6th Meeting – Inter-American Coalition for Business Ethics in the Medical Technology Sector

Buenos Aires – July 24th, 2019

Inter-American Coalition for Business Ethics
MEDICAL TECHNOLOGY SECTOR

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Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde

Legal Notice

As Participants of this meeting of the Inter-American Coalition of Ethics in the Medical Devices Sector, we declare to be aware of the restrictions of the antitrust regulations. Thus, we will not discuss agreements, actions or issues that may affect competition in the medical devices industry or any other.

This prohibition includes the exchange of information about prices, rates, coverage, commercial practices or any other competitive aspect of the operational conduct of the companies that are part of the associations present here.

Any participant is required to alert if he/she identifies contrary conduct to this statement, in order to prevent and avoid any discussion on prohibited subjects.

Global MedTech industry scenario and prospects

The global MedTech market is worth US$ 438 billion, and Latin America is expected to drive growth in the coming years. Technological innovations and acquisitions foster growth, while regulatory and reimbursement aspects are barriers.

MedTech global revenue segmented by region.

Source: IQVIA World Review 2019

Região	Vendas (US$ bi)		CAGR	Fatores que Influenciam a Taxa de Crescimento do mercado de MedTech				
	2017	2022	% Crescimento	Impacto de Autoridades Regulatórias	Processo de Reembolso	Gastos com P&D	M&A	Desenvolvimento de Tecnologias Avançadas
América do Norte	162	207	5%	++++	+++	++	+++	++++
Europa	134	163	4%	++++	++++	++	+++	++++
APAC	103	157	8,8%	+++	+++	+++	++	+++
América Latina	27	40	8,6%	++++	++++	+++	++	++
MEA	13	18	7,3%	++++	++	++	++	++

+ Impacto Positivo
+ Impacto Negativo

Global MedTech industry scenario and prospects

Expected revenues, by country, in US$ bn:

Country	2017	2022
USA	155	198
Canada	7	9
Brazil	8	12,2
Mexico	6	7
Colombia	2	3,7
Germany	36	44
Japan	29	33,7
China	20,4	30,6
India	4,9	8,4

Growth in key MedTech areas:

- Neurology; 9%
- Endoscopy: 7,5%
- Cardiology: 6,9%
- Ophtalmology: 6,5%
- General Surgery and plastic: 6,5%
- Orthopaedics: 5,2%
- IVD: 4,5%

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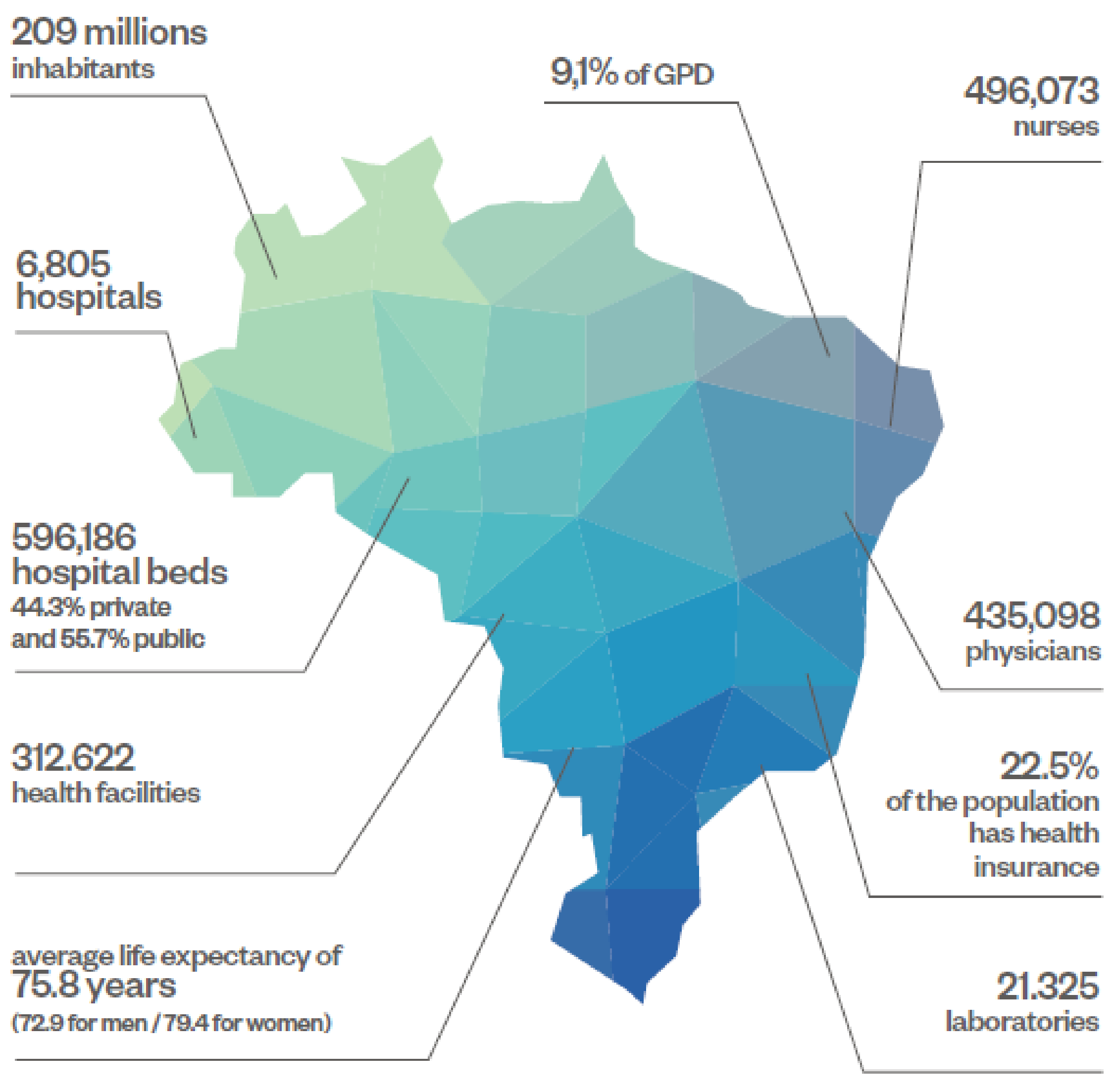
Source: IQVIA World Review 2019

Brazilian scenario

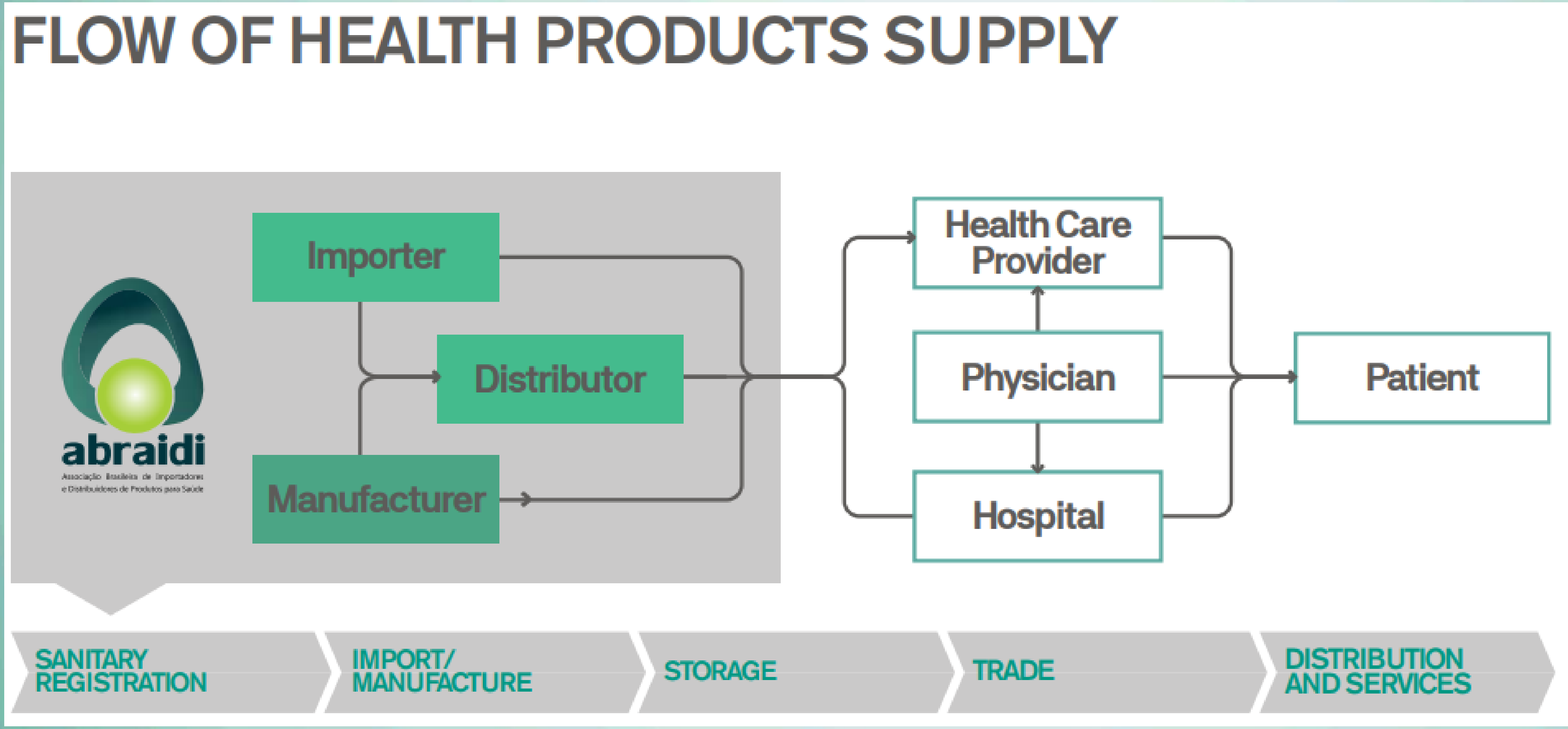
Macroeconomic health data from Brazil - 2018



- Universal public health system, with significant participation of the private system;
- Public System: 210 million people
- Private System: 47 million (Source: ANS)
  - 5 largest individual health insurance operators carries 29% of lives
  - Unimed's together carries 36,5% of lives
  - Total: 65,5% concentrated in 6 large groups
- 4.397 private hospitals (source: FBH)
  - 56,5% with SUS care
  - 43,5% only private service
- Tabulated prices in the public system
- Strong pression to reduce costs in the private system
- Large regional differences, dominated by some hospitals and health insurance operators in some regions.

MedTech sector dynamics of operation in Brazil

Brazil is one of the unique countries in the world in which health care insurance companies buy directly from suppliers.



Regulatory Bodies:

- Ministry of Health
- ANVISA
- ANS

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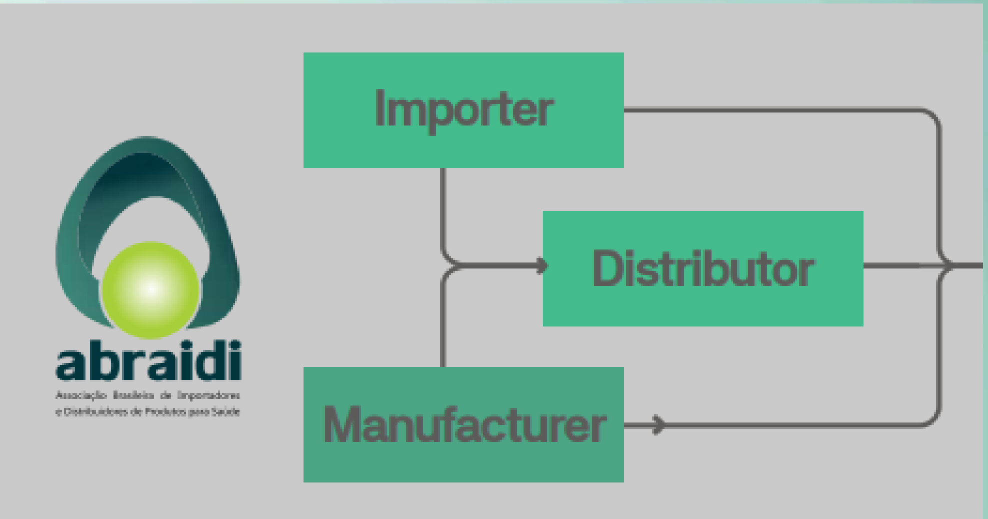
- 294 associates in 23 states
- R$ 4,8 billion (US$ 1.28 bi) revenue in 2018
- 73% private and 27% public
  - From private, 51% are from health insurance operators, 34% are from hospitals and 15% are from others
- 94% importers and/or distributors | 6% manufacturers
- 74% micro, small or medium-sized companies
- 863 thousand surgeries per year
- 90% have some action in *compliance* | 25,9% with fully implemented program
- R$ 1.391 billion (US$ 370 mi) of sales to SUS in 2018



Some discourses prevailing in Brazil

- Incorporation of new technologies as a villain in the increase of health costs - mainly for hospitals and health insurance companies - without an adequate evaluation by the Government;
- New MDs contribute to medical inflation;
- MD's prices in Brazil are the highest in the world and contemplate illicit practices;
- Some regulators and proposals in the Congress understand that <u>**economic regulation**</u> is the way to reduce prices, reduce inflation in the industry and end with illegal

Medical Devices' prices comparison in selected countries

Average annual prices for ***non-drug-eluting (bare-metal) stents*** paid by health care insurers or hospitals in Latin American countries, the United States, and European countries

In US$, from 2014 to 2018

PAÍSES	2014	2015	2016	2017	2018	VARIA ÇÃO 2018/2014
Alemanha	$ 123,33	$ 117,47	$ 112,58	$ 108,58	$ 105,34	- 14,6%
Espanha	$ 1.203,27	$ 1.062,12	$ 944,53	$ 848,07	$ 769,95	- 36%
França	$ 628,89	$ 570,59	$ 522,03	$ 482,19	$ 449,93	- 28,5%
Reino Unido	$ 255,84	$ 237,83	$ 222,82	$ 210,51	$ 200,54	- 21,6%
Itália	$ 387,64	$ 355,74	$ 329,16	$ 307,37	$ 289,71	- 25,3%
EUA	$ 716,47	$ 715,58	$ 713,24	$ 707,53	$ 694,94	- 3%
Brasil	$ 642,36	$ 597,23	$ 556,50	$ 519,85	$ 486,96	- 24,2%
Argentina	$ 135,94	$ 133,03	$ 130,28	$ 127,68	$ 125,21	- 7,9%
Colômbia	$ 466,88	$ 442,74	$ 419,91	$ 398,49	$ 378,52	- 18,9%
México	$ 782,02	$ 742,94	$ 706,01	$ 671,34	$ 639,02	- 18,3%

Average: -19,8%

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Medical Devices' prices comparison in selected countries

Average annual prices for ***drug-eluting stents*** paid by health care insurers or hospitals in Latin American countries, the United States, and European countries

In US$, from 2014 to 2018

PAÍSES	2014	2015	2016	2017	2018	VARIAÇÃO 2018/2014
Alemanha	$ 246,85	$ 239,87	$ 232,89	$ 226,08	$ 219,57	**-11,1%**
Espanha	$ 1.487,06	$ 1.404,70	$ 1.322,34	$ 1.241,91	$ 1.165,09	**-21,7%**
França	$ 1.041,20	$ 988,13	$ 935,04	$ 883,21	$ 833,70	**-19,9%**
Reino Unido	$ 583,23	$ 560,56	$ 537,89	$ 515,75	$ 494,60	**-15,2%**
Itália	$ 750,46	$ 717,80	$ 685,14	$ 653,24	$ 622,78	**-17%**
EUA	$ 1.316,59	$ 1.243,20	$ 1.173,86	$ 1.108,34	$ 1.046,44	**-20,5%**
Brasil	$ 1.570,87	$ 1.481,90	$ 1.397,80	$ 1.318,87	$ 1.245,28	**-20,7%**
Argentina	$ 611,16	$ 574,66	$ 541,12	$ 510,44	$ 482,50	**-21,1%**
Colômbia	$ 1.674,24	$ 1,578,12	$ 1.487,25	$ 1.401,97	$ 1.322,47	**-21%**
México	$ 1,711,92	$ 1.635,97	$ 1.564,17	$ 1.496,79	$ 1.433,97	**-16,2%**

Average: -18,4%

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Medical Devices' prices comparison in selected countries

Average annual prices of ***primary total knee prosthesis*** paid by health care insurers or hospitals in Latin American countries, the United States, and European countries

In US$, from 2014 to 2018

PAÍSES	2014	2015	2016	2017	2018	VARIA ÇÃO 2018/2014
Alemanha	$ 1.435,3	$ 1.429,8	$ 1.424,1	$ 1.418,10	$ 1.411,8	**- 1,6%**
Espanha	$ 2.154,2	$ 2.139,5	$ 2.124,2	$ 2.108,3	$ 2.091,9	**- 2,9%**
França	$ 2.343,2	$ 2.327,3	$ 2.311,4	$ 2.295,3	$ 2.279,2	**- 2,7%**
Reino Unido	$ 2.290,7	$ 2.274,9	$ 2.258,6	$ 2.242,0	$ 2.224,9	**- 2,9%**
Itália	$ 2.157,0	$ 2.143,9	$ 2.130,5	$ 2.116,7	$ 2.102,6	**- 2,5%**
EUA	$ 4.496,0	$ 4.387,2	$ 4.280,3	$ 4,175,8	$ 4.074,1	**- 9,4%**
Brasil	$ 2.151,8	$ 2.148,0	$ 2.143,5	$ 2.138,0	$ 2.131,4	**- 0,9%**
Argentina	$ 2.244,0	$ 2.240,3	$ 2.236,0	$ 2.230,8	$ 2.224,5	**- 0,9%**
Colômbia	$ 1.127,4	$ 1.121,1	$ 1.114,1	$ 1.106,0	$ 1.096,1	**- 2,8%**
México	$ 867,6	$ 862,7	$ 857,1	$ 850,7	$ 842,9	**- 2,8%**

Average: -2,9%

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Current situation of importers and distributors

- High operating costs, due to the unpaid services that are provided (surgical technologists, equipments and other services);
- High investments in instruments and other items necessary to sale the products;
- Low level of formalization and contracting between suppliers and customers;
- Difficulties of understanding about conditions of partnership between manufacturers and distributors, besides the challenge: sales goals X compliance;
- Extremely elongated receipt deadlines, requiring large cash flow, with financial cost;
- Anti-ethical practices among market players:
- Billing Retention
- Linear disallowances
- Defaults
- Low adherence to compliance initiatives by hospitals and insurance companies.

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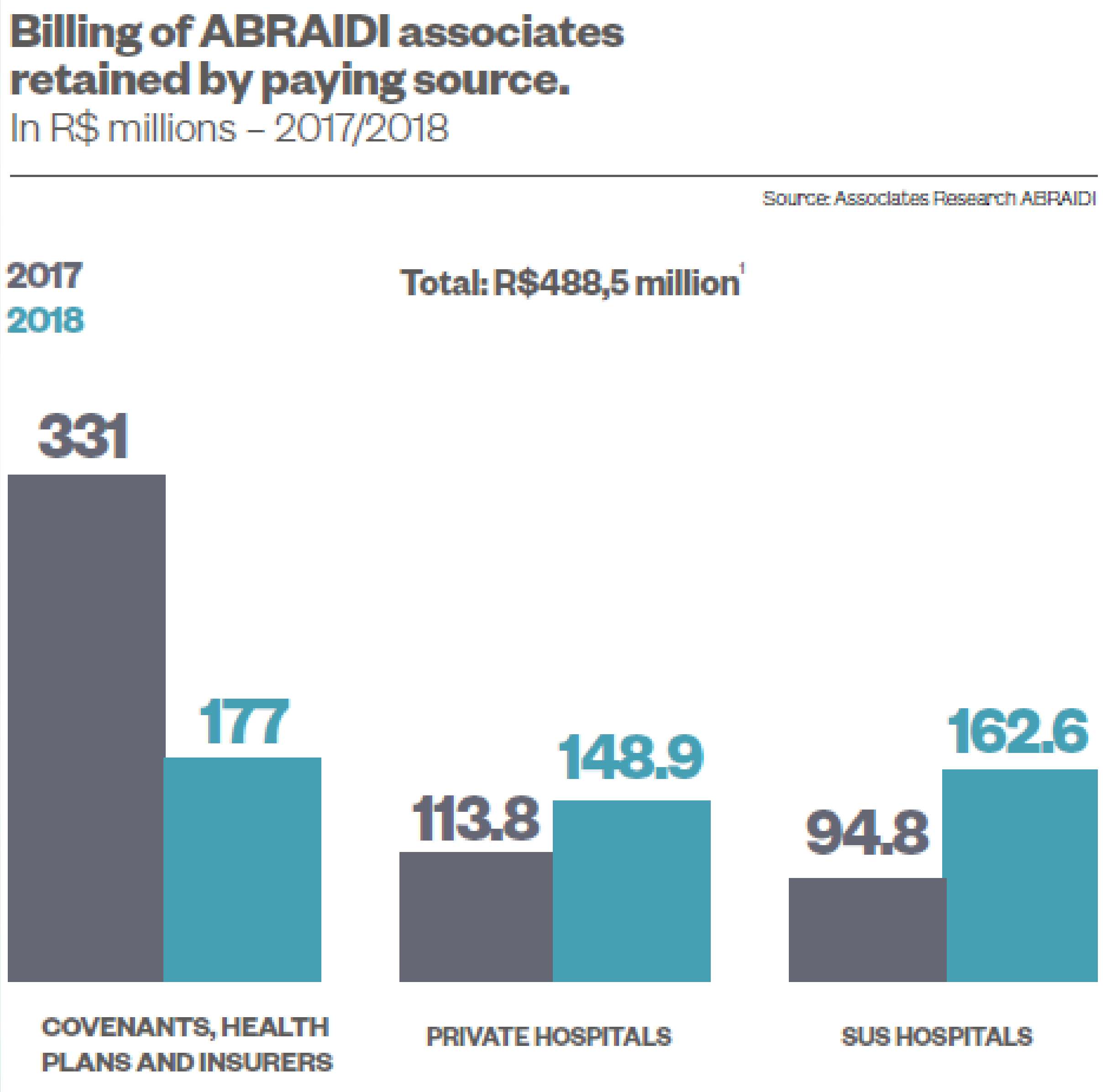
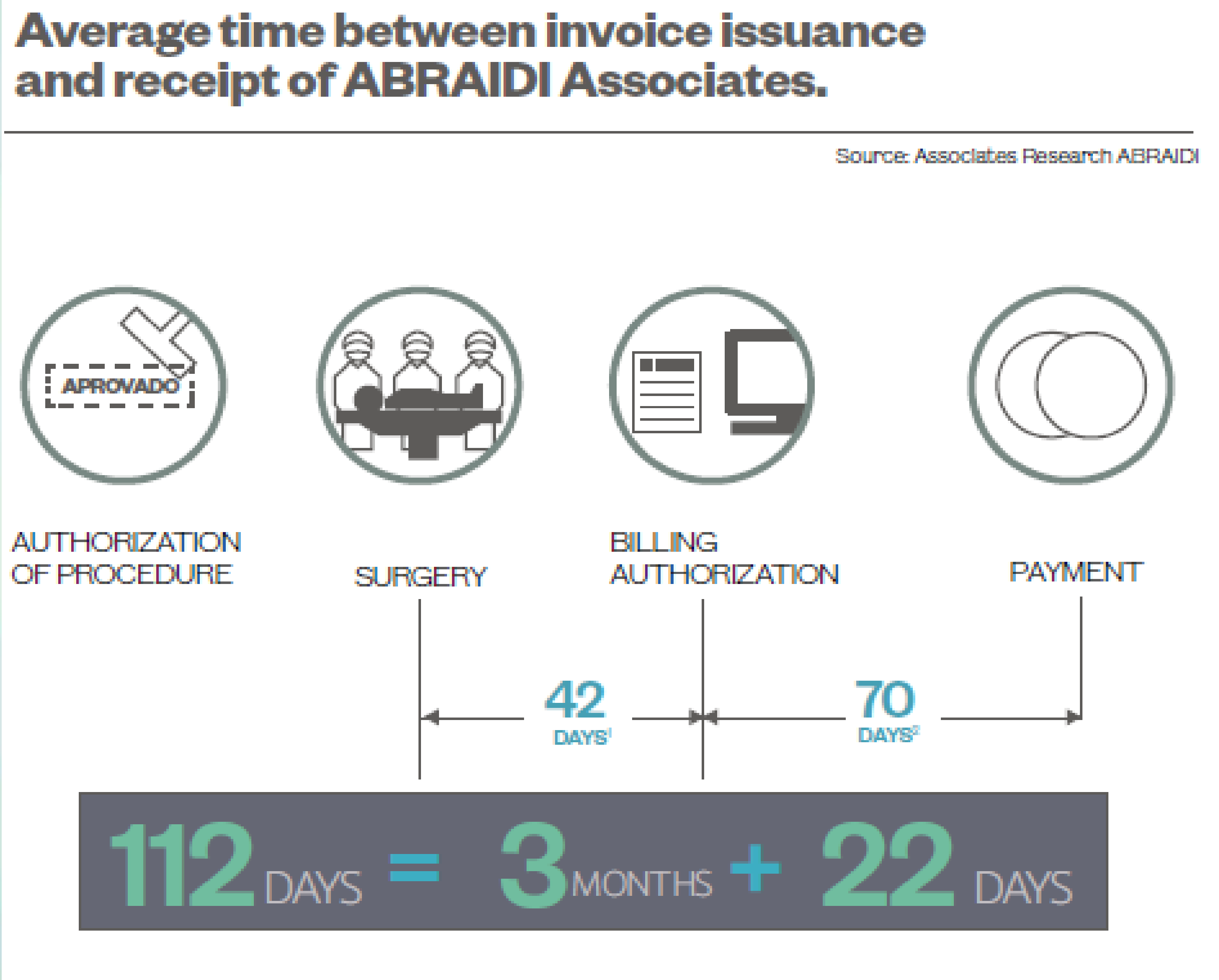
Current situation of importers and distributors

Billing retention



Current situation of importers and distributors

Effective payment deadline:
112 days



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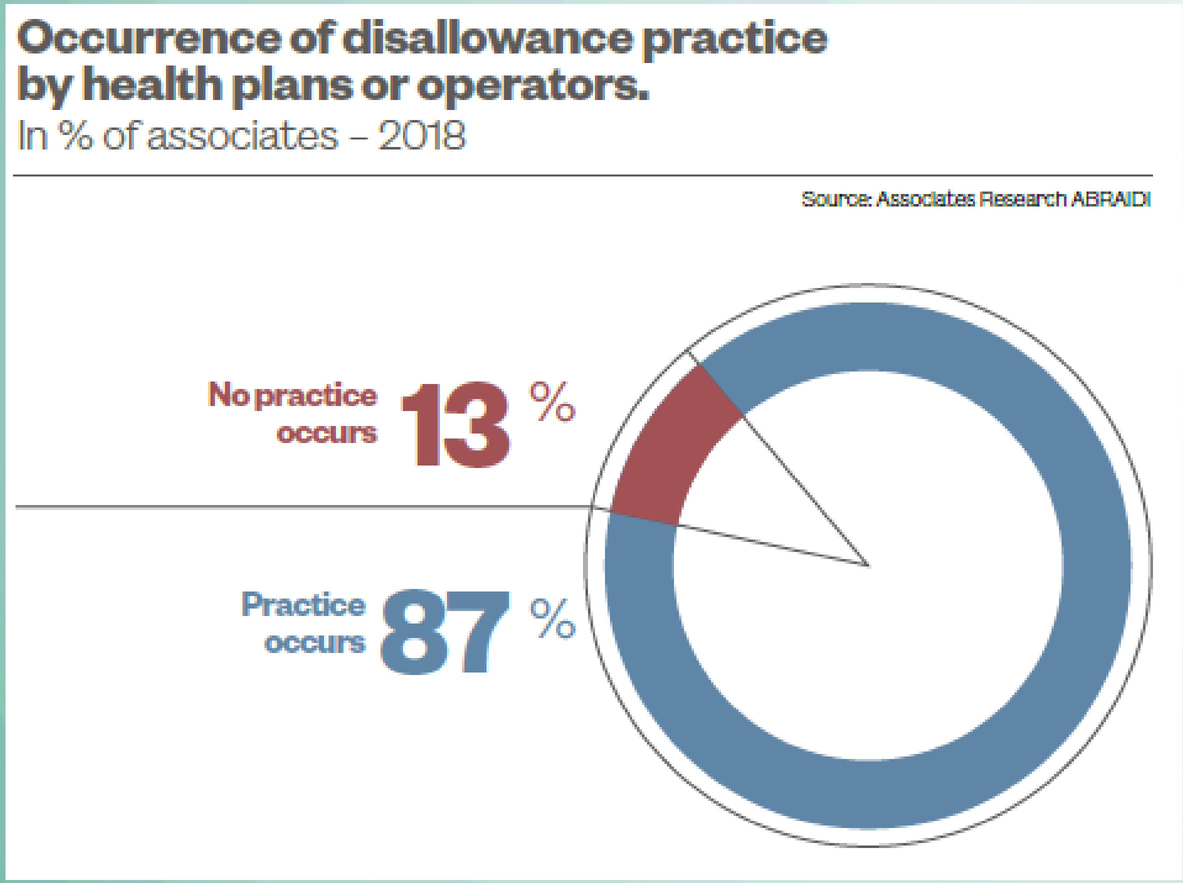
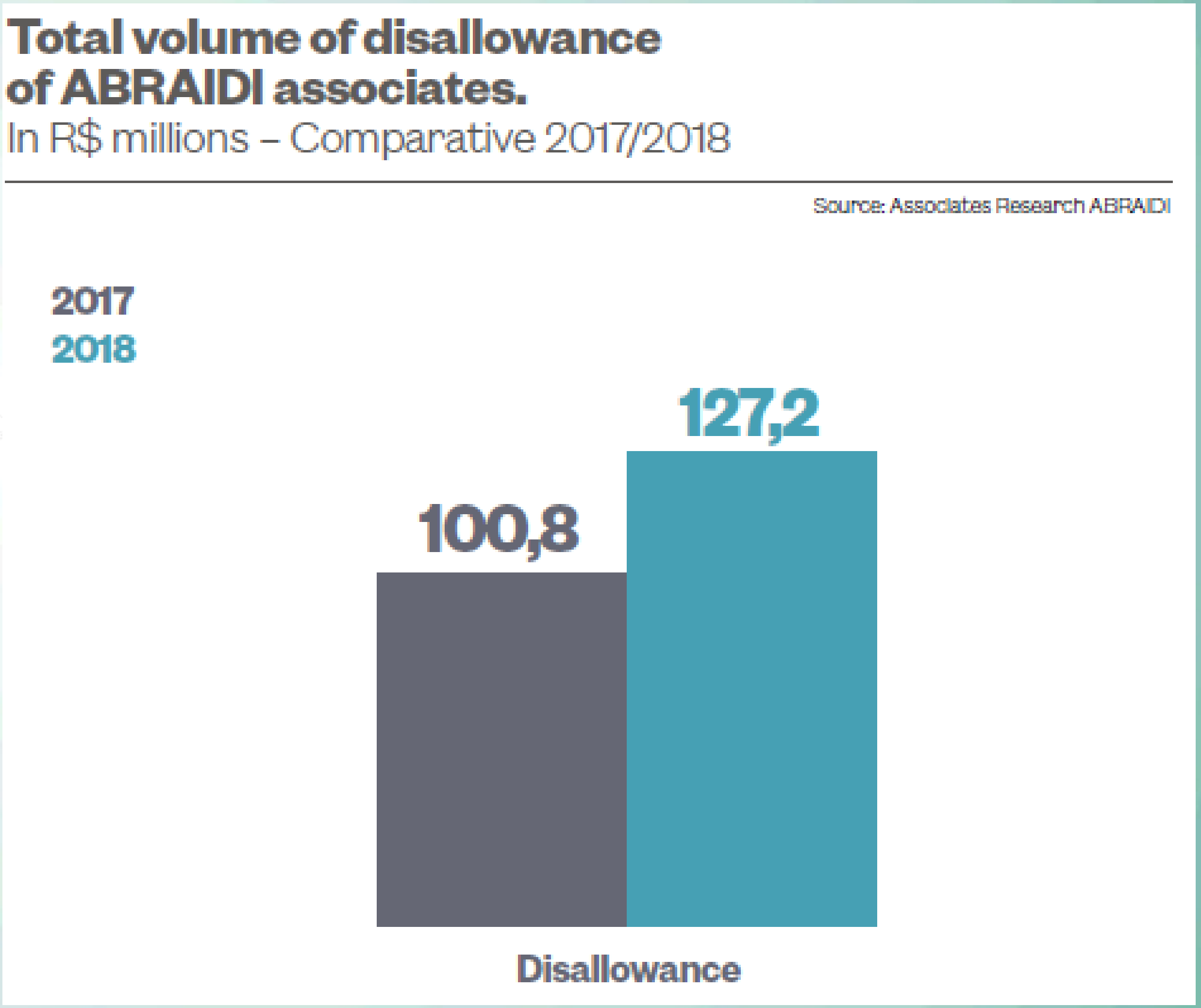
Current situation of importers and distributors

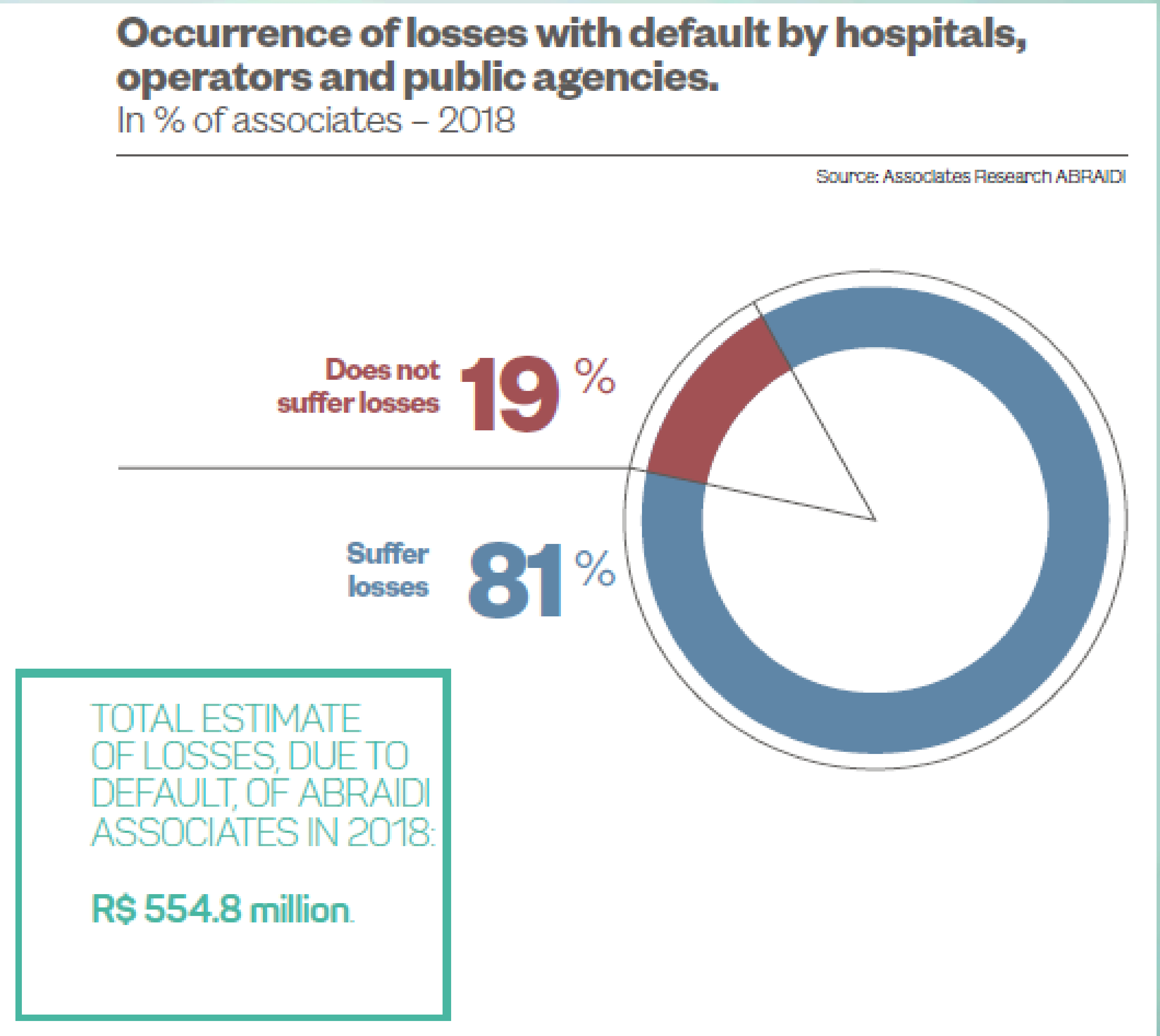
Disallowances grew 26%





Current situation of importers and distributors

Financial default pressures more than 80% of companies



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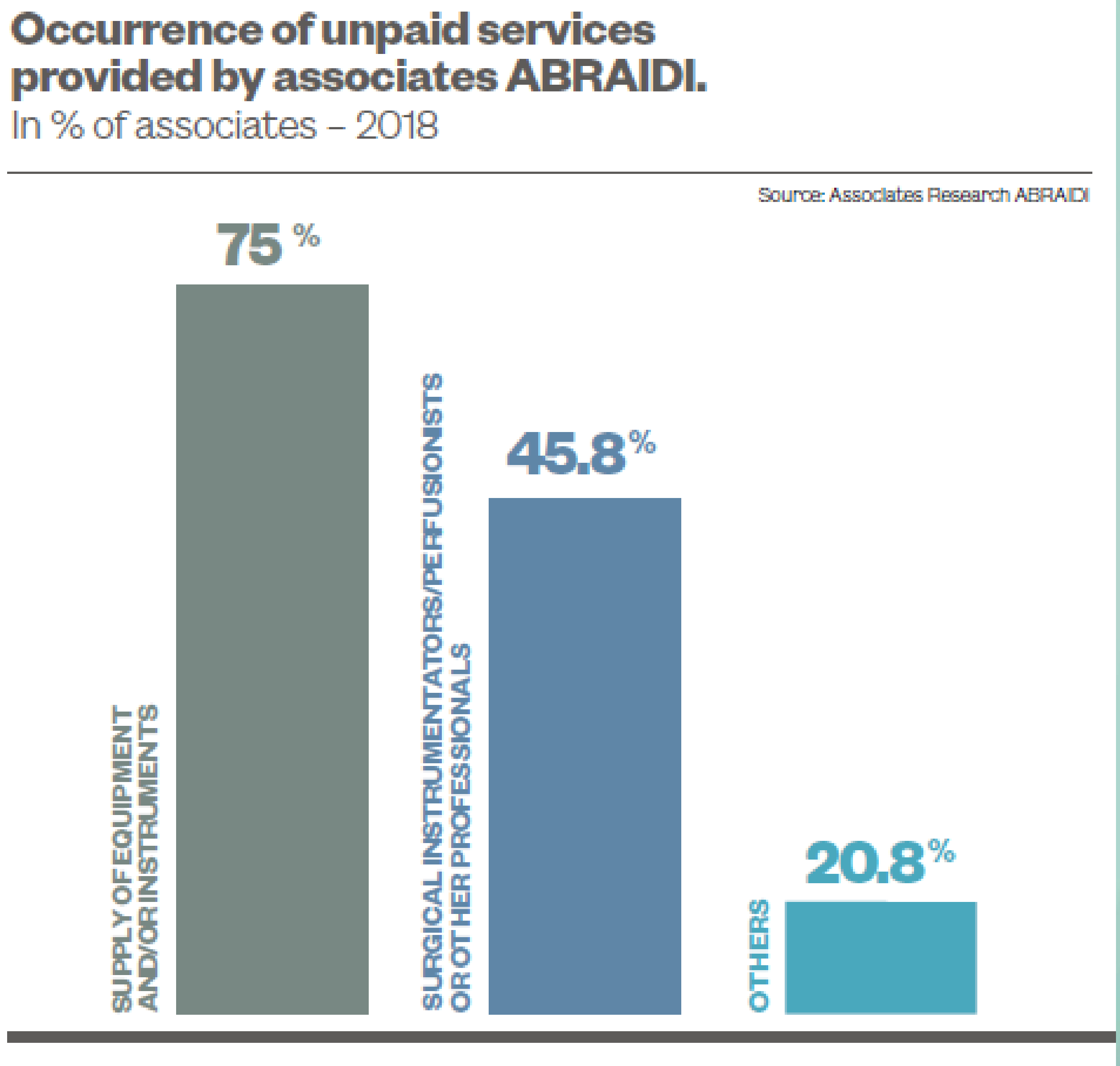
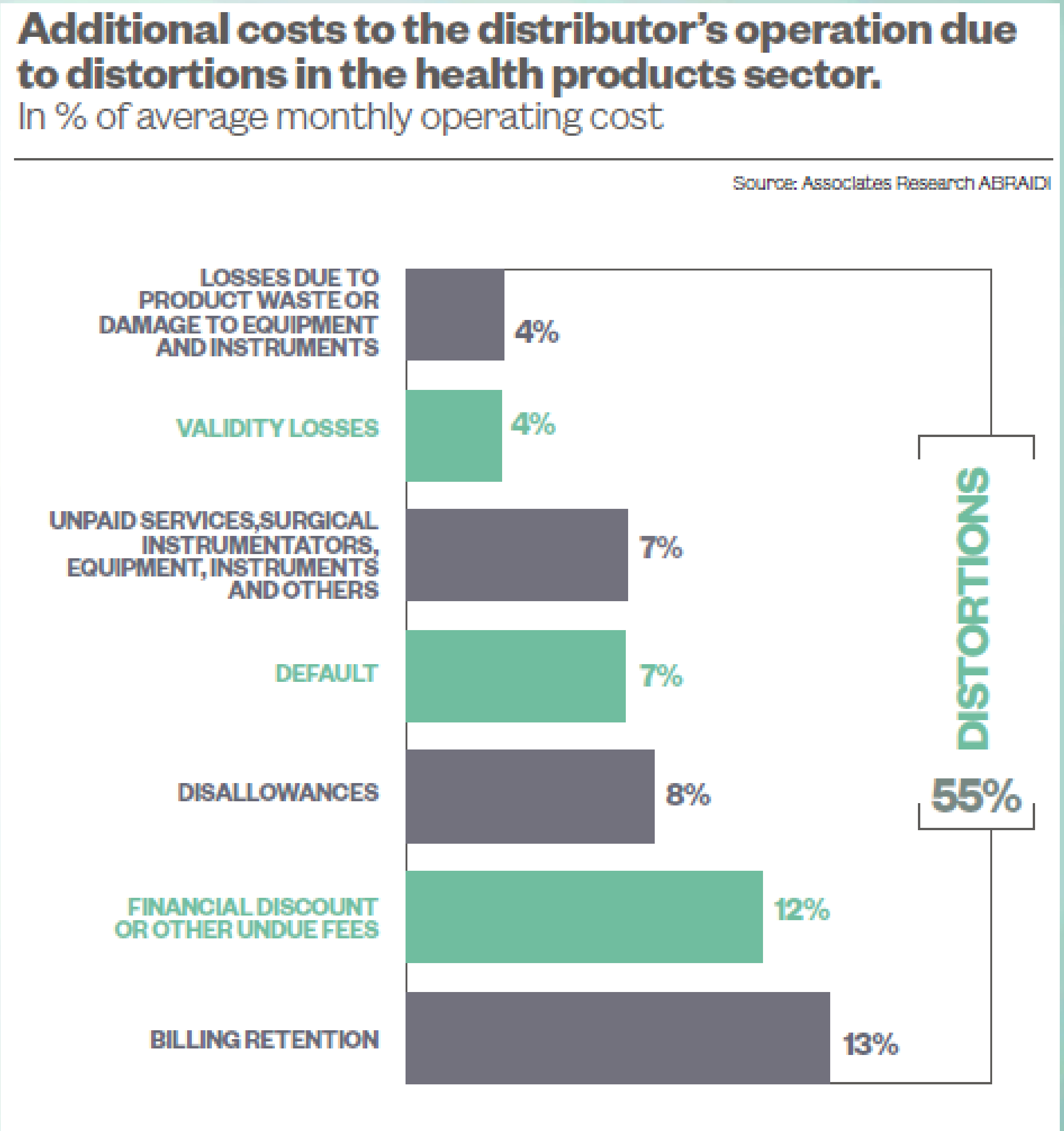
Current situation of importers and distributors

Unpaid services



Current situation of importers and distributors

Distortions represents more than half of the operations cost



Important questions for discussion

- Compliance
  - Relationship with health professionals
  - Relationship with hospitals | discounts | requirements (equipments, materials, professionals, etc)
  - Relationship with the public sector
- Relations between manufacturers-distributors
  - Contracts
  - Sales X Compliance
- Relations with other players in the sector
  - Contracts
  - Payment deadlines
  - Supply conditions

- What is (are) the biggest problem(s) of Compliance?
- How does the commercialization of medical devices works in the country?
- Characteristics of local market and the entity

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What can be handled jointly?

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