

Target Product Profile for an Ideal Longer-Acting Injectable Contraceptive

Item	Desired target	Minimally acceptable target
Intended use	Safe and effective contraception for at least 6 months but not more than 12 months	Safe and effective contraception for at least 6 months
Target population	All reproductive-age non-pregnant women (including adolescents, lactating and HIV-positive women) who would like to space their pregnancies for at least one year	<i>Same as desired target</i>
Contraindications, warnings, precautions	Pregnancy; minimal other contraindications; can be used immediately after birth and should not interfere with breastfeeding	Pregnancy; minimal other contraindications; can be used 4-6 weeks after birth and should not interfere with breastfeeding
Effectiveness	Perfect use greater than 99%	Perfect use greater than 98%
Route of administration	Concealable administration; subcutaneous or intramuscular injection; injectable in arm, abdomen or anterior upper thigh	<i>Same as desired target</i>
Dosage schedule	Single injection every 6 to 12 months* (± 1 month grace period); no follow up visits * <i>duration will depend on identified product</i>	One administration** every 6 to 12 months (± 1 month grace period); no follow up visits
Return to fertility	At least 80% of women desiring a pregnancy should conceive (positive pregnancy test) within 12 months following the period of product effectiveness (includes grace period)	At least 80% of women desiring a pregnancy should conceive (positive pregnancy test) within 18 months following the period of product effectiveness (includes grace period)
Side effect profile	Predictable bleeding pattern after 3 months of use; no hypoestrogenism or associated side effects (e.g., vaginal atrophy; bone density effects), no effect on breastfeeding	Irregular bleeding may occur after starting the product, but side effects are no worse than progestin-only products
Shelf life	60 months in developing world conditions	36 months in developing world conditions
Storage	Suitable for warm humid climate; no cold chain required (product must be stable at prolonged exposure of 40°C and 75% relative humidity)	Suitable for warm, humid climates; no cold chain required (product must be stable at prolonged exposure of 30°C +/- 2°C and 75% relative humidity; stable through short-term exposures of 40°C and 75% relative humidity)
Cost	Less than \$4 per year for the public sector	<i>TBD</i>
Product presentation	Single-dose, pre-packaged, disposable injection system (e.g., Uniject)	Presentation has to allow for practical distribution in developing countries; non-reusable injection system
Infrastructure requirement	Self-administration possible; trained community health workers can provide; no special equipment/infrastructure required	Trained community health workers can provide; no special equipment required
Health benefits	Additional non-contraceptive health benefits	<i>None</i>