

REQUIREMENTS FOR HANDLING DRUG PRECURSORS A BRIEF OVERVIEW

	CATEGORY 1	CATEGORY 2	CATEGORY 3	CATEGORY 4
SPECIAL LICENCE	√			
SPECIAL REGISTRATION		√ [*]	√ (in case of export transactions that require an export authorization)	
IMPORT AUTHORISATION	√ (in case of import from non-EU countries)			
EXPORT AUTHORISATION	√ (in case of export to non-EU countries)	√ (in case of export to non-EU countries)	√ ^{***}	√
APPOINT A RESPONSIBLE OFFICER	√	√ ^{**}		
DOCUMENTATION	√	√ ^{**}		
CUSTOMER DECLARATION	√	√ ^{**}		
ANNUAL REPORTING	√	√	√ (in case demanded by the State Agency of Medicines)	
LABELLING	√	√		
NOTIFICATION OF SUSPICIOUS TRANSACTIONS	√	√	√	

* this requirement is not valid if the amount of 2B category substances placed on market and amounts of 2A category substances used in a year do not exceed the following: acetic anhydride 100l, potassium permanganate 100kg, anthranilic acid 1kg, phenylacetic acid 1kg, piperidine 0,5kg. The registration requirement is not valid also in case of end users of 2B category substances, who own and use the substances and do not supply them to others as drug precursors or mixtures containing them

** this requirement is not valid if the amount of category 2 substances handled in a year does not exceed the following: acetic anhydride 100l, potassium permanganate 100kg, anthranilic acid 1kg, phenylacetic acid 1kg, piperidine 0,5kg.

*** an export authorization is required if acetone, ethyl ether, methylethyl ketone and toluene are exported to the following third countries: Afghanistan, Antigua & Barbuda, Argentina, Australia, Benin, Bolivia, Brazil, Canada, Cayman Islands, Chile, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, El Salvador, Ethiopia, Ghana, Guatemala, Haiti, Honduras, India, Jordan, Kazakhstan, Lebanon, Madagascar, Malaysia, Maldives, Mexico, Nigeria, Oman, Pakistan, Paraguay, Peru, Philippines, Republic of Korea, Republic of Moldova, Russian Federation, Saudi Arabia, Tajikistan, Turkey, United Arab Emirates, United Republic of Tanzania, Uruguay and Venezuela. In case of hydrochloric acid and sulphuric acid an export authorization is required are exported to the following third countries: Bolivia, Chile, Colombia, Ecuador, Peru, Russian Federation, Turkey and Venezuela