



PREDECIZER™



Decision-Making Analysis

PREDECIZER™



OFFERS YOU THE BEST PREDICTABILITY!!



CONSIDERS THE ENTIRE REIMBURSEMENT PROCESS

PREDECIZER™

Reimbursement Decision Practice
for the latest 12 months



updated March 2021

(every 2 months continuously since May 2014)



POSITIVE DECISIONS AND RECOMMENDATIONS (1/2)



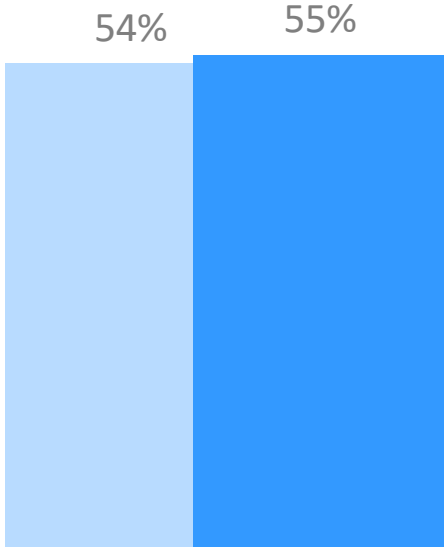
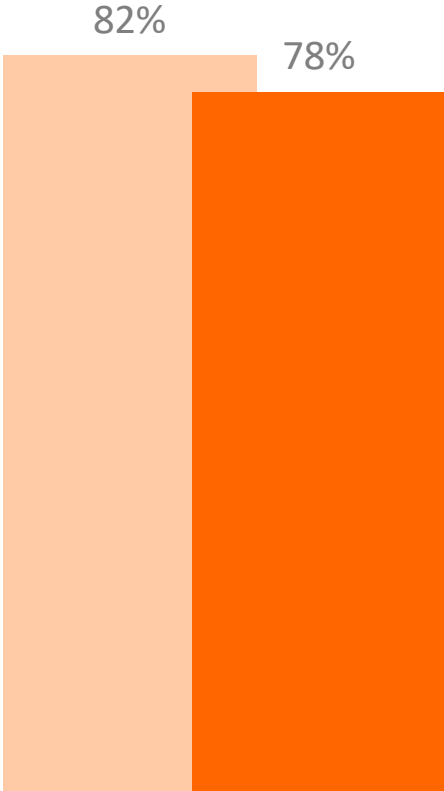
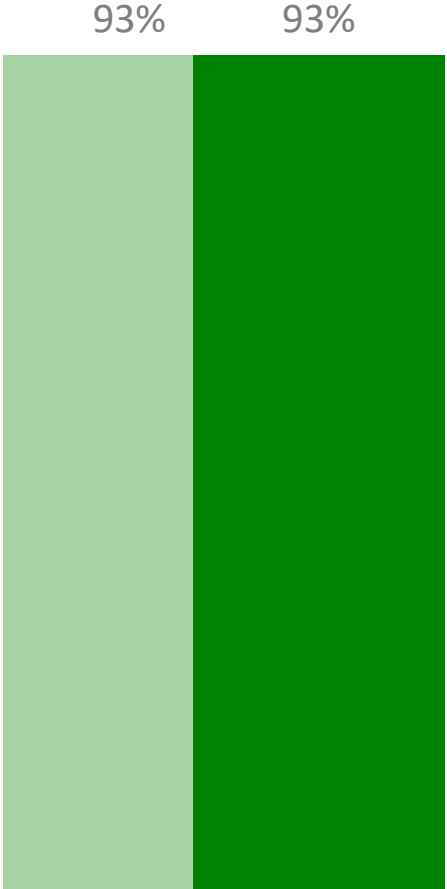
TRANSPARENCY COUNCIL



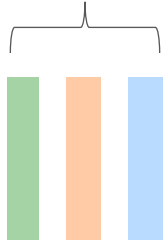
AHTAPOI PRESIDENT



MINISTER OF HEALTH



03.2020-02.2021



05.2020-04.2021



POSITIVE DECISIONS AND RECOMMENDATIONS (2/2)



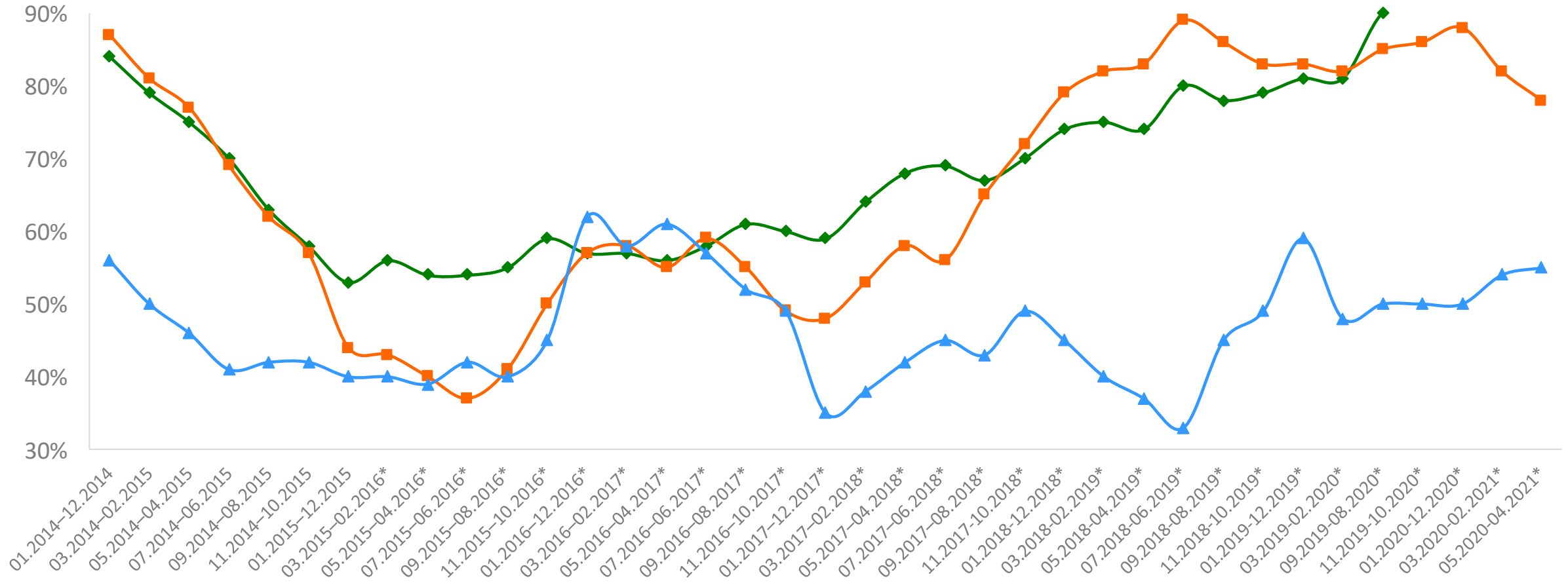
TRANSPARENCY COUNCIL



AHTA PoI PRESIDENT



MINISTER OF HEALTH



*Statutory processing time for Drug Programme = 240 days, Pharmaceutical reimbursement; Chemotherapy = 180 days



POSITIVE DECISIONS AND RECOMMENDATIONS (05.2020–04.2021)



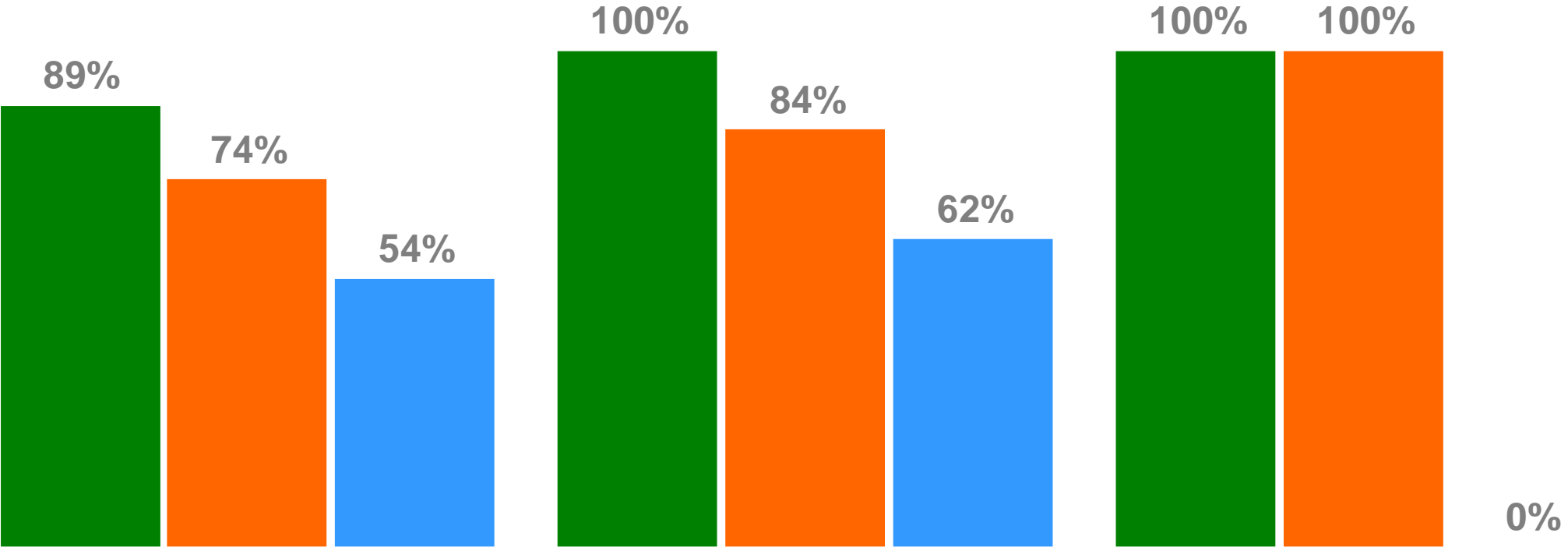
TRANSPARENCY COUNCIL



AHTAPoI PRESIDENT



MINISTER OF HEALTH



Drug Programme

Pharmaceutical Reimbursement

Chemotherapy









Correspondence between the recommendation of AHTAPol President and the Transparency Council (TC) statement








05.2020–04.2021
(12 months)

03.2020–02.2021
(12 months)

Level of Association using Cramer's V:
0,47

Level of Association using Cramer's V:
0,53

		 Statement of the TC	
			
 Recommendation of the President of AHTAPol		62 (78%)	0
		12 (15%)	6 (8%)

Statement of the TC			
			
55 (82%)	0		
7 (10%)	5 (7%)		 Recommendation of the President of AHTAPol
			



Correspondence between the recommendation of the President of AHTAPol and the statement of the Transparency Council (TC) (05.2021–04.2021)

Drug Programme



Statement of the TC



Recommendation of the President of AHTAPol



40
(74%)

0

8
(15%)

6
(11%)

Level of Association using Cramer's V:
0,53*

Pharmaceutical Reimbursement

Statement of the TC



21
(84%)

0

4
(16%)

0

Level of Association using Cramer's V:
0,NA**

Chemotherapy



Statement of the TC



1
(100%)

0

0

0

Recommendation of the President of AHTAPol



Level of Association using Cramer's V:
NA**

* Unful filled assumptions of the Chi2 test, Yates' correction applied

**NA – not applicable









Correspondence between the decision of the MoH and recommendation of AHTAPoI president







05.2020–04.2021
(12 months)

03.2020–02.2021
(12 months)

Level of Association using Cramer's V:
0,14

Level of Association using Cramer's V:
0,09

				Decision of the MoH	
					
 Recommendation of the President of AHTAPoI		55 (48%)	39 (34%)		
		8 (7%)	12 (11%)		

		Decision of the MoH			
					
 Recommendation of the President of AHTAPoI		46 (47%)	37 (38%)		
		6 (6%)	8 (8%)		



Correspondence between the decision of the MoH and recommendation of AHTAPoI President (05.2020–04.2021)

Drug Programme



Decision of the MoH	
42 (46%)	31 (34%)
8 (9%)	11 (12%)

Recommendation of the President of AHTAPoI



Level of Association using Cramer's V: 0,05*

Pharmaceutical Reimbursement

Decision of the MoH



13 (62%)	7 (33%)
0	1 (5%)



Level of Association using Cramer's V: 0,13*

Chemotherapy



Decision of the MoH	
0	1 (100%)
0	0

Recommendation of the President of AHTAPoI



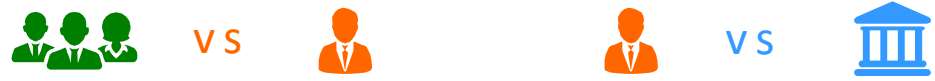
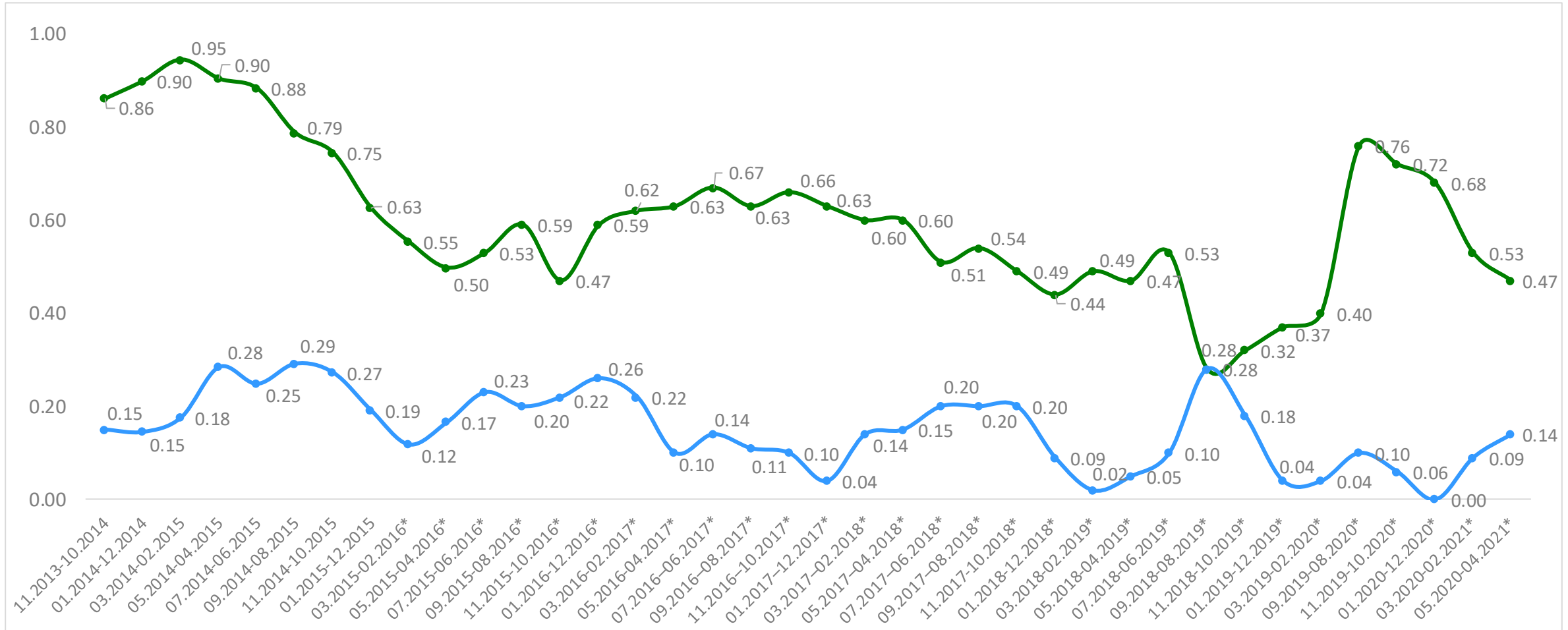
Level of Association using Cramer's V: NA**

* Unful filled assumptions of the Chi2 test, Yates' correction applied

**NA – not applicable



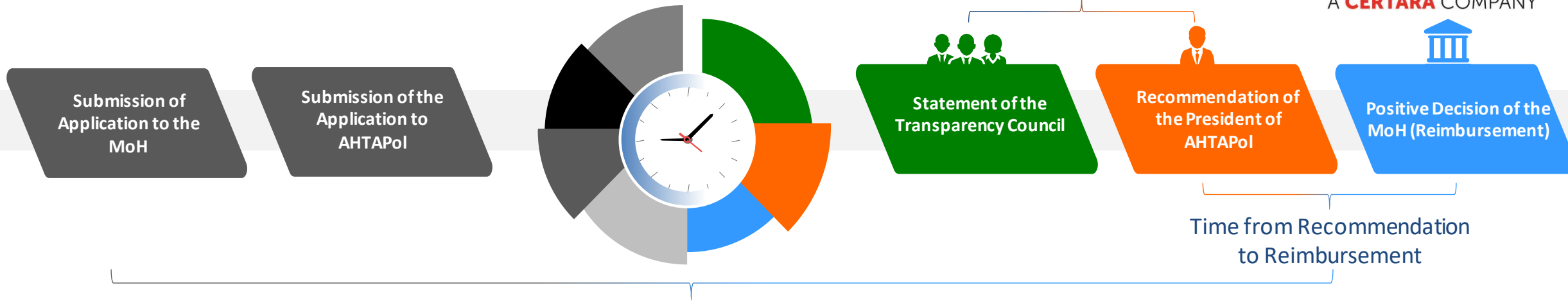
LEVEL OF ASSOCIATION USING CRAMER'S V



*Statutory processing time for Drug Programme = 240 days, Pharmaceutical reimbursement; Chemotherapy = 180 days



DURATION OF THE PROCESS



Duration of the Process with a positive decision from the Minister of Health for the periods:

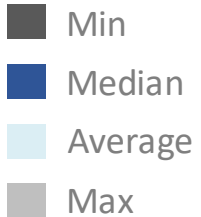
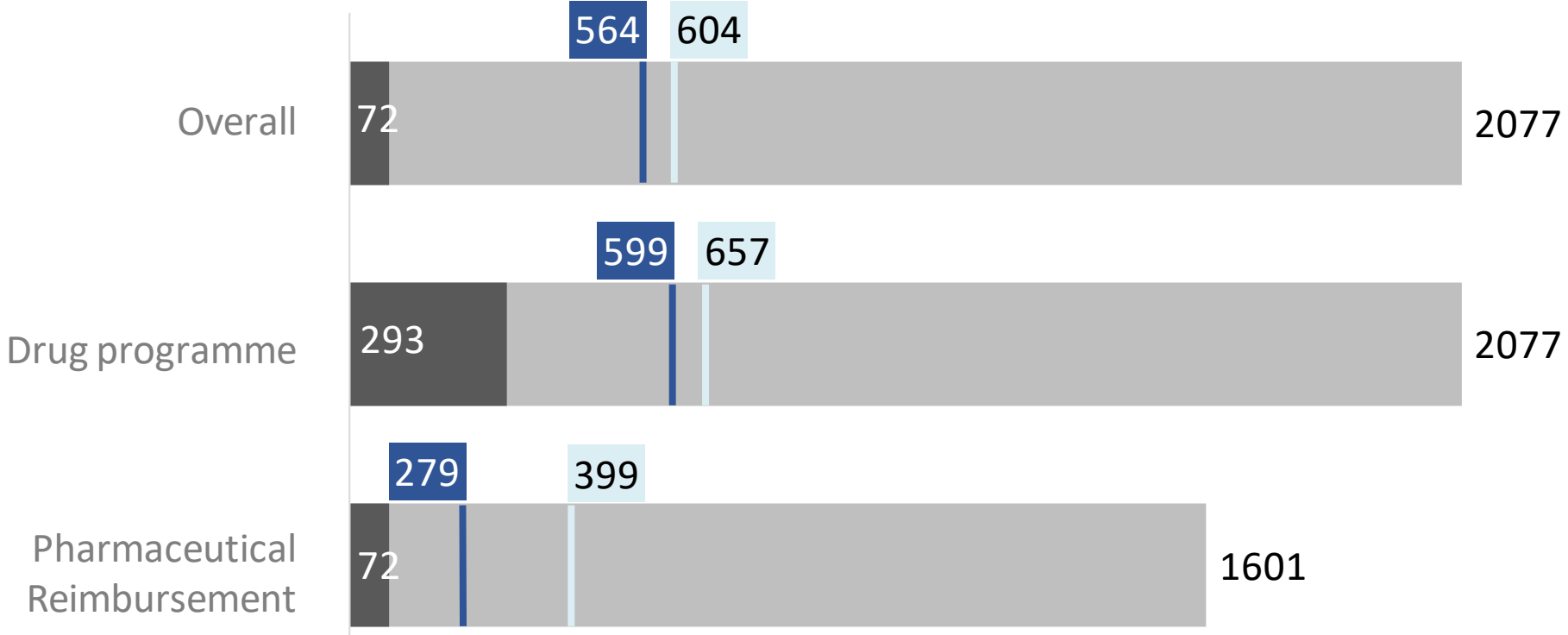
05.2020–04.2021 (I)

03.2020–02.2021 (II)

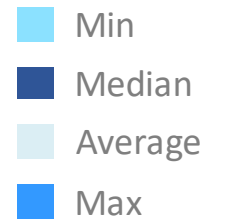
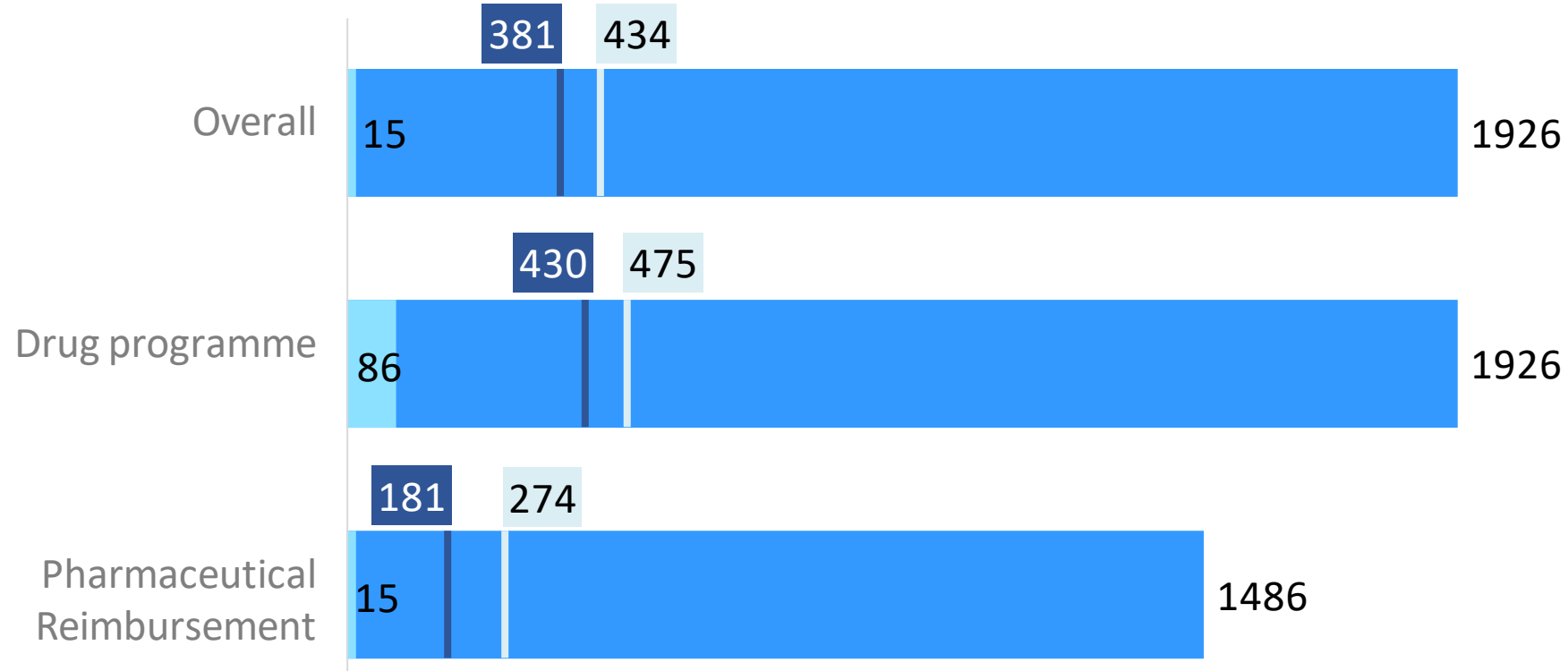
Statistics [Days]	Full Duration of the Process		Effective Time at AOTMIT		From Recommendation to Reimbursement	
	Stage I	Stage II	Stage I	Stage II	Stage I	Stage II
Median	564	528	84	90	381	335
Average	604	587	96	104	434	418
MIN	72	72	20	20	15	15
MAX	2 077	2 077	205	205	1 926	1 926



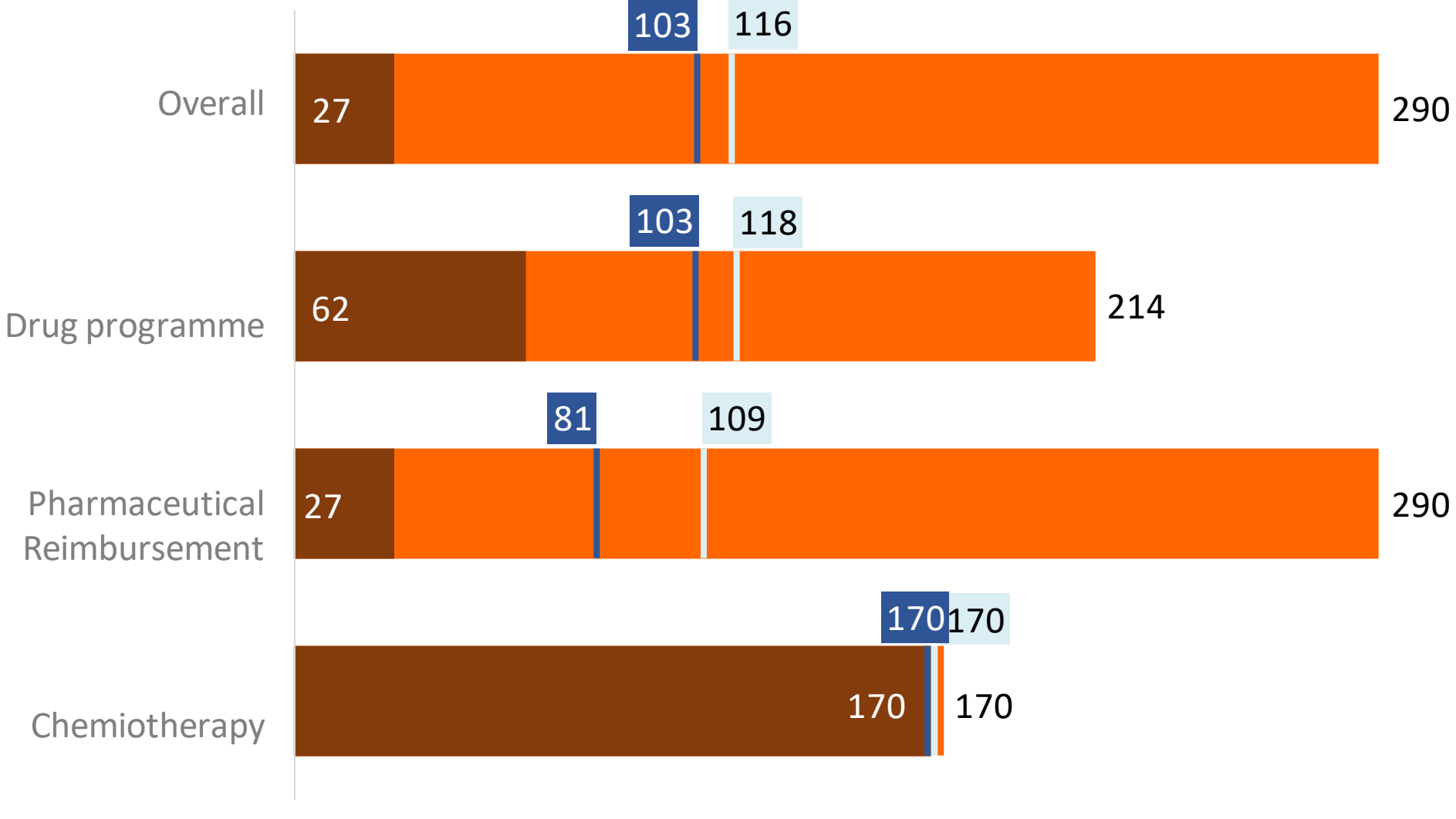
Duration of the Process (05.2020–04.2021)



Time between the Recommendation of the President of AHTAPol and Positive Decision of the MoH (05.2020–04.2021)



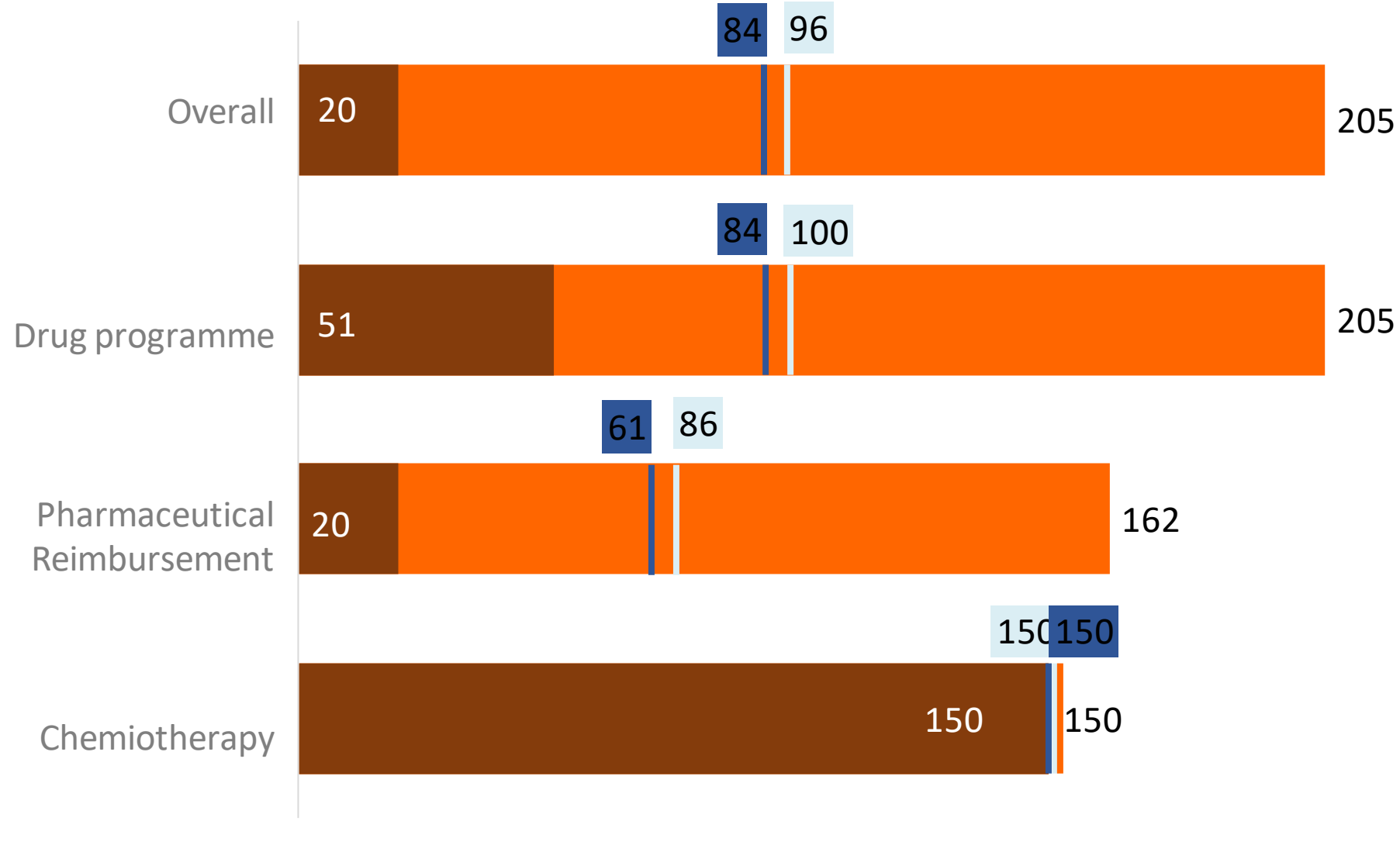
Real time for Preparation of Recommendation from President of AHTAPol (05.2020–04.2021)



- Min
- Median
- Average
- Max



Effective time for Preparation of Recommendation of the President of AHTAPoI (05.2020–04.2021)

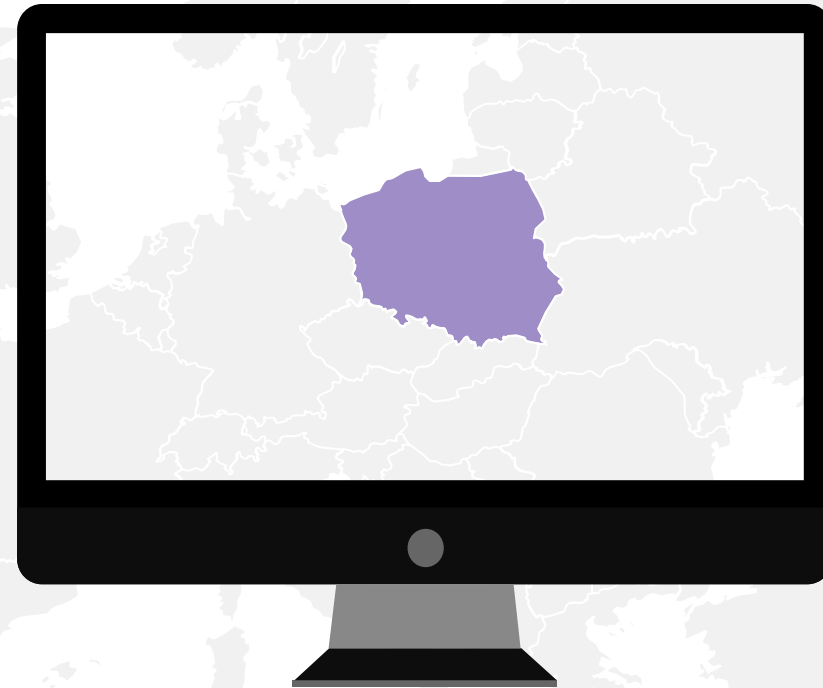


REIMBURSEMENT & REGULATORY DATABASE

Since 2012

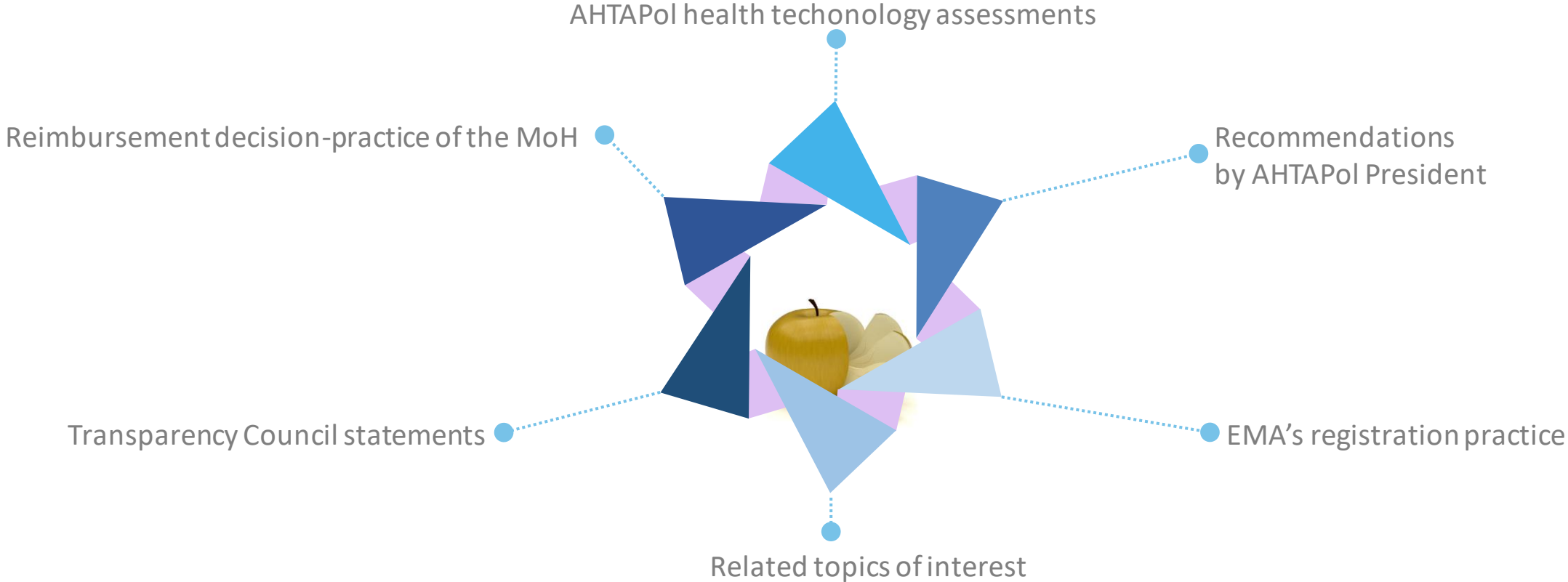
INAR

A CERTARA COMPANY



REIMBURSEMENT & REGULATORY DATABASE

WE ANALYZE:



CONTENTS OF THE DATABASE

INAR

A **CERTARA** COMPANY





REGISTRATION DATA

PROCESS, PRODUCT, APPLICATION

APPLICATION PROCEEDINGS BY AHTAPOL

MINISTRY OF HEALTH

OTHER DATA

CONTENTS OF THE DATABASE



REGULATORY & REIMBURSEMENT DATABASE



A CERTARA COMPANY

Predecizer

Data ▾ Charts ▾ Logout (production@inar.pl)

REIMBURSEMENT PROCESS

PRODUCT INFORMATION

SUBMITTED TERMS

INDICATIONS

MARKETING AUTHORIZATION (MA)

PROCESSING OF THE APPLICATION BY AOTMIT

POSITIVE

PROBABLY NEGATIVE

IN PROGRESS

COST ASPECTS

CLINICAL ASPECTS

REIMBURSEMENT PROCESS

PRODUCT INFORMATION

MARKETING AUTHORIZATION

Reimbursement under submitted conditions [YES/NO]	Positive decision (date)	No. of order	Applicant	Brand name	Active substance	EAN	Formulation	Route of administration	Original/generic drug	Name of original drug (if applicable)	Reimbursement status (moment of application)	Current reimbursement mode [the same/other/NA]	Type of MA procedure	Date of first MA permission	Date of MA for i
YES	2016-09-01	55/2016	Ipsen	Somatuline AUTOGEL	Ianreotide	5909991094515; 5909991094614; 5909991094416	solution for injection	subcutaneous	original drug	-	Pharmacy Chemotherapy	the same	centralised	2014-04-29	2014
NO	-	4/2016	Alcon	Simbrinza	brinzolamide + brimonidine tartrate	5909991142490	suspension	ophthalmic	complex drug product	-	Not reimbursed	NA	centralised	2014-07-18	2014
YES	2016-09-01	2/2016	AstraZeneca	Lynparza	olaparib	5902135480052	hard capsules	oral	original drug	-	Not reimbursed	NA	centralised	2014-12-16	2014
YES	2016-07-01	1/2016	EUSA Pharma	Erwinase	crisantaspase	5060146290302	powder for solution for injection	intravenous or intramuscular	original drug	-	Not reimbursed	NA	national	2015-07-27	2015
YES	2016-07-01	169/2015	GSK	Incruse	umedidinium bromide	5909991108953	inhalation powder	inhalation use	original drug	-	Not reimbursed	NA	centralised	2014-04-28	2014
YES	2016-07-01	161/2015	Sandoz	Nasometin	mometasone	5909991031275	nasal spray, suspension	intranasal	generic	Nasonex	Not reimbursed	NA	unknown	2012-12-12	2012
YES	2016-09-01	158/2015	Adamed	Hitoff	pramipexole	5909990804405; 5909990804443; 5909990804467; 5909990804474; 5909990804498; 5909990804481	tablets	oral	generic	Mirapexin/ Sifrol	Not reimbursed	NA	national	2010-08-04	2010



REIMBURSEMENT PROCESS				COST ASPECTS			CLINICAL ASPECTS
Reimbursement under submitted conditions [YES/NO] [⚙]	Positive decision (date) [⚙]	No. of order	Applicant [⚙]	Incremental cost in BIA	Population in BIA	ICER (min, max, best case scenario)	Clinical conclusions (from the main part of President's recommendation)
NO	-	233b/2014	BRITANNIA PHARMACEUTICALS	Perspektywa podmiotu zobowiązanego do finansowania świadczeń ze środków publicznych bez RSS/z RSS 1 ...	Pacjenci ze wskazaniem określonym we wniosku Rok 1: 1 833 Rok 2: 1 857 Rok 3: 1 882 Pacjenci, u któr ...	Porównanie APO-go PEN+OTD vs OTD Perspektywa podmiotu zobowiązanego do finansowania świadczeń ze śro ...	Eksperti praktyki klinicznej poproszeni przez Agencję o przekazanie opinii uważają zgodnie, że apomo ...
YES	2015-03-01	231/2014	Actelion	porównanie terapii EPR vs TRE unknow	Pacjenci ze wskazaniem określonym we wniosku 2015: minimalny 56 Wariant prawdopodobny 58 Wariant ma ...	NA	Prezes Agencji, przychylając się do stanowiska Rady Przejrzystości, uważa że dostępne dowody naukowe ...
YES	2015-03-01	229/2014	Kedrion	2014: 0,00 2015: -20,85 mln 2016: -20,85 mln Zgodnie z oszacowaniami wnioskodawcy, zmiana sposobu fi ...	NA	NA	Mimo braku możliwości wzajemnych porównań skuteczności i bezpieczeństwa stosowanych preparatów można ...
YES	2016-07-01	228/2014	Biogen Idec	Unknown	Pacjenci ze wskazaniem określonym we wniosku 2013: 6053; 2014: 6697 Pacjenci, u których wnioskowana ...	Interwencja: Tecfidera (fumaranu dimetylu) NFZ Avonex (interferon beta-1a) ICUR = 363 759,02 (bez R ...	Obecnie, na temat efektywności klinicznej fumaranu dimetylu względem aktywnej terapii w rzutowo-remi ...
YES	2015-03-01	227/2014	Octapharma	Wydatki inkrementalne: w tym wydatki na produkt Octagam [zł] 2015, 2016: -1 077 676,84, -1 077 676, ...	Populacja pacjentów z GBS, w której będą stosowane IVg; w tym leczonych Octagam 2015/2016: 56/56 w ...	Zgodnie oszacowaniami wnioskodawcy, w przypadku obydwu rozważanych perspektyw: płatnika publicznego ...	dostępne wyniki badań wysokiej lub średniej, rzadziej niskiej jakości (zależnie od typu wskazania), ...
YES	2015-03-01	226/2014	Boehringer Ingelheim	Brak RSS Perspektywa NFZ 1 rok: -6 038 713; rok 2: -9 579 878	Pacjenci ze wskazaniem określonym we wniosku : 66 327 Pacjenci, u których	Brak RSS CUA: DAB vs VKA ICUR = 29 714,43 (NFZ); 74 049,29 (poszerzona) CUA: DAB vs HDC	dostępne dowody naukowe potwierdziły porównywalną efektywność dabigatranu w porównaniu do antagonist ...



New molecule/new indication

NEW INDICATION

NEW MOLECULE

Years

2012

2013

2014

2015

2016

2017

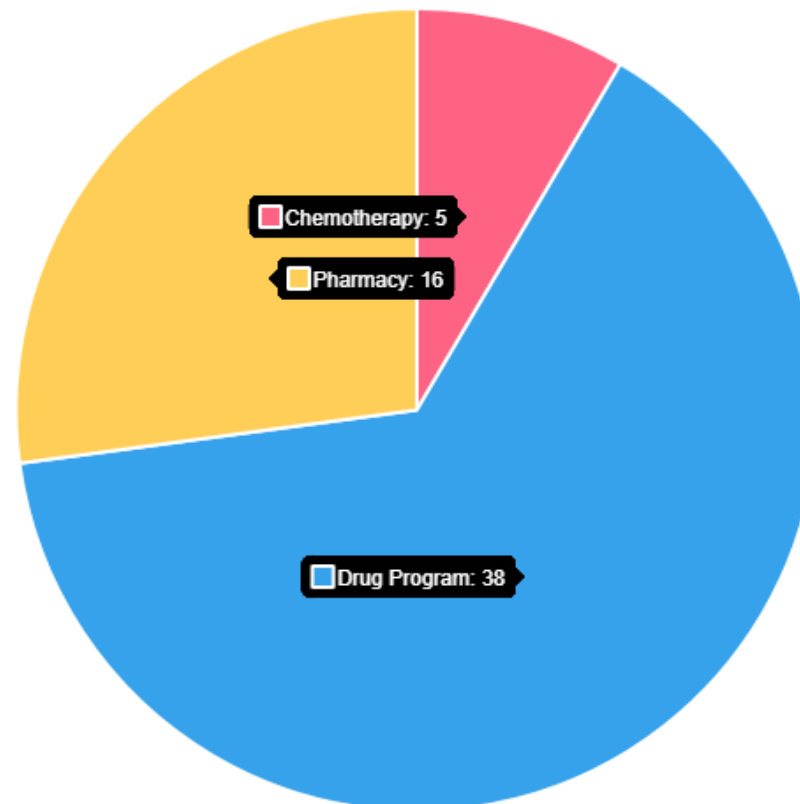
ALL

CLEAR FILTERS

EXPORT AS IMAGE

Mode of reimbursement	No of new molecules/indications
Chemotherapy	5
Drug Program	38
Pharmacy	16

Chemotherapy Drug Program Pharmacy



New molecule/new indication

NEW INDICATION **NEW MOLECULE**

Reimbursement mode

CHEMOTHERAPY **DRUG PROGRAM**

PHARMACY

Years

2012 2013 **2014** 2015 2016

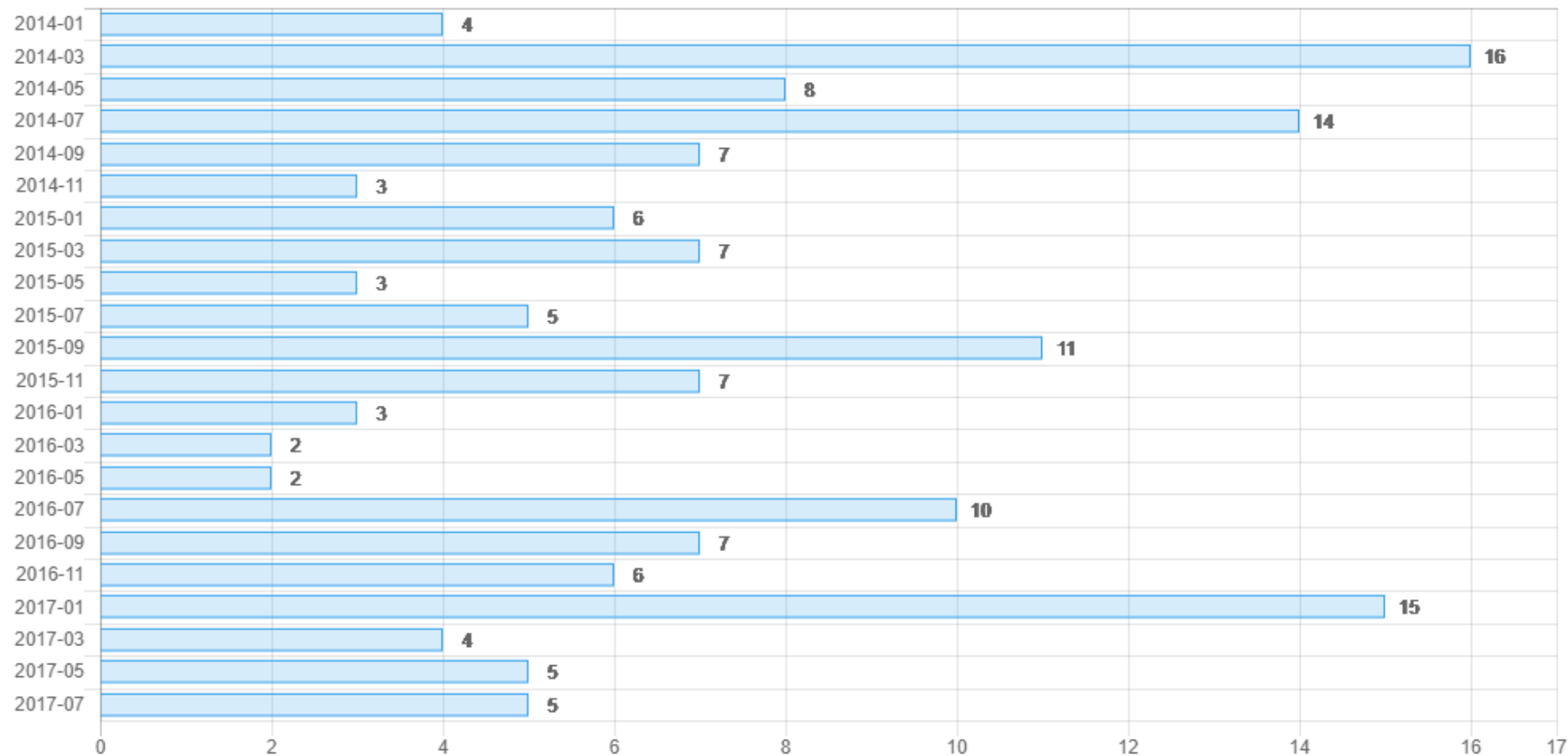
2017 ALL

CLEAR FILTERS

EXPORT AS IMAGE

Date of reimbursement list publication	No of new molecules/new indications
2014-01	4
2014-03	16
2014-05	8
2014-07	14
2014-09	7
2014-11	3
2015-01	6

Number of new products and indications on reimbursement list



New molecule/new indication

NEW INDICATION NEW MOLECULE

Reimbursement mode

CHEMOTHERAPY **DRUG PROGRAM**

PHARMACY

Years

2012 2013 2014 2015 2016

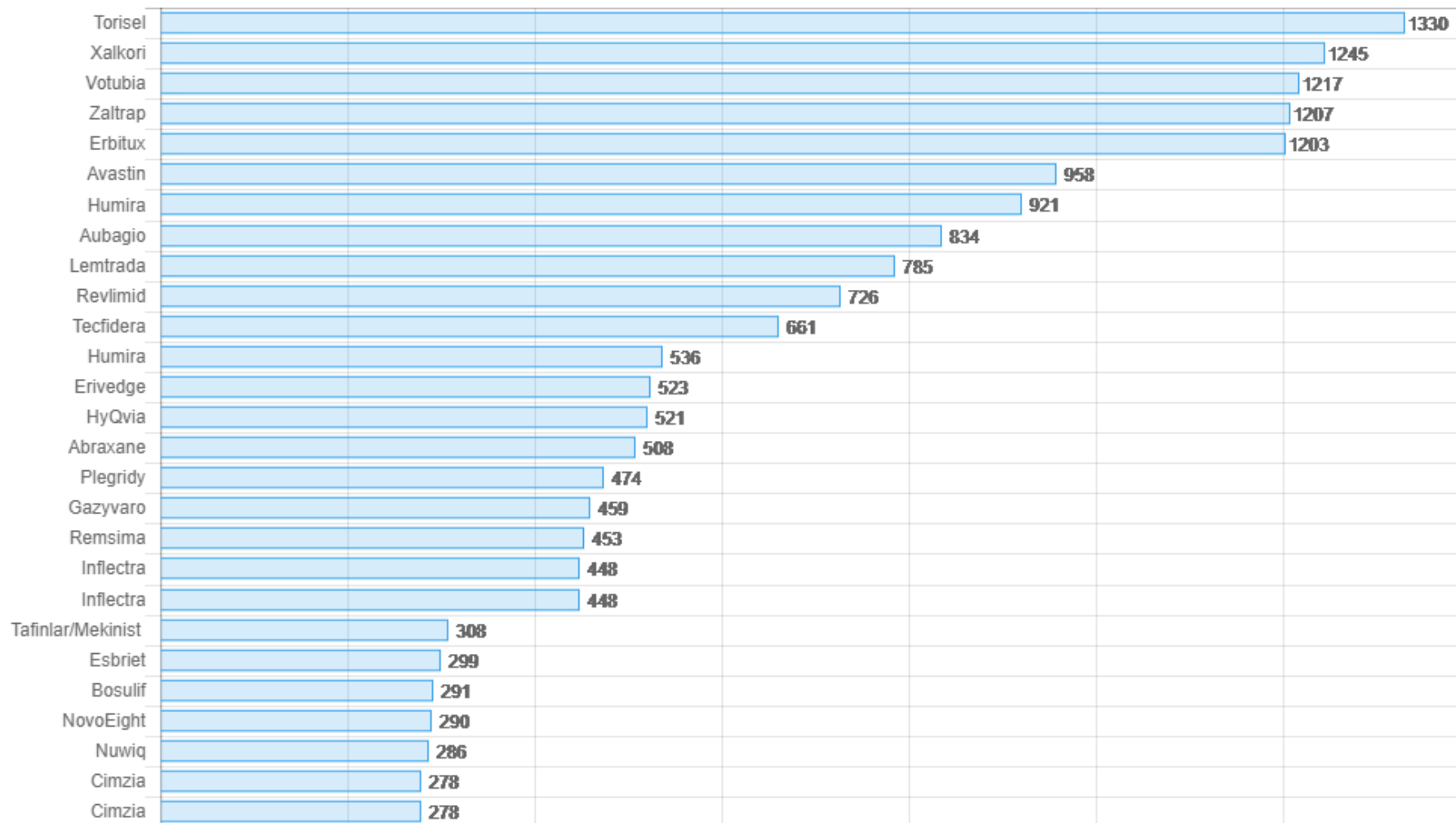
2017 ALL

CLEAR FILTERS

EXPORT AS IMAGE

Applicant	Brand Name	No of Order	Time
Pfizer	Torisel	42/2013	1330
Pfizer	Xalkori	151/2013	1245
Novartis	Votubia	2/2014	1217
Sanofi	Zaltrap	68/2014	1207
Merck	Erbitux	69/2014	1203
Roche	Avastin	277/2014	958
AbbVie	Humira	138/2014	921
Sanofi	Aubagio	14/2015	834
Genzyme	Lemtrada	44/2015	785

Duration of the process with positive decision [days]



HTA & MARKET ACCESS SERVICES

EVIDENCE SYNTHESIS

- HTA MASTER FILE
- REIMBURSEMENT DOSSIER
- LITERATURE REVIEW & META-ANALYSIS
- PHARMACOECONOMIC MODELING
- SURROGATE VALIDATION
- PHARMACOVIGILLANCE

VALUE & ACCESS

- P&R OVERVIEW
- MARKET ACCESS STRATEGY
- LOCAL SUBMISSIONS

EVIDENCE GENERATION

- REAL WORD DATA
- STUDY PROTOCOL
- BURDEN OF DISEASE
- DIRECT AND INDIRECT COST OF TREATMENT

TOOLS

- R&R DATABASE
- QUANTITATIVE DATA SYNTHESIS SOFTWARE
- RWD E-SURVEY PLATFORM
- MARKET ACCESS SENTINEL

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