

Roche Position on Prevention of Misuse of Chemical and Biological Materials for Warfare and Terrorism

Roche uses chemical and biological materials for research, development and production of pharmaceutical and diagnostic products for the benefit of patients. Roche is aware that some of these materials (defined here as regulated materials) and associated technologies can be misused for the purposes of warfare or terrorism. The aim of this paper is to highlight Roche's position and to describe the measures Roche is taking to avoid any violation of laws and regulations.

Roche's position

Considering that achievements in the field of biology and chemistry should be used exclusively for the benefit of mankind, Roche is determined to exclude or deter the risk of regulated biological and chemical materials and associated technologies being used for any prohibited purpose whilst supporting authorized trade, international cooperation and exchange of scientific and technical know-how. Therefore, Roche is strongly committed to complying with all obligations derived from the current international disarmament agreements covering regulated materials: The Biological Weapons Convention (BWC), the Australia Group arrangement and the Chemical Weapons Convention (CWC).

The global situation

In alignment with the principles, objectives and obligations under the Prohibition of the Use in War of Asphyxiation, Poisonous or Other Gases, and of Bacteriological Methods of Warfare (the Geneva Protocol of 1925), targeting effective progress towards general and complete disarmament and recognizing the growing threat of the malicious use of regulated materials to cause mass terror, several international agreements between states have been signed over the past decades:

The Biological Weapons Convention, BWC ¹:

Entered into force in 1975 as the first multilateral disarmament treaty, the BWC currently has 164 State Parties. It effectively prohibits the development, production, acquisition, transfer, retention, stockpiling and use of biological and toxin weapons. The enforcement of the Convention's obligations is controlled at national level and regular conferences pursue initiatives to improve the implementation of the Convention.

The Australia Group arrangement ²:

An informal group established in 1985 which currently has 41 members. It has identified chemical and biological materials, some not in the scope of the CWC, and has defined common export control obligations. The implementation of these regulations is administered by the National Authorities of States Parties.

The Chemical Weapons Convention, CWC ³:

Effective since April 1997 and signed in the meantime by 188 Countries, the CWC is an agreement which outlaws the production, stockpiling and use of chemical weapons and regulates their precursors. It is administered by the independent Organisation for the Prohibition of Chemical Weapons (OPCW), which ensures the implementation of the CWC provisions through cooperation with specific National Authorities but also through on-site inspections of chemical facilities.

The obligations on regulated materials resulting from these agreements have limited impact on legitimate research, development, production and trade activities but they significantly increase their visibility, providing an opportunity for the competent National Authorities of States Parties to interfere in cases of concern. This allows preventing direct and inadvertent involvement in the spread of materials for chemical and biological weapons. Global chemical and biological industries firmly support this principle.

The situation at Roche

Despite the broad variety of chemical and biological materials used for pharmaceutical and diagnostic products, the international pharmaceutical industry in general and Roche in particular are unlikely to be a source of misuse, as the vast majority of materials handled are not in scope of the regulations derived from international disarmament agreements. For instance, CWC-schedule 1 chemicals (chemical weapon or final precursor of it) and biological materials of risk group 4 (high individual and community risk) are neither handled nor stored in a Roche Group facility. Hence, the regulated materials at Roche are generally of lower criticality.

Nevertheless, Roche has set up internal rules and processes to comply with the different international conventions on regulated materials, which are also applicable for Group companies located in countries which are not members of the aforementioned Conventions. These requirements, described in a Roche Group Directive, are:

- In each Group company impacted by international agreements, a responsible person for co-ordination and supervision must be appointed and appropriate training must be established.

- Following the national laws and regulations derived from international agreements, required permits to import, procure, store, handle, sell or export regulated materials must be obtained from Authorities. Subsequent activities must fulfill all the legal obligations and be reported, when required.
- Presence of regulated materials in a Group Company requires that permits and local reports submitted to Authorities also be communicated annually to the Group SHE department through the Roche SHE reporting program.
- Enforcement of these elements is regularly validated through internal and external audits.
- Relevant updates to international agreements are provided to the Group companies, as needed.

More information

¹ The Biological Weapons Convention: <http://www.unog.ch>, Disarmament Tag

² The Australia Group: <http://www.australiagroup.net/en/index.html>

³ The Organization for the Prohibition of Chemical Weapons: <http://www.opcw.org/>

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