

# Is It Possible to Contaminate Monoclonal Antibodies by Cytotoxic Drugs in Centralized Preparation Units ? A Consensus Conference From the French Society of Oncology Pharmacy

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## -Background-

Pharmacy centralized handling of anticancer drugs is mandatory in many countries, especially in EU. The use of monoclonal antibodies (mAbs) in oncology is growing, mainly associated with cytotoxic drugs. Despite mAbs are not considered as hazardous, they are considered as anticancer drug and handled in the same isolators or laminar-flow hoods (LAF) that cytotoxics drugs. Nevertheless, there is no generally accepted guideline and some national health authorities consider that mAbs should be handled in separate safety cabinets to avoid cross-contamination with cytotoxic drugs. However, this position is not scientifically based and should induce high additional costs and logistic problems for hospitals.

## -Methods-

French Society of Oncology Pharmacy (SFPO) performed a consensus conference to analyse available data and to propose guidelines.

Handled drugs were classified in 4 groups:

Group I: **cytotoxics** (as listed by international safety agencies - NTP, IARC, OSHA, NIOSH, AGGIH);

Group II: **mAbs used for cancer patients receiving also cytotoxics**;

Group III: **mAbs in monotherapy used in patients for cancer or another pathologies** (i.e. auto-immune disorders)

Group IV: others.

## -Results-

According to the current practices, the group considered that **low-level** external contaminations can not be excluded for gloves, drug containers and preparation area. Since environmental risks induced by mAbs were considered as low, the safety concern is mainly due to external cross-contamination of mAbs-containing bags by cytotoxics.

EXPOSITION	Nurse	Patient
Due to an external contamination	<b>Not excluded</b> Individual protection procedures	<b>Négligible</b> (no contact with contaminated areas)
Due to an internal contamination	NA	No risk

No published data is available on internal cross-contamination during simultaneous preparation of drugs in the same flow laminar cabinet or isolator. Moreover, a recent experimental study from a Swiss group showed that no internal contamination occurred even if external contamination of working area and containers was present. However, the consequences of an accidental contamination of mAbs by a cytotoxic such as the use of the same needle to withdraw both products, remain questionable and experimental works should be initiated to clarify this point since a potential consequence could be the induction of mAbs aggregation leading to immunogenic-based side-effects.

## -Conclusion-

SFPO considers there is no objective risk of internal cross contamination during simultaneous handling of different drugs in centralized units **if accepted procedures for sterile preparations are respected**. Therefore, there is no reason to prepare cytotoxic drugs and mAbs in separate safety equipments. This recommendations were elaborated in order to respect the High French Authority Health good practices guidelines.

