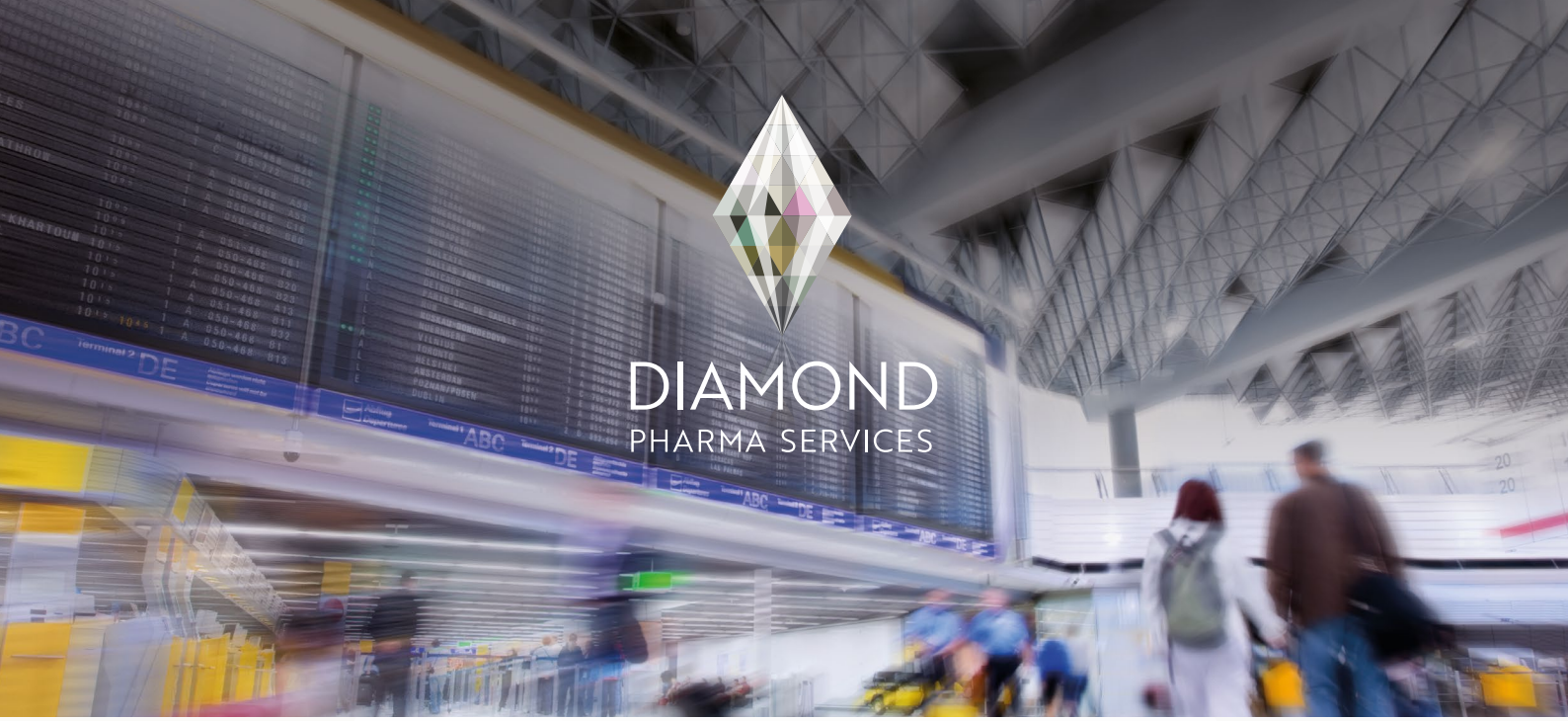

DIAMOND PHARMA SERVICES BREXIT PACKAGE

DEPARTURES

All EU marketed products will need to be registered with a legal entity in the EU. To meet the requirements post-Brexit we offer the following Departure Service:

- Reference member state switching and transfer of ownership applications.
- PSMF summary variation updates & XEVMPD.
- Importer batch release changes including QC sites.

Similarly, orphan designations and SME status will need to be held by a legal entity in the EU.

- Annex your orphan designation to Diamond Pharma Services whilst you establish your own legal entity in the EU.
- Diamond can help to transfer your orphan designation or SME status to your own EU legal entity.

Diamond Pharma Services are EU regulatory specialists with a legal entity in the EU. We are continuing business as usual, but now with enhanced capability within Europe.

ARRIVALS

The UK government is yet to define the regulatory pathway for UK marketed medicines post-Brexit. However, we are UK regulatory experts with many combined years of experience dealing with MHRA. We can:

- Help your company to be ready to maximise opportunities in UK registrations.
- Support your local UK regulatory requirements.
- Support CTA submissions in the UK.
- Provide the most current state of the art regulatory submissions and post-marketing life cycle management for existing UK licenses.
- De-risk the impact of Brexit to your portfolio of products and development programmes.
- Provide UK specific pharmacovigilance including local QPPV and PSMF.
- Offer UK compliance solutions including UK QPs and Inspections.
- Cover all national post-marketing requirements.

REGULATORY ♦ PHARMACOVIGILANCE ♦ COMPLIANCE

For further information please call **+44 (0) 203 911 9410** Email: **info@diamondpharmaservices.com**
Web: **www.diamondpharmaservices.com**