KYMOS
PHARMA SERVICES, S.L.

PHARMAPROGRESS
a KYMOS company

BREXIT:
CHALLENGES AND OPPORTUNITIES IN THE PHARMACEUTICAL SECTOR

October 31st 2019

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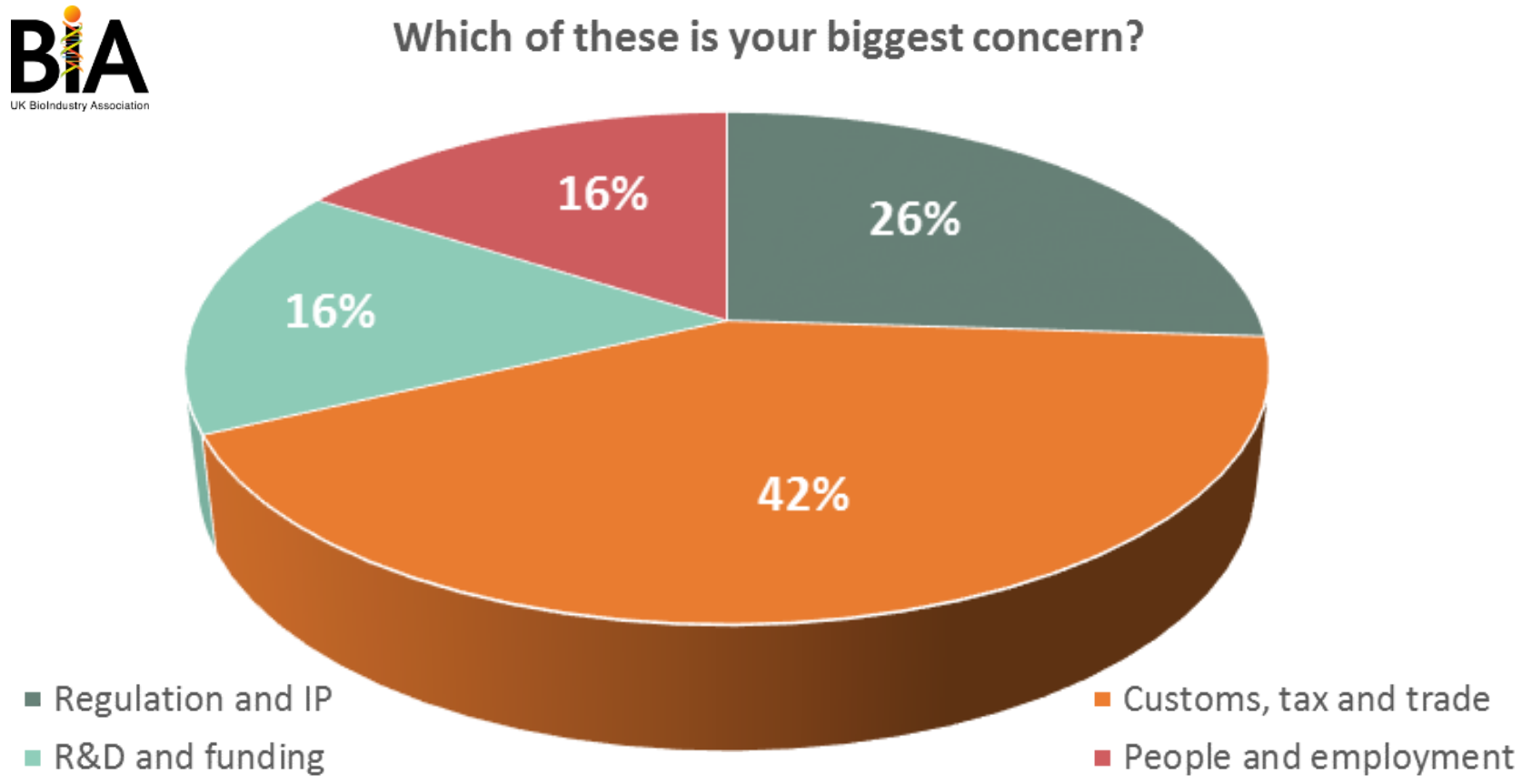
BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

A Different Perspective:

- Kymos's testimony goes beyond the conventional "CRO trades with UK client" and overcoming **barriers to internationalization**.
- Our services are part of a complex **international supply chain** which, while less straightforward, makes the effects of Brexit more **visible and quantifiable**.
- UK is among the **greatest trading regions** and cannot be understood in isolation: From the first Guilds of London to the East India Company the UK pioneered modern international trade.
- Working in the UK global business one becames aware of certain **non-tariff indicators** which capture the **mood of the market**:

Some of them subtle…

25/10/2019 UK BioIndustry Association Quickpoll

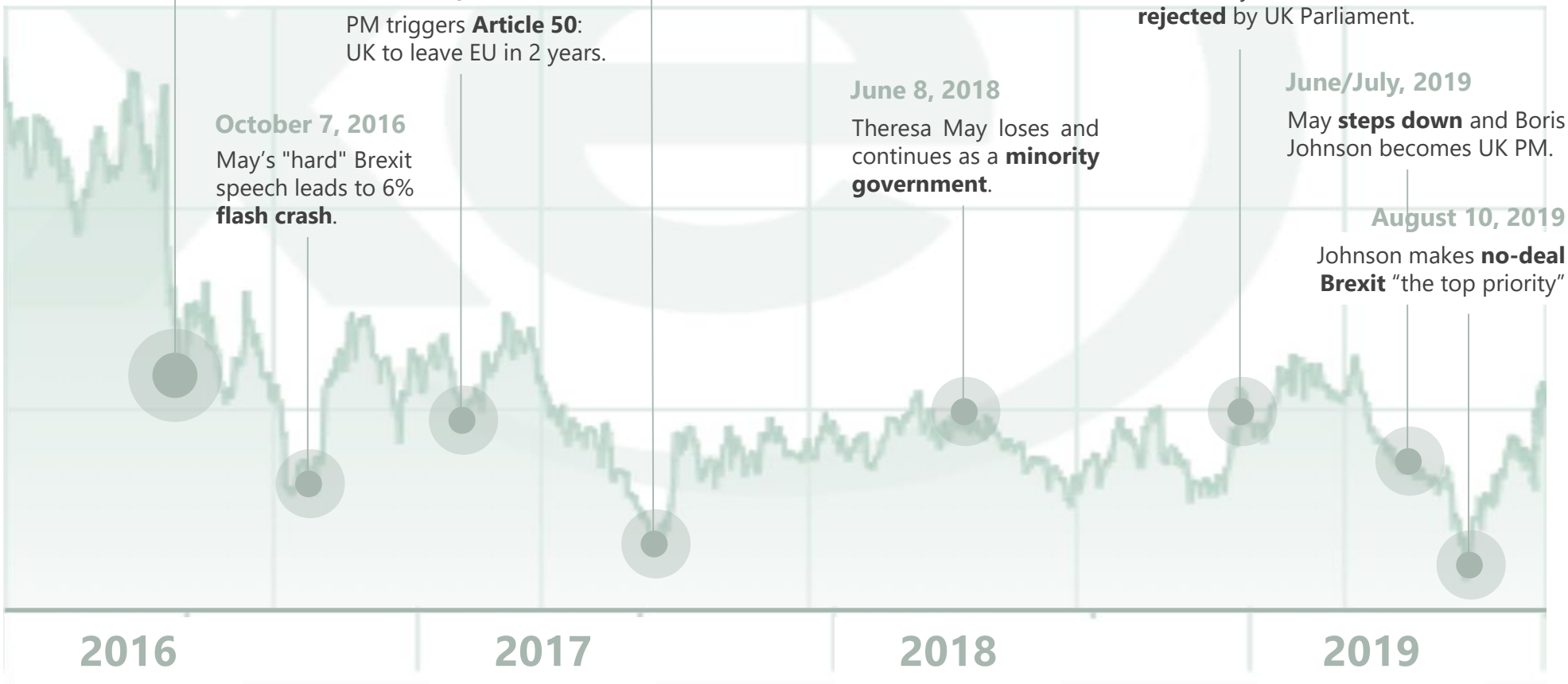


BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

XE Currency Charts: GBP to EUR

https://www.xe.com/currencycharts/

Some of them more obvious…



BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

A short-sighted media focus on Brexit:

- Most of the press is currently focused on the **theatrics** of the **power struggle** between UK and the EU.

  Some would claim it is hard not to…
- But the "hard vs soft" Brexit debate **trivializes** a longer term problem.
- In order to understand the **lasting impact of Brexit** we must focus on the **transition period** and what follows beyond Brexit itself.

BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

The new Withdrawal Agreement (WA) - Where are we now?

- **Transition period** up to **end of 2020** (possibly extended to Dec 2022). During the transition:
  - UK and EU will negotiate the terms of their **future trade agreement (FTA)**.
  - "*The parties will also explore the possibility of cooperation of the UK authorities with Union agencies such as the **EMA***". Excerpt from Johnson's WA (and also May's).
  - Firms could continue **UK batch release**, **testing** and **QP certification**.
  - **MA holders**, QPs, QPPVs could continue to be **based in the UK**.
  - Manufacturing and distribution **licenses** and **inspections** would be **recognized**.
  - UK would be **treated as a Member State** for the purposes of **MRAs**.
- But also…
  - **No UK participation** in EU institutions and no UK "leading authority".
  - Medicines and Healthcare products Regulatory Agency **out of EU regulatory network**.
  - **Readmittance** entirely subject to negotiation.
- After the transition:
  - If a FTA is not agreed, **Northern Ireland** would apply **EU rules** while the rest of the **UK** would move to a **no-deal/WTO relationship**. MHRA to apply two sets of rules.
  - No EU database access. **UK no longer "pure"** third country to EU.
  - "*UK aiming towards **mutual recognition of medicinal products** produced in UK and EU*" Matthew Hancock; Secretary of State for Health and Social Care.

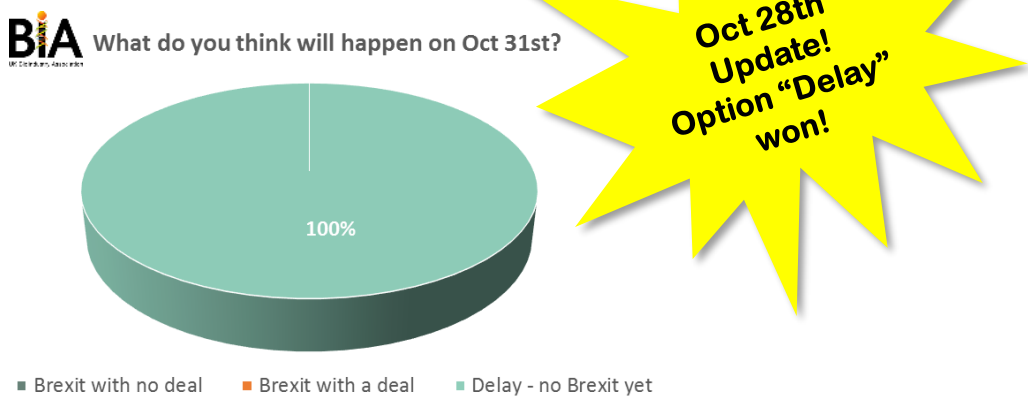
BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

The new Withdrawal Agreement – What happens next?

A TECHNICAL DELAY: Oct 31st – Jan 31st → WITHDRAWAL BILL UN-PAUSED → FULL ALIGNMENT TO EU CUSTOMS UNION → SECOND REFERENDUM REQUIRED BEFORE RATIFICATION

A LONGER EXTENSION → NEW AMENDMENTS → GOVT PUSHED FOR GENERAL ELECTION BEFORE 2020? → SECOND REFERENDUM?

NO DEAL? →

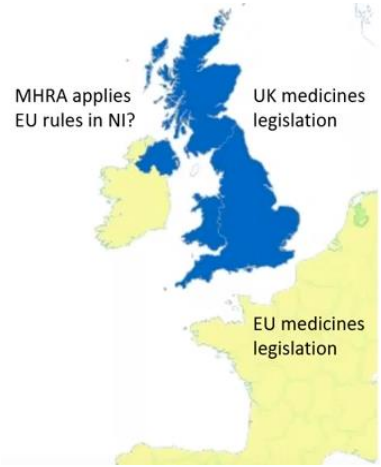


Oct 28th Update! Option "Delay" won!

BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

The new Withdrawal Agreement – If No Deal:

- UK ensuring **medicine supply** until absolutely clear a no-deal Brexit is off the table.
- **MHRA guidance** on **submissions** and QPPVs update.
- Ferry and freight additional services for **priority goods**.
- **National Supply Disruption Response** for medicines, devices, trials & vaccines.
- Simplified **customs, imports and tariff** procedures.
- **Immigration**: Salary thresholds and point-based system.



BREXIT: Challenges and Opportunities in the Pharmaceutical Sector

The new Withdrawal Agreement – If No Deal:

- In spite of all UK Government measures the situation will remain **highly volatile**, with **uncertainty** pushing clients to make **subjective**, **potentially long-term choices**.
- Word on the street is:

Kymos:
A different perspective

A different perspective - Company overview

KYMOS
PHARMA SERVICES, S.L.

Our Value Proposition

Kymos is a company devoted to provide analytical expertise and testing capabilities to third parties for research, development, regulatory and marketing purposes.

	Small molecules	Biologics
Bioanalysis (preclinical & clinical)	Mass Spectrometry	Immunology
CMC (chemistry, manufacturing & control)	Analytical Development Stability Studies Batch Testing Batch Release	Characterization

A different perspective – Company overview

Locations

Cerdanyola del Vallès, Barcelona, Catalonia, Spain

Camerata Picena, Ancona, Marche, Italy

Barcelona
Headquarters and Laboratories
Staff of 100 people

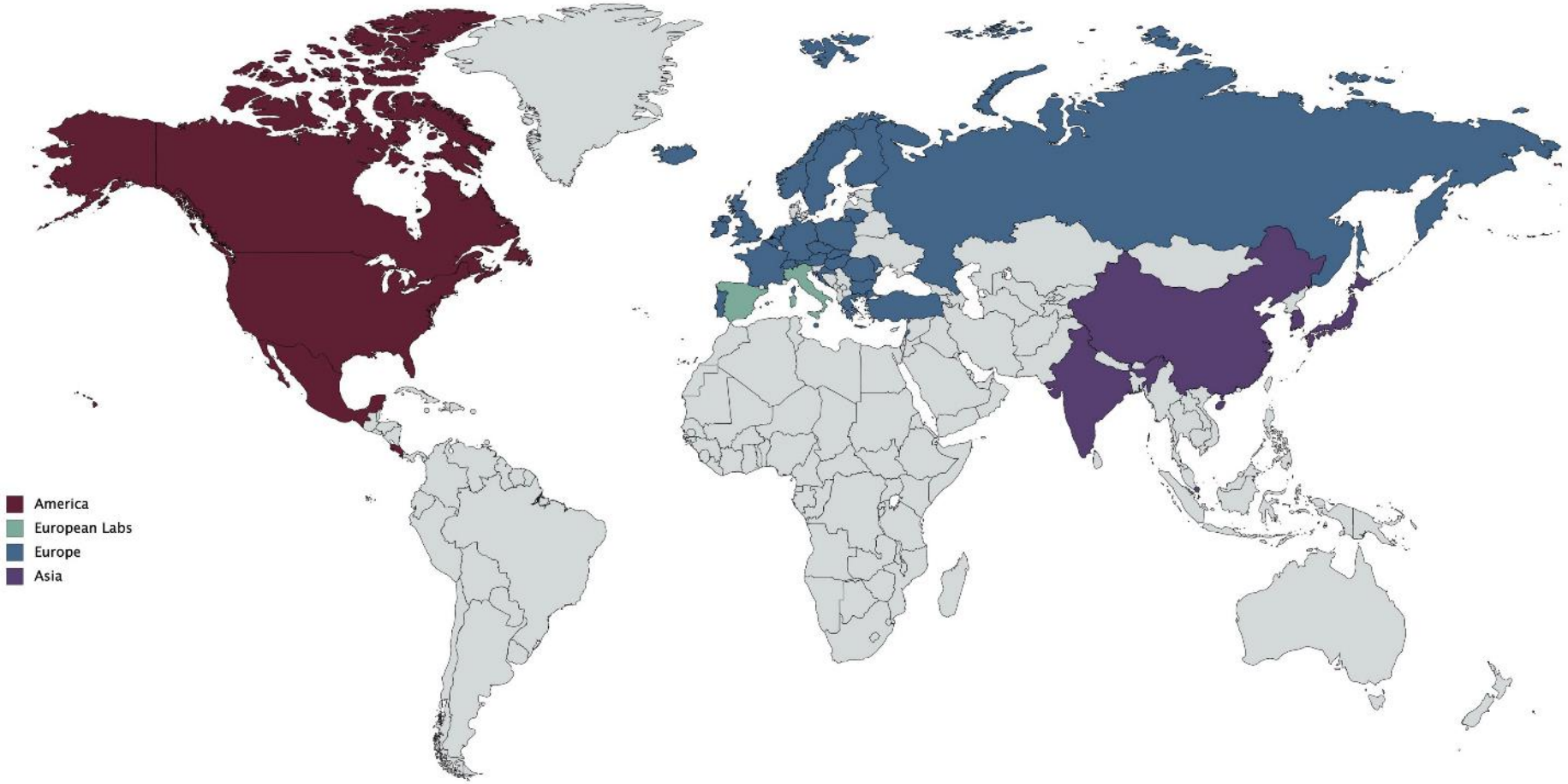
Ancona
Laboratories
Staff of 15 people

A different perspective – Company overview

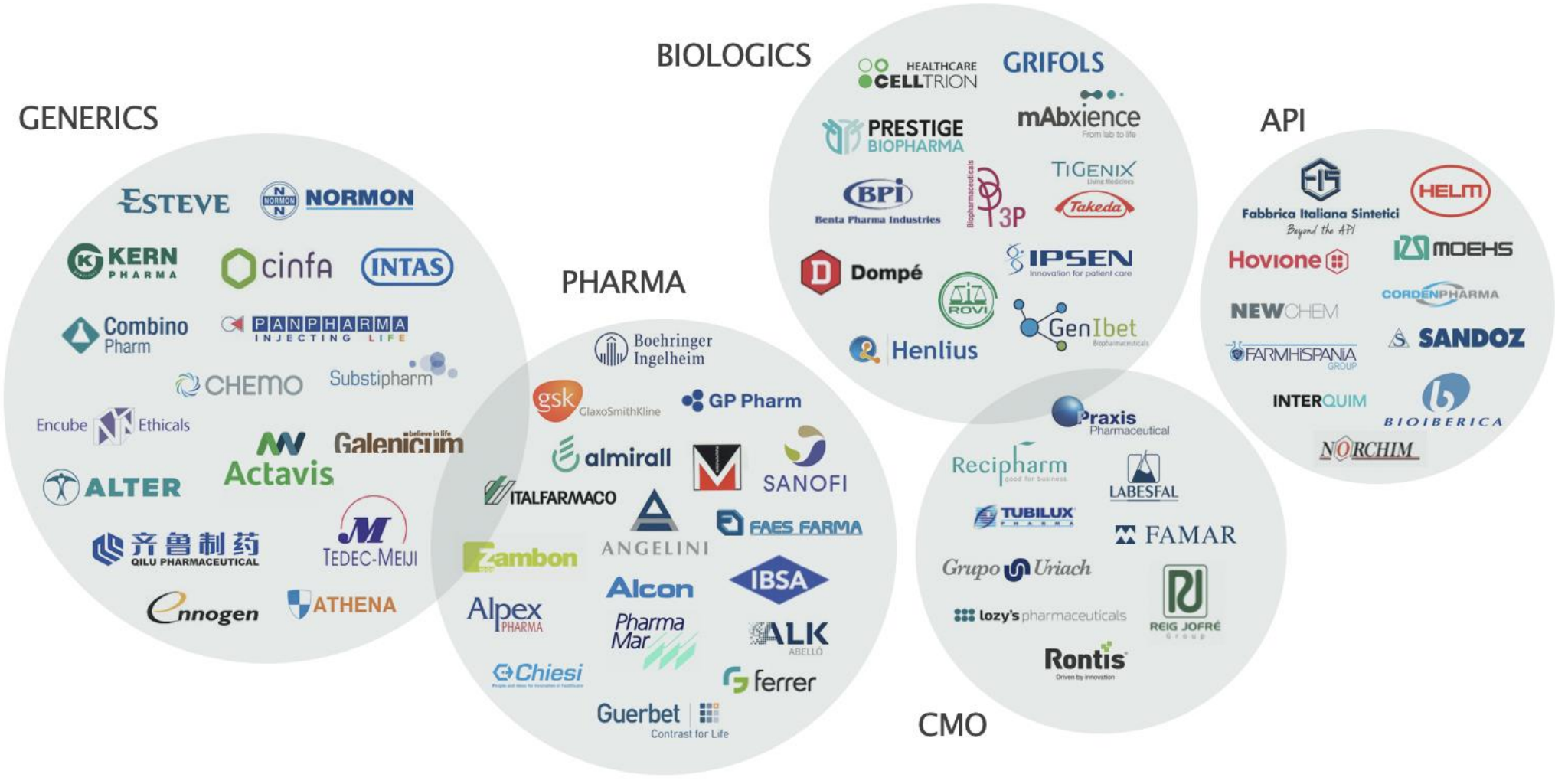
Global presence

Europe: business development headquarters in Barcelona and offices in Milan and Paris. Strong presence in southern and central Europe

Asia: relevant partners in South Korea, India, China and Japan



A different perspective – Company overview



A different perspective – Company overview

Headquarters

Barcelona, Spain

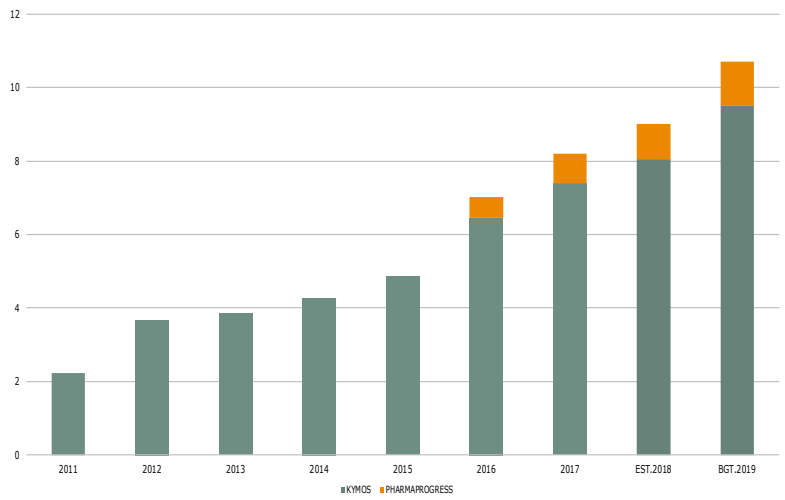
Laboratories (1,500 sqm)

- Fit to purpose building: technical gas station, emergency electric supply, purified water plant, and IT data room
- 6 main laboratories: **Bioanalysis**, **Immunology**, **Microbiology**, **Physical-Chemical Analysis, Analytical Development, and Biopharma Testing** and auxiliary facilities for sample storage, inflammables, residues…
- Clean room for microbiology testing.
- Containment room for high potency products (HAPI) up to OEL4.
- Sample reception and sample storage area with room <25ºC, climatic chambers, freezers, and ultra-freezers.

A different perspective – Company overview

Fast growing European CLO (contract laboratory organization)

reliable and experienced management team & solid financial structure



Shareholders:

- Founder Managers
- Key Managers
- Family Office from pharma sector

Governance:

- CEO, COO and CFO
- Steering Committee
- Board of Directors of 4 members with quarterly meetings
- External member in the Board
- General Assembly with a yearly meeting

Compliance:

- Audited company
- Board Attorney and External Legal Advisor
- Code of Conduct
- Environmental & Safety
- Privacy & Confidentiality
- Quality certifications

Future:

- Opened to deals & acquisitions based on opportunities

A different perspective – Batch Testing & Release

Among our many CMC services, Batch Testing & Release have experienced significant boosts:

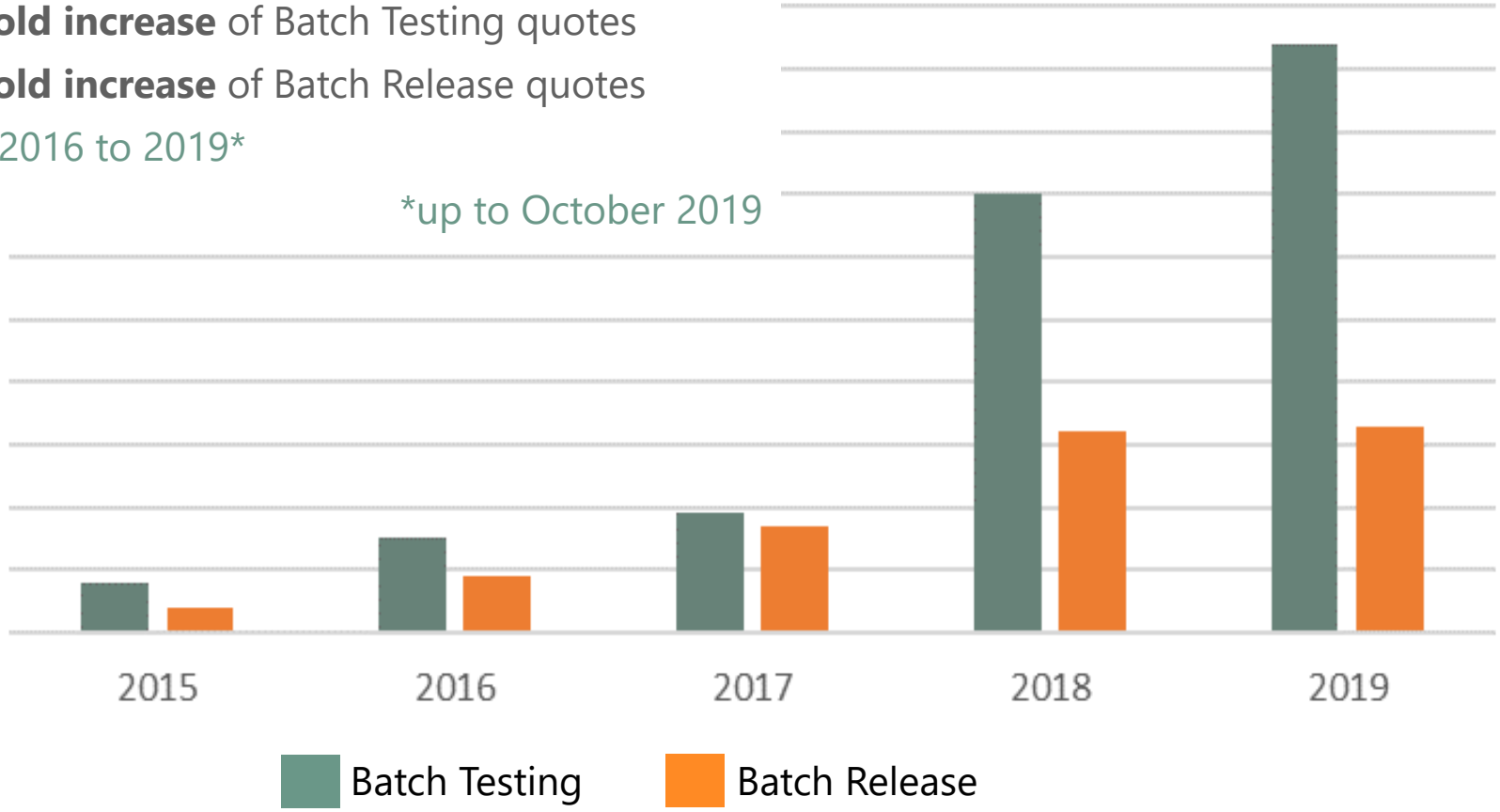
Batch Testing & Release Annual Evolution:

5.3-fold increase of Batch Testing quotes

2.7-fold increase of Batch Release quotes

from 2016 to 2019*

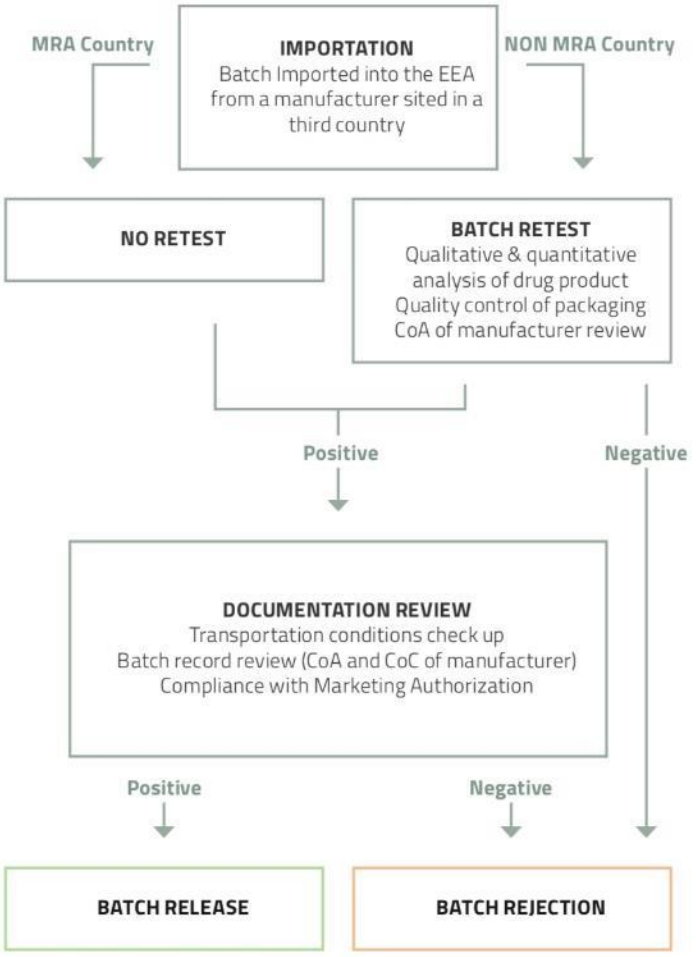
*up to October 2019



A different perspective – Batch Testing & Release

What is Batch Testing & Release?

- Imported products manufactured outside of the EEA must be tested by a **GMP-compliant lab** before being released into the market.
- Under current legislation, manufacturers must test batches **from non-EU/EEA third countries** if not covered by a **MRA**.
- This also applies to **batch release** and **pharmacovigilance** activities, which must be performed by **QP** & **QPPVs within the EU/EEA**.
- During the **transition period**, firms could **continue these activities within Britain**, with UK inspections and MIA licenses still recognized.
- **Beyond the transition** and depending on the FTA/MRA deal, the UK will become a "third country" and **all EU law will cease to apply**.



A different perspective – Batch Testing & Release

What is Batch Testing & Release?

- Kymos is **GMP-compliant**, FDA inspected, holds a **Manufacturing Authorisation (MIA),** is certified as **importer**, and count with **multiple QPs** to provide a full service pack.
- Kymos provides services for human, veterinary and investigational medicinal products with capabilities to release small molecules, biologics, sterile and non-sterile DPs. We offer:

Importation

- Request of importation license to AEMPS
- Importation in the European Union (IMP and DP)
- Warehousing, EU depot and shipment, if necessary

Support activities

- QP Declaration (template 5.22)
- Manufacturing plant audit for EU-GMP compliance
- PQR yearly review

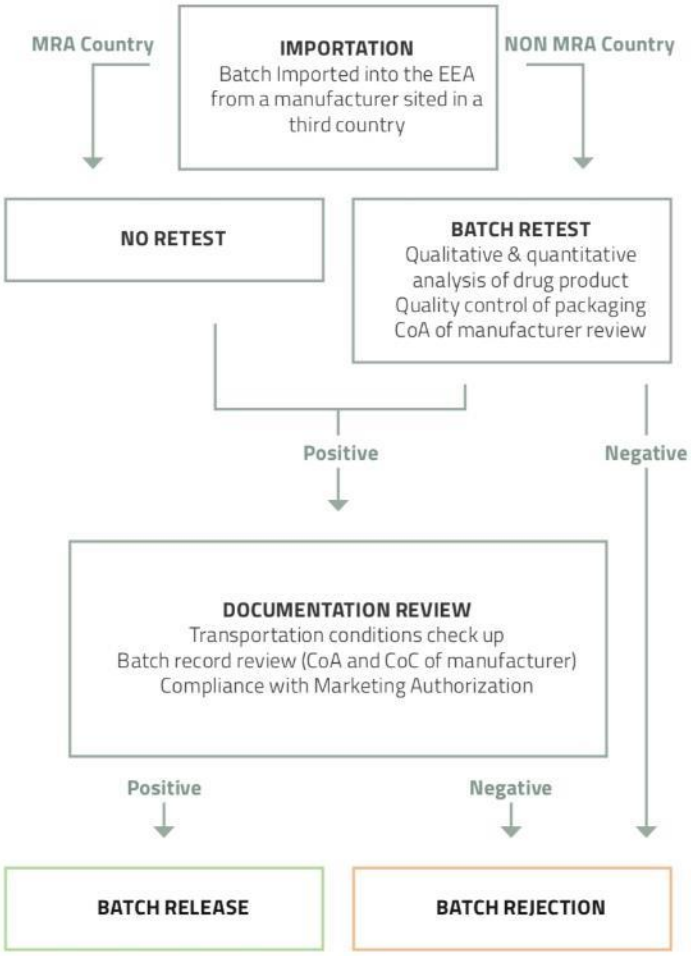
Batch Release

- Certificate of Analysis
- OOS, deviations, CAPAs and change control management
- Certificate of Release

A different perspective – Batch Testing & Release

Batch Testing & Release as an Empirical Indicator:

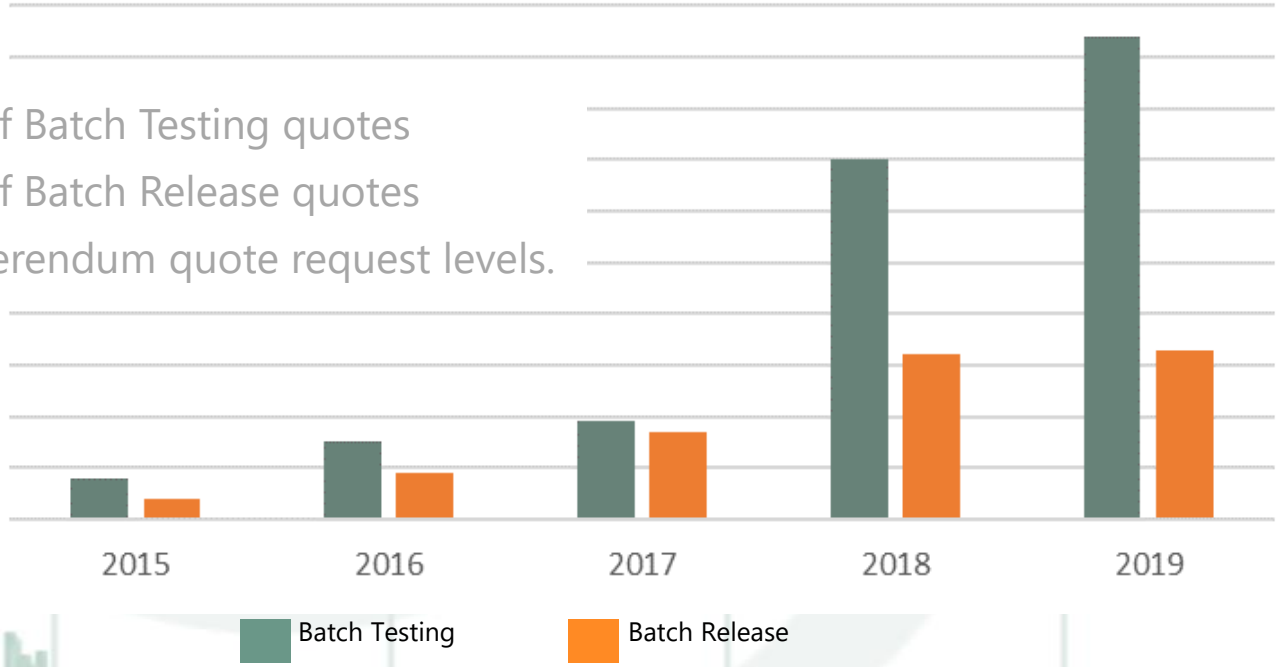
- First take-home message: 5.3/2.7-fold increases in Batch T&R demand imply a **lack of trust** in UK Govt mitigating **measures post-Brexit**.
- While the rise in demand **cannot be attributed solely to Brexit**, the fact that Kymos has not actively promoted Batch T&R services indicates the increase is at least a relevant **indicator**.
- Most of Kymos' UK Batch T&R clients **manufacture** their DPs **outside GB**. They seek to ensure **project continuity** and **minimize risk** by opting for **continental CROs** and **QPs**.
- If these assumptions are correct, **the trend should persist** during the 2020 transition and beyond. Firms that went through the hassle of shifting to a continental CRO may demand **significant guarantees** to shift back.



A different perspective – Batch Testing & Release

Batch Testing & Release as an Empirical Indicator:

5.3-fold increase of Batch Testing quotes
2.7-fold increase of Batch Release quotes
relative to Pre-Referendum quote request levels.



Brexit:
Closing remarks

Brexit: Closing remarks

Closing remarks:

- **Batch Testing & Release** will continue being allowed within the UK during the 2020 transition but the market is **preparing for the worst**.
- Batch T&R, Clinical Trials and Regulation to remain **key negotiation milestones** and good indicators of the **mood of the market**.
- Market shifts induced by uncertainty and volatility, with subjective, **non-tariff barriers** including **risk perception**, **cultural** and **linguistic**.
- UK likely to **strike a FTA/MRA deal** with the EU during negotiations. Post-Brexit likely trend: To keep **outsourcing to continental CROs**.
- Great Britain likely to become both **protective** (immigration, border control) and business-friendly in order to **sustain international trade**.
- **Nobody really knows** what will happen

...not even our decision makers!

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THANK YOU FOR YOUR ATTENTION!

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