

**Evaluation of procurement prices
in Ukraine across 4 programmes managed
by Crown Agents:
Cardio – Paediatric dialysis
Peritoneal dialysis - Diabetes
2016-2017-2018**

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BACKGROUND

The present report analyses changes in prices of medical devices under four Crown Agents procurement programmes in Ukraine from 2016 to 2018. The programmes we considered for the analysis, and the number of different products in each programme, are the following:

- **Cardio (Part 4):** 23 items
- **Paediatric dialysis:** 24 items
- **Peritoneal dialysis:** 18 items
- **Diabetes (Glucose test strips):** 1 item

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2017 and 2018 compared to 2016 in terms of best value for money and individual item/overall savings.

For each programme we analysed these aspects:

- **Price variations:** this analysis included two important aspects
 - o Variation of the price per unit 2016->2017 and 2016->2018 for each item (% increase or decrease)
 - o Improvement of the overall spending for each programme comparing the “Supplier value” for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices.
- **Quality:** we have examined if the selected products can also be found in international markets and if they therefore carry the CE mark and/or the FDA authorization. For products that are only available in local markets we have searched evidence of their proper certification and quality assessment
- **Price benchmarking:** although price benchmarking for medical devices in different markets has several limitations, we attempted to provide some reference data, mostly from the proprietary PriceGuide™ database from ECRI Institute

NOTE: in this report we refer to items purchased in year 2016/2017/2018 with the meaning that those items were purchased within the allotted budget for that year. The actual purchase, and the corresponding invoicing and items delivery, may have happened during the reference year as well as after that year. This is due to several factors e.g. the complexity of the tendering process, the availability of funds for additional purchases, etc.

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 changes in prices of medical devices under four Crown Agents procurement programmes in Ukraine from 2016 to 2018. The programmes we considered for the analysis, and the number of different products in each programme, are the following:

- **Cardio (Part 4):** 23 items
- **Paediatric dialysis:** 24 items
- **Peritoneal dialysis:** 18 items
- **Diabetes (Glucose test strips):** 1 item

Overall, we have considered the price variations of 65 items from 2016 to 2017 and 63 items from 2016 to 2018. **The majority of individual items prices have decreased or remained stable both in the period 2016-2017 (36 of 65 with a mean difference of -4,09%) and in the period 2016-2018 (37 of 63 with a mean difference of -5,60%).**

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we have selected those items that had been purchased from the same supplier across 2016-2017 and made a linear regression analysis. The resulting correlation is very low ($R^2=0,10734$; $p=0,02$) and the final conclusion is that across all programmes **the price variations are not strictly linked to the variations in the quantities purchased in different years.**

We then considered the improvement of the overall spending comparing the “Supplier value” for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices. The actual savings achieved through the procurement of medical devices in all programmes considered in this analysis resulted the following:

- **Savings in 2017: \$ 554.019,62** **-7,3% relative to 2016 prices**
- **Savings in 2018: \$ 803.054,53** **-11,1% relative to 2016 prices**

The total expenditure for 2017+2018 for the items considered in this analysis was \$ 13.498.821,32. Comparing this figure with the overall value 2017+2018 at 2016 prices \$ 14.855.895,47 we finally obtained:

- **Overall savings achieved in years 2017 and 2018: \$ 1.357.074,15**
- **Overall cost reduction: -9,1% relative to 2016 prices**

In terms of quality, we collected evidence that **all products purchased within the programmes we analysed are of good quality as they are medical devices sold and certified in international markets (CE Mark, FDA approval), or are available in Ukraine after proper state registration and quality assurance processes.**

Although price benchmarking for medical devices in different markets has several limitations, we attempted to provide some reference data.

- For programme Cardio (Part 4) we investigated several items; the price differences with the US prices collected in the database PriceGuide™ from ECRI Institute resulted very big, with much lower prices paid by Crown Agents in Ukraine.
- For programmes Paediatric and Peritoneal dialysis we considered the Peritoneal dialysis solution DIANEAL PD4 from Baxter Healthcare; the prices paid for this product by Crown Agents in Ukraine resulted lower or in line with the lowest end of the prices stored in the ECRI database, and are very much lower than the registered price available from the Saudi Food & Drug Authority website that we considered for comparison.
- For programme Diabetes (glucose test strips) we had only one item to consider, the “Accu-Chek® Performa test strips” manufactured by Roche Diabetes Care GmbH. For this kind of consumable material, the volume of purchased items can make a big difference for the unit price. We considered some reference prices for bulk purchases and concluded that the prices paid by Crown Agents for each test strip are in line with the reference prices we have highlighted.

Overall, the procurement activity by Crown Agents in the four programmes analysed for years 2017 and 2018 compared to 2016 proved effective, with total cost savings in the range of -7% to -11% relative to 2016 prices, good quality products selected from reliable manufacturers and a price benchmark in line or better than the international prices we considered for reference.

GENERAL CONSIDERATIONS

Price variations

For each of the programmes to be evaluated we have considered the items purchased within the Ukraine government allotted budget for years 2016, 2017 and 2018.

The goal of the analysis is to provide a detailed evaluation of the performance of Crown Agents in 2017 and 2018 compared to 2016 in terms of best value for money and individual item/overall savings.

We have based our analysis on the procurement data provided by Crown Agents. For each year and programme those data are organized in spreadsheets providing the following detailed information:

- Programme ID
- Item ID
- Name (Item description, Generic name)
- Brand name
- Manufacturer
- Supplier
- Catalogue number
- Pack size
- Est delivery (according to contract)
- Shelf life
- Date of delivery
- Quantity contract
- Price per unit (supplier)
- Supplier Value

Each file also contains additional information that we did not consider in the framework of this analysis (CA fee, additional payment, custom duties, VAT, etc.).

These data needed to be re-organized in order to highlight the item-by-item and overall performance of 2017/2018 in terms of comparison to 2016 procurement. We have therefore prepared separate spreadsheets, divided for each programme, and included the following data:

- Name (Item description, Generic name)
- Brand name
- Manufacturer
- Supplier
- Quantity contract 2016
- Price per unit 2016
- Supplier value 2016
- Quantity contract 2017
- Price per unit 2017

- Supplier value 2017
- Quantity contract 2018
- Price per unit 2018
- Supplier value 2018

The first goal of this data re-organization was to highlight the items purchased in 2017 and 2018 that have a direct correspondence to the same items purchased in 2016. We based this linking activity on the item's identifiers (name, brand name, manufacture and supplier) and in some cases also used the catalogue numbers to make sure the connections were exact. Different situations were highlighted:

- **Exact correspondence of items purchased in 2016 with those purchased in 2017 and/or 2018 (same brand name/manufacture).** In this case no further pre-processing of the data was necessary.
- **An item purchased in 2016 was also purchased in 2017 and/or 2018 but a different brand name/manufacture was selected.** In this case, we reported both lines in the spreadsheet, as this is important to highlight the different products (see the "Quality" chapter for details). We also copied the data for 2017 and/or 2018 in the corresponding 2016 line (these cells are highlighted in yellow and a "Note" is reported in the file) to allow the purchase performance analysis.
- **An item was purchased in 2016 but no corresponding item could be found in 2017 and 2018.** In this case we discarded the item from the price variations analysis as no comparison could be done.
- **An item was purchased in 2017 and/or 2018 but no corresponding item could be found in 2016.** Also, in this case we discarded the item from the price variations analysis as no comparison could be done.

All details of this analysis are reported in the chapters dedicated to each individual programme; the complete spreadsheets with the items selected for the analysis are available as **Annex A**.

This pre-processing activity allowed us to include in the analysis a significant number of items:

- **Cardio (Part 4): 23 items**
- **Paediatric dialysis: 24 items**
- **Peritoneal dialysis: 18 items**
- **Diabetes (Glucose test strips): 1 item**

For each item we conducted two kinds of cost analysis:

- 1) **Variation of the price per unit 2016->2017 and 2016->2018 for each item** (% increase or decrease)
- 2) **Improvement of the overall spending for each programme** comparing the "Supplier value" for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 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.

Currency exchange rates

All prices included in this analysis were examined in US dollars (USD). In principle this would mean that the exchange rate of Ukrainian Hryvnia (UAH) to the USD did not impact the analysis. However, two considerations are necessary:

- 1) A substantial depreciation in the UAH:USD rate between 2016-2017-2018 means the budget of the Ministry of Health in Ukraine overall is characterised by decreased buying power in 2017/2018 compared with the previous year.
- 2) For items that the local supplier is purchasing in Euro (EUR) and re-selling to Crown Agents, a depreciation in the USD:EUR rate could lead to the increase of USD prices. This was highlighted for a list of items in the Paediatric dialysis programme (detailed considerations are in the dedicated chapter)



Figure 1 - Graph of the USD vs. UAH exchange rate across 2016-2017-2018

Although relevant periodic variations are visible in the graph, the USD:UAH exchange rate has slowly increased in the 2016-2017-2018 period, with an overall range between 24.7 (in mid 2016) and 28.9 (in January 2018).



Figure 2 - Graph of the EUR vs. USD exchange rate across 2016-2017-2018

The EUR:USD exchange rate remained quite stable in 2016 at around 1.10 with a significant decrease toward the end of the year (maximum 1.15 – minimum 1.04). In 2017 this rate grew consistently reaching a maximum of 1.20 and in 2018 the growth continued for the first month of the year reaching 1.25 and finally started to decrease to stabilize at around 1.14

Price reduction through negotiations and diversity of suppliers

Price reduction (better expressed with the concept of improved “value for money”) in the procurement of medical devices can be achieved through different strategies:

- **Better negotiations with suppliers:** a typical leverage to obtain this is through increased volumes of purchased items. An analysis of the possible effect of quantities on the prices is therefore presented for each program
- **Introduction of new/alternative suppliers:** more competition and diversity in suppliers usually leads to price reductions both because of cheaper suppliers and because previous suppliers may be available to provide discounts to keep the contract. The most critical aspect with this is the quality of the new products, and this will be carefully assessed in this report

Transparent procurement processes, good negotiations, improved diversity with the introduction of new suppliers are all important to achieve the best value for money.

Quality

Since July 1st, 2015 the legislative requirements regarding introducing medical devices to the market in Ukraine have changed: the "old" system of state registration has been replaced by a national conformity assessment of medical devices to Technical regulation requirements.

The introduction of the Technical Regulations is conditioned by the harmonization of the Ukrainian legislation with the European one, with the aim of gradual integration of Ukraine into the European Union. Technical regulations for medical devices are based on the relevant European Directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices; Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices).

It should be noted that the presence of a CE mark, as well as the availability of a Certificate/ Declaration of Conformity to the European Directives on medical devices, does not authorize the placement of the product on the Ukrainian market without passing the national conformity procedure. However, the CE certificate can significantly simplify the receipt of the national certificate, since the results of the conformity assessment carried out by some EU notified bodies can be recognized in Ukraine.

[source: <https://cratia.ua/en/national-conformity-assessment-medical-devices.html>]

In this report we are not assessing that all the products 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 therefore carry the CE mark and/or the FDA authorization; being subject to international scrutiny and post-market surveillance procedures such products are thoroughly tested not only for initial certification, but for life-long quality compliance.

Most of the products purchased within the programs examined in this report come from international manufacturers and are available worldwide. We have highlighted this situation in the relevant chapters that follow, and we put more attention to those few products that are not available in international markets.

Price benchmarking

The concept of "market value" for medical devices must be assessed in a very different way from that of drugs, as it brings with it an intrinsic variability due to a series of peculiar factors in this sector, such as:

- **Systematic application of extremely high and variable discounts compared to the list prices deposited.** It is not uncommon for sales prices to be discounted by 20%, 50% but also up to 80% of the corresponding list prices. These lists, therefore, take on a meaning of pure relative reference and are useful only to give a rough indication of congruity of a selling price where the average discount usually applied is known.
- **Commercial policies by suppliers that sell the same devices at very different prices to customers at different times.** This may be due to the willingness of the company to enter a specific healthcare facility to which it will offer particularly advantageous prices, or to the possibility of selling a large number of devices within the same order. It is not uncommon to record prices that, for the same device, differ by 20% and even more.
- **Extreme diversity for the same type of devices.** Different models for the same type of device can have very different prices due to versions, configurations, accessories, etc. therefore, to compare prices it's necessary to exactly identify each specific model.

The prices of drugs in different markets are more homogeneous than those of medical devices, and they are very often made available to the public by national authorities. The same information is generally not widely available for medical devices. For these reasons, a precise benchmark of the prices paid by Crown Agents in Ukraine compared to the prices of the same items in other markets is not feasible (especially those of neighbouring countries such as Slovenia, Poland, Hungary, Moldova, Belarus, Bulgaria, Romania, Slovak Republic, Czech Republic, Latvia, Armenia, Kyrgyzstan, Kazakhstan).

Thanks to the availability of a wide proprietary database of prices-paid for medical equipment and medical devices (PriceGuide™, comprising information on more than \$40 Billion worth of medical devices purchased), ECRI Institute can provide some reference prices coming from countries like the United States and Italy. In this report we'll provide some of these reference data where available.

CARDIO (PART 4)

Our analysis of the programme “Cardiovascular and cerebrovascular diseases” focused on Part 4 of that program, dedicated to devices such as stents and catheters. We refer to this as Cardio (Part 4).

Based on the files provided by Crown Agents we have identified 23 different items that were purchased in all three years 2016, 2017 and 2018, with an exact correspondence of these items in the three years under evaluation:

Items considered in Cardio (Part 4) programme

1. Medical devices for endovascular embolization of cerebral aneurysm with detachable microcoils including one microcoil
2. Medical devices for endovascular embolization of cerebral aneurysm with detachable microcoils including one microcatheter
3. Medical devices for endovascular embolization of cerebral aneurysm with detachable microcoils including one micro guidewire
4. Medical devices for carotid artery stenting including one carotid stent system
5. Medical devices for carotid artery stenting including one filter-basket for embolic protection
6. Medical devices for carotid artery stenting including one introducer sheath for carotid artery stenting
7. Medical devices for carotid artery stenting including one predilatation balloon
8. Balloon catheter for treatment of carotid-cavernous fistula including one detachable balloon guide microcatheter
9. Balloon catheter for treatment of carotid-cavernous fistula including one detachable balloon
10. Intracranial stents for the treatment of wide-necked cerebral aneurysms
11. Balloon catheters for wide-necked cerebral aneurysms
12. Medical devices for diagnostic cerebral angiography including one puncture needle
13. Medical devices for diagnostic cerebral angiography including one introducer
14. Medical devices for diagnostic cerebral angiography including one guidewire
15. Medical devices for diagnostic cerebral angiography including one catheter
16. Cerebral aneurysm clips
17. Medical devices to stop bleeding including one soluble hemostatic surgical dressing (size 7,5 x 5 cm)
18. Medical devices to stop bleeding including one soluble hemostatic surgical dressing (size 20 x 10 cm)
19. Medical devices for embolization of brain arteriovenous malformations including one implant for embolization of vessels
20. Medical devices for embolization of brain arteriovenous malformations including one delivery micro catheter
21. Medical devices for embolization of brain arteriovenous malformations including one hydrophilic guide wire
22. Surgical local hemostatic agents for neurosurgery (hemostatic cotton wool made of soluble oxidized regenerated cellulose, size 2,5 x 5,1 cm)
23. Elongated guiding catheter for distal endovascular access

Price variations

Variation of the price per unit for each item

Line #	Price per unit 2016	Price per unit 2017	Price per unit 2018	Variation 2016-2017	Banding 2016-2017	Variation 2016-2018	Banding 2016-2018
1	\$259,00	\$259,00	\$259,00	0,00%	[0%]	0,00%	[0%]
2	\$252,00	\$247,00	\$220,00	-1,98%	[-10%;0%[-12,70%	[-20%;-10%[
3	\$126,00	\$115,00	\$115,00	-8,73%	[-10%;0%[-8,73%	[-10%;0%[
4	\$309,00	\$290,00	\$280,00	-6,15%	[-10%;0%[-9,39%	[-10%;0%[
5	\$349,00	\$320,00	\$310,00	-8,31%	[-10%;0%[-11,17%	[-20%;-10%[
6	\$8,00	\$8,00	\$8,00	0,00%	[0%]	0,00%	[0%]
7	\$102,00	\$100,00	\$100,00	-1,96%	[-10%;0%[-1,96%	[-10%;0%[
8	\$369,00	\$426,00	\$421,00	15,45%	[10%;20%[14,09%	[10%;20%[
9	\$134,00	\$143,00	\$214,50	6,72%]0%;10%[60,07%]50%;[
10	\$1.060,00	\$1.060,00	\$1.060,00	0,00%	[0%]	0,00%	[0%]
11	\$706,00	\$415,00	\$395,00	-41,22%	[-50%;-40%[-44,05%	[-50%;-40%[
12	\$2,08	\$2,20	\$1,50	5,77%]0%;10%[-27,88%	[-30%;-20%[
13	\$15,00	\$9,32	\$10,95	-37,87%	[-40%;-30%[-27,00%	[-30%;-20%[
14	\$9,78	\$5,50	\$5,50	-43,76%	[-50%;-40%[-43,76%	[-50%;-40%[
15	\$16,76	\$8,80	\$16,80	-47,49%	[-50%;-40%[0,24%]0%;10%[
16	\$193,00	\$160,00	\$176,00	-17,10%	[-20%;-10%[-8,81%	[-10%;0%[
17	\$13,34	\$14,14	\$13,34	6,00%]0%;10%[0,00%	[0%]
18	\$25,54	\$25,91	\$25,91	1,45%]0%;10%[1,45%]0%;10%[
19	\$430,00	\$405,00	\$300,00	-5,81%	[-10%;0%[-30,23%	[-40%;-30%[
20	\$407,00	\$370,00	\$370,00	-9,09%	[-10%;0%[-9,09%	[-10%;0%[
21	\$200,00	\$243,00	\$258,00	21,50%	[20%;30%[29,00%	[20%;30%[
22	\$41,46	\$41,85	\$41,46	0,94%]0%;10%[0,00%	[0%]
23	\$309,00	\$327,00	\$315,00	5,83%]0%;10%[1,94%]0%;10%[

Table 1 - 2016-2017-2018 price per unit variations for programme Cardio (Part 4)

The relative increase/decrease in price from 2016 to 2017 and from 2016 to 2018 is shown in this table for all devices where prices were available for these years (n=23).

The main statistical indicators are summarized below:

Period	Price difference observations (n)	Mean difference	Median difference	Lowest difference	Highest difference
2016-2017	23	-7,21%	-1,96%	-47,49%	+21,50%
2016-2018	23	-5,56%	-1,96%	-44,05%	+60,07%

Table 2 - Price difference indicators for programme Cardio (Part 4)

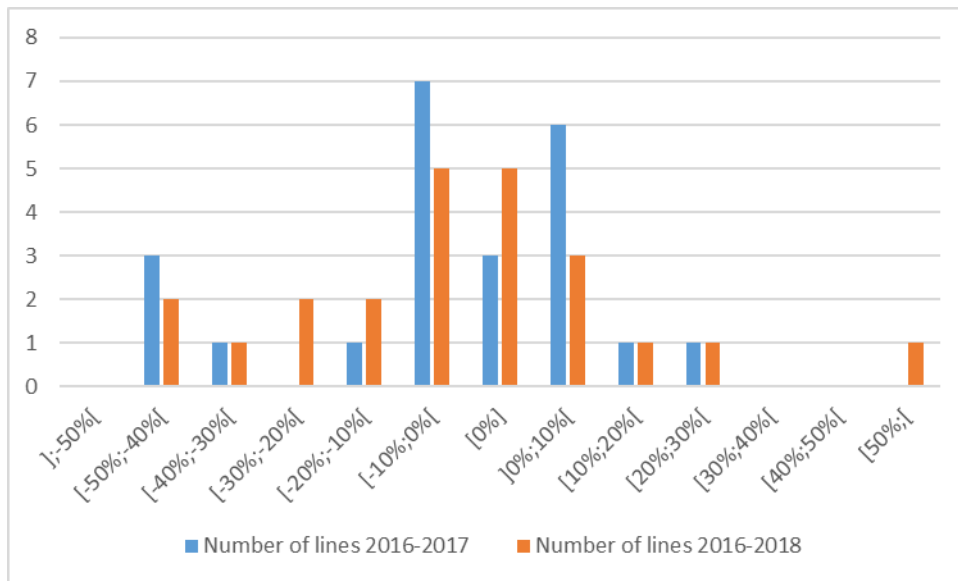


Figure 3 - Banding of price variations for programme Cardio (Part 4)

Most of the price variations are comprised in a small interval between -10% and +10%. **Overall, the majority of individual items prices have decreased or remained stable both in the period 2016-2017 (15 of 23) and in the period 2016-2018 (17 of 23).**

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we have selected those items that had been purchased from the same supplier across 2016-2017 and made a linear regression analysis. We could identify 12 items; a plot of changes in prices versus changes in quantities is represented below. The correlation between these two variables is very low ($R^2=0,2743$; $p=0,08$), therefore we conclude that **the price variations were not strictly linked to the variations in the quantities purchased in different years.**

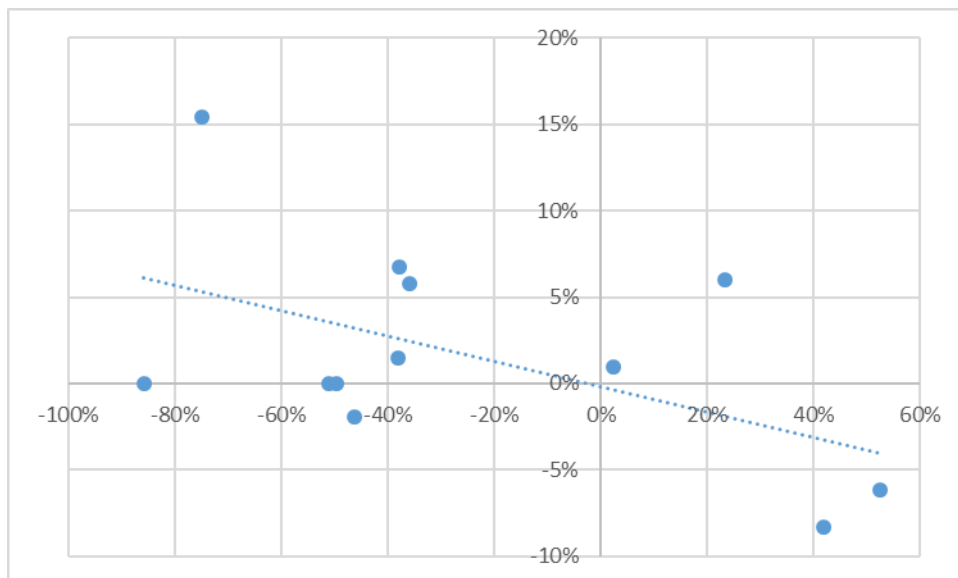


Figure 4 - Change in prices relative to change in quantities for programme Cardio (Part 4)

As can be seen in the complete spreadsheets with the items selected for the analysis (Annex A), **most price improvements for individual items have been achieved through the selection of different suppliers in 2017/2018 from those of 2016.** For 11 items (of 23) there was a change in supplier in 2017 and/or 2018. An assessment of the quality of the devices purchased in this programme for each item (both old and new suppliers) is presented below.

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 for the programme Cardio (Part 4) comparing the "Supplier value" for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices.

Programme – Number of items	Supplier value 2017	Supplier value 2017 at 2016 prices	Supplier value 2018	Supplier value 2018 at 2016 prices
Cardio (Part 4) 23 items	\$ 588.877,70	\$ 636.651,72	\$ 781.635,80	\$ 850.908,24

Table 3 - Total savings in programme Cardio (Part 4)

This table highlights the actual savings achieved through the procurement of medical devices in programme Cardio (Part 4) in years 2017-2018 compared to year 2016:

- **Savings in 2017: \$47.774,02** **-7,5% relative to 2016 prices**
- **Savings in 2018: \$69.272,44** **-8,1% relative to 2016 prices**

Quality

The programme Cardio (Part 4) includes several different items purchased from many suppliers of different manufacturers. We have therefore summarized the Supplier/Manufacturer/Products list in a table for easy analysis of the quality of brands and products proposed in this programme.

For each manufacturer we have reported an excerpt of the company profile from the ECRI Institute database "Sourcebase™", highlighting geographic sales area and company certifications.

For manufacturers that are well recognized global players in the industry (note "GLOBAL") we have sample checked the specific models for certification in the USA and Europe.

Supplier	Manufacturer	Products	Notes
Balton	BALT EXTRUSION, France	MAGIC Flow-dependant microcatheter, GOLDBALLOON Detachable balloon, ECLIPSE 2L Occlusion Balloon Catheter, HYBRID WIRE Hydrophilic guidewire, Guiding catheter FARGO/FARGOMA X	Balt Extrusion is a Medtech company specializing in neurovascular diseases with products distributed in more than 100 countries. Website: https://www.balt-corp.com/ Geographic sales area: Worldwide Year business started: 1977 GLOBAL
Balton	BALTON Sp. z o.o., Poland	ANGIOGRAPHIC NEEDLE, INTRODUCER, TEFLON COATED GUIDE WIRES, CEREBRAL CATHETER HEADHUNTER, CEREBRAL CATHETER SIMMONS	Balton Sp. is a manufacturer of disposable medical equipment for anesthesia, dialysis, surgery, gynecology, cardiology and radiology and urology with products exported in more than 90 countries. Website: https://balton.pl/en/ Geographic sales area: Worldwide Year business started: 1980 Quality system registration: CE-Mark, ISO 9001:2000 and ISO 13485 GLOBAL
Balton	Ethicon, Inc.	SONIC Microcatheter	Ethicon Ing. is a Johnson & Johnson company, one of the global leaders in medical devices. Website: http://www.ethicon.com Geographic sales area: Worldwide Quality system registration: CE-Mark and EN 46001 GLOBAL
Covidien	Micro Therapeutics/ev3 Neurovascular	Axium™ Helix, Axium™ 3D, Axium™ Prime Bare Platinum Extra Soft 3D, Axium™ Prime Bare 3D, Echelon™ Micro Catheter, X-Pedion Hydrophilic Guidewire, SpiderFX Embolic Protection Device, Solitare™ AB Neurovascular Remodeling Device, HyperGlide™ Occlusion Balloon	Micro Therapeutics, Inc., doing business as ev3 Neurovascular, provides medical devices. It's now a division of Medtronic, one of the global leaders in medical devices. Website: https://www.medtronic.com/ Geographic sales area: Worldwide Quality system registration: CE-Mark GLOBAL

		System, Apollo™ Onyx™ Delivery Micro Catheter, Protégé RX™ Carotid Stent System	
Ecomed	Ethicon, Inc.	Surgicel Absorbable Haemostats	Ethicon Ing. is a Johnson & Johnson company, one of the global leaders in medical devices. Website: http://www.ethicon.com Geographic sales area: Worldwide Quality system registration: CE-Mark and EN 46001 GLOBAL
Fifth Element	Micro Vention, Inc.	Headway Microcatheter, Chaperon Guiding Catheter System, PHIL Liquid Embolie System	MicroVention Inc is a division of Terumo, one of the global leaders in medical devices. Website: http://www.microvention.com Geographic sales area: Worldwide Year business started: 1997 Quality system registration: CE-Mark GLOBAL
Harwood&Brooks	Arrow International, Inc.	Super Arrow-Flex® Percutaneous Sheath Introducer (PSI) Set	Teleflex Medical Arrow International Inc Website: http://www.arrowintl.com https://www.teleflex.com/ Geographic sales area: Worldwide Year business started: 1975 Quality system registration: CE-Mark GLOBAL
Medical Commerce	Aesculap AG, Germany	Neurosurgery clips	Aesculap is part of B-Braun, one of the global leaders in medical devices and is particularly specialized in quality neurosurgery clips. Website: https://www.bbraun.com/en/company/organization-facts-figures/bbraun-aesculap-partner-for-surgery.html GLOBAL
Medtronic	Medtronic Inc.	Input Introducer	Medtronic is one of the global leaders in medical devices. Website: https://www.medtronic.com/ Geographic sales area: Worldwide Quality system registration: CE-Mark GLOBAL

Medtronic	Invatec S.p.A.	Submarine Rapido PTA balloon catheter	This device is manufactured by Medtronic, one of the global leaders in medical devices. Website: https://www.medtronic.com/ Geographic sales area: Worldwide Quality system registration: CE-Mark GLOBAL
Merit Medical	Merit Medical Systems Inc.	Advance® Angiography Needles, Prelude® Sheath Introducer, InQwire® Guide Wires PTFE Coated, Performa® Angiographic Catheter	Merit Medical Systems, Inc. is a leading manufacturer and marketer of disposable medical devices used in interventional, diagnostic and therapeutic procedures, particularly in cardiology, radiology, oncology, critical care and endoscopy. Website: http://www.merit.com Geographic sales area: Worldwide Year business started: 1987 Quality system registration: CE-Mark and EN 46001 GLOBAL
Technology for life	Mizuho Corporation	Sugita Titanium Aneurysm Clip II	The Sugita Aneurysm Clip is available in approximately 320 varieties, and more than 100,000 clips are manufactured every year for retail in some 50 countries. Website: http://www.mizuho.co.jp/english/ Geographic sales area: Worldwide Year business started: 1939 Products formerly sold under: Mizuho Ikakogyo Co Ltd GLOBAL

Table 4 - Supplier/Manufacturer/Products list for programme Cardio (Part 4)

All products purchased in the Cardio (Part 4) programme are manufactured by global players in the medical device industry. We have checked the products data sheet and identified **they are distributed worldwide carrying the proper certifications.** A selection of brochures and data sheets has been collected and is available for reference.

Price benchmarking

Despite the difficulties in price benchmarking of medical devices that we have explained in the introduction chapter, we utilized the ECRI Institute PriceGuide™ database and were able to find several items purchased in the Cardio (Part 4) programme. The exact correspondence is confirmed thanks to the availability of the catalogue number in the files provided by Crown Agents. For the same item listed in the Crown Agents files there could be more than one sub-item with different

catalogue numbers; we retrieved information for these different items and listed them in the summary table reported below.

Product	Manufacturer catalogue number	ECRI DB low	ECRI DB high	Crown Agents 2016	Crown Agents 2017
Axium™ Helix	QC1640HELIX	\$547,00	\$919,00	\$259,00	\$259,00
Axium™ Helix	QC720HELIX	\$605,00	\$1.100,00	\$259,00	\$259,00
Axium™ Helix	QC830HELIX	\$605,00	\$981,00	\$259,00	\$259,00
Axium™ Helix	QC720HELIX	\$605,00	\$1.100,00	\$259,00	\$259,00
Axium™ Helix	QC930HELIX	\$547,00	\$1.061,00	\$259,00	\$259,00
Axium™ Helix	QC1030HELIX	\$547,00	\$1.250,00	\$259,00	\$259,00
Axium™ Helix	QC410HELIX	\$700,00	\$1.140,00	\$259,00	\$259,00
Axium™ Prime Bare Helix	APB620HXSS	\$710,00	\$710,00	\$259,00	\$259,00
Axium™ Prime Bare Helix	APB410HXSS	\$419,00	\$1.139,00	\$259,00	\$259,00
Axium™ Prime Bare Helix	APB515HXSS	\$459,00	\$1.200,00	\$259,00	\$259,00
Echelon™ Micro Catheter	1055091150	\$490,00	\$985,00	\$252,00	
Echelon™ Micro Catheter	1455092150	\$504,00	\$1.125,00	\$252,00	
Echelon™ Micro Catheter	1055092150	\$482,00	\$954,00	\$252,00	
Chaperon Guiding Catheter System	GC695M2SI	\$306,00	\$360,00		\$115,00
Chaperon Guiding Catheter System	GC695BUVT	\$288,00	\$288,00		\$115,00
SpiderFX Embolic Protection Device	SPD2US050320	\$800,00	\$1.595,00	\$349,00	\$320,00
SpiderFX Embolic Protection Device	SPD2US060320	\$800,00	\$1.595,00	\$349,00	\$320,00
SpiderFX Embolic Protection Device	SPD2US070320	\$800,00	\$1.595,00	\$349,00	\$320,00
HyperGlide™ Occlusion Balloon System	104-4113	\$825,00	\$1.810,00		\$415,00
HyperGlide™ Occlusion Balloon System	104-4112	\$943,00	\$1.995,00		\$415,00
HyperGlide™ Occlusion Balloon System	104-4127	\$845,00	\$1.867,00		\$415,00
HyperGlide™ Occlusion Balloon System	104-4515	\$833,00	\$1.901,00		\$415,00
Sugita Titanium Aneurysm Clip II	1700101	\$306,08	\$487,00		\$160,00
Sugita Titanium Aneurysm Clip II	1700102	\$306,08	\$487,00		\$160,00
Sugita Titanium Aneurysm Clip II	1700181	\$306,08	\$487,00		\$160,00
Apollo™ Onyx™ Delivery Micro Catheter	105-5095-000	\$1.437,00	\$2.321,00		\$370,00

Table 5 - Price benchmarking for programme Cardio (Part 4)

The price differences are very big, with Crown Agents prices in Ukraine much lower than the US prices collected in the ECRI database.

This evidence also confirms what we have stated in the introduction: price benchmarking of medical devices is very difficult as the same item can be sold in different countries (but also in different health facilities in the same country) at very different prices due to several reasons, mostly linked to the commercial policies of manufacturers and suppliers.

PAEDIATRIC DIALYSIS

With reference to the programme “Paediatric dialysis”, based on the files provided by Crown Agents we have identified 24 different items that were purchased in all three years 2016, 2017 and 2018, with an exact correspondence of these items in the three years under evaluation:

Items considered in Paediatric dialysis programme

1. Pediatric haemodialysis kit (dialyzer 1,0-1,1 m², AV-lines, fistula needles G17-19, bicarbonate BiBag cartridge or equivalent)
2. Pediatric haemodialysis kit (low-flux dialyzer with membrane surface area 1,2-1,4 m², AV-lines, fistula needles G17-19, bicarbonate BiCart cartridge or equivalent)
3. Pediatric haemodialysis kit (dialyzer 1,2-1,4 m², AV-lines, fistula needles G17-19, bicarbonate BiBag cartridge or equivalent)
4. Dual lumen haemodialysis catheters Kit
5. Kit for pediatric continuous veno-venous haemodialysis CRRT/SCUF (multiFiltrate Kit paed CRRT/SCUF) or equivalent, Filtrate bag 10 L
6. Kit for membrane plasma separation MPS P1 (multiFiltrate Kit MPS P1 dry) or equivalent, Filtrate bag 10 L or equivalent
7. Kit for continuous hemodiafiltration (multiFiltrate Kit Midi CVVHDF400) or equivalent
8. Haemodialysis consumables kit with hemodiafiltration function in children (high-flux dialyzer with membrane surface area 0,6-0,7 m², AV-lines, fistula needles G17-19, bicarbonate BiBag cartridge)
9. Dialysis fluid filter Diasafe Plus or equivalent (1 filter per 50 haemodialysis kits with hemodiafiltration function in children - to the position 11)
10. Set of consumables for the 4008H hemodialysis machine with extracorporeal liver support module “Prometheus”
11. Hemodialysis Acid Concentrate D204 or its analogues in no less than 7.8 liters cans (diluted to 1/44)
12. Peritoneal dialysis solution with 1,35-1,5% glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis, 5 bags per box)
13. Peritoneal dialysis solution with 2,25-2,5% glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis, 5 bags per box)
14. Disinfectant cap (detachable)
15. Peritoneal dialysis solution with 1,35-1,5% glucose concentration for hardware peritoneal dialysis (5-liter bags, 2 per box)
16. Peritoneal dialysis solution with 2,25-2,5 % glucose concentration for hardware peritoneal dialysis (5-liter bags, 2 per box)
17. Peritoneal dialysis solution with 3,85-4,25 % glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis, 5 bags per box)
18. Peritoneal dialysis solution with 3,85-4,25% glucose concentration for hardware peritoneal dialysis (5-liter bags, 2 per box)
19. Peritoneal dialysis catheter (with size indication: small, medium, large) in set with titanium adapter
20. Peritoneal dialysis catheter (with size indication: small, medium, large) in set with titanium adapter
21. Transfer tube (catheter extension)
22. Lines clamp (switch)
23. Consumables kit for hardware peritoneal dialysis (cassette for peritoneal dialysis machine (pediatric kit), drainage set)
24. Peritoneal dialysis catheter (with size indication: small, medium, large) in set with titanium adapter

Price variations

Variation of the price per unit for each item

Line #	Price per unit 2016	Price per unit 2017	Price per unit 2018	Variation 2016-2017	Banding 2016-2017	Variation 2016-2018	Banding 2016-2018
1	\$44,41	\$38,94	\$38,17	-12,32%	[-20%;-10%[-14,05%	[-20%;-10%[
2	\$26,23	\$27,14	\$27,14	3,47%]0%;10%[3,47%]0%;10%[
3	\$47,64	\$41,98	\$39,24	-11,88%	[-20%;-10%[-17,63%	[-20%;-10%[
4	\$102,44	\$112,78	\$113,67	10,09%	[10%;20%[10,96%	[10%;20%[
5	\$130,44	\$143,61	\$144,76	10,10%	[10%;20%[10,98%	[10%;20%[
6	\$243,39	\$267,99	\$270,11	10,11%	[10%;20%[10,98%	[10%;20%[
7	\$102,57	\$128,42	\$129,44	25,20%	[20%;30%[26,20%	[20%;30%[
8	\$57,13	\$50,85		-10,99%	[-20%;-10%[
9	\$354,89	\$170,68	\$168,00	-51,91%];-50%[-52,66%];-50%[
10	\$4.221,64		\$4.645,28			10,03%	[10%;20%[
11	\$12,96	\$12,68	\$12,78	-2,16%	[-10%;0%[-1,39%	[-10%;0%[
12	\$7,20	\$6,30	\$6,30	-12,50%	[-20%;-10%[-12,50%	[-20%;-10%[
13	\$7,20	\$6,30	\$6,30	-12,50%	[-20%;-10%[-12,50%	[-20%;-10%[
14	\$0,55	\$0,41	\$0,41	-25,45%	[-30%;-20%[-25,45%	[-30%;-20%[
15	\$10,63	\$11,33	\$11,33	6,59%]0%;10%[6,59%]0%;10%[
16	\$10,68	\$11,33	\$11,33	6,09%]0%;10%[6,09%]0%;10%[
17	\$7,48	\$6,30	\$6,30	-15,78%	[-20%;-10%[-15,78%	[-20%;-10%[
18	\$10,99	\$11,33	\$11,33	3,09%]0%;10%[3,09%]0%;10%[
19	\$80,68	\$80,68	\$80,68	0,00%	[0%]	0,00%	[0%]
20	\$80,00	\$80,00	\$80,00	0,00%	[0%]	0,00%	[0%]
21	\$27,00	\$30,94	\$30,94	14,59%	[10%;20%[14,59%	[10%;20%[
22	\$1,97	\$2,01	\$2,01	2,03%]0%;10%[2,03%]0%;10%[
23	\$29,46	\$24,50	\$29,62	-16,84%	[-20%;-10%[0,54%]0%;10%[
24	\$80,00	\$80,00		0,00%	[0%]		

Table 6 - 2016-2017-2018 price per unit variations for programme Paediatric dialysis

The relative increase/decrease in price from 2016 to 2017 and from 2016 to 2018 is shown in this table for all devices where prices were available for these years. The cells filled in grey correspond to item 10 (that was not purchased in 2017) and items 8 and 24 (that were not purchased in 2018). Therefore, we have considered 23 price variations for 2016-2017 and 22 price variations for 2016-2018.

A note is necessary for items 1, 3, 8 and 9 (haemodialysis kits and filters) purchased from the company Renart. For each of these items we have identified two separate groups of purchases related to the 2016 budget:

- Item 1: 388 purchased at \$29,24 and 100 additional at \$44,41

- Item 3: 2088 purchased at \$31,99 and 100 additional at \$47,64
- Item 8: 65 purchased at \$48,56 and 20 additional at \$57,13
- Item 9: 76 purchased at \$301,69 and 5 additional at \$354,89

We have investigated this situation and obtained a communication from Renart to Crown Agents explaining that:

I am writing to inform You on request in your letter dated February 19, 2018 that: yes, we can make an additional supply of medicines and medical devices for pediatric dialysis under the contract CA-107412/0001/003 until May 19, 2018. However, we have to recalculate prices for these reasons:

1) *The exchange rate of the EUR has increased significantly.*

The interbank rate of the USD was 27.042536 UAH and the interbank rate of the EUR was 28.49472 UAH on the day of the price calculation (February 22, 2017).

The highest interbank rate in 2018 was for USD - 28.9100 UAH., and for EUR - 35.8348 UAH.

We consider the ratio of these two currencies in calculating of the selling price since we purchase goods in EUR.

Whereas the delivery will not be implemented soon, we take in calculation the highest rate from the beginning of 2018.

This is the only situation in the items we have considered in this report where a clear correlation of a price variation with the changes in currency exchange rates was found. In order to make more homogeneous the comparison of the 2016 prices to those 2017 and 2018, we have decided to consider for these items the “new” prices for 2016 adjusted as here explained.

Due to the much lower number of devices that we have therefore considered for these items in 2016, in the linear regression model presented below to verify if the price variations were correlated to the variations in the quantities purchased for each item, we had to remove these 4 items.

The main statistical indicators are summarized below:

Period	Price difference observations (n)	Mean difference	Median difference	Lowest difference	Highest difference
2016-2017	23	-3,52%	-0,00%	-51,91%	+25,20%
2016-2018	22	-2,11%	-1,29%	-52,66%	+26,20%

Table 7 - Price difference indicators for programme Paediatric dialysis

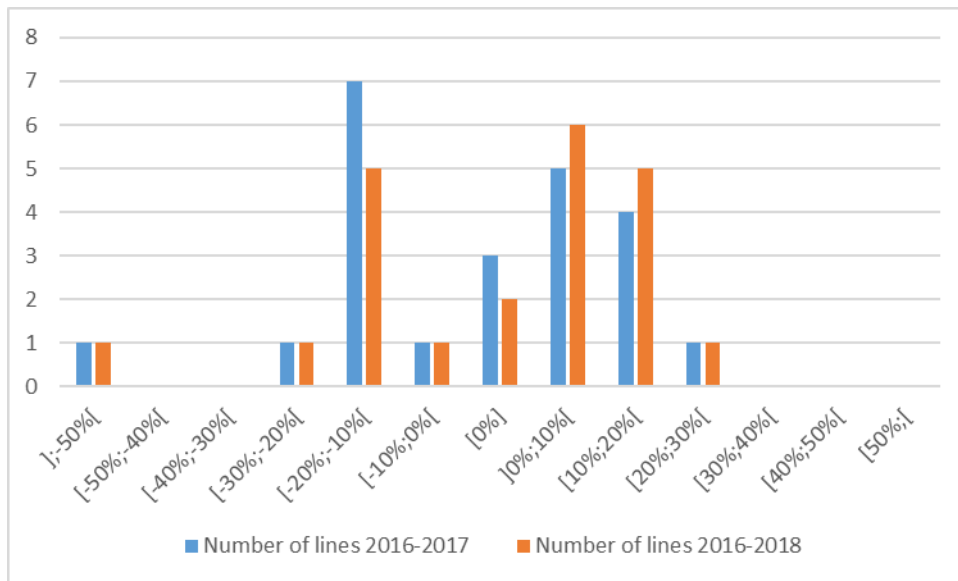


Figure 5 - Banding of price variations for programme Paediatric dialysis

Most of the price variations are comprised in the interval between -20% and +20%. **Overall, the majority of individual items prices have decreased or remained stable in the period 2016-2017 (13 of 23) while in the period 2016-2018 some more items increased in price (12 of 22).**

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we have selected those items that had been purchased from the same supplier across 2016-2017 and made a linear regression analysis. After removing the 4 items (1, 3, 8 and 9 as explained before), we could identify 19 items; a plot of changes in prices versus changes in quantities is represented below. The correlation between these two variables is very low ($R^2=0,1189$; $p=0,15$), therefore we conclude that **the price variations were not strictly linked to the variations in the quantities purchased in different years.**

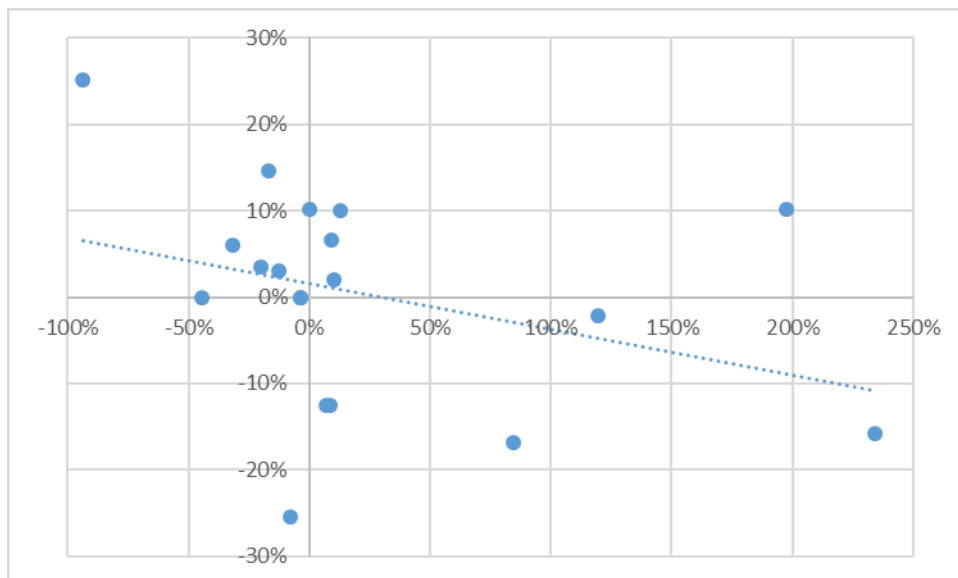


Figure 6 - Change in prices relative to change in quantities for programme Paediatric dialysis

As can be seen in the complete spreadsheets with the items selected for the analysis (Annex A), **no price improvement for individual items could be achieved through the selection of different suppliers in 2017/2018 from those of 2016**. All items continued to be purchased from the same suppliers as in 2016.

Improvement of the overall spending

As we have mentioned before, to evaluate actual savings and procurement efficiency it's necessary to also consider the total volume of purchased items.

Here we present the improvement of the overall spending for the programme Paediatric dialysis comparing the "Supplier value" for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices.

Programme – Number of items	Supplier value 2017	Supplier value 2017 at 2016 prices	Supplier value 2018	Supplier value 2018 at 2016 prices
Paediatric dialysis 24 items	\$ 658.134,58	\$ 727.375,01	\$ 281.141,24	\$ 292.197,72

Table 8 - Total savings in programme Paediatric dialysis

This table highlights the actual savings achieved through the procurement of medical devices in programme Paediatric dialysis in years 2017-2018 compared to year 2016:

- **Savings in 2017: \$69.240,43** **-9,5% relative to 2016 prices**
- **Savings in 2018: \$11.056,48** **-3,8% relative to 2016 prices**

For the items we have included in the analysis, the volumes purchased in 2018 have been much lower than in 2017. This reduced the positive effect of the savings that were achieved individually for the most relevant items, that has a very relevant impact in the achievement for 2017.

Quality

In the chapter dedicated to the analysis of the quality of brands and products proposed in the Cardio (Part 4) programme we have seen that it included several different items purchased from many suppliers of different manufacturers. The situation is very different in the programme Paediatric dialysis, where all products have been sourced from a very limited list of suppliers and manufacturers.

Supplier	Manufacturer	Products
Baxter	Gambro Dialysatoren GmbH, Germany; Gambro Renal Products S.A. de C.V., Mexico; Nipro Corporation	Capillary Dialyzer Polyflux 14L; Blood tubing set for haemodialysis: Cartridge Extended Patient Lines; Fistula Needle F 17AS G; BiCart® 720g
Baxter	Baxter Healthcare SA	DIANEAL PD4 solution for peritoneal dialysis, Locking Titanium PD Chatheter Adapter, MiniCap Extended Life PD Transfer Set with Twist Clamp, Clamp for Outlet Port of PD Bags, Cycle Drainage Set
Renart	Fresenius Medical Care; JV Frebor Ltd. Republic of Belarus; SIS-TER S.p.A. , Italy; NOVAMED GmbH Turkey	Pediatric haemodialysis kit (different items), Double Lumen Catheters Set proVen care, multiFiltrate Kit paed CRRT/SCUF, multiFiltrate Kit MPS P1 dry, MultiFiltrate Kit Midi CVVHDF400, DIASAFE plus dialysis filter, Set of consumables for the 4008H hemodialysis machine, Liquid acid concentrate

Table 9 - Supplier/Manufacturer/Products list for programme Paediatric dialysis

All products supplied (with the sole exception of some components of the multi-product haemodialysis kits) come from two main manufacturers:

- **Baxter (with its subsidiary Gambro) - <https://www.baxter.com/>**
- **Fresenius Medical Care - <https://www.freseniusmedicalcare.com/>**

Both companies are international leaders specialized in the haemodialysis sector with decades of business history in the field. **The quality of the products supplied meets the highest standards and is out of question.**

Some additional manufacturers have been introduced to provide sub-components of the dialysis kits. Following is a brief profile for each of those.

Nipro Corporation

Geographic sales area: Worldwide

Year business started: 1954

Quality system registration: CE-Mark and EN 46001

<https://www.nipro.co.jp/en/business/device/>

Nipro Europe Group Companies is part of Nipro Corporation Japan, a leading global healthcare company established in 1954.

Other companies under Fresenius Medical Care:

SIS-TER Spa is a biotechnology company based in Italy, part of the Fresenius Medical Care group of companies since 1989.

JV FreBor LLC is a Belarusian manufacturer of medical devices <http://frebor.by/en/> Production unitary enterprise "FreBor" was established on 1991 as Belarusian-German joint venture Fresenius-Borisov-Dializotechnik Ltd by the agreement between the Government of the Soviet Union and the German firm "Fresenius Medical Care". It has a Certificate of conformity of the integrated management system created on the basis of the requirements of international standards EN ISO 13485: 2016. According to the ECRI Institute "Sourcebase" database, we have

Geographic sales area: Belarus

Year business started: 1995

Quality system registration: CE-Mark, ISO 9001:2000, EN 46002, ISO 13485 and ISO 13488

NovaMed GmbH is a Turkish company part of the Fresenius Medical Care group of companies. From the company website: as NovaMed, we produce Blood Sets and other medical consumables used in dialysis machines all over the world in our factory, which has been operating in Antalya Free Zone since 2000 under the roof of Fresenius Medical Care. We aim to be a company that creates a difference and adds value to life in the world we live in by producing with high quality standards, aware of our responsibilities towards our patients, society, employees and partners.

<http://www.novamedgmbh.com.tr/>

No alternative suppliers/manufacturers have been introduced in this programme in years 2017 and 2018.

No further analysis is therefore needed regarding the quality of the products in programme Paediatric dialysis.

Price benchmarking

Trying to benchmark the prices for the dialysis kits is very difficult, as these items are composed of different devices from different vendors and it's not always possible to find the exact same combination to compare. In the introduction chapter we also explained why international pricing of medical devices is much more difficult to get than the pricing for drugs.

For these reasons **we focused this benchmarking on a specific and well identified product: the Peritoneal dialysis solution DIANEAL PD4 from Baxter Healthcare**. This product was purchased in the programme Paediatric dialysis and also in the Peritoneal dialysis and we were able to find comparison prices to draw some considerations.

To find comparison prices in the ECRI Institute PriceGuide™ database we needed to find the exact catalogue numbers for these items. Unfortunately, the catalogue numbers for Europe are different from those utilized in the United States; however, we could find a document with a

correspondence table for a list of DIANEAL PD4 products, so we could retrieve the necessary information from the ECRI database.

Description of the product	US catalogue number	EU catalogue number	Ukraine catalogue number
DIANEAL PD4 Glucose 1,36 % w/v / 13,6 mg/ml. 5000 ml	L5B4826	SPB5215RC	ACPB5215RL or FJPB5215R
DIANEAL PD4 Glucose 2,27 % w/v / 22,7 mg/ml. 5000 ml	L5B5202	SPB5225RC	ACPB5225RL or FJPB5225R
DIANEAL PD4 Glucose 3,86 % w/v / 38,6 mg/ml. 5000 ml	L5B5203	SPB5235RC	ACPB5235RL or FJPB5235R

Table 10 - DIANEAL PD4 catalogue numbers

In addition to the American prices retrieved from the ECRI PriceGuide™ database, we could get an additional reference price from Saudi Arabia (Saudi Food & Drug Authority website: <https://www.sfda.gov.sa/>). We used the current exchange rate from Saudi Riyal to USD at the date of writing (1 Riyal = 0,27 USD).

We could not get the “equivalent” US catalogue numbers for the 2000ml and the 2500ml items. However, we could get the corresponding prices from the Saudi Food & Drug Authority, that is 60 Riyal (or \$ 15,99) for all items in these bag sizes.

Description of the product	ECRI low	ECRI high	Saudi Arabia	Crown Agents 2016	Crown Agents 2017
DIANEAL PD4 Glucose 1,36 % w/v / 13,6 mg/ml. 2000 ml			\$ 15,99 (Riyal 60)	\$ 7,20	\$ 6,30
DIANEAL PD4 Glucose 2,27 % w/v / 22,7 mg/ml. 2000 ml			\$ 15,99 (Riyal 60)	\$ 7,20	\$ 6,30
DIANEAL PD4 Glucose 3,86 % w/v / 38,6 mg/ml. 2000 ml			\$ 15,99 (Riyal 60)	\$ 7,48	\$ 6,30
DIANEAL PD4 Glucose 1,36 % w/v / 13,6 mg/ml. 5000 ml	\$ 11,10	\$ 54,15	\$ 26,75 (Riyal 100)	\$ 10,63	\$ 11,33
DIANEAL PD4 Glucose 2,27 % w/v / 22,7 mg/ml. 5000 ml	\$ 17,06	\$ 73,90	\$ 26,75 (Riyal 100)	\$ 10,68	\$ 11,33
DIANEAL PD4 Glucose 3,86 % w/v / 38,6 mg/ml. 5000 ml	\$ 17,06	\$ 73,48	\$ 26,75 (Riyal 100)	\$ 10,99	\$ 11,33

Table 11 - DIANEAL PD4 price benchmarking

The prices paid for this product by Crown Agents in Ukraine are lower or in line with the lowest end of the prices stored in the ECRI database, and are very much lower than the registered price available from the Saudi Food & Drug Authority website.

PERITONEAL DIALYSIS

With reference to the programme “Peritoneal dialysis”, based on the files provided by Crown Agents we have identified 18 different items that were purchased in all three years 2016, 2017 and 2018, with an exact correspondence of these items in the three years under evaluation:

Items considered in Peritoneal dialysis programme

1. Peritoneal dialysis catheter
2. Adapter for peritoneal dialysis catheter
3. Transfer tube (catheter extension)
4. Lines clamp (switch)
5. Disinfecting cap (detachable)
6. Drainage set for automated peritoneal dialysis machine
7. Cassette for automated peritoneal dialysis machine
8. Peritoneal dialysis solution with 1,35-1,5 % glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis)
9. Peritoneal dialysis solution with 2,25-2,5% glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis)
10. Peritoneal dialysis solution with 3,85-4,25% glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis)
11. Peritoneal dialysis solution with 1,35-1,5 % glucose concentration in 2500 ml double bags (Y-set for peritoneal dialysis)
12. Peritoneal dialysis solution with 2,25-2,5% glucose concentration in 2500 ml double bags (Y-set for peritoneal dialysis)
13. Peritoneal dialysis solution with 3,85-4,25% glucose concentration in 2500 ml double bags (Y-set for peritoneal dialysis)
14. Long-acting glucose-free peritoneal dialysis solution in 2000 ml double bags (Y-set for peritoneal dialysis)
15. Amino acid (AA)-based peritoneal dialysis solution in 2000 ml double bags (Y-set for peritoneal dialysis)
16. Peritoneal dialysis solution with 1,35-1,5 % glucose concentration in 5000 ml single plastic bag, equipped with injection site and connector
17. Peritoneal dialysis solution with 2,25-2,5 % glucose concentration in 5000 ml single plastic bag, equipped with injection site and connector
18. Peritoneal dialysis solution with 3,85-4,25 % glucose concentration in 5000 ml single plastic bag, equipped with injection site and connector

Price variations

Variation of the price per unit for each item

Line #	Price per unit 2016	Price per unit 2017	Price per unit 2018	Variation 2016-2017	Banding 2016-2017	Variation 2016-2018	Banding 2016-2018
1	\$72,00	\$72,00	\$72,00	0,00%	[0%]	0,00%	[0%]
2	\$80,68	\$80,68	\$43,00	0,00%	[0%]	-46,70%	[-50%;-40%[
3	\$27,00	\$30,94	\$30,94	14,59%	[10%;20%[14,59%	[10%;20%[
4	\$1,97	\$0,65	\$0,65	-67,01%];-50%[-67,01%];-50%[

5	\$0,53	\$0,41	\$0,41	-22,64%	[-30%;-20%[-22,64%	[-30%;-20%[
6	\$4,96	\$5,12	\$5,12	3,23%]0%;10%[3,23%]0%;10%[
7	\$18,69	\$19,06	\$19,06	1,98%]0%;10%[1,98%]0%;10%[
8	\$7,20	\$6,30	\$6,13	-12,50%	[-20%;-10%[-14,86%	[-20%;-10%[
9	\$7,20	\$6,30	\$5,82	-12,50%	[-20%;-10%[-19,17%	[-20%;-10%[
10	\$7,48	\$6,30	\$5,88	-15,78%	[-20%;-10%[-21,39%	[-30%;-20%[
11	\$6,58	\$8,10	\$6,13	23,10%	[20%;30%[-6,84%	[-10%;0%[
12	\$6,58	\$8,10	\$5,82	23,10%	[20%;30%[-11,55%	[-20%;-10%[
13	\$6,58	\$8,10		23,10%	[20%;30%[
14	\$19,06	\$19,68	\$19,68	3,25%]0%;10%[3,25%]0%;10%[
15	\$17,43	\$18,02	\$18,02	3,38%]0%;10%[3,38%]0%;10%[
16	\$10,63	\$11,33	\$11,33	6,59%]0%;10%[6,59%]0%;10%[
17	\$10,68	\$11,33	\$11,33	6,09%]0%;10%[6,09%]0%;10%[
18	\$10,99	\$11,33	\$11,33	3,09%]0%;10%[3,09%]0%;10%[

Table 12 - 2016-2017-2018 price per unit variations for programme Peritoneal dialysis

The relative increase/decrease in price from 2016 to 2017 and from 2016 to 2018 is shown in this table for all devices where prices were available for these years. The cells filled in grey correspond to item 13 that was not purchased in 2018. Therefore, we have considered 18 price variations for 2016-2017 and 17 price variations for 2016-2018.

The main statistical indicators are summarized below:

Period	Price difference observations (n)	Mean difference	Median difference	Lowest difference	Highest difference
2016-2017	18	-1,05%	+3,16%	-67,01%	+23,10%
2016-2018	17	-9,88%	0,00%	-67,01%	+14,59%

Table 13 - Price difference indicators for programme Peritoneal dialysis

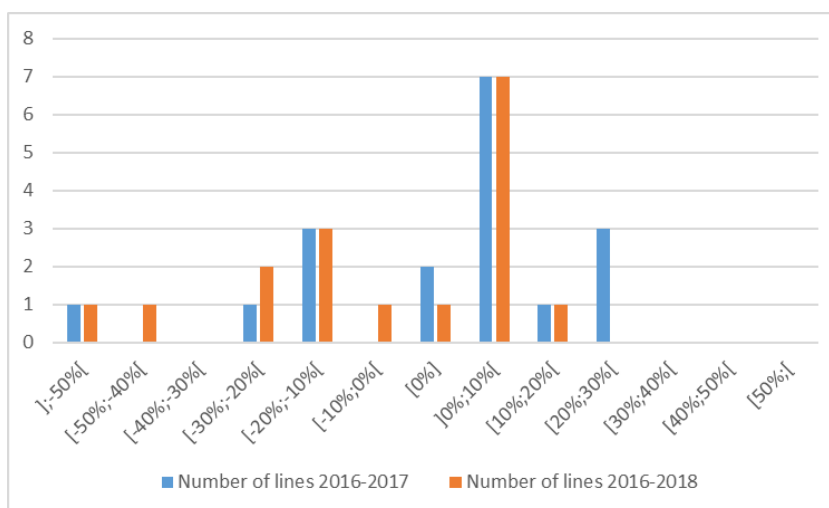


Figure 7 - Banding of price variations for programme Peritoneal dialysis

Most of the price variations are comprised in the interval between 0% and +10%. **Overall, the majority of individual items prices have increased in the period 2016-2017 (11 of 18) while in the period 2016-2018 some more items decreased in price (9 of 17).**

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we have selected those items that had been purchased from the same supplier across 2016-2017 and made a linear regression analysis. We could identify 17 items; a plot of changes in prices versus changes in quantities is represented below. The correlation between these two variables is very low ($R^2=0,0702$; $p=0,30$), therefore we conclude that **the price variations were not strictly linked to the variations in the quantities purchased in different years.**

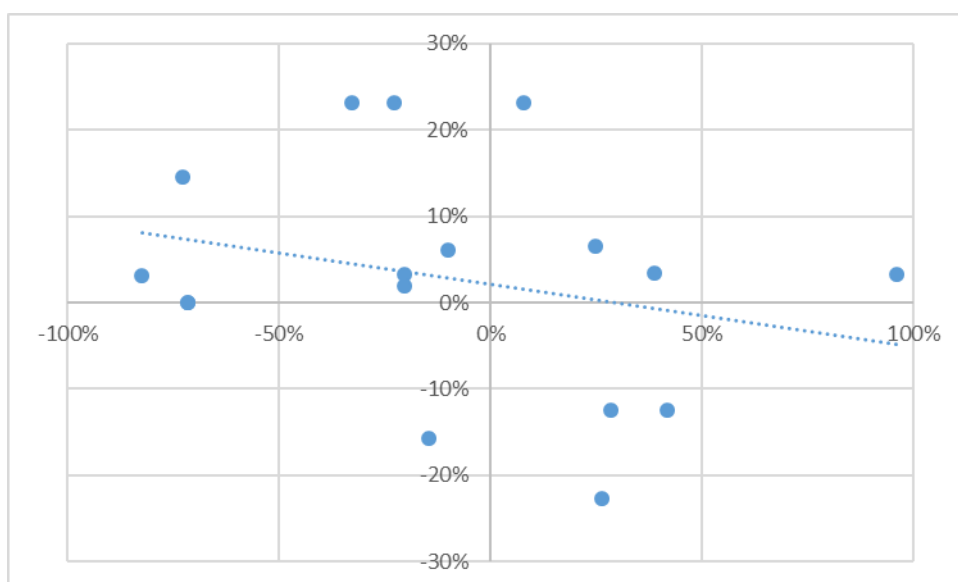


Figure 8 - Change in prices relative to change in quantities for programme Peritoneal dialysis

As can be seen in the complete spreadsheets with the items selected for the analysis (Annex A), **most price improvements for individual items have been achieved through the selection of different suppliers in 2017/2018 from those of 2016.** For 1 item (of 18) there was a change in supplier in 2017; for 7 items (of 17) a new supplier was introduced in 2018 (Yuria Pharm LLC). An assessment of the quality of the devices purchased in this programme for each item (both old and new suppliers) is presented below.

Improvement of the overall spending

As we have mentioned before, to evaluate actual savings and procurement efficiency it's necessary to also consider the total volume of purchased items.

Here we present the improvement of the overall spending for the programme Peritoneal dialysis comparing the “Supplier value” for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices.

Programme – Number of items	Supplier value 2017	Supplier value 2017 at 2016 prices	Supplier value 2018	Supplier value 2018 at 2016 prices
Peritoneal dialysis 18 items	\$ 5.094.906,41	\$ 5.531.911,58	\$ 4.661.254,79	\$ 5.299.473,56

Table 14 - Total savings in programme Peritoneal dialysis

This table highlights the actual savings achieved through the procurement of medical devices in programme Peritoneal dialysis in years 2017-2018 compared to year 2016:

- **Savings in 2017: \$437.005,17** **-7,9% relative to 2016 prices**
- **Savings in 2018: \$638.218,77** **-12,0% relative to 2016 prices**

The programme Peritoneal dialysis shows the biggest total savings across the programmes examined in this report. The main reason for this result is in the much higher volume of purchases for this programme, in particular for items 8 “Peritoneal dialysis solution with 1,35-1,5 % glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis)” and 9 “Peritoneal dialysis solution with 2,25-2,5% glucose concentration in 2000 ml double bags (Y-set for peritoneal dialysis)”.

Quality

The situation related to the list of suppliers and manufacturers for the programme Peritoneal dialysis is similar to the programme Paediatric dialysis, where all products have been sourced from a very limited list of suppliers and manufacturers. In this case, the scenario is even more extreme as in 2016 all items were purchased from one single company (Baxter) with the sole exception of a catheter manufactured by Covidien.

Starting from 2017, and increasingly in 2018, some products have been purchased from an alternative supplier, the Ukrainian company Yuria Pharm LLC.

As highlighted in the Price variation analysis, a significant portion of the cost savings achieved in this programme derive from this introduction of an alternative supplier. The analysis of the quality provided is therefore critical to assess the efficacy of the procurement in this programme.

Supplier	Manufacturer	Products
Svmed	Covidien, USA	Peritoneal dialysis catheter - Argyle Peritoneal Dialysis Catheter Curl Cath, 2 Cuff 62 cm
Baxter	Baxter Healthcare SA	All products in the programme
Yuria Pharm LLC - Ukraine	Yuria Pharm LLC - Ukraine	PERITONEAL DIALYSIS CATHETER ADAPTER PERITONEAL DIALYSIS CATHETER EXTENSION PERITONEAL DIALYSIS CLAMP DISINFECTION CAP FOR PERITONEAL DIALYSIS DIAVITEC® PD 1,5% 2,5% 4,25% Solution for peritoneal dialysis

Table 15 - Supplier/Manufacturer/Products list for programme Peritoneal dialysis

As already highlighted for the Paediatric dialysis programme, Baxter is an international leader specialized in the haemodialysis sector with decades of business history in the field. **The quality of the products supplied meets the highest standards and is out of question.**

The same can be stated regarding Covidien, acquired by Medtronic in 2015.

The focus of our quality assessment goes therefore to the Ukrainian company Yuria Pharm LLC, and in particular on the product DIAVITEC® PD 1,5% 2,5% 4,25% Solution for peritoneal dialysis.

Documentation regarding Yuria Pharm LLC

We could find no information on Yuria Pharm from international sources and it's not currently included in the ECRI Institute Sourcebase™ database.

From the company website <https://www.uf.ua/en/> we found the following information.

GMP: Certificate of GMP Compliance.

GMP EU: European GMP Certificate, the manufacturer's conformity to Article 111 (5) of Directive 2001/83/EC.

GMP KENYA

ISO STATE STANDARDS OF UKRAINE ДСТУ ISO 9001-2009 (ISO 9001:2008, IDT): Quality Management System. Requirements. Quality Management System Certificate.

ISO STATE STANDARDS OF UKRAINE ДСТУ ISO 13485:2005 (ISO 13485:2003, IDT): Medical Devices. Quality Management System. Requirements. Quality Management System Certificate.

ISO 13485:2003: European Quality Management System Certificate.

However, no copies of the quality certificates are available for download.

We have retrieved a catalogue of products manufactured by Yuria Parm and found a page dedicated to the DIAVITEC® PD 1,5% 2,5% 4,25% Solution for peritoneal dialysis:

DIALYSIS SOLUTIONS

DIAVITEC® PD



DIAVITEC® PD 1,5 % / DIAVITEC® PD 2,5 % / DIAVITEC® PD 4,25 %

1 liter of solution DIAVITEC® PD 1.5% containing: sodium chloride solution 5.669 g; sodium lactate 3,922 g; calcium chloride hexahydrate 0.383 g; magnesium chloride hexahydrate 0.102 g; glucose monohydrate 15 g - 1.5% (equivalent to 13.6 g anhydrous glucose - 1.36%);

1 liter of solution DIAVITEC® PD 2.5% containing: sodium chloride solution 5.669 g; sodium lactate 3,922 g; calcium chloride hexahydrate 0.383 g; magnesium chloride hexahydrate 0.102 g; glucose monohydrate 25 g - 2.5% (equivalent to 22.7 g anhydrous glucose - 2.27 %);

1 liter of solution DIAVITEC® PD 4.25% containing: sodium chloride solution 5.669 g; sodium lactate 3,922 g; calcium chloride hexahydrate 0.383 g; magnesium chloride hexahydrate 0.102 g; glucose monohydrate 42.5 g - 4.25% (equivalent to 38.6 g anhydrous glucose - 3.86 %);

Excipients: Water for injections

Indications.

- Acute renal failure;
- Chronic renal failure;
- Severe water retention in the body;
- Electrolyte imbalance;
- Intoxication by drugs if another treatment is ineffective.

How supplied:
2 000 ml polymer containers

Apparently, the product does not carry a CE mark, therefore we asked evidence about national registration in Ukraine, and we received the registration certificates with the following codes:

- № UA/11876/01/01 - DIAVITEC® PD 1,5 % Solution for peritoneal dialysis
- № UA/11876/01/02 - DIAVITEC® PD 2,5 % Solution for peritoneal dialysis
- № UA/11876/01/03 - DIAVITEC® PD 4,25 % Solution for peritoneal dialysis

Moreover, quality certificates are available providing evidence of the manufacturing of these products according to the applicable GMPs (Good Manufacturing Practices), including the laboratory analysis results confirming the composition of the dialysis solution.

Here below are reported a few low-resolution copies of these certificates that are fully available in **Annex B**.



Figure 9 – Registration certificate № UA/11876/01/01 - DIAVITEC® PD 1,5 % Solution for peritoneal dialysis

Ф-09.07.006

СЕРТИФІКАТ ЯКОСТІ № 2772-1

Назва лікарського засобу: Діалітех
Номер реєстраційного посвідчення: UA/11876/01/01
Сила дії/активність: 1 л розчину містить: глюкози моногідрату - 15 г, натрію хлориду - 5,669 г, натрію лактату - 3,922 г, кальцію хлориду дигідрату - 0,257 г, магнію хлориду гексагідрату - 0,102 г

Лікарська форма: розчин для перитонеального діалізу
Розмір та тип пакування: по 2000 мл у контейнерах поліамінок
Номер серії: BSH1291-1
Розмір серії: 1796 шт.
Дата виробництва: 02.09.2019
Термін придатності до: 09.2021
Юридична адреса: Україна, 03038, м. Київ, вул. М. Амосова, 10
тел: (044) 275-01-08, (044) 281-01-01

Назва дільниці виробництва та контролю якості: Виробничий департамент ТОВ «Юрія-Фарм»
Адреса дільниці виробництва та контролю якості: Департамент контролю якості ТОВ «Юрія-Фарм»
Україна, 18030, м. Черкаси, вул. Кобзарська, 108
тел: (0472) 71-00-98

Номер ліцензії на виробництво лікарських засобів: АП 598091
Сертифікат GMP: 071/2018/СДМР

№ з/п	Характеристики якості	Вимоги НД	Методи випробувань	Результати
1	Смак	Прозора безбарвна або біла злегка опалювана рідина	п. 1 НД	Відповідає
2	Ідентифікація			
2.1	Напір	Продукт має сорптерну реакцію (с) на натрій	п. 2.1 НД	Відповідає
2.2	Кальцій	Продукт має сорптерну реакцію (с) на кальцій	п. 2.2 НД	Відповідає
2.3	Магній	Продукт має сорптерну реакцію на магній	п. 2.3 НД	Відповідає
2.4	Хлориди	Продукт має сорптерну реакцію на хлориди	п. 2.4 НД	Відповідає
2.5	Лактати	Продукт має сорптерну реакцію на лактати	п. 2.5 НД	Відповідає
2.6	Глюкоза	Продукт має сорптерну реакцію на глюкозу	п. 2.6 НД	Відповідає
3	Прозорість розчину	Продукт повинен бути прозорим	п. 3 НД	Відповідає
4	Ступінь забарвлення розчину	Забарвлення препарату має бути не інтенсивніше за стандарту	п. 4 НД	Відповідає
5	pH	Від 4,00 до 6,50	п. 5 НД	5,67

Сторінка 1/2

Ф-09.07.006

СЕРТИФІКАТ ЯКОСТІ № 2772-1

№ з/п	Характеристики якості	Вимоги НД	Методи випробувань	Результати
6	5-гідроксиметилтетрафуроза	Співвідношення розчину препарату, що містить 1 г глюкози, повинні бути не більше 0,25	п. 6 НД	0,021
7	Кальцій	Вміст натрію-іону в 1 мл препарату повинен бути від 2,73 мг до 3,34 мг	п. 12.1 НД	3,08
7	Кальцій-іон	Вміст кальцій-іону в 1 мл препарату повинен бути від 0,083 мг до 0,077 мг	п. 12.2 НД	0,070
7	Магній-іон	Вміст магній-іону в 1 мл препарату повинен бути від 0,0109 мг до 0,0134 мг	п. 17.3 НД	0,0124
7	Хлорид-іон	Вміст хлорид-іону в 1 мл препарату повинен бути від 3,420 мг до 3,780 мг	п. 12.3 НД	3,643
7	Лактат-іон	Вміст лактат-іону в 1 мл препарату повинен бути від 2,95 мг до 3,28 мг	п. 12.4 НД	3,13
7	Глюкоза	Вміст глюкози моногідрату в 1 мл препарату повинен бути від 14,25 мг до 15,75 мг	п. 12 НД	15,26
8	Суміш, що випадає	Не більше номінального	п. 7 НД	2,033,3
9	Мезаніон випадає	Повинні випадавати вміст JCF ² : 2.9.19, метод 1, JCF ² : 2.9.20	п. 11 НД	1,2 0,0
10	Стерильність	Препарат повинен бути стерильним	п. 10 НД	Відповідає
11	Прозорість	Препарат повинен бути прозорим	п. 8 НД	Відповідає
12	Активна токсичність	Препарат повинен бути неактивним	п. 9 НД	Відповідає

Висновок:
Лікарський засіб Діалітех відповідає вимогам НД до ПП UA/11876/01/01 із зміною МОЗ № 853 від 14.12.2015, із зміною МОЗ № 1155 від 31.10.2016

Коментарі:
Зберігати в сухому місці при температурі не вище 25°C. Не заморозувати.
Цим в закладі, що надає цю інформацію є достовірною і точною. Цей сертифікат лікарського засобу було вироблено (власником ліцензії/виробником) виробним департаментом ТОВ «Юрія-Фарм» та проведено контроль якості в спеціалізованій лабораторії якості ТОВ «Юрія-Фарм» у повній відповідності з акредитованим відомим та признаним власником виробничим процесом, встановленими національними регуляторним органом, а також є відповідно до специфікації, що міститься у реєстраційному довідку.
Продукти виробництва, наведені на контроль якості були перекриті на підставі встановленої відповідності ліцензійним умовам та признаним власником виробничим процесом

Уповноважена особа ТОВ «Юрія-Фарм» Г.А. Артежко
18.09.2019

Сторінка 2/2

Figure 10 – Quality certificate for DIAVITEC® PD 1,5 % Solution for peritoneal dialysis

As additional documentation, we retrieved a letter, signed by Yuria Pharm, providing a declaration that their dialysis products are fully compatible with the technologies provided by Baxter Healthcare SA. The products that are declared compatible are the devices under certificate of

conformity № UA.TR.039.394 (PERITONEAL DIALYSIS CATHETER ADAPTER, PERITONEAL DIALYSIS CATHETER EXTENSION, PERITONEAL DIALYSIS CLAMP, DISINFECTION CAP FOR PERITONEAL DIALYSIS) and the DIAVITEC® Solution for peritoneal dialysis (in different concentrations). The letter also lists the specific products from Baxter that are declared compatible. This document is available in **Annex C**.



Figure 11 – Declaration from Yuria Pharm of compatibility with the products from Baxter

In conclusion, we have evidence that the products purchased from Yuria Pharm are duly registered in Ukraine and we have laboratory confirmation of their quality characteristics. The supplier confirms, under its own responsibility, that such products are fully compatible with the products from Baxter.

Therefore, we consider appropriate the decision of Crown Agents to purchase these devices from Yuria Pharm as an alternative supplier.

Close attention should be placed in the post-market phase for these products in order to confirm their quality and detect any issues or defects during utilization.

Price benchmarking

Please refer to the Price benchmarking paragraph related to programme Paediatric dialysis for the benchmarking on the **Peritoneal dialysis solution DIANEAL PD4 from Baxter Healthcare**.

DIABETES (GLUCOSE TEST STRIPS)

With reference to the programme “Diabetes (glucose test strips)”, based on the files provided by Crown Agents we have identified 1 single item that was purchased in years 2016, 2017 and 2018:

Items considered in Diabetes (glucose test strips) programme

1. Individual blood glucose test strip

The device is “Accu-Chek® Performa test strips” manufactured by Roche Diabetes Care GmbH, Germany and supplied in Ukraine by Dialogue Diagnostic.

Price variations

Variation of the price per unit for each item

Line #	Price per unit 2016	Price per unit 2017	Price per unit 2018	Variation 2016-2017	Banding 2016-2017	Variation 2016-2018	Banding 2016-2018
1	\$0,0839	\$0,0839	\$0,0749	0,00%	[0%]	-10,73%	[-20%;-10%]

Table 16 - 2016-2017-2018 price per unit variations for programme Diabetes (glucose test strips)

Since there’s only one item for this programme, it’s not necessary or possible to perform statistical analysis on the data.

The price for the glucose test strips remained stable in 2017 and decreased by 10,73% in 2018.

Of course, no regression analysis to investigate a relationship between quantity and price reduction is possible in this case.

Improvement of the overall spending

As we did for the other programmes, here we present the improvement of the overall spending for the programme Diabetes (glucose test strips) comparing the “Supplier value” for 2017/2018 to the cost Crown Agents would have incurred to purchase the same number of each item at 2016 prices.

Year	Price per unit	Quantity	Supplier value
2016	\$ 0,0839	8.427.450	\$ 707.063,06
2017	\$ 0,0839	8.695.900	\$ 729.586,01
2018	\$ 0,0749	9.389.650	\$ 703.284,79

Table 17 - 2016-2017-2018 price per unit, quantity and supplier value for programme Diabetes (glucose test strips)

The aim of the evaluation of Accu-Chek Performa was to

- *assess the analytical quality under standardised and optimal conditions, performed by a biomedical laboratory scientist in a hospital environment*
- *examine the variation between three lots of test strips*
- *evaluate the Accu-Chek Performa owner's booklet and the user-friendliness of Accu-Chek Performa (by one biomedical laboratory scientist)*

Materials and methods

Capillary samples from 78 persons with diabetes and 12 persons without diabetes were collected. The sampling was carried out at Haralds plass Diaconal Hospital. For each person two measurements on Accu-Chek Performa were carried out, and a capillary sample was directly prepared for measurement with a selected comparison method. Three lots of test strips were used. The user-friendliness of Accu-Chek Performa was assessed by means of a questionnaire.

Results

- *The precision of Accu-Chek Performa was good. The repeatability CV was between 2,9 and 4,1%. The suggested quality goal for precision was obtained*
- *Accu-Chek Performa showed glucose results in agreement with the comparison method for glucose concentrations <10 mmol/L. For glucose concentrations >10 mmol/L Accu-Chek Performa had a deviation from the comparison method of -0,5 mmol/L*
- *The assessment of the accuracy showed that Accu-Chek Performa glucose results were within the accepted quality limits according to ISO 15197*
- *One of the three lots gave glucose results in agreement with the comparison method. For the two other lots the deviation was -0,28 mmol/L and -0,41 mmol/L, respectively*
- *The user-friendliness and the owner's booklet were assessed as satisfactory by the biomedical laboratory scientist*
- *Fraction of technical errors was <2%*

Conclusion

The precision of Accu-Chek Performa was good. For glucose concentrations above approximately 10 mmol/L, the results on Accu-Chek Performa were systematically lower than the results from the selected comparison method. The bias was -0,5 mmol/L. The results fulfilled the quality goal proposed in ISO 15197. The user-friendliness and the owner's booklet were assessed as satisfactory. The fraction of technical errors was <2%, and the quality goal was fulfilled.

Price benchmarking

For this kind of consumable material, **the volume of purchased items can make a big difference for the unit price.** Purchasing millions of pieces at national level is very different from the retail prices (usual sizes are packages of 50 or 100 test strips) or even from the price paid by an individual hospital for their diabetes management program.

We searched for the biggest bulk purchases of Accu-Chek Performa test strips we could find, and here are summarized our findings:

- E-shop in India: 500 pieces at Rs. 4.749 At the day of writing the exchange rate between Indian rupees and USD is 0,014 therefore this price equals \$66,85 or **\$0,132** per single test

strip (source: <https://www.sportsuncle.com/500-strips-for-accu-chek-performa-sugar-monitor.html>)

- Alibaba: the best price we could find for a bulk purchase of Accu-Chek Performa test strips is \$3,50-\$5,50/box of 100 pieces (minimum order 100 boxes). The price per single strip would be **\$0,035-\$0,050** (source: <https://www.alibaba.com/showroom/accu-chek-performa-strips.html>)

Similar prices can be easily found on the Internet, but they can't really represent a correct benchmark against a national program like the one we are analysing. We consider these prices just a reference and we can conclude that **the prices paid by Crown Agents (\$0,0839-\$0,0749) for each test strip are in line with the reference prices we have highlighted**, once the following factors are considered:

- Total quantity of test strips purchased per year
- Reliability of suppliers: in the two samples highlighted above we only considered the wholesale price. No considerations are made on the reliability of the supplier, shipping conditions, quantities of strips per week that can be delivered, etc.
- Glucose test meters: as we have noted above, for each year of the programme Crown Agents received thousands of Accu-Check test devices free of charge included in the yearly supply

CONCLUSIONS

All necessary considerations regarding price variations, quality of the products and price benchmarking (where available) have been presented in the previous chapters of this report, divided for each individual programme.

In this final section we provide some aggregated results regarding the price variations and cost savings achieved in 2017 and 2018 compared to 2016, and we present a summary of the considerations we made regarding the quality of the products.

Price variations

Overall, we have considered the price variations of 65 items from 2016 to 2017 and 63 items from 2016 to 2018.

Banding	Number of lines 2016-2017	Number of lines 2016-2018
];-50%[2	2
[-50%;-40%[3	3
[-40%;-30%[1	1
[-30%;-20%[2	5
[-20%;-10%[11	11
[-10%;0%[8	7
[0%]	9	8
]0%;10%[18	16
[10%;20%[6	7
[20%;30%[5	2
[30%;40%[0	0
[40%;50%[0	0
[50%;[0	1
TOTAL	65	63

Table 19 – Summary of 2016-2017-2018 price per unit variations

The main overall statistical indicators are summarized below:

Period	Price difference observations (n)	Mean difference	Median difference	Lowest difference	Highest difference
2016-2017	65	-4,09%	0,00%	-67,01%	+25,20%
2016-2018	63	-5,60%	0,00%	-67,01%	+60,07%

Table 20 - Price difference indicators for all programmes in the analysis

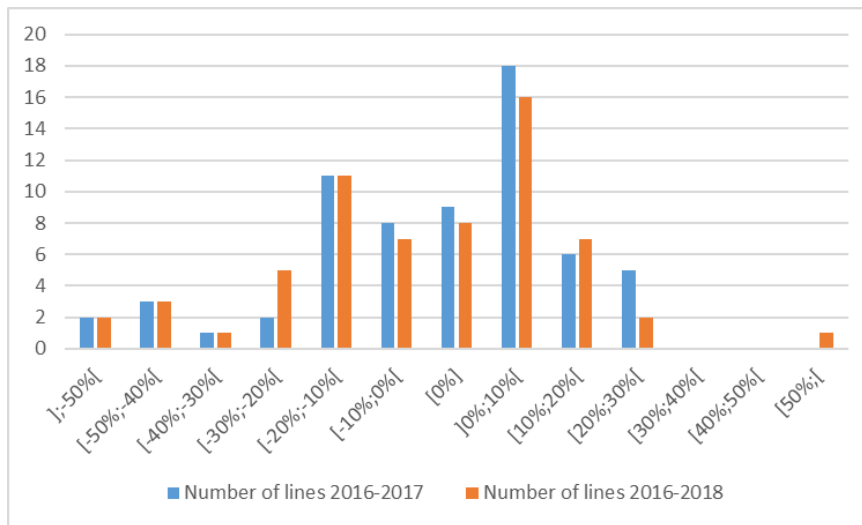


Figure 12 – Banding of price variations for all programmes in the analysis

Most of the price variations are comprised in the interval between -20% and +10%. **Overall, the majority of individual items prices have decreased or remained stable both in the period 2016-2017 (36 of 65) and in the period 2016-2018 (37 of 63).**

In order to verify if the price variations were correlated to the variations in the quantities purchased for each item, we have selected those items that had been purchased from the same supplier across 2016-2017 and made a linear regression analysis. The correlation between these two variables resulted very low for each single programme and we concluded that the price variations were not strictly linked to the variations in the quantities purchased.

If we aggregate with the same criteria all the items for the 4 programmes, we can do a linear regression for all 48 data points. Also in this case the resulting correlation is very low ($R^2=0,10734$; $p=0,02$) and the final conclusion is that across all programmes **the price variations are not strictly linked to the variations in the quantities purchased in different years.**



Figure 13 - Change in prices relative to change in quantities for all programmes

Aesculap, Gambro, Roche Diabetes, etc.). **The quality of the products supplied meets the highest standards and is out of question.**

Some products come from manufacturers that, **although not among the “big names” of the field, have international experience and produce high quality medical devices with all necessary international certifications** (Balt Extrusion, Balton Sp., Teleflex Medical Arrow International, Merit Medical Systems, Mizuho Corporation, etc.). **For these companies we made a more detailed analysis searching evidence that their products are sold worldwide and carry the necessary certifications.**

Particular attention was dedicated to the analysis of one specific company, Yuria Pharm LLC, a Ukrainian manufacturer of medical devices that was selected to achieve better “value for money” within the Peritoneal dialysis programme. The products we considered are certified for the Ukrainian market and we found evidence of the manufacturing quality. A letter from the manufacturer is available that confirms their products are fully compatible with those manufactured by Baxter Healthcare.

In conclusion, we collected evidence that all products purchased within the programmes we analysed are of good quality as they are medical devices sold and certified in international markets (CE Mark, FDA approval), or are available in Ukraine after proper state registration and quality assurance processes.

Price benchmarking

Although price benchmarking for medical devices in different markets has several limitations, we attempted to provide some reference data; all considerations are made in the chapters dedicated to each specific programme.

KEY FINDINGS

The present report analysed changes in prices of medical devices under four Crown Agents procurement programmes in Ukraine from 2016 to 2018. The programmes we considered for the analysis, and the number of different products in each programme, are the following:

- **Cardio (Part 4):** 23 items
- **Paediatric dialysis:** 24 items
- **Peritoneal dialysis:** 18 items
- **Diabetes (Glucose test strips):** 1 item

PRICE VARIATION OF INDIVIDUAL ITEMS

Overall, the majority of individual items prices have decreased or remained stable both in the period 2016-2017 (36 of 65) and in the period 2016-2018 (37 of 63).

- **Mean difference 2016-2017:** -4,09%
- **Mean difference 2016-2018:** -5,60%

The price variations are not strictly linked to the variations in the quantities purchased in different years.

TOTAL SAVINGS

The savings in 2017 for the items analysed have been \$ 554.019,62; -7,3% relative to 2016 prices. The savings in 2018 for the items analysed have been \$ 803.054,53; -11,1% relative to 2016 prices

- **Overall savings achieved in years 2017 and 2018:** \$ 1.357.074,15
- **Overall cost reduction:** -9,1% relative to 2016 prices

We collected evidence that **all products purchased within the programmes we analysed are of good quality** as they are medical devices sold and certified in international markets (CE Mark, FDA approval), or are available in Ukraine after proper state registration and quality assurance processes.

Although price benchmarking for medical devices in different markets has several limitations, we attempted to provide some reference data; **the prices paid by Crown Agents for each item considered are in line or better than the reference prices.**

Overall, the procurement activity by Crown Agents in the four programmes analysed for years 2017 and 2018 compared to 2016 proved effective, with total cost savings in the range of -7% to -11% relative to 2016 prices, good quality products selected from reliable manufacturers and a price benchmark in line or better than the international prices we considered for reference.