Checklist on Due Diligence (DD) for External Business Partners (ExBP)

ExBP Lifecycle Management

**Example:** Excellence in Distributor Management (EiDM) Lifecycle Toolkit Diagnostics

- Holistic ExBP lifecycle management is the best approach
- BP management is the accountability of the engaging business
- All models include due diligence as part of entering a new relationship, as well as a periodic review of the DD

*Suggested focus: Due Diligence for Distributors, Agencies that interact with HCPs/HCOs*
Flowchart for ExBP DD – risk based approach

1. Segmentation of ExBP: Identify critical (high risk) segments
   - Low risk segment AND Existing ExBP → Minimal verification**
   - High risk segment* OR new ExBP

2. Perform basic DD and Risk Assessment to identify individual high risk BPs***
   - F previous DD documented
     - (<3y) → no update required
     - (>3y) → review/update DD
   - Perform basic DD and Risk Assessment

3. Perform In-Depth DD
   - F previous DD documented
     - (<3y) → no update required
     - (>3y) → review/update DD
   - Perform full/in-depth DD

Accept risk, mitigate risk or exit relationship

* Other ExBP like distributors, agencies, patient organisations, or ExBP who interact with HCPs/HCOs. Government officials should equally be classified as high risk (from a healthcare compliance perspective)
** Depending on the type or specific situation of the ExBP more DD may be necessary
*** Long standing relationship, low risk ExBP with good track record: Based on documented approval from LT or compliance committee DD can be waived as exception to step 2

ExBP DD - General Guidance

- Roche Group Code of Conduct mandates that we get assurance about the integrity, quality, suitability and credibility of our business partners before and during a business engagement

- DD is a critical element of ExBP lifecycle management and needs to be performed initially and periodically

- Depth, scope and criteria of the DD should be risk-based and address all relevant risk areas

- The business is accountable for conducting DD

- The documentation should include: risk assessment, information collected and result of the DD. The result of the DD should be shared with the ExBP. DD documentation should be documented as an official record in compliance with the Roche COREMAP Directive (e.g., on TouchPoint/Sharepoint).

- This checklist provides good practice examples and is not mandatory

Tools available:
- EEMEA Due Diligence Documentation Checklist (Pharma)
- APAC Due Diligence Documentation Checklist (Pharma)
- EiDM Lifecycle Toolkit (Diagnostics)
In case there is further advice or information needed with regard to the DD, please get in touch with your local Procurement/Compliance function. The business relation with a potential new ExBP bears various risks. The following risks were identified as typical when dealing with an ExBP. It is recommended to specifically address these risks in the course of the DD of a potential ExBP.

Financial Risk:
- Are there any risks that the ExBP could not fulfill its financial liabilities with Roche or any other third party that could have a negative financial impact on Roche or on the services provided by the ExBP?

Supply Risk:
- Are there any risks that the services provided by the ExBP could have a negative impact on the supply of our products (e.g. single source, logistics, war zone)?

Quality and Safety Risk:
- Are there any risks that the services provided by the ExBP could have a negative impact on the quality or safety of our products?

Legal Risk:
- Does the nature of the services provided by the ExBP require a contract (e.g. distribution and/or service agreement)?
- A contract with an ExBP needs to be coordinated and approved by a Roche lawyer:
  - Is the contract based on Roche’s standard contract template i.e. terms, clauses and templates developed by Roche Legal?
  - Have there been any changes to contract terms and conditions or to the scope of the contract and have those changes (minor, major) been reviewed by a Roche lawyer?
  - Are the services provided clearly defined and is the payment for the services market related?

Reputation/ SHE/ Social/ Ethics/ Human Rights Risk:
- Are there any indicators that an engagement with the ExBP could negatively impact our reputation (e.g. ExBP may already have negative media attention that could also impact Roche)?
- Is there a risk of violation of human rights (e.g. forced labor)?
- Is there a SHE or ethics risk identified?

Other Risks if applicable (e.g. Commercial risk, Innovation/ Technology/ IP Risk):
- Does the supplier know and properly protect Roche’s IP rights & Trademark, and is the ExBP willing to inform Roche about ExBP’s own innovations early?

---

### Human Rights Assessment & Implementation Framework

Collection of Information → Identification of Impacts → Analysis of Impacts → Implementation

- **Business Assessment**
  - Actual
  - Potential
- **Stakeholder Engagement**
- **Public Domains**
- **Red Flags**

- **Cause, Contribute, Linked to**
- **Scale, Scope, Remediability**
- **Severity & Likelihood**

- **Integration in processes and operations**
- **Remediation actions**
- **Communication**

Continuous improvement
BASIC DD for ALL ExBP

1. Validate legal entity, address details and accounting information of the ExBP (Minimal verification covers bullet 1 only):
   - Legal entity/Owner structure
   - Detailed invoicing and site address
   - Banking connection, number, and other related details

2. Compliance background check on ExBP based on available information
   - Review ExBP’s website and other public information and run detailed internet check on the ExBP in order to find out if there are any publicly known issues and get publicly available information (e.g., annual report to assess basic financial data, scandals related to the ExBP, investigations, withdrawal of license to operate, Denied Parties List)
   - Verify Anti-Corruption Compliance information
   - Receive signed Anti-Corruption Compliance Assurance Confirmation
   - Receive ExBP’s commitment to Roche (Supplier) Code of Conduct or receive BP equivalent

3. Perform Risk Assessment if not already conducted
   - Investigate the Procurement risk areas to identify the high risk ExBPs
   - Document identified high risks and assess with relevant SME the ability to mitigate

Training of BP:
- Assess the training capability and historic performance. Propose what relevant trainings need to be conducted, check the ability to invite ExBPs to participate into e-learning “(Supplier) Code of Conduct”
- Training on Interactions with HCPs/HCOs (if applicable)
- Check on successful training participation

* SME: Subject Matter Expert

Tools available:
- Roche Supplier Code of Conduct (Dia and Pharma)
- Due Diligence Process for Suppliers (Pharma Procurement)
- e-learning “Supplier Code of Conduct” (Dia and Pharma)
- Training on Pharma Directive on Interaction with HCPs and HCOs
- Training on Dia Divisional Standard on Interactions with HCPs and HCOs (DS092)
- Qualification, Selection and Evaluation of Providers of Indirect Goods and Services (Pharma LATAM)
- Anti-Corruption Compliance Questionnaire for Roche Business Partners (Dia and Pharma)
- EEMEA Pharma: 3rd Party Management & Due Diligence in EEMEA Guideline
- APAC Pharma: 3rd Party Management & Due Diligence Toolkit
- Site Basel: Template “Site Procurement – Lieferanten-Präqualifikation”

Obtain information on subcontractors/sub distributors/collaborative parties
- External Due Diligence Report
  - A recommendation, obtain and use the external background report and verify against information received from the ExBP (e.g., E&Y Report). Recommendation for extended E&Y report.
  - Depending on the services performed by a potential Distributor further information might be necessary.

Export Compliance Due Diligence
- Any business partner relationship needs to be assessed if it does not violate an embargo or a potential partner that is blacklisted. Verify with the Local Export Compliance Officer (LECO) to complete the screening regarding the Denied Party Lists.

Financial and Credit Due Diligence
- Roche party requests general, financial and banking information from the potential ExBP.
  - (e.g., working capital financing, mutual dependency, financial health, risk of insolvency). Please consult the Finance Department and follow their guidance. Consider external credit rating assessment.

Pharmacovigilance/Materiovigilance Due Diligence (if applicable)
- Where applicable, in order to evaluate if an ExBP is able to adhere to Roche’s Pharmacovigilance (PV)/ Materiovigilance requirements, the ExBP also needs to be assessed by Roche’s PV/ Materiovigilance organization. Consult and document with the relevant function in the organization and follow their guidance (e.g., PV Checklist).

Supply Chain Quality Due Diligence
- In order to assess if a potential ExBP is eligible to contribute to Roche’s Supply Chain, the ExBP needs to provide insights into the warehousing and distribution related facilities as well as capabilities. Please contact your Supply Chain Department for the detailed steps and process of the Supply Chain Quality Due Diligence and potential Audit.

Technical & SHE Due Diligence if applicable (for License, Supply and Quality Agreements only)
- In case Roche wants to engage in a License, Supply & Quality Agreement with a potential ExBP, a Technical & SHE DD is required too and follows the Compliance DD process and potential Audit.
- Get copy of License to Operate, permits

Tools available:
- Roche Group Code of Conduct
- Anti-Corruption Compliance Questionnaire for Roche Business Partners (Dia and Pharma)
- Anti-Corruption Compliance Assurance Confirmation (Dia and Pharma)
- RDI DC Distributors Score Card DC (MD12072013) (Roche DC)
- Business Partner Training (Pharma)
- Export Compliance Questionnaire EEMEA and APAC ( Pharma)
- EEMEA Customer Self-Information Questionnaire ( Pharma)
- APAC Business Partner Self-Information Questionnaire ( Pharma)
- Qualification, Selection and Evaluation of Providers of Indirect Goods and Services ( Pharma LATAM)
- EEMEA PV Checklist ( Pharma)
- Supply Chain Quality Questionnaire ( Pharma)
- Dia, EIM Life cycle toolkit (e.g., Turkey Business Partner/Distributor Compliance Assessment Process)
- Dia, EIM Life cycle toolkit (e.g., Selection And Assessment Of Roche Diagnostics Polska Distributors)
- Dia, EIM Life cycle toolkit (e.g., Korea Roche’s Warehouse Questionnaire for Distributor)
- Distributors Improvement Project (DIP) at ME1&J Sub-Regional Level ( Pharma)
- Dia, EIM Life cycle toolkit (e.g., Korea Roche’s Quality Control Questionnaire for Distributor)
In Depth DD for EVENT AGENCIES

In case there is further advice or information needed with regard to the DD of an Event Agency, please get in contact with your local Compliance function. In case the risk assessment of the ExBPs in this high risk segment led to the conclusion that it is a high risk individual ExBP an in depth DD needs to be performed. In case the basic Due Diligence has given reason to believe that aspects relevant for the decision upon the ExBP relationship should be investigated in more depth, an “In-Depth Due Diligence” has to be initiated to gain that information. The Business Manager should run the actions as described below. Depending on the contractual obligation with the ExBP, the process of the DD should contain at minimum the following elements:

- As a recommendation, obtain and use an external background report and verify against information received from the ExBP (e.g. E&Y Report)
- Check if the ExBP is listed on an Exclusion or any Denied Parties List (e.g. Trade Law Compliance List; please liaise with Roche Export Compliance)
- Get detailed information from the ExBP on how he/she will perform services for Roche, including information on personnel and/or legal entities related to the External Business Partner (detailed Business Model)
- Obtain references from other customers/stakeholders/certifications of the ExBP and interview them about their experiences with the ExBP
- Conduct an interview with the ExBP and complete the Roche Anti-Corruption Compliance Questionnaire for Roche Business Partners
- Asses if there is/was any ongoing or recent investigations by the authorities (if feasible) or any negative publicity related to the ExBP or it’s management and/or the materials or services provided by him/her (review any information available on public domain)
- Check for any conflict of interest
- Receive and document the following information from the ExBP
  - Copy of License to Operate (Registration) and any further permits and certifications that are required to provide the specific service
  - Copy of the ExBP’s business continuity plan
- Perform an Audit at ExBP’s premise serving Roche (if needed)

For any new ExBP with the potential to become a critical, strategic or preferred supplier or an existing one categorized as critical, strategic or preferred, an In-Depth Due Diligence has to be conducted in addition to a basic DD.

Criteria for In-Depth Due Diligence:
- High risk ExBP based on the performed risk assessment of that high risk ExBP segment
- Single provider available in the market
- More expense of the company, that is within 20% of providers presenting 80% of the company’s expense (excluding goods and services that are found out of reach of the present policy)
- Has any special regulation of any Public or Private entity
- Confidential Information handling
- Intellectual Property or Copyright
- Its shortage can present a high risk for the business continuity
- Roche represents more than 50% of the provider’s business
- If the contract duration is longer than 3 years
- Impact on Patient’s or employee’s safety

As part of the DD process, the ExBP needs to:

- Sign and adhere to the **Roche Group Code of Conduct**.
  (Check if the ExBP Code of Conduct is at par with Roche’s standards.)

- Adhere to respective Compliance provisions; **Right to Audit and Monitoring** provisions must be in the agreement.

- Complete the **External Business Partner Training**
  (Depending on the nature of services provided by the External Business Partner, also consider additional face-to-face training session).
Setting a Risk Based Focus for DD

- **All segments of ExBPs**
  - Criticality assessment → leads to Segmentation

- **High Risk Segment**
  - High Risk ExBP
  - Risk assessment (close up look)

- **Low Risk ExBP**

- **Basic DD**
- **In Depth DD**
- **DD action**
- **Basic DD**

- **All ExBP**

- **Group of ExBP**
  - e.g. Distributors, Event agencies that interact with HCPs, HCOs, patient organisations, Government officials, ...

- **Individual ExBP**
Governance

**Guidance: Checklist on Due Diligence for External Business Partners:**
Non-mandatory reference (good practice) how to perform risk prioritized due diligence
Recommends holistic BP LCM

**CoC mandates:**
Obtain and maintain assurance about the integrity, quality, suitability and credibility of our business partners before and during a business engagement

→ Perform a form of due diligence for all BP

**Procurement Policy mandates:**
DD for suppliers with addressable spend (and few selected exceptions). Practically not all >65k suppliers covered

→ Adequate DD for most / high risk suppliers across Pharma is defined

**Regional DD guidelines:**
Mandated / recommended key elements of BP relationship (beyond suppliers), includes DD.

→ EEMEA, APAC: For all new BPs adequate DD is defined

2017 Target: Review or Perform DD for all BP in high risk segment of Distributors and Event Agencies who interact with HCP/HCO at the minimum to the level of the Group Guidance:

→ DD ensured for all Distributors & Event Agencies across Pharma

**Note:** We do not have a mechanism to maintain the level of assurance in place

---

Doing now what patients need next