TAKING A FRESH LOOK AT **COUNTERFEITING** IN **PHARMA** & **MEDICAL DEVICES:** FROM ROOT CAUSES TO CURRENT SOLUTIONS

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SPEAKERS

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Pharma at Clariant

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WHO DEFINITION

- **“Substandard”** medical products (also called “out specification”) are authorised by national regulatory authorities, but fail to meet either national or international quality standards or specifications – or in some cases, both.

- **“Falsified”** medical products deliberately or fraudulently misrepresent their identity, composition or source.

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Source: http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refuguees/en/

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6 - 8% OF MEDICAL DEVICES ARE **FAKES**

Source: http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refuguees/en/

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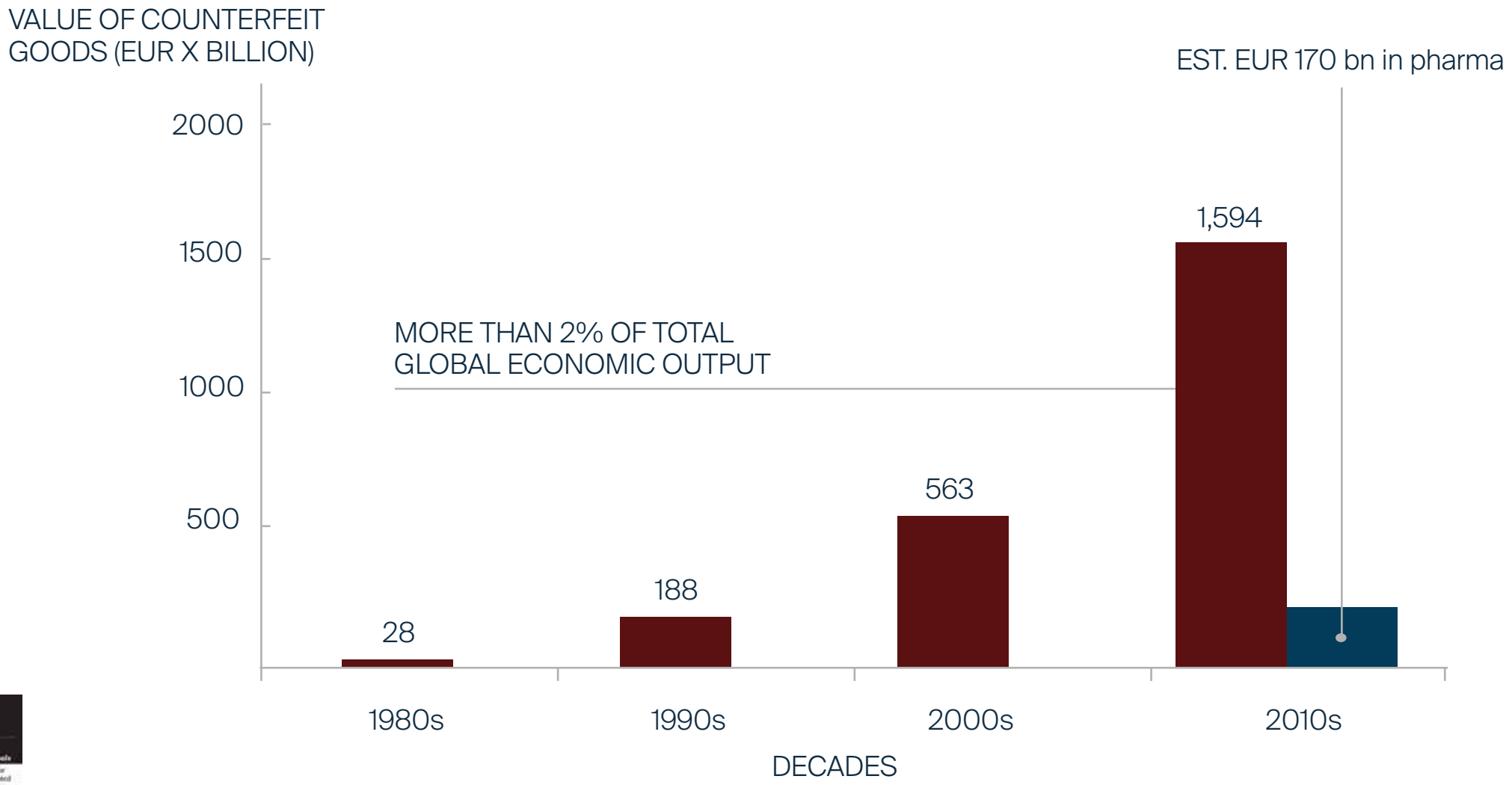
COST OF COUNTERFEITED GOODS (EUR X BILLION)



Source: Strategy& PwC, "Fighting counterfeit pharmaceuticals: New defences for an underestimated – and growing – menace", 2017

ROOT CAUSES

COUNTERFEITING IN PHARMACEUTICALS & MEDICAL DEVICES

- SIGNIFICANT PROGRESS IN CONTRIBUTING TO HUMAN HEALTH = BUSINESS SUCCESS
- BUSINESS SUCCESS ATTRACTS INVESTORS AND COUNTERFEITERS
- COUNTERFEITING TAKES SHORTCUT TO FINANCIAL GAINS VIA PARALLEL PRODUCT LIFE CYCLE

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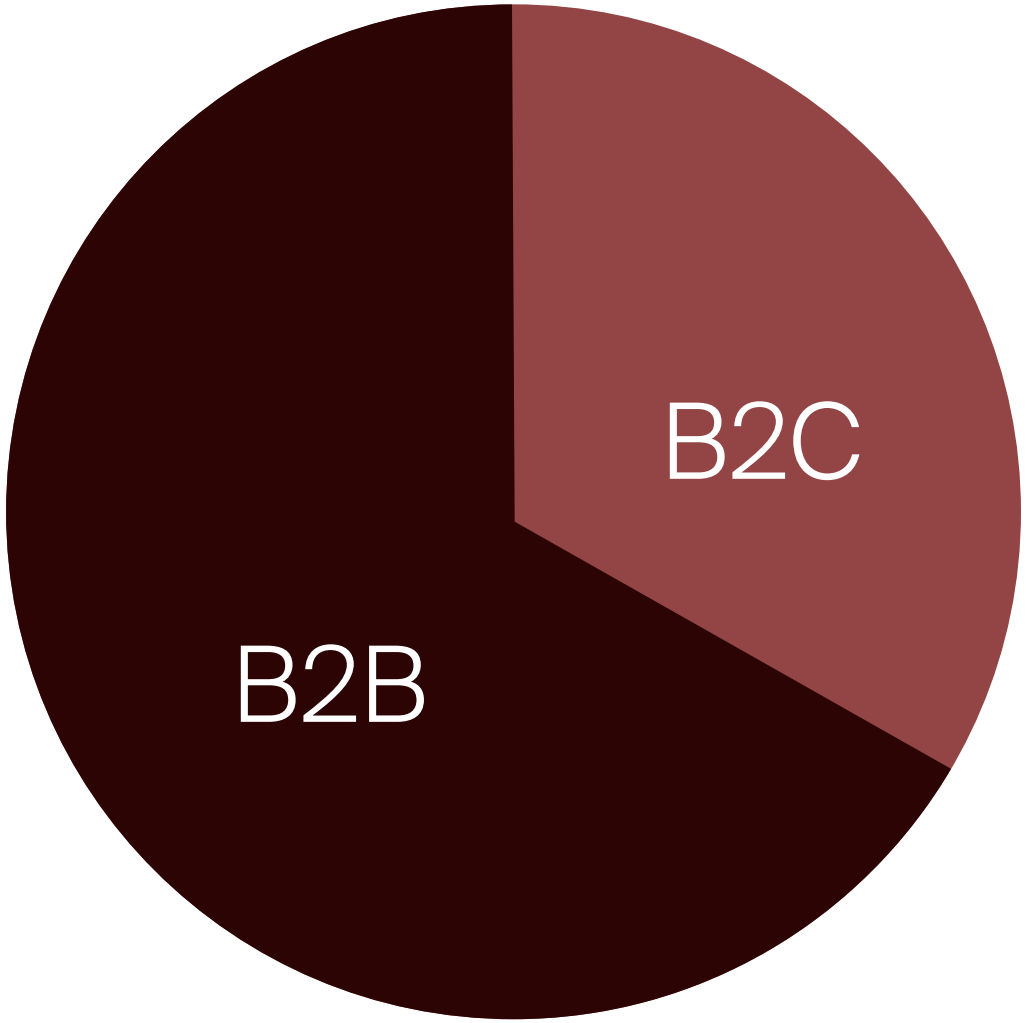
EST. E-COMMERCE SALES IN 2020

USD 6.7 trillion in B2B

USD 3.2 trillion in B2C

TOTAL:
USD 10 TRILLION



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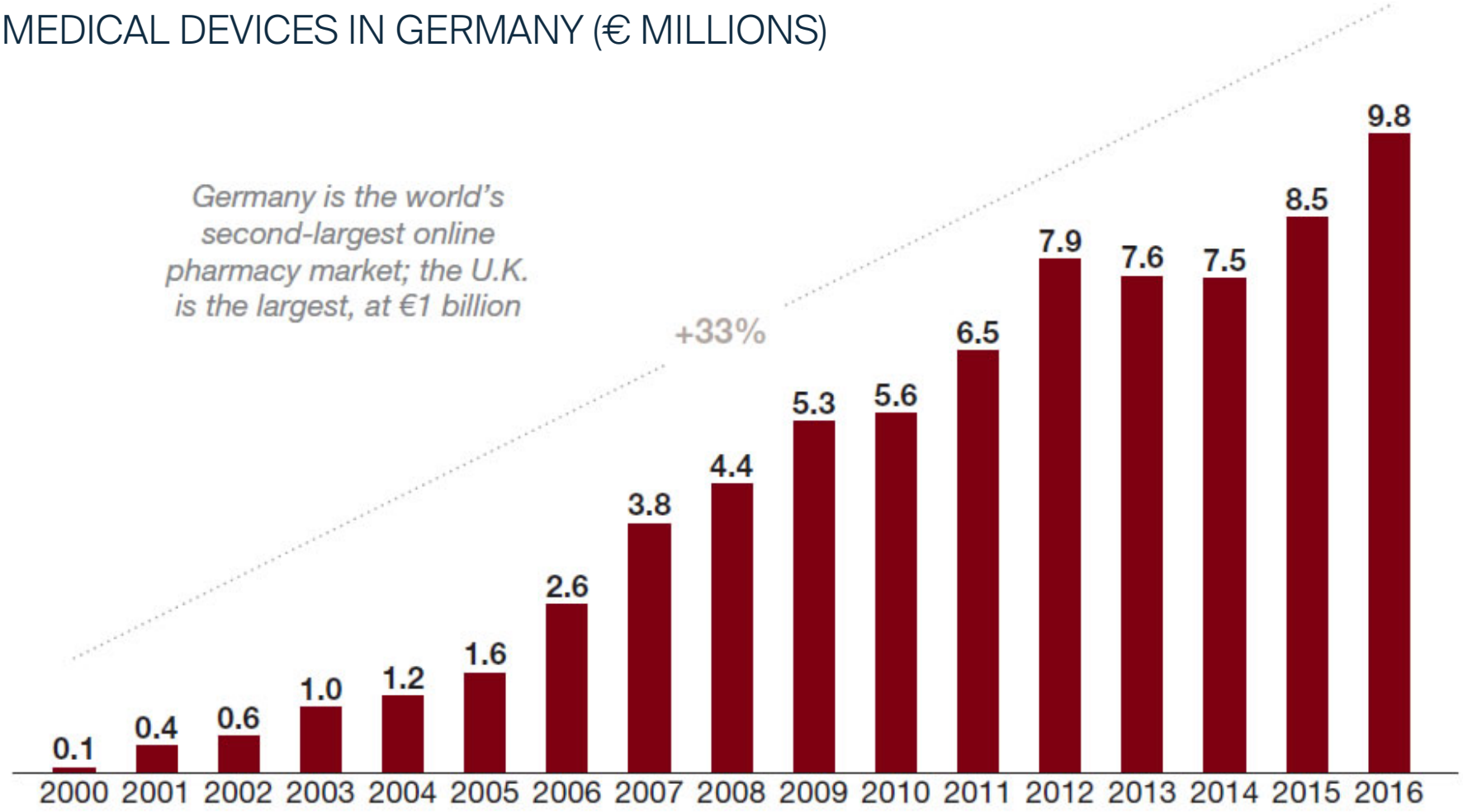
Source: Frost & Sulivan, The Global B2B E-commerce Market Will Reach 6.7 Trillion USD", media release, 9 April 2015

ONLINE PURCHASES

PHARMA & MEDICAL DEVICES IN GERMANY (€ MILLIONS)



Source: Strategy& PwC, "Fighting counterfeit pharmaceuticals: New defences for an underestimated – and growing – menace", 2017

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NEXT GENERATION

EXTERNAL PROVIDERS' OFFERINGS ARISING FROM NEXT GENERATION ANTI-COUNTERFEITING TECHNOLOGIES

Product ← Spectrum of possible offerings → Solution

Bulk chemicals

Sell taggants as bulk chemicals

Integrated system

Sell taggants with unique signatures, readers, and encrypted data backbone

Detector maintenance

Remotely control readers
Provide reader-associated services (e.g., maintenance and repair)

Data management services

Create and validate product-specific data sets
Automatically report incidents
Inactivate recalled products and clear associated data sets

Brand Protection solutions

Monitor product and data streams along the supply chain
Encourage players to report incidents
Trigger follow-up processes
Operate 24/7 hotline

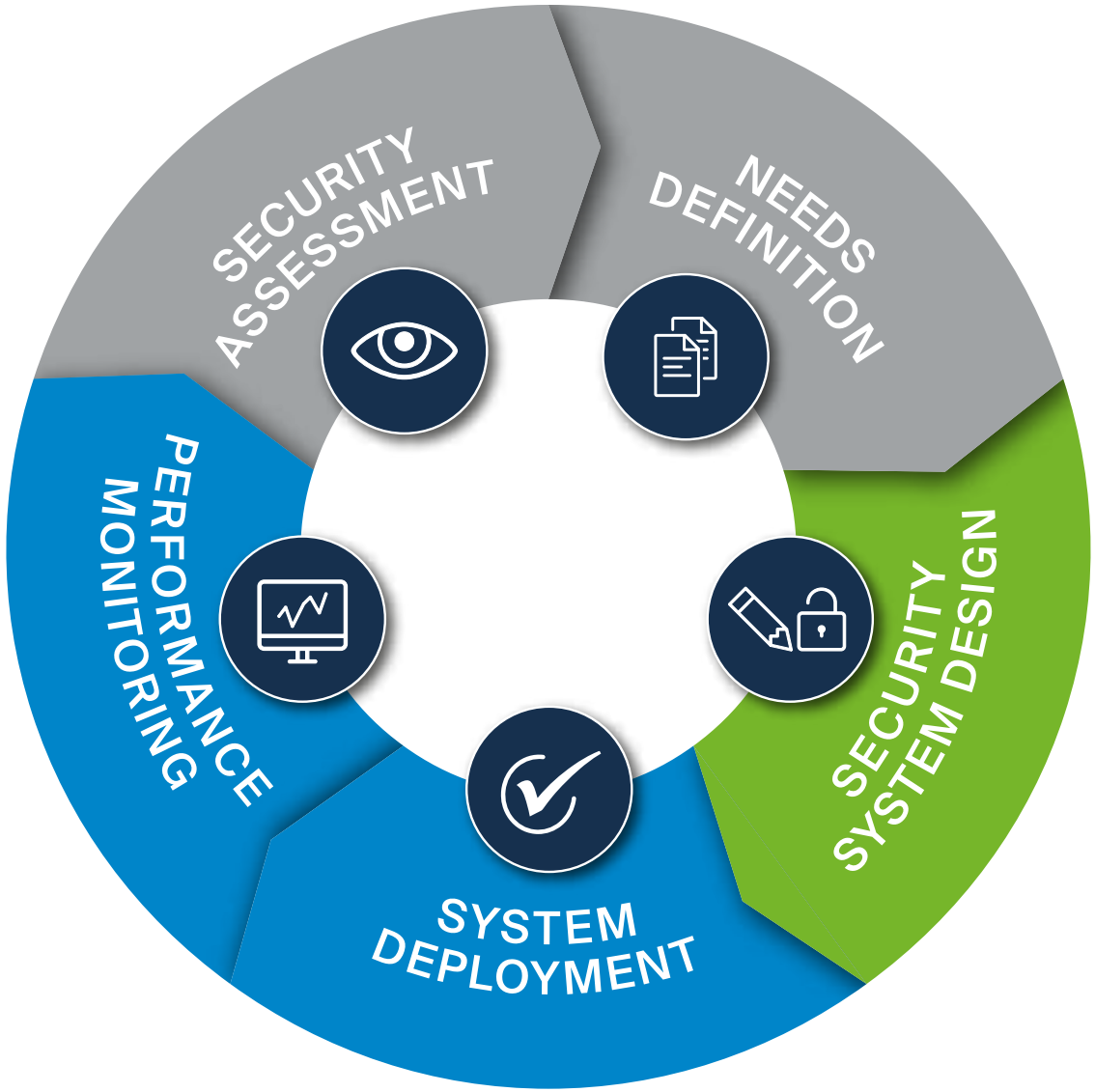
Additional value-added services

Consult task forces to efficiently resolve incidents
Assist originators in prosecution of counterfeiting activities
Support brand owners' recall management

Potential value creation

Source: Strategy& PwC, "Fighting counterfeit pharmaceuticals: New defences for an underestimated — and growing — menace", 2017

END-TO-END RISK MANAGEMENT PROCESS



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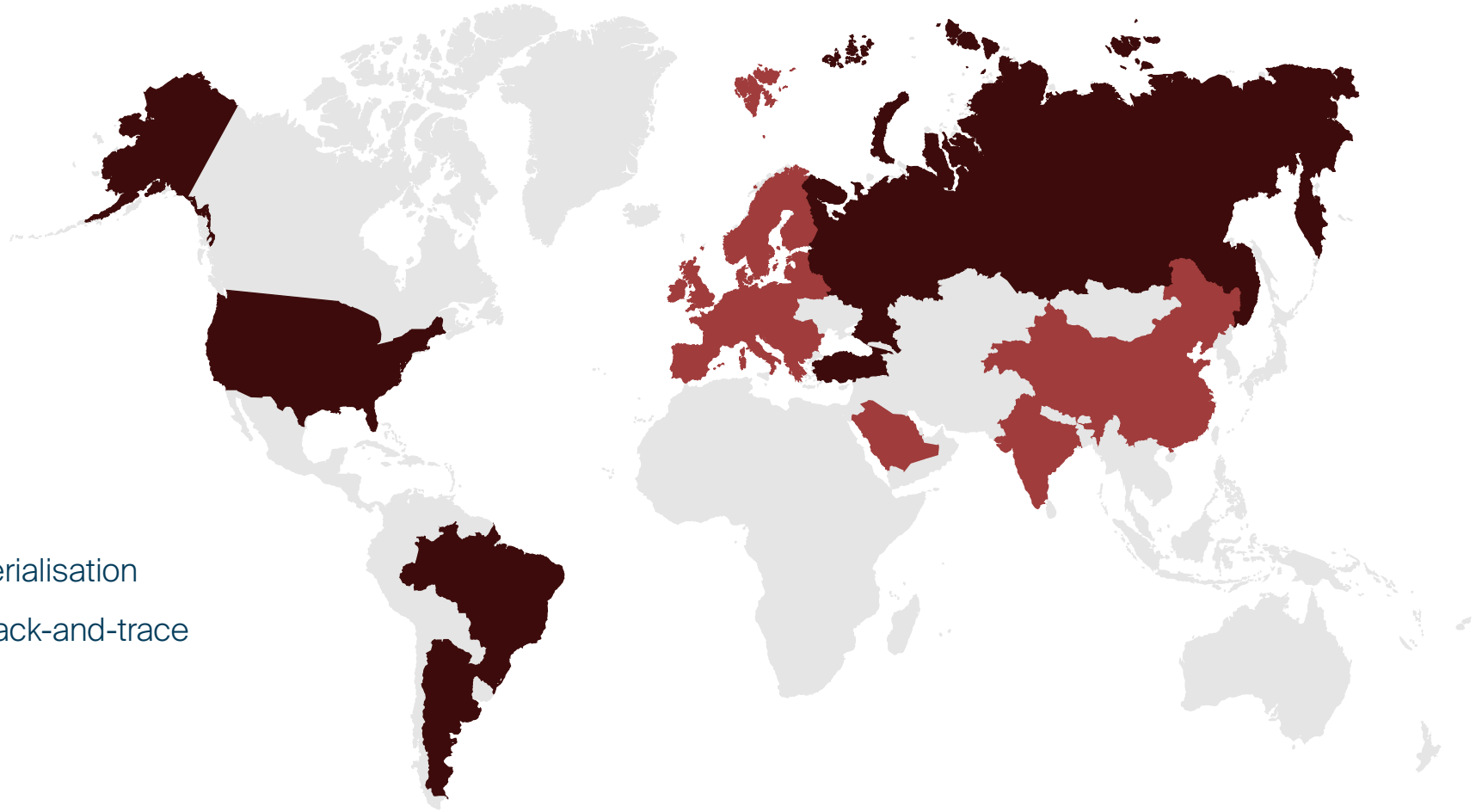
PHARMA SERIALISATION

MASS SERIALISATION AND TRACK-AND-TRACE AROUND THE WORLD



Source: Strategy& PwC, "Fighting counterfeit pharmaceuticals: New defences for an underestimated – and growing – menace", 2017

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DEFINITIONS

- **SERIALISATION** ASSIGNS A UNIQUE NUMBER TO A PRODUCTION UNIT SUCH THAT IT CAN BE IDENTIFIED LATER
- **TRACK AND TRACE** IMPLIES THE ABILITY TO KNOW WHERE A PRODUCT WENT (TRACK) AND WHERE IT CAME FROM (TRACE)
- **AUTHENTICATION** ANSWERS THE QUESTION: "IS THIS PRODUCT GENUINE?"

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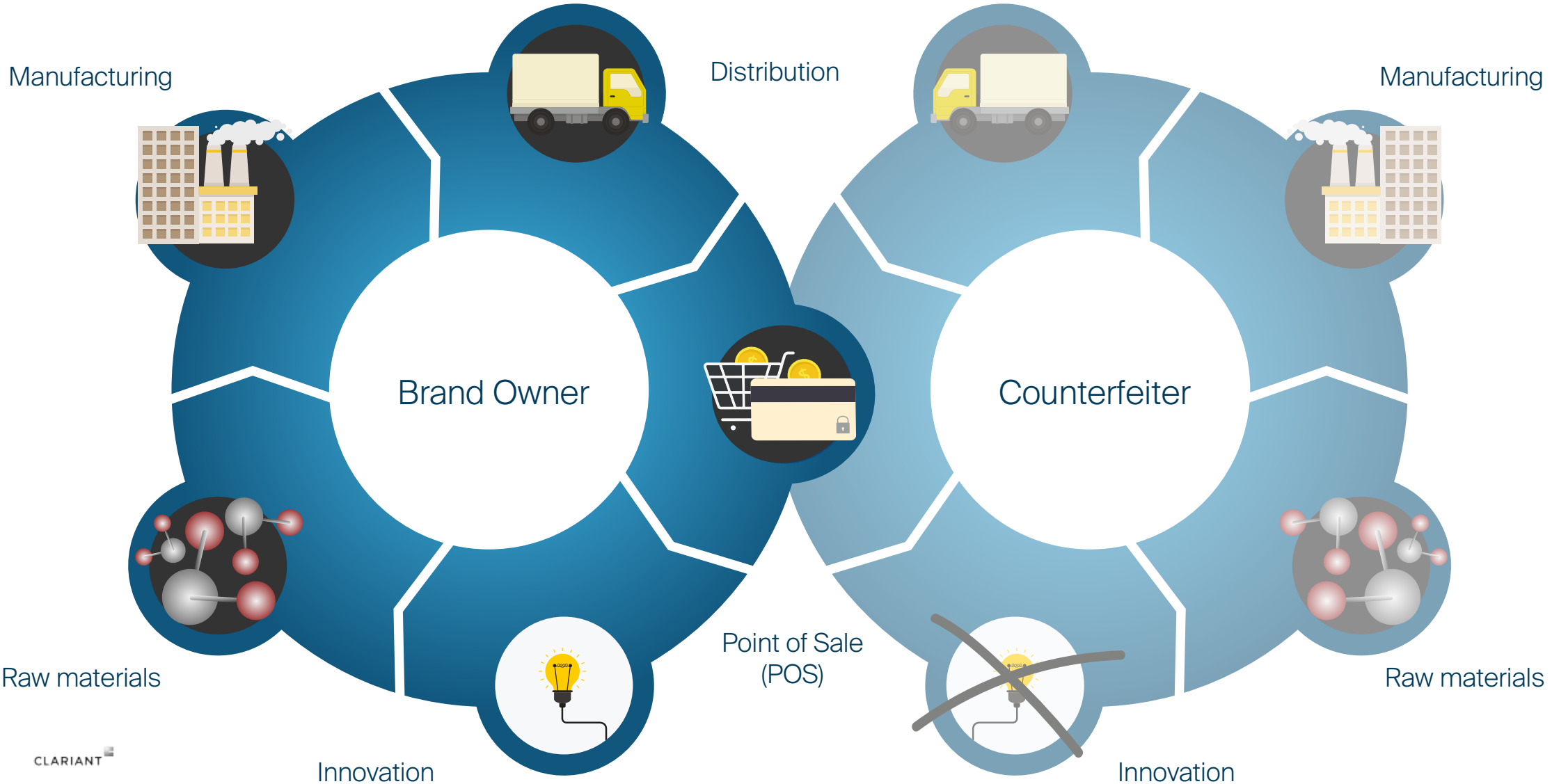
Source: M Davison, *Pharmaceutical Anti-Counterfeiting*, 2011, p 231

PRODUCT LIFE CYCLE & PARALLEL LIFE CYCLE



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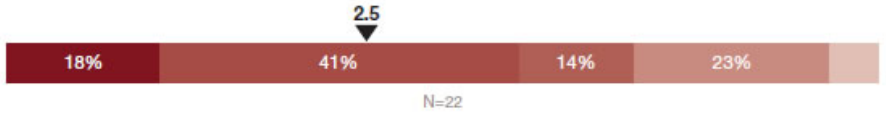
STRATEGY& PWC SURVEY

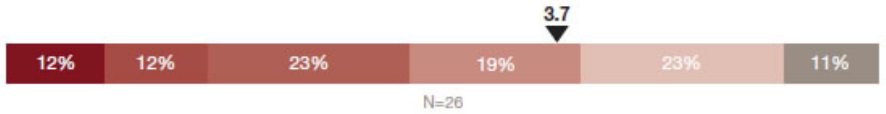
How satisfied are you with your company's current approach to ensure supply chain integrity?

On a scale of 1 (highly satisfied) to 6 (highly dissatisfied)



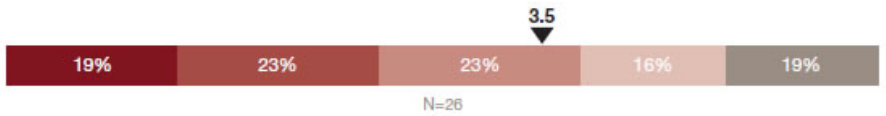
How would you quantify the need for more secure technologies to monitor supply chain integrity and fight counterfeiting?

On a scale of 1 (no need) to 6 (high unmet need)



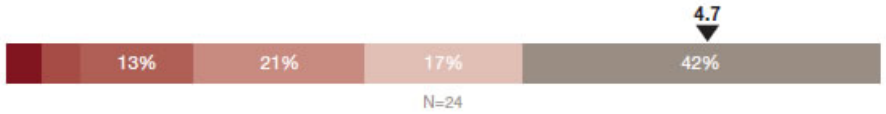
Do you agree with the following statement: "A future track-and-trace technology should go beyond the package level and focus on the blister or even pill level"?

On a scale of 1 (strongly disagree) to 6 (strongly agree)



Do you agree with the following statement: "A future anti-counterfeiting solution needs to offer additional capabilities like provision of lot data and monitoring of trade flows beyond pure brand protection"?

On a scale of 1 (strongly disagree) to 6 (strongly agree)



Source: Strategy& PwC, "Fighting counterfeit pharmaceuticals: New defences for an underestimated – and growing – menace", 2017

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ROBUST ANTI-COUNTERFEITING SYSTEMS

COMBINING MATERIAL & DIGITAL TECHNOLOGIES FOR:

- MULTILAYER BRAND PROTECTION
- SWIFT COUNTERMEASURES
- REAL-TIME MONITORING PERFORMANCE TRACKING

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SUMMARY OF KEY POINTS

- **RISK-MANAGEMENT APPROACH:**
  FOR A HOLISTIC VIEW OF YOUR VALUE CHAIN
- **ANTI-COUNTERFEITING TECHNOLOGY:**
  HARDER TO FAKE YOUR PRODUCT & EASIER TO SPOT A FAKE
- **AUTHENTICATION:**
  A COMPLEMENT TO SERIALISATION

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PLASTIWARD™

RE-THINKING **IN-PLASTIC PROTECTION** FOR PLASTIC MEDICAL DEVICES AND PHARMACEUTICAL PACKAGING

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7 December 2017

14:30 CET (Berlin) / 08:30 EDT (New York)

Registration details to follow from MPN

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Clariant at CPhI Worldwide

InnoPack Zone, Booth 42L20

24 - 26 October 2017

Frankfurt/Main, Germany

Clariant with SICPA at CPhI

Presentation at

“Pharma Insight Briefing”

24 October 2017 at 13:10

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