Medicine/Brand Drug items for 2019**, with only two missing pricing data (therefore the actual products considered are 88). Of these, we could get the corresponding **pricing for 2018 for 85 Medicines** (no information regarding the specific Brand Drug is available), and **pricing for 2015 for 56 Medicines**.

For 2015, 32 Medicines have the same Brand Drug as in 2019, while the remaining 24 have a different Brand Drug. In our price variations analysis we considered the correspondence for all 56 items.

Additional columns were prepared for the analysis on Quality (SRA or GMP approvals) and for the international benchmarking with several countries.

Pareto analysis

The total expenditure for 2019 (sum of column “Supplier value”) is \$34,762,264.87. As we have already highlighted, this is distributed across 90 Medicines, with some Medicines accounting for several hundred thousand dollars, and some accounting for much smaller amounts.

It is therefore very important, in order to understand the quality of procurement in 2019, to discriminate among these items, because it is much more important to achieve savings in the price per unit for Medicines that count for a big portion of the expenditure, rather than focusing on the lower expenditure items.

For this reason, we have ranked all Medicines in the list according to the aggregated “Supplier value 2019”; **the top 30 Medicines in the list have an aggregated value of \$28,906,405.01 that is more than 83% of the total.**

This result was very much expected based on the **Pareto principle** (also known as the 80/20 rule, the law of the vital few, or the principle of factor sparsity), that states that, for many events, roughly 80% of the effects come from 20% of the causes; in general, it states that the vast majority of the effects come from a minority of the causes (in our analysis, 83% of the total expenditure comes from 33% of the Medicines).

Some of the considerations in the following chapters are therefore focused on these top 30 Medicines, where most of the results in terms of procurement efficiency are achieved.

Non-disclosure agreements

For some of the Brand Drugs procured in 2019 Crown Agents has signed a non-disclosure agreement regarding pricing with their suppliers. Some of these Medicines are very significant in terms of overall expenditure and procurement efficiency, therefore we wanted to include these in the analysis. In order to avoid any risk of breaching the non-disclosure agreements in place, we have omitted any details regarding specific “Price per unit” or “Supplier value” that could provide information (in a direct or indirect way).

Therefore, we present data on expenditures and savings in an aggregated way, and all details regarding single line items (e.g. the variation of the price per unit 2018->2019) are presented without a direct reference to the specific Medicines or Brand Drugs.

Factors affecting the price of Medicines

The main issues regarding the price of Medicines are very well highlighted by the World Health Organization in its pages dedicated to *Essential medicines and health products – Medicines Pricing and Financing*: <https://www.who.int/medicines/areas/access/en/>

Promoting affordable and fair pricing and effective financing

Equitable access to essential, high-quality and affordable essential medicines and other medical technologies depends on affordable and fair pricing and effective financing schemes. Promoting affordable and fair prices and cost-effective interventions is central to the achievement of universal health coverage.

An ‘affordable and fair’ price is one that can reasonably be funded by patients and health budgets and simultaneously sustains research and development, production and distribution within a country.

Medicines prices are not static

The ‘price’ of a medicine or a technology is generally a function of markets, and changes over time. Prices can be measured and evaluated as the price paid to the manufacturer, the price paid by the consumer or patient, or prices from suppliers. Typically, a new medicine is launched under patent and may have a high price until the patent expires and competition and/or generic products emerge. Prices of generic versions that are registered following patent expiry usually decrease rapidly, often by more than 90% compared to originator brand.

Many countries are unable to benefit from lower priced generics due to delays with market entry or lack of effective competition. However, public pressure and legal challenges decreased the price of several antiretroviral medicines in countries with high burdens of human immunodeficiency virus before patent expiry.

Flexibilities under the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement allow countries to gain access to medicines that in other countries may still be under patent, in the interest of public health.

High medicines prices: a growing challenge for health systems

Currently, high prices of many new medicines are challenging public health care systems or patients who have to pay for them out of pocket (as is the situation in most low- and middle-income countries). The recent approval of novel high-priced medicines for many conditions has prompted a new global debate on medicine costs and calls for a fair pricing model for both drug development and drug supply.

Strategies for measuring, monitoring and managing prices are essential for promoting access to medicines. There is not one single approach that suits all systems. But all systems need to promote equity in access to new products, by ensuring that medical advances are affordable and working with a viable pharmaceutical industry that responds to public health needs.

Almost all high-income countries with largely publicly funded medicines expenditures control and regulate medicines through a range of policy measures. These are also relevant for low- and middle-income countries, especially for systems working towards implementing universal health coverage.

These considerations set the basis for high level policies on the pricing of Medicines and Brand Drugs, and the topic of the cost of Medicines, and of cancer drugs in particular, is object of many studies in the most relevant medical journals worldwide.

In a 2015 article published in THE LANCET – Oncology (**“Actual costs of cancer drugs in 15 European countries”** – [http://dx.doi.org/10.1016/S1470-2045\(15\)00486-6](http://dx.doi.org/10.1016/S1470-2045(15)00486-6)), highlights the difficulties in analysing the prices of cancer drugs, as these do not show clear correlations with external factors that normally account for price levels and fluctuations of other kinds of goods and

technologies (e.g. currency exchange rates, cost of input prices, etc.). The article presents statements like:

- *The financial sustainability of cancer services as part of national health systems is a major challenge; oncology consumes up to 30% of total hospital expenditure and the amount spent on expensive cancer drugs is rising fast*
- *One element increasingly under scrutiny is the pricing policy of pharmaceutical companies. Both in the recent American Society of Clinical Oncology (ASCO) meeting*
- *and in various publications, attention has been drawn to the lack of transparency on the pricing of various drugs.*
- *An overview of actual prices in European countries does, to our knowledge, not exist, and anecdotal evidence has suggested that differences in price levels might be high.*
- *We noted that official or list prices differ substantially between countries (up to 92% lower than the highest), and actual prices also differ between countries (up to 58%*
- *lower). Additionally, reductions on list prices were very different between countries.*
- *No correlation of cost with the existence of central purchasing authorities could be found*
- *If a pattern can be detected, we conclude that pricing seems to be highest in the wealthier countries such as the Netherlands, but a strict association between GDP per person and pricing level could not be established*
- *In some cases only list or official prices were available or only one official price, because of central purchasing. Many institutions report that confidentiality clauses in their contracts make it difficult for them to freely report prices they pay.*
- *To date, the pharmaceutical industry has not presented transparent explanations or calculations underlying their pricing decisions.*
- *In conclusion, we noted substantial price differences in the prices of cancer drugs in this illustrative example from 15 European countries.*

Similar remarks were reported more recently in article “**Pricing of oral generic cancer medicines in 25 European countries; findings and implications**”, published in 2019 in the Generics and Biosimilars Initiative Journal (GaBI Journal) – <http://gabi-journal.net/pricing-of-oral-generic-cancer-medicines-in-25-european-countries-findings-and-implications.html>

Authors found the following issues: (a) *variable approaches to the pricing of generic cancer medicines, which will continue;* (b) *no concerns with substitution for oral generic cancer medicines;* (c) *substantial price reductions versus originators for generic capecitabine (up to -93.1%), generic imatinib (up to -97.8%) and generic temozolomide (up to -80.7%). Prices for oncology medicines are not generally indication specific, and are not affected by population size although influenced by pricing approaches. There have also been price increases for some non-patented cancer medicines following manufacturer changes although now stabilizing.*

The following paragraph is particularly relevant for the approach we have followed in the present analysis:

In general, prices for generic medicines in Europe are 20% to 80% below originator prices; however, some generics can be priced as low as 2% to 4% of the originator price before the patent was lost. As a result, substantial differences can occur in the prices of generics across Europe. Overall, low prices can potentially be achieved for generic cancer medicines because of the low cost of goods that have been reported at just 1% or more of originator prices for some new cancer medicines.

These low cost of goods have already resulted in considerable discounts for generic imatinib across countries versus pre-patent loss prices. However, this is not universal. For instance, in China, generic imatinib is only 10%–20% below originator prices although generic capecitabine is 50% lower than originator prices. There have also been low prices for generic versions of paclitaxel in Europe at just over 1% of originator prices. Docetaxel also has a low price in some European markets enhanced by an appreciable number of generic versions available. Having said this, changes in the manufacturer have resulted in the prices of some low volume old anticancer medicines rising appreciably among European countries including Italy and the UK. However, pharmaceutical companies are now being fined for such behaviour.

Finally, in 2018 the **World Health Organization** published a technical report on **“Pricing of cancer medicines and its impact”**. According to this report, *“The literature describes four broad determinants of medicine prices from the industry perspective: (a) costs of R&D; (b) costs of production and commercialization; (c) the “value” of medicine; and (d) sufficient returns on R&D.”* but the WHO remarks that *“Overall, the analysis suggests that the costs of R&D and production may bear little or no relationship to how pharmaceutical companies set prices of cancer medicines. Pharmaceutical companies set prices according to their commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine. This pricing approach often makes cancer medicines unaffordable, preventing the full benefit of the medicines from being realized.”*

Having such evidence of the extreme variability of the prices of cancer drugs in different countries and over the course of time, with very limited correlation with input prices or other common factors, in line with the literature retrieved **we could not establish any clear link between the variation of prices paid by Crown Agents in 2019 compared to the prices paid in 2018 and 2015, and possible contributing factors such as the variation of currency exchange rates and the change in input prices (API price trends).**

Instead, we see that **elements such as the selection of new suppliers providing a different Brand Drug for the same Medicine (e.g. with the availability of alternative generics and biosimilars) and the procurement of higher volumes of drugs, can lead to significant efficiencies in procurement and overall cost reductions.**

In the next paragraphs we provide analytical evidence of the effectiveness of procurement for the list of cancer drugs purchased by Crown Agents in 2019, and we'll provide considerations and explanations, taking into account the limitations and specific characteristics of the pricing of cancer medicines as we have here highlighted.

RESULTS OF THE ANALYSIS

Price variations

As already highlighted, we have received all pricing information regarding the Medicines purchased by Crown Agents in 2019. For 2018, we have a list of prices for each Medicine with one to one correspondence with the Medicines purchased by Crown Agents in 2019. The procurement in 2018 was not managed by Crown Agents, therefore we do not have any details regarding the Brand Drugs for each Medicine, however the coverage of most Medicines makes this comparison very significant. For 2015, the procurement was managed by Crown Agents, therefore we have the detailed list of Medicines procured including all Brand Drugs details; the correspondence with 2019 is not complete, but a significant number of Medicines correspond, so we could perform a significant analysis also in this case. No data has been made available for years 2017 and 2016. We have therefore considered the Medicines purchased in years 2019, 2018 and 2015.

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2019 compared to 2018 and 2015 in terms of best value for money and individual item/overall savings.

For each Medicine we conducted two kinds of cost analysis:

- 1) **Variation of the price per unit 2018->2019 and 2015->2019 for each Medicine** (% increase or decrease)
- 2) **Improvement of the overall spending for each programme** comparing the “Supplier value” for 2019 to the cost Crown Agents would have incurred to purchase the same number of each item at 2018 and 2015 prices.

It's important to understand that both aspects are important. In fact, only considering the % increase or decrease of the price per unit for individual items could lead to wrong conclusions because improving the procurement efficacy for high volume/high cost items is much more important than achieving efficacy for low volume/low cost items. It's therefore necessary to also consider the total volume of purchased items: this cost analysis provides for each programme a synthetic indicator of the efficacy achieved in percentage terms and in absolute \$ values.

Variation of the price per unit for each Medicine

We have included in the analysis all Medicines where a correspondence could be found between the list of 2019 and the lists of 2018 and 2015. We considered only the correspondence of Medicines, regardless of the exact correspondence of the related Brand Drugs; this was done because for 2018 we did not have any information regarding the Brand Drugs purchased (85 Medicines are covered), and for 2015 the correspondence between Brand Drugs was exact only for 32 Medicines out of 56. However, the analysis is significant because choosing a different Brand

Drug for the same Medicine is part of the overall procurement strategy and is an important way to achieve procurement efficacy.

The main statistical indicators are summarized below:

Period	Price difference observations (n)	Mean difference	Median difference	Lowest difference	Highest difference
2018-2019	85	+7.64%	-2.54%	-85.34%	+400.75%
2015-2019	56	-31.89%	-46.28%	-97.95%	+292.28%

Table 1 – Price difference indicators

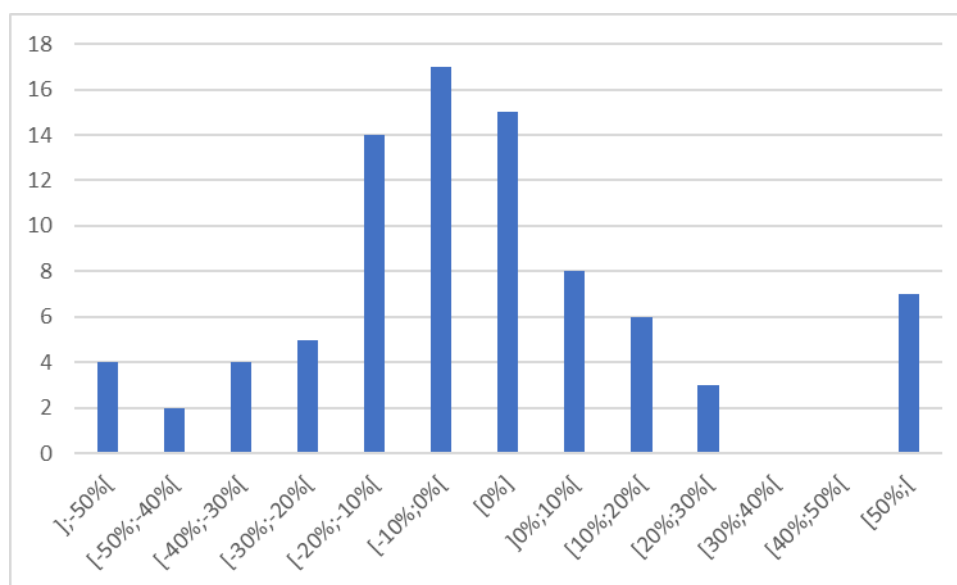


Figure 1 – Banding of price variations 2018-2019

The variation of prices from 2018 to 2019 for individual Medicines show that **for 61 of the 85 Medicines considered (71.8%) the price has remained stable or has decreased**. Most of the Medicines had a variation between -20% and +10%, although there were some individual extreme variations.

The mean of price variations across all Medicines considered show an increase of +7.64%, while the median of price variations is a 2.54% reduction. As we have already highlighted, though, these values have little significance because it’s much more important to achieve price reductions for the most expensive Medicines, and this effect is analysed in the next paragraph “*Improvement of the overall spending*”.

Since no information is available regarding the Brand Drugs purchased in 2018 and the quantities for each Medicine, we can’t draw any further considerations regarding these factors.

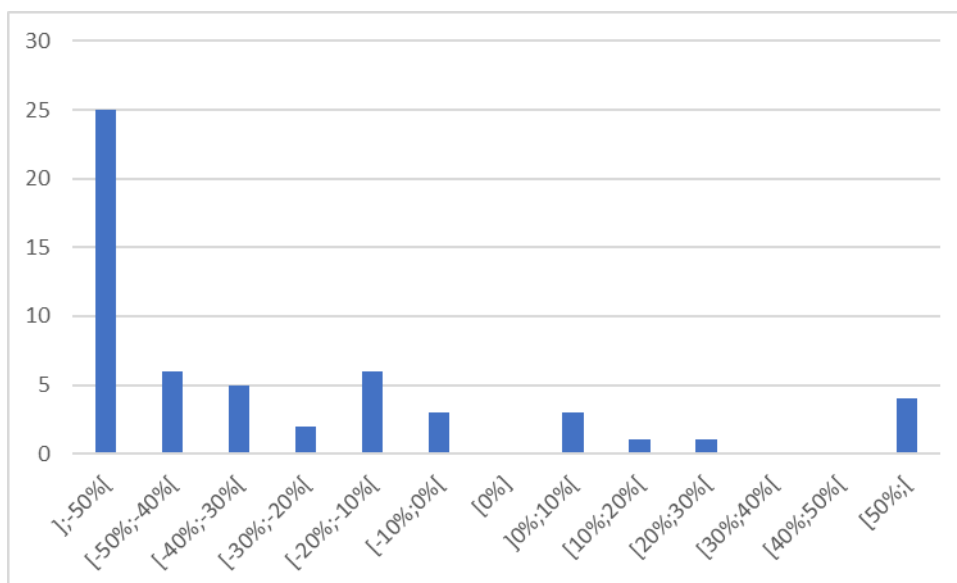


Figure 2 – Banding of price variations 2015-2019

The variation of prices from 2015 to 2019 for individual Medicines are much more relevant than the variations from 2018 to 2019. This can be explained in terms of the high dynamics of the pricing of cancer drugs in international markets, with the development of new drugs, the expiration of patents and the availability of new generics and biosimilars. The data show that **for 47 of the 56 Medicines considered (83.9%) the price has decreased.**

The mean of price variations across all Medicines considered show a decrease of 31.89%, while the median of price variations is a 46.28% reduction. Again, these values have little significance because it's much more important to achieve price reductions for the most expensive Medicines, and this effect is analysed in the next paragraph "Improvement of the overall spending".

For 24 of the 56 Medicines considered there was a change of Brand Drug, and 22 of these have decreased in price.

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we made a linear regression analysis. In doing this we have removed two outliers (with quantity variations of +20.000%). A plot of changes in prices versus changes in quantities is represented below. Although a trend of price decrease linked to the increase in purchased quantities is graphically visible, the correlation between these two variables is very low ($R^2=0,079$; $p=0,04$), therefore we conclude that the price variations were not strictly linked to the variations in the quantities purchased.

It's also significant to highlight that the quantities purchased in 2015 for most of the Medicines are much lower than those purchased in 2019. The overall effect (increased quantities and reduced prices) will be discussed in the next paragraph "Improvement of the overall spending".

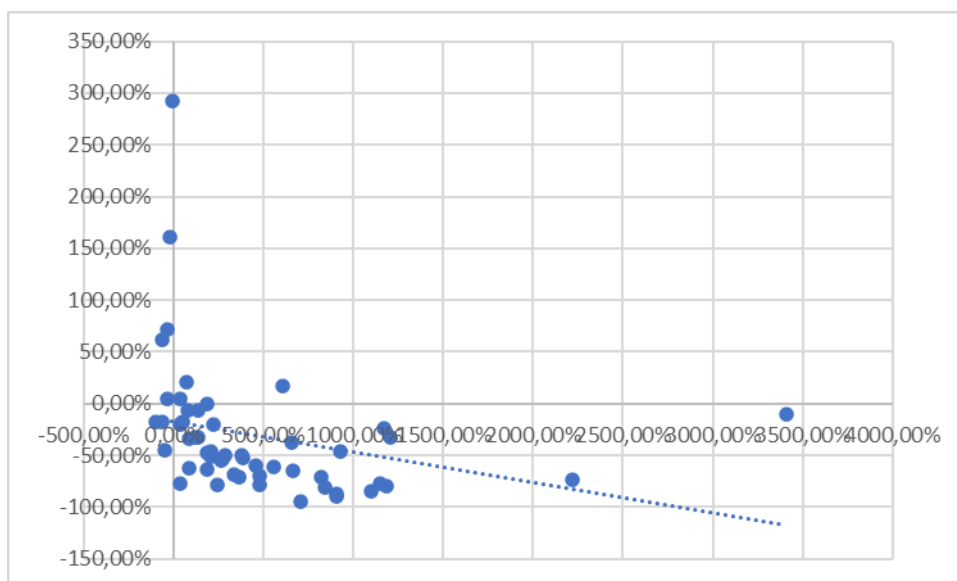


Figure 3 – Change in prices relative to change in quantities 2015-2019

Improvement of the overall spending

As we have mentioned in the introductory general considerations, only considering the % increase or decrease of the price per unit for individual items could lead to wrong conclusions because improving the procurement efficacy for high volume/high cost items is much more important than achieving efficacy for low volume/low cost items and vice versa. It's therefore necessary to also consider the total volume of purchased items.

Here we present the improvement of the overall spending comparing the “Supplier value” for 2019 to the cost Crown Agents would have incurred to purchase the same number of each item at 2018 and 2015 prices.

Supplier value 2019 (for 85 Medicines that have a corresponding price in 2018)	Supplier value 2019 at 2018 prices	Savings achieved in 2019	% reduction relative to 2018 prices
\$33.724.169,67	\$37,670,133.51	\$3,945,963.84	10.48%

Table 2 – Total savings 2018-2019

This table highlights the actual savings achieved through the procurements of Medicines in 2019 compared to the prices paid in 2018 (assuming the same quantities of 2019 for both years).

Supplier value 2019 (for 56 Medicines that have a corresponding price in 2015)	Supplier value 2019 at 2015 prices	Savings achieved in 2019	% reduction relative to 2015 prices
\$25,970,596.74	\$88,384,142.36	\$62,413,545.62	70.61%

Table 3 – Total savings 2015-2019

This table highlights the actual savings achieved through the procurements of Medicines in 2019 compared to the prices paid in 2015 (assuming the same quantities of 2019 for both years). As we have already discussed, the quantities purchased in 2015 were much lower for almost all Medicines than those purchased in 2019, but these data are very significant to show the improvement in procurement efficacy achieved in 2019. Purchasing the same quantities of cancer Medicines at 2015 prices would have costed an extra budget of more than \$60M, with a significant impact on the actual possibility to purchase these Medicines for the people of Ukraine.

The main explanation for this big improvement is the selection of different Brand Drugs made available thanks to the availability of new generics and biosimilars, and the price decrease from some of the same Brand Drugs due to improved negotiations, more volumes and the presence of competing alternatives on the market.

Quality

In this report we are not assessing that all the Brand Drugs purchased have fulfilled the requirements to be placed on the Ukrainian market as this should be an obvious pre-requisite for tender participation and overall procurement by Crown Agents. However, we have examined if the selected products can also be found in international markets and if they received an official approval by drug regulatory authorities (SRA-Stringent Regulatory Authority). For the Brand Drugs where we could not find an SRA record, we have searched for GMP (Good Manufacturing Practices) certificates for the corresponding manufacturer. We have focused this analysis on the Top 30 Medicines in terms of overall expenditure (sum of column “Supplier value”).

As a first step we have searched the specific Brand Drugs in the database of the European Medicine Agency on the website <https://www.ema.europa.eu/en/medicines>

For the Brand Drugs that we could not find in the EMA database, we have made a further research in the website of the Italian drug agency Agenzia Italiana del Farmaco (AIFA) <https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci>

We have then searched for the remaining Brand Drugs in additional data banks.

Finally, for the Brand Drugs where no SRA approval could be found, we have checked the websites of their manufacturers and retrieved evidence of Good Manufacturing Practice GMP certification.

The overall results of this analysis are summarised in the following table:

Type of certification		Number	Sub-total	Percentage
SRA	EMA	15	22	73.3%
	AIFA	2		
	OTHER	5		
GMP		4	4	13.3%
No certification		4	4	13.3%

Table 4 – Quality of Brand Drugs: SRA authorization, GMP

The vast majority of the Brand Drugs purchased in 2019 by Crown Agents are SRA approved or come from manufacturers with GMP certification (86.6%).

There is clearly no evidence to suggest that prices have decreased due to sourcing from manufacturers with lower quality standards.

International price benchmarking

In order to provide a comparison of the prices paid by Crown Agents in 2019 with the international prices for the same Medicines, we have focused this analysis on the Top 30 Medicines in terms of overall expenditure (sum of column “Supplier value”).

We have explored many international sources of drug prices and found available information from the following:

- **Public price lists approved by ministries of health/national drug authorities** for: Czech Republic, Slovak Republic, Moldova, Saudi Arabia, Brazil, Italy
- **Publicly available procurement data** from WHO MSH International Medical Products Price Guide (ed. 2015)
- **Public tenders awarding** documents in Italy

The public price lists from national drug authorities are usually higher than actual procurement prices, but for most countries is the only publicly available source of data. The WHO MSH and Italian public tenders are more realistic data points to consider (for both of these we considered the median of the available price points collected).

In order to compare all values in US Dollars we have used the average yearly conversion rates (at 31st December 2019) as published by the OECD <https://data.oecd.org/conversion/exchange-rates.htm>

OECD data are available for all currencies except for the LEU (Moldova) where we used the exchange rate provided by the National Bank of Moldova <https://www.bnm.md/en/content/official-exchange-rates> as of 31st December 2019.

Public price list: Czech Republic

Official information for Czech Republic is available online on the website of the State Institute for Drug Control (SUKL – Státní Ústav pro Kontrolu Léčiv)

<http://www.sukl.cz/modules/medication/search.php>

All Medicines can be searched online and the website provides results on all the Brand Drugs registered in the country. For most of these Brand Drugs the official pricing is published, and the following data are presented (with additional information of the characteristics of the drug):

- Maximum ex-factory price
- Maximum reimbursement from health insurance
- Rough price for the final consumer
- Rough payment for the final consumer (for 1 prescribed package dispensed)

We have considered the Maximum ex-factory price, that is generally lower than the price for the final consumer.

We found prices for 23 of the top 30 Medicines. Of these, in 7 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 16 we have selected the lower priced alternative Brand Drug available.

CrownAgents prices are better for 20 of these 23 (87.0%).

Exchange rate: 1 CZK=0,0436 USD

Public price list: Slovak Republic

Official information for Slovak Republic is available online on the website of the Ministry of Health (Ministerstvo zdravotníctva Slovenskej Republiky)

<https://www.health.gov.sk/?kategorizacia-a-ceny>

The webpage presents the lists of categorized medicines with monthly updates from January 2018 to the current date. We have downloaded the file *Ceny_Lieky_cast_B_k_01_12_2019.xls* with the list of oncology drugs valid at the end of 2019.

This list of officially priced medicinal products presents the following data:

- Progressive number
- ATC code
- State code
- Name of the Brand Drug

- Details of the packaging
- Registration holder code
- Country of the registration holder
- Official price

We found prices for 17 of the top 30 Medicines. Of these, in 10 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 7 we have selected the lower priced alternative Brand Drug available.

CrownAgents prices are better for 16 of these 17 (94.2%).

Exchange rate: 1 EUR=1,12 USD

Public price list: Moldova

Official information for Moldova is available online on the website of the Medicines and Medical Devices Agency (AMDM – Agenția Medicamentului și Dispozitivelor Medicale)

<http://nomenclator.amdm.gov.md>

The list of drugs can be viewed online and a complete excel file can also be downloaded. We have retrieved file *MOLDOVA-nomenclator-preturi.xls* that presents a lot of data, such as:

- Brand Drug
- Pharmaceutical form
- Dose
- Volume
- Holder of the certificate of registration of the drug
- ATC code
- Name of the Medicine
- Ex-factory price

We found prices for 12 of the top 30 Medicines. Of these, we could not find exactly the same Brand Drug as the one purchased by Crown Agents in 2019, therefore we have selected the lower priced alternative Brand Drug available.

CrownAgents prices are better for 10 of these 12 (83.3%).

Exchange rate: 1 MDL=0,058 USD

Public price list: Saudi Arabia

Official information for Saudi Arabia is available online on the website of the Saudi Food & Drug Authority SFDA

<https://www.sfda.gov.sa/ar/drug/search/Pages/default.aspx>

All Medicines can be searched online and a complete excel file can also be downloaded. We have retrieved file *Human-Drug-List.csv* that presents a lot of data, such as:

- Registration number
- Trade name (Brand Drug)
- Concentration and its unit
- Pharmaceutical form
- Size/Unit size/Package size
- Agent
- Price
- ATC Code 1

We found prices for 15 of the top 30 Medicines. Of these, in 7 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 8 we have selected the lower priced alternative Brand Drug available.

Crown Agents prices are better for 14 of these 15 (93.3%).

Exchange rate: 1 SAR=0.27 USD

Public price list: Brazil

Official information for Brazil is available online on the website of the Medicines and Medical Devices Agency (ANVISA – Agencia Nacional de Vigilancia Sanitaria)

<http://portal.anvisa.gov.br/listas-de-precos>

The list of Medicines Prices includes the Factory Price or Manufacturer Price (PF), which is the price to be practiced by manufacturers, importers or distributors. The PF is the maximum price allowed for sale to pharmacies, drugstores and to entities of the Public Administration.

This List also presents the Maximum Consumer Price (PMC), which is the price to be practiced by the retail trade of medicines, that is, pharmacies and drugstores, considering that this includes both the profit margin and the inherent taxes to these types of trade.

The Maximum Selling Price to the Government – PMVG is the result of applying the Price Adequacy Coefficient (CAP) to the Factory Price – PF, $PMVG = PF * (1-CAP)$. CAP is a mandatory minimum discount to be applied whenever sales of medications are included in the list.

We have retrieved file *xls_conformidade_gov_site_2019_11_14* that presents a lot of data, such as:

- Name of the Medicine
- Manufacturer
- Brand Drug
- Pharmaceutical form
- Type of product (generic, biosimilar, etc.)
- PF price (without tax and with different tax rates according to the specific Brazilian state)
- PMVG (without tax and with different tax rates according to the specific Brazilian state)

We have considered the lowest possible price for each Medicine, that is the PMVG without tax.

We found prices for 22 of the top 30 Medicines. Of these, in 5 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 17 we have selected the lower priced alternative Brand Drug available.

Crown Agents prices are better for 19 of these 22 (86.4%).

Exchange rate: 1 BRL=0.255 USD

Public price list: Italy

Official information for Italy is available online on the website of the Italian Medicines Agency (AIFA – Agenzia Italiana del Farmaco)

<https://www.aifa.gov.it/liste-farmaci-a-h>

The webpage presents the lists of categorized medicines with last update 15/10/2019. We have downloaded the file *Classe_H_Per_nome_commerciale_16-09-2019.csv* with the list of oncology drugs valid at the end of 2019, including the following data:

- Name of the Medicine
- Brand Drug and pharmaceutical form
- Price to the public
- Price Ex-factory
- Maximum selling price
- Authorization holder

We have considered the lowest possible price for each Medicine, that is the Price Ex-Factory.

We found prices for 26 of the top 30 Medicines. Of these, in 12 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 14 we have selected the lower priced alternative Brand Drug available.

Crown Agents prices are better for 24 of these 26 (92.3%).

Exchange rate: 1 EUR=1,12 USD

Public tenders: Italy

All public entities in Italy (and public hospital in particular) have a legal obligation to publish all data related to their purchases of goods and services. The legal basis for this obligation is in a law of 2012 (law 190/2012) that in its article 1/32 states “... *the contracting stations are in any case required to publish on their institutional websites: the proposing structure; the subject of the announcement; the list of operators invited to tender; the contractor; the award amount; the timing of completion of the work, service or supply; the amount of the liquidated sums. The contracting authorities are also required to transmit the aforementioned information to the commission referred to in paragraph 2 every six months. By 31 January of each year, this information, with respect to the previous year, is published in summary tables which can be freely*

downloaded in a digital format an open standard that allows computer data to be analysed and re-processed, also for statistical purposes.”

These data are published in the form of huge excel files, where every line corresponds to a single purchase.

In addition to this, in the websites of all public hospitals in Italy there's a section named "Albo pretorio" where the hospital administration publishes daily their official documents related to all purchases of services and good. These documents (named "Delibere" or "Determine") often contain a lot of details of every single purchase, including the price offered by the company that was awarded the contract, and also the prices offered by the other companies that did not win. The actual information that can be retrieved this way varies case by case (price, quantities, etc.), and sometimes after a few weeks of publication the hospital removes the documents from their website. Retrieving the pricing information this way, therefore, implies downloading a lot of available documents and checking them one by one to find the relevant pricing information to be uploaded in the database.

For this analysis we have retrieved documents related to public tenders for the purchase of oncology drugs in Italy. We searched for at least 3 tenders for each Medicine considered, possibly from 2019 or the closest possible year of purchase.

We considered the median of the 3 prices we could retrieve for each Medicine.

We found prices for 25 of the top 30 Medicines. Of these, in 9 cases we found exactly the same Brand Drug as the one purchased by Crown Agents in 2019; for the remaining 16 we have selected tenders for other Brand Drugs for the same Medicines.

Crown Agents prices are better for 20 of these 25 (80.0%).

Exchange rate: 1 EUR=1.12 USD

WHO MSH International Medical Products Price Guide

The International Medical Products Price Guide was formerly known as the International Drug Price Indicator Guide. It provides a guide to pharmaceutical and medical products prices on the international market. The Guide, published by MSH (Management Sciences for Health) since 1986, and in collaboration with WHO (World Health Organization) since 2000, provides a spectrum of prices from non-profit suppliers and commercial procurement agencies, based on their current catalogues or price lists. It also contains prices obtained from international development agencies and from government agencies.

The document is available from the following website (latest version available is from 2015; the next edition will be published in July 2020):

<https://www.msh.org/resources/international-medical-products-price-guide>

For each Medicine the book presents one or more prices paid by different procurement agencies. The book does not present data for specific Brand Drugs.

We found prices for 15 of the top 30 Medicines. We have considered the median of the prices available.

Crown Agents prices are better for 9 of these 15 (60.0%).

The document presents prices in USD.

Summary of the international price benchmarking results

The results of the international benchmark of prices for the Medicines we have analysed are reported in the table below.

Country	Data source	Number of Medicines considered	Crown Agents price lower n.	Crown Agents price lower %
Czech Republic	State Institute for Drug Control - SUKL	23	20/23	87.0%
Slovak Republic	Ministry of Health	17	16/17	94.2%
Moldova	Medicines and Medical Devices Agency - AMDM	12	10/12	83.3%
Saudi Arabia	Saudi Food & Drug Authority - SFDA	15	14/15	93.3%
Brazil	Medicines and Medical Devices Agency - ANVISA	22	19/22	86.4%
Italy	Italian Medicines Agency - AIFA	26	24/26	92.3%
Italy	Public tenders	25	20/25	80.0%
International	MSH-WHO	15	9/15	60.0%

Table 5 – Summary of the international price benchmarking results

KEY FINDINGS

The present report analyses the prices of oncology drugs in Ukraine under the procurement Programme 3 “Chemotherapeutic agents, radiopharmaceuticals and support drugs for cancer patients” managed by Crown Agents in 2019, in comparison with prices paid in previous years and compared to international benchmarks.

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2019 compared to previous years where price data are available (2018 and 2015).

PRICE VARIATION OF INDIVIDUAL ITEMS

The variation of prices from 2018 to 2019 for individual Medicines show that for 61 of the 85 Medicines considered (71.8%) the price has remained stable or has decreased. Most of the Medicines had a variation between -20% and +10%, although there were some individual extreme variations.

The variation of prices from 2015 to 2019 for individual Medicines show that for 47 of the 56 Medicines considered (83.9%) the price has decreased.

This can be explained in terms of the high dynamics of the pricing of cancer drugs in international markets, with the development of new drugs, the expiration of patents and the availability of new generics and biosimilars.

The price variations from 2015 to 2019 were not strictly linked to the variations in the quantities purchased (no information on quantities is available for 2018)

TOTAL SAVINGS

The savings in 2019 for the 85 Medicines analysed in relation to 2018 have been \$3,945,963.84; an improvement of 10.48% relative to 2018 prices.

The savings in 2019 for the 56 Medicines analysed in relation to 2015 have been \$62,413,545.62; an improvement of 70.61% relative to 2015 prices.

The quantities purchased in 2015 were much lower for almost all Medicines than those purchased in 2019, but these data are very significant to show the improvement in procurement efficacy achieved in 2019. Purchasing the same quantities of cancer Medicines at 2015 prices would have costed an extra budget of more than \$60M, with a significant impact on the actual possibility to purchase these Medicines for the people of Ukraine.

The main explanation for this big improvement is the selection of different Brand Drugs made available thanks to the availability of new generics and biosimilars, and the price decrease from some of the same Brand Drugs due to improved negotiations, more volumes and the presence of competing alternatives on the market.

QUALITY

The vast majority of the Brand Drugs purchased in 2019 by Crown Agents are SRA approved or come from manufacturers with GMP certification (86.6%).

There is clearly no evidence to suggest that prices have decreased due to sourcing from manufacturers with lower quality standards.

PRICE BENCHMARKING

In order to provide a comparison of the prices paid by Crown Agents in 2019 with the international prices for the same Medicines, we have focused this analysis on the Top 30 Medicines in terms of overall expenditure.

The results of the international benchmark of prices for the Medicines we have analysed show that Crown Agents in 2019 got better prices for the vast majority of Medicines purchased.

Overall, the procurement activity by Crown Agents in 2019 compared to 2016 and 2015 proved effective, with significant cost savings, good quality products selected from reliable manufacturers and a price benchmark better than the international prices we considered for reference.

APPENDIX – LIST OF DRUGS

In the table below is the full list of drugs we have considered in this analysis. The list is strictly in alphabetical order (by generic name). The drugs in the Top 30 expenditure for 2019 are highlighted in blue.

Name (item description, generic name)	Brand name	Manufacturer	Supplier	Pack size
6-Mercaptopurine 50 mg tablet, capsule, pill	PURI-NETHOL™ 50 mg tablets bottle of 25 tablets	Excella GmbH & Co. KG, Germany	ASPEN	25
Amphotericin B - Lipid Complex 50 mg vial	AMPHOLIP, 5mg/ml suspension for solution for infusion 10 ml in vial 1 vial in box	Bharat Serums and Vaccines Limited, India	Bharat Serums and Vaccines Limited, India	1
Asparaginase 10 000 IU ampoule, vial, syringe	ONCONASE 10 L-Asparaginase for Injection 10000 KU 1 vial per pack	United Biotech (P) Limited, India	Pube Global	1
Bendamustine 25 mg ampoule, vial, syringe	BendamusVista, powder for concentrate for solution for infusion, 25 mg 1 vial in cardboard pack	Synthon, s.r.o., Czech Republic/ Synthon Hispania,S.L. Spain	Mistral Capital	1
Bendamustine 100 mg ampoule, vial, syringe	BendamusVista, powder for concentrate for solution for infusion, 100 mg 1 vial in cardboard pack	Synthon, s.r.o., Czech Republic/ Synthon Hispania,S.L. Spain	Mistral Capital	1
Bicalutamide, tablet, capsule, pill, 150 mg	BICALUTAMIDE-TEVA film-coated tablets, 150 mg 7 tablets in blister, 4 blisters in pack	Teva Pharmaceutical Industries Ltd., Israel	Actavis	28
Bicalutamide, tablet, capsule, pill, 50 mg	BICALUTAMIDE-TEVA film-coated tablets, 50 mg 7 tablets in blister, 4 blisters in pack	Teva Pharmaceutical Industries Ltd., Israel	Actavis	28
Bleomycin, ampoule, vial, syringe, 15 mg	BLEOCIN-S, lyophilisate for solution for injection, 1 vial (15 000 IU) in carton box,	"LUMIER PHARMA" LLC, Ukraine	Lumier Pharm	1
Bortezomib 1 mg ampoule, vial, syringe	BortezoVista, powder for concentrate for solution for injection, 1 mg 1 vial in cardboard pack	Synthon, s.r.o., Czech Republic/ Synthon Hispania,S.L. Spain	Mistral Capital	1
Bortezomib 3.5 mg ampoule, vial, syringe	BortezoVista, powder for concentrate for solution for injection, 3,5 mg 1 vial in cardboard pack	Synthon, s.r.o., Czech Republic/ Synthon Hispania,S.L. Spain	Mistral Capital	1
Bosutinib 100 mg tablet, capsule, pill	Bosulif® 100 mg film-coated tablets bosutinib 28 tablets per pack № 28 (14x2)	Pfizer Manufacturing Deutschland GmbH Germany	Pfizer	28
Bosutinib 500 mg tablet, capsule, pill	Bosulif® 500 mg film-coated tablets bosutinib 28 tablets per pack № 28 (14x2)	Pfizer Manufacturing Deutschland GmbH Germany	Pfizer	28
Calcium Folate 30 mg ampoule, vial, syringe	CALCIUM FOLINATE, solution for injection, 10 mg/ml 3 ml in ampoule; № 5 (5x1)	PJSC Lekhim-Kharkiv Ukraine	Lekhim	5

Calcium Folate 50 mg ampoule, vial, syringe	LEUCOVORIN-TEVA solution for injection, 10 mg/ml 5 ml in vial; 1 vial in cardboard pack	TEVA Pharmaceutical Works Private Limited Company, Hungary Pharmachemie B.V., Netherlands	Actavis	1
Calcium Folate 50 mg ampoule, vial, syringe	CALCIUM FOLINATE, solution for injection, 10 mg/ml 5 ml in ampoule; № 5 (5x1)	PJSC Lekhim-Kharkiv Ukraine	Lekhim	5
Calcium Folate 100 mg ampoule, vial, syringe	LEUCOVORIN-TEVA solution for injection, 10 mg/ml 10 ml in vial; 1 vial in cardboard pack	TEVA Pharmaceutical Works Private Limited Company, Hungary Pharmachemie B.V., Netherlands	Actavis	1
Capecitabine, tablet, capsule, pill, 150 mg	Apcibin, film coated tablets 150 mg, 10 tablets in blister; 1 or 6 blisters in a carton box	Dr. Reddy's Laboratories Ltd, India	Diatom	60
Capecitabine, tablet, capsule, pill, 500 mg	Capecitabine KRKA, film coated tablets 500 mg, 10 tablets in blister; 12 blisters in a carton box	Intas Pharmaceuticals Limited, India/ KRKA, d.d., Novo mesto, Slovenia	KRKA	120
Carboplatin 150 mg ampoule, vial, syringe	CARBOPLATIN "EBEWE" concentrate for solution for infusion, 10 mg/ml 15 ml (150 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Carboplatin 450 mg ampoule, vial, syringe	CARBOPLATIN "EBEWE" concentrate for solution for infusion, 10 mg/ml 45 ml (450 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Chlorambucil 2 mg #25 in vials tablet, capsule, pill	Leukeran® 2 mg Film-coated tablets bottle of 25 tablet	Excella GmbH, Germany	Aspen	25
Cisplatin 100 mg ampoule, vial, syringe	CISPLATIN "EBEWE" concentrate for solution for infusion, 1 mg/ml 100 ml (100 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Cisplatin 50 mg ampoule, vial, syringe	CISPLATIN "EBEWE" concentrate for solution for infusion, 0,5 mg/ml 100 ml (50 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Cladribine 2 mg/ml in 5 ml vials injection solution	Litak, injection solution, 2 mg/ml 5 ml vials in 5 vials pack	Lipomed AG Fabrikmattenweg 4, 4144, Arlesheim, Switzerland	Julko	5
Cyclophosphamide 1000 mg ampoule, vial, syringe	ENDOXAN®1g, powder for solution for injections 1 g,	Baxter Oncology GmbH, Germany	Baxter	1
Cyclophosphamide 500 mg ampoule, vial, syringe	ENDOXAN® 500 mg, powder for solution for injections 500 mg,	Baxter Oncology GmbH, Germany	Baxter	1
Cytarabine 1 000 mg ampoule, vial, syringe	Cytosar®, liophilisate for solution for injection 1000 mg , 1 vial in carton box	Actavis Italy S.p.A, Italy	Pfizer	1
Cytarabine 100 mg ampoule, vial, syringe	Cytosar®, liophilisate for solution for injection 100 mg , liophilisat in 1 vial and 5 ml ampoule with solvent (BnOH, water for injection) in carton box	Actavis Italy S.p.A, Italy	Pfizer	1

Dacarbazine, ampoule, vial, syringe, 200 mg	DACARBAZIN MEDAC, powder for solution for injection or infusion, 200 mg 10 vials in pack	Medac Gesellschaft fur klinische Spezialpraparate m.b.H., Germany	BADM	10
Dasatinib 20 mg tablet, capsule, pill	Dazatinib-Vista, film-coated tablets, 20 mg 30 or 60 tablets in vial, 1 vial in cardboard pack	Synthon Hispania,S.L. Spain	Mistral Capital	60
Dasatinib 50 mg tablet, capsule, pill	Dazatinib-Vista, film-coated tablets, 50 mg 30 or 60 tablets in vial, 1 vial in cardboard pack	Synthon Hispania,S.L. Spain	Mistral Capital	60
Daunorubicin 20 mg vial	DAUNOBLASTINA, powder and solvent for solution for injection, 20 mg, powder in 1 vial with solvent in 1 ampoule (sodium chloride, water for injection) in cardboard pack	Actavis Italy S.p.A, Italy	Pfizer	1
Docetaxel, ampoule, vial, syringe, 20 mg	DOCETAXEL "EBEWE" concentrate for solution for infusion, 10 mg/ml 2 ml (20 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Docetaxel, ampoule, vial, syringe, 80 mg	DOCETAXEL "EBEWE" concentrate for solution for infusion, 10 mg/ml 8 ml (80 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Doxorubicin 100 mg ampoule, vial, syringe	DOXORUBICIN "EBEWE" concentrate for solution for infusion, 2 mg/ml 50 ml (100 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Doxorubicin, ampoule, vial, syringe, 50 mg	DOXORUBICIN "EBEWE" concentrate for solution for infusion, 2 mg/ml 25 ml (50 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Epirubicin 50 mg ampoule, vial, syringe	Episindan, lyophilisate for solution for infusion, 50 mg, 1 vial in cardboard pack	S.C. Sindan-Pharma S.R.L., Romania Actavis Italy S.p.A., Italy	Actavis	1
Epirubicin 10 mg ampoule, vial, syringe	Episindan, lyophilisate for solution for infusion, 10 mg 1 vial in cardboard pack	S.C. Sindan-Pharma S.R.L., Romania Actavis Italy S.p.A., Italy	Actavis	1
Etoposide 200 mg ampoule, vial, syringe	ETOPOSID "EBEWE" concentrate for solution for infusion, 20 mg/ml 10 ml (200 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Etoposide, ampoule, vial, syringe, 100 mg	ETOPOSID "EBEWE" concentrate for solution for infusion, 20 mg/ml 5 ml (100 mg) in vial 1vial in cardboard pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Exemestane, tablet, capsule, pill, 25 mg	Aromasin®, suger-coated tablets 25 mg № 30 (15x2) in blisters	Pfizer Italia S.r.l. Italy	Pfizer	30
Filgrastim, 48 mil IU, ampoule, vial, syringe	ZARZIO® solution for injection or infusion, 48 MU/0,5 ml 0,5 ml solution in syringe, with plunje, needle, tip cap and protection mechanism to prevent injury after injection, in blister packaging 1 or 5 blister packagings in cardboard pack	Sandoz GmbH - BP Kundl, Austria	Sandoz	5

Fludarabine 50 mg ampoule, vial, syringe	Fludarabine Phosphate for Injection, USP 50mg/50ml 1 vial in pack	Zydus Hospira Oncology Private Limited, India	Pfizer	1
Fluorouracil 500 mg ampoule, vial, syringe	5-FLUOROURACIL "EBEWE" concentrate for solution for infusion, 50 mg/ml 10 ml (500 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Gemcitabine, ampoule, vial, syringe , 1 000 mg	GEMTERO, lyophilisate for solution for infusion 1,0 g, 1 g in vial; 1 vial in a cardboard box	Hetero Labs Limited, India	Hetero	1
Gemcitabine, ampoule, vial, syringe, 200 mg	GEMTERO, lyophilisate for solution for infusion 200 mg, 200 mg in vial; 1 vial in a cardboard box	Hetero Labs Limited, India	Hetero	1
Goserelin, ampoule, vial, syringe, 10.8 mg	ZOLADEX, capsule for subcutaneous administration of prolonged action, 10.8 mg 1 capsule in a syringe applicator in box	AstraZeneca UK Limited, United Kingdom	AstraZeneca UK Limited	1
Goserelin, ampoule, vial, syringe, 10.8 mg	GOSERELIN ALVOGEN, implant 10.8 mg 1 implant in syringe applicator in box	AMW GmbH Arzneimittelwerk, Germany	R pharma	1
Hydroxycarbamide 500 mg tablet, capsule, pill	HYDROXYCARBAMID TEVA, 500 mg, 100 capsules per pack	Teva Czech Industries s.r.o., Czech	Mepha	100
Idarubicin 5 mg ampoule, vial, syringe	Zavedos, Lyophilisate for Solution for infuzion 5 mg, 1 vial per pack	Actavis Italy S.p.A, Italy	Pfizer	1
Ifosfamide 1 000 mg ampoule, vial, syringe	HOLOXAN® 1 g, powder for solution for injections 1 g vial № 1	Baxter Oncology GmbH, Germany	Baxter	1
Imatinib 100 mg tablet, capsule, pill	IMATERO®, film coated tablets 100 mg, 10 tablets in a blister; 1 or 10 blisters in a cardboard box	Hetero Labs Limited, India	Hetero	100
Imatinib 400 mg tablet, capsule, pill	IMATERO®, film coated tablets 400 mg, 10 tablets in a blister; 1 or 10 blisters in a cardboard box	Hetero Labs Limited, India	Hetero	100
Interferon Alpha-2b 3 mil IU ampoule, vial, syringe	Laferobionum® lyophilizate for injection solution 3 000 000 IU 10 vials in pack	LLC "PP "BIOFARMA", Ukraine	BioFarma	10
Irinotecan 300 mg ampoule, vial, syringe	Irinotecan Amaxa, concentrate for solution for infusion, 20 mg/ml 15 ml in vial; 1 vial in cardboard pack	AqVida GmbH, Germany	Amaxa	1
Irinotecan, ampoule, vial, syringe, 100 mg	Irinotecan Amaxa, concentrate for solution for infusion, 20 mg/ml 5 ml in vial; 1 vial in cardboard pack	AqVida GmbH, Germany	Amaxa	1
Lenalidomide 10 mg tablet, capsule, pill	LENANGIO, 10 mg capsules 28 capsules in container, 1 container in carton box	Dr. Reddy's Laboratories Ltd, India	BADM	28
Lenalidomide 25 mg tablet, capsule, pill	Lenalidomide-Vista, 25 mg in harde capsules, 3 capsules in blister, 7 blisters in cardboard pack	Synthon Hispania,S.L. Spain	Mistral Capital	21
Letrozole, tablet, capsule, pill, 2.5 mg	LETROVISTA, film-coated tablets, 2,5 mg, 10 tablets in a blister; 3 blisters per carton	Synthon Hispania,S.L. Spain	Mistral Capital	30

Lomustine 40 mg tablet, capsule, pill	LOMUSTINE MEDAC, 40 mg capsules 20 capsules per container	Medac Gesellschaft fur klinische Spezialpreparate m.b.H., Germany	BADM	20
Melphalan 2 mg tablet, capsule, pill	ALKERAN® 2 mg Film-coated tablets bottle of 25 tablets	Excella GmbH & Co. KG, Germany	Aspen	25
Mesna 400 mg ampoule, vial, syringe	UROMITEXAN® 400 mg, solution for injections, 100 mg/ml ampoule 4 ml (400 mg) №15	Baxter Oncology GmbH, Germany	Baxter	15
Methotrexate 1 000 mg ampoule, vial, syringe	METHOTREXATE-TEVA solution for injection, 100 mg/ml 10 ml in vial; 1 vial per pack	Pharmachemie B.V., Netherlands	Teva	1
Methotrexate, ampoule, vial, syringe, 50 mg	METHOTREXATE-TEVA solution for injection, 25 mg/ml 2 ml in vial; 1 vial per pack	Pharmachemie B.V., Netherlands	Actavis	1
Mitoxantrone 20 mg ampoule, vial, syringe	MITOXANTRON "EBEWE" concentrate for solution for infusion, 2 mg/ml 10 ml (20 mg) in vial 1vial per pack	EBEWE Pharma Ges.m.b.H Nfg. KG, Austria	Sandoz	1
Nilotinib 200 mg tablet, capsule, pill	TASIGNA, hard capsules, 200 mg 14 capsules in blister; 2 blisters in carton	Novartis Pharma Stein AG, Switzerland	BaDM	28
Oxaliplatin 100 mg	Oxaliplatin 5 mg/ml concentrate for solution for infusion, 20 ml 1 vial in pack to be registered	Accord Healthcare Limited, United Kingdom/ Intas Pharmaceuticals Limited, India	Accord	1
Oxaliplatin 50 mg	Oxaliplatin 5 mg/ml concentrate for solution for infusion, 10 ml 1 vial in pack to be registered	Accord Healthcare Limited, United Kingdom/ Intas Pharmaceuticals Limited, India	Accord	1
Paclitaxel 30 mg ampoule, vial, syringe	PACLITERO®, concentrate for solution for infusion, 6 mg/ml, 5 ml (30 mg) in vial; 1 vial in a cardboard box	Hetero Labs Limited, India	Hetero	1
Paclitaxel, ampoule, vial, syringe, 100 mg	PACLITERO®, concentrate for solution for infusion, 6 mg/ml, 16,7 ml (100mg) in vial; 1 vial in a cardboard box	Hetero Labs Limited, India	Hetero	1
PEG-Asparaginase 3 750 IU ampoule, vial, syringe	ONCASPAR, powder for solution for injection/infusion, 750 IU/ml 5 ml in vial; 1 vial in cardboard pack will be submitted for registration	Les Laboratoires Servier Industrie, France	Servier	1
Piperacillin/Tazobactam 4 500 (4 000/ 500 mg) ampoule, vial, syringe	AUROTAZ-P, powder for solution for injection 4,5 g in vial, 1 vial in cardboard box № UA/12809/01/02 unlimited	Aurobindo Pharma Limited, Unit-XII/India	BADM	1
Procarbazine 50 mg tablet, capsule, pill	Glocarbazin Capsule 50 mg 10 capsules in pack	Globela Pharma Pvt. Ltd, India	Pube Global	10
Radiopharmaceuticals, Samarium (153Sm) Lexidronam Samarium (153Sm) Oxabifor 2 000 MBq in 10 ml vials injection solution				
Radiopharmaceuticals, Sodium iodide Na131I for injections 4 000 MBq injection solution	SODIUM IODIDE Na131I INJECTION solution for injection 37-740 MBq/ml, in vial 10 ml, 4000 MBq portions in 10 ml vial, 1 vial in 1 lead container	National Centre for Nuclear Research, Poland	Izotop	1

Radiopharmaceuticals, Sodium Iodide Na131I POLATOM 4 000 MBq hard capsule	Sodium Iodide Na131I POLATOM hard capsule 5500MBq, 1 hard capsule in polyethylene vial in a lead protective container	National Centre for Nuclear Research, Poland	Izotop	1
Radiopharmaceuticals, Technetium (99mTc) Pertechnetate Poltechnet 15 000 MBq radionuclide generator (solution in a vial is obtained from the generator 99mTc by means of elution)	Poltechnet radionuclide generator (solution in a vial is obtained from the generator 99mTc by means of elution), Radionuclide generator, 15 GBq, in vial 10 ml no 1 in package along with the elution kit, consisting of two cardboard packages: one- with 16 vials with 10 ml of eluent (solution 9mg/ml (0,9%) NaCl), the second one - with 16 vacuum vials intended for eluate) and container for transportation № UA/3526/01/01 till 26.08.2021	National Centre for Nuclear Research, Poland	Izotop	1
Rituximab 100 mg ampoule, vial, syringe	RIXATHON, concentrate for solution for infusion, 10 mg/ml 1 or 2 vials of 10 ml (100 mg) in cardboard pack	Sandoz GmbH – Business Unit Biologics Technical Development and Manufacturing Drug Product Schaffhausen (BTDM DPS), Austria	Sandoz	2
Rituximab 500 mg ampoule, vial, syringe	RIXATHON, concentrate for solution for infusion, 10 mg/ml 1 or 2 vials of 50 ml (500 mg) in cardboard pack	Sandoz GmbH – Business Unit Biologics Technical Development and Manufacturing Drug Product Schaffhausen (BTDM DPS), Austria	Sandoz	1
Tamoxifen 20 mg tablet, capsule, pill	TAMOXIFEN-ZDOROVYE, tablets 20 mg, 10 tablets in blisters; 3 blisters in carton box	Pharmaceutical company "Zdorovye" LLC, Ukraine	Pharmaceutical company "Zdorovye" LLC, Ukraine	30
Thalidomide 100 mg tablet, capsule, pill	MYRIN 100, coated tablets, 100 mg 10 tablets in blister, 3 blisters in carton box	Lipomed AG, Switzerland	Julko	30
Topotecan, ampoule, vial, syringe, 4 mg	HYCAMTIN™, lyophilizate for solution for infusion of 4 mg 1 vial in pack	GlaxoSmithKline Manufacturing S.p.A., Italy	BADM	1
Trastuzumab, ampoule, vial, syringe , 150 mg	Trazimera 150 mg powder for concentrate for solution for infusion 1 vial in pack	Pfizer Manufacturing Belgium	Pfizer	1
Vancomycin 500 mg ampoule, vial, syringe	Vancotex, powder, 500 mg 10 vials in carton box	Fisiopharma S.R.L., Italy	Pube Global	10
Vinblastine 5 mg ampoule, vial, syringe	VINBLASTINE SULFATE, powder (substance) Vinblastine solution for infusion 5mg/50ml 20 plastic bags in cardboard box	Minakem High Potent SA, Belgium/ Pharmacy №2 "Chemoteka" (Private enterprise "Infusion"), Ukraine	Infusion	20
Vincristine, ampoule, vial, syringe, 1 mg	VINCRIStINE-TEVA solution for injection, 1 mg/ml 1 ml in vial; 1 vial in cardboard pack	Pharmachemie B.V. Netherlands	Actavis	1
Vinorelbine, ampoule, vial, syringe, 50 mg	NAVIREL, concentrate for solution for infusion, 10 mg/ml 5 ml (50 mg) in vial; 1 vial in cardboard pack	Medac Gesellschaft fur klinische Spezialpraparate m.b.H., Germany	Medac	1

Voriconazole 200 mg tablet, capsule, pill	VORICONAZOLE ALVOGEN, film coated tablets, 200 mg 7 tablets in blisters, 2 blisters in carton box	Pharmathen S.A., Greece	R Pharma	14
Voriconazole 200 mg vial	VORICONAZOLE ALVOGEN, powder for solution for infusion 200 mg 1 vial in carton box	Pharmathen S.A., Greece	R Pharma	1
Zoledronic Acid, ampoule, vial, syringe, 4 mg	ZOLEDRONIC ACID-PHARMEX, concentrate for solution for infusion, 0,8 mg/ml 5 ml in vial; 1 vial in blister, 1 blister in cardboard pack	PHARMEX GROUP LLC, Ukraine	Pharmex GROUP	1