Roche Position\(^1\) on Safety, Security, Health and Environmental Protection (SHE) in the Supply Chain

**Background**

The characteristics of the supply chain within the pharmaceutical industry have changed significantly over the past years. Initially the supply chain took the shape of a relatively small number of suppliers feeding in raw materials which were converted to finished products within the company. Today more and more outsourcing is taking place, increasing the complexity at suppliers’ operations who are themselves subcontracting.

Outsourcing of in-house manufacturing steps to suppliers bears some additional risk. While the suppliers themselves carry the legal responsibility in the country where they are situated, the companies employing them cannot delegate away the accountability for the overall supply chain.

Companies that neglect their responsibility regarding SHE, social responsibility and ethical standards at their suppliers increase the probability of reputation loss, which in turn can lead to loss of business, especially in the event of a severe incident/accident. On the other hand companies which manage the supply chain in a responsible way contribute to the sustainability of the industry as a whole and create new opportunities, thus positively impacting society.

**Stakeholders’ Expectations and Concerns**

Stakeholders want to see increasing evidence that companies demonstrate adherence to local and international standards of SHE, social responsibility and ethics. There is an acceptance that the supply chain is being sourced from countries having lower labor costs but not at the expense of the worker or environment. Stakeholders want to know that basic norms e.g. child labor and the preservation of universal employment rights are being protected. Also, stakeholders increasingly ask companies to demonstrate that they know their supply chain risks, and how they use a risk based approach in order to identify the relevant SHE, social and ethics risks along their supply chain and mitigate these risks.

\(^1\) Pertains to SDGs 3, 6, 7, 8, 12 and 13
Roche’s Position

We want to maintain high ethical and social standards in business relationships, in our approach to medical science, in our efforts to protect the environment and ensure good citizenship. We will maintain these standards by adherence to local, national and international laws and cooperating with authorities (1).

Our suppliers (of materials, service providers and contract manufacturers) play an important role as enablers of our sustainable growth and overall success (2).

Roche works on the principle that there is only one standard for social, ethics and SHE which applies to all business done internally and externally. We expect that the behavior of our suppliers complies with applicable laws, regulations and contractual terms, as well as with generally accepted standards.

Although Roche cannot take the primary responsibility for the activities of a supplier, we recognize our ability and responsibility to positively influence the performance of suppliers. Therefore we aim to develop long term relationships with them. We are aware of differences in culture and the challenges associated with interpreting and applying these principles globally. Therefore, while we believe that what is expected is universal, it is understood that the approach for meeting these expectations may be different in different cultures and must be consistent with the laws, values and cultural expectations of the different societies of the world.

Our aim is to ensure that suppliers doing business with Roche meet not only all relevant legal requirements, but Roche standards as well, thus reducing the risks of business interruptions and liabilities and also protecting Roche’s general commitments, obligations, interests and overall reputation.

Commitment to our suppliers:

At Roche we believe that it is not enough to assess our supply chain and use on-site audits and other means to identify the highest risks in the area of SHE, social and ethics. We take a proactive approach to mitigate these risks in collaboration with our suppliers and also seize opportunities to make our supply chain more resilient for the benefit of all involved.

Before entering into a business engagement, Roche performs due diligence of the potential supplier to get assurance about its integrity, quality, suitability and credibility.

Roche’s approach is based on the International Chamber of Commerce’s (ICC) Policy statement “ICC guidance on supply chain responsibility” (4).
Roche has also endorsed the Pharmaceutical Industry Principles for Responsible Supply Chain Management (“PSCI Principles”) for ethics, labor, environment, health and safety (5), and we are committed to integrating these principles into our business practices.

In 2003 Roche introduced the K15 Directive, which is an internal “Directive on dealing with third party manufacturers and service providers”. This Directive defines the necessary measures which have to be taken before signing a contract and engaging the services of a supplier. The Roche Group K15 Directive includes the following principles:

- The degree of Roche’s engagement at suppliers depends on the nature of the business relationship
- Supplier segmentation: Suppliers are categorized using risk-based selection criteria
- Before entering a new business relationship or prior to a contract renewal the supplier’s standards and performance are assessed in the following areas: labor, ethics, SHE management systems and infrastructure.
- Audits are carried out depending upon the results of the assessment. Minimal performance standards are set.

Roche’s suppliers are asked to commit to the sustainability principles outlined in the “Roche Supplier Code of Conduct” (2). Furthermore social responsibility, ethical and SHE compliance requirements as well as the right to carry out social, ethical and SHE audits are usually part of our contracts with suppliers. A supplier e-learning on the Roche Supplier Code of Conduct (3) has been made available in 5 languages on the Roche Suppliers website and more than 15’000 supplier representatives have already completed it (status December 2017).

In the event that a business partner does not comply with applicable laws, regulations and contractual terms, as well as with generally accepted social responsibility standards, we request appropriate remedial measures and will, if necessary, terminate the cooperation with a business partner that does not respect our standards.

**Outlook / Status / Current engagement and initiatives**

In 2010 a Roche Supply Chain goal was set to have only acceptable suppliers and service providers. The goal has 2 parts:

- Part 1: To select only acceptable new suppliers and service providers
- Part 2: Existing business critical suppliers and service providers assessed (>90%) and all those below expectations abandoned within a set period of time.
The auditing of suppliers for both divisions Pharmaceuticals and Diagnostics takes place using internal and selected external auditors.

As of January 2018 more than 1'000 on-site audits have been conducted at critical suppliers and service providers and they generally followed up on the actions from the audits. Less than 1% was unwilling to follow up on the actions and was found to be unacceptable, and business with them was discontinued. In case of major findings follow-up audits were made to verify the implementation of recommendations. Amongst other criteria, the frequency of re-audits depends on the number and severity of findings from earlier audits and will be higher in case of major or higher number of findings. Roche collaborates with more than 20 other pharmaceutical companies (status January 2018) to improve the standards of suppliers to the industry in the Pharmaceutical Supply Chain Initiative (PSCI). One of the goals of PSCI is the sharing of sustainability audit reports amongst PSCI members (with the permission of the supplier) based on harmonized audit standards in order to reduce duplication of audits and save cost and time for all involved. In 2017, 68 supplier audit reports and self-assessment questionnaires were received via PSCI, up from 51 in 2016. We aim to further leverage the PSCI collaboration in the future. We also work with suppliers to convert the audits into sustainability assurance visits with the aim to create benefits for all parties involved.

Links

(1) Roche Group Code of Conduct: [http://www.roche.com/about/governance/code_of_conduct.htm](http://www.roche.com/about/governance/code_of_conduct.htm)


(4) ICC guidance on supply chain responsibility: [http://www.iccwbo.org](http://www.iccwbo.org)

(5) PSCI Principles: [http://www.pscinitiative.org](http://www.pscinitiative.org)


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