**የመድኃኒትጎጂባህርያትክትትልስርአትለምንያስፈልጋል?**

እንደሚታወቀውመድኃኒቶችተዘጋጅተውለህዝብጥቅምከመዋላቸውበፊትየቅድመፈቃድምርምሮችይካሄዱባቸዋልነገርግንእነዚህምርምሮችመድኃኒቶቹበተጠቃሚዎችላይሊያስከትሉስለሚችሉትጎጂባህርያትወይምሳይድኢፌክትበበቂመጠንአያስገነዝቡም።ስለዚህማንኛውንምመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያለህዝብጥቅምላይበሚውልበትወቅትበተጠቃሚውላይሊያስከትላቸውየሚችሉትንአላስፈላጊጎጂባህርያትመከታተልናእንደአስፈላጊነቱእርምጃእየወሰዱማስተካከልናጉዳቶችንመከላከልያስፈልጋል።

በተለይምተጠቃሚዎችየጤናባለሙያሳያዝላቸውናሳያማክሩበግላቸውገዝተውወይምከሰውወስደውየሚጠቀሙባቸውመድኃኒቶችከፍተኛአደጋሊኖራቸውስለሚችልጉዳቱበድጋሚእንዳይከሰትባቸውወይምደግሞበተመሳሳይሌላተጠቃሚእንዳይኖርመከታተል፣መረጃማዳበርናመከላከልይገባል።

**የመድኃኒትጎጂባህርያትሪፖርትንለየትኛውየመንግስትአካልነውሪፖርትየምናደርገው?**

ይህንንክትትልበሳይንሳዊመንገድለመፈጸምናህብረተሰቡንበመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያአጠቃቀምወቅትከሚከሰትጎጂባህርይወይምየጥራትጉድለትለመከላከልየኢትዮጵያየምግብናመድኃኒትቁጥጥርባለስልጣንበአዋጅበተሰጠውመብትበመጠቀምጉዳቱበሚደርስበትወቅትሪፖርቶችንከተጠቃሚዎችወይምከጤናባለሙያዎችይሰበስባልየማጣራትናየምርመራስራምይሰራል።የምርመራውንውጤትምተጠቅሞምበተለያዩመድኃኒቶች፣የህክምናአገልግሎትመስጫግብአቶችናየላቦራቶሪመመርመሪያመሳሪያዎችላይየማስተካከያእርምጃዎችንይወስዳል።

**የትኞቹንየመድኃኒትጎጂባህርያትነውሪፖርትየምናደርገው?**

በመሆኑምየማንኛውምመድኃኒት፣የህክምናአገልግሎትመስጫግብአቶችናየላቦራቶሪመመርመሪያመሳሪያዎችጎጂባህርያት፣እንዲሁምየመድኃኒትየጥራትጉድለትበሚያጋጥምበትወቅትየሚከተሉትንአራትሪፖርትየማድረጊያመንገዶችበመጠቀምለባለስልጣኑማሳወቅይገባል።

ማንኛውም**የመድኃኒትጎጂባህርያትበሚያጋጥምበትወቅትለኢትዮጵያየምግብናመድኃኒትባለስልጣን**ሪፖርትየማድረጊያመንገዶቹየሚከተሉትናቸው።

1. ፖስታመሰልቢጫፎርም

ይህሪፖርትማድረጊያመንገድባለስልጣኑከረጅምጊዜጀምሮአዘጋጅቶበጤናተቋማት፣በጤናቢሮዎችናበቅርንጫፍመስሪያቤቶችያስቀመጠውቢጫፎርምነው።በዚህፎርምውስጥአስፈላጊየሆኑናበአግባቡተሞልተውመላክያለባቸውመረጃዎችየሚከተሉትሲሆኑ

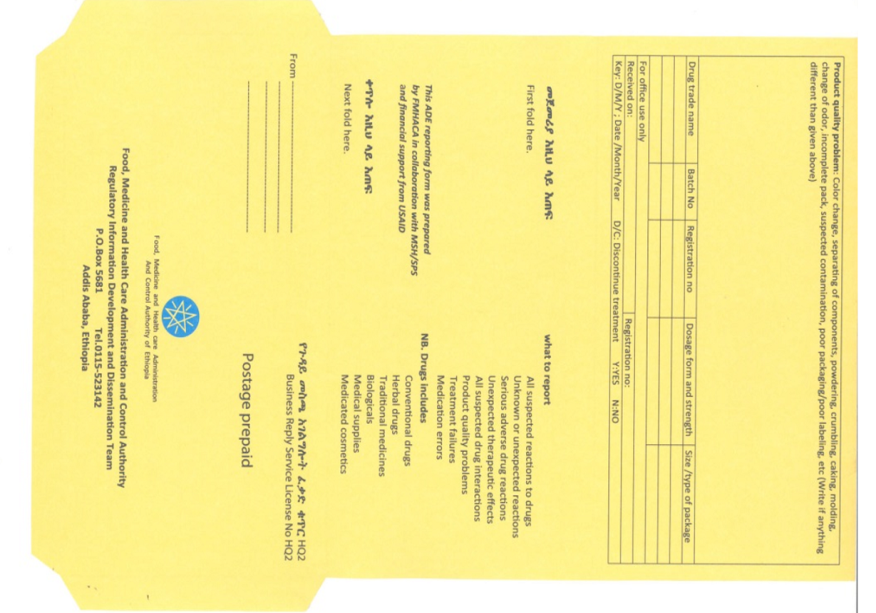
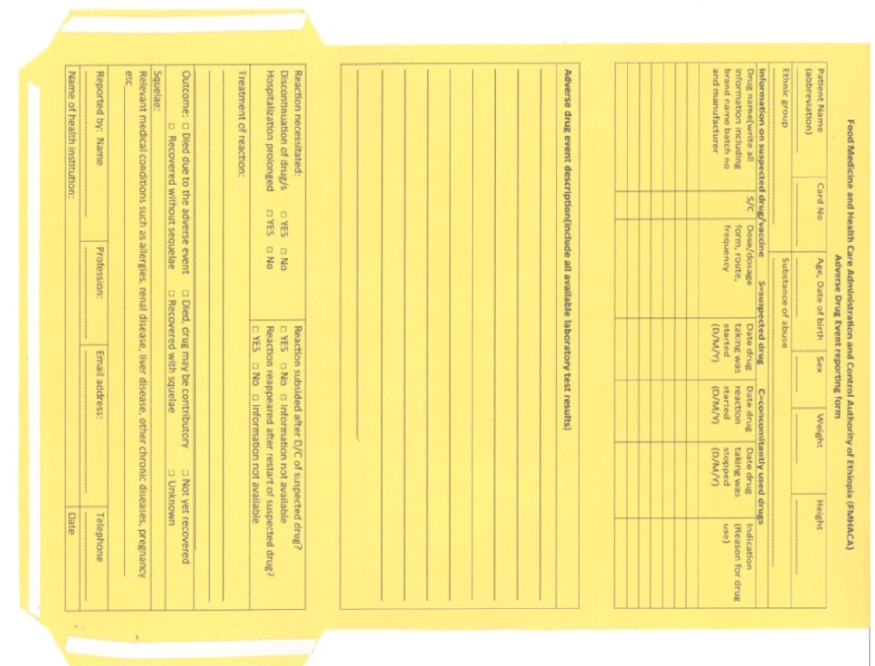
* የመጀመሪያውመረጃ፡መድኃኒትወይምየህክምናአገልግሎትመስጫግብአቶችወይምየላቦራቶሪመመርመሪያመሳሪያዎችተጠቅሞጉዳትየደረሰበትሰውመገለጫዎችማለትምእድሜ፣ጾታ፣ክብደት፣ቁመትሲሆኑ (**Patient information)**
* ሁለተኛውመረጃ፡ጉዳቱንያደረሰውመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያመሳሪያዎችመገለጫዎችናቸውአነዚህም፤( ስም፣መለያቁጥር፣የንግድስም፣አምራችወይምአከፋፋይ፣የተመረተበትቀን፣የአገልግሎትዘመኑየሚያበቃበትቀን፣መድኃኒቱመወሰድየተጀመረበትቀንወይምጥቅምላይየዋለበትቀን፣ጎጂባህርይመታየትየጀመረበትቀን፣መድኃኒቱተቋርጦከሆነየተቋረጠበትቀን፣መድኃኒቱየታዘዘበትወይምየተወሰደበትምክንያትናቸው**(Drug information)**
* ሶስተኛውመረጃ፡መድኃኒቱወይምየህክምናአገልግሎትመስጫግብአቱወይምየላቦራቶሪመመርመሪያመሳሪያውያደረሰውጉዳትወይምሳይድኢፌክትምልክቶችዝርዝርናቸው**(Adverse drug event description)**
* አራተኛውመረጃ፡መድኃኒቱወይምየህክምናአገልግሎትመስጫግብአቱወይምየላቦራቶሪመመርመሪያመሳሪያውጥቅምላይከመዋልተቋርጦከሆነ፣ሲቋረጥየጉዳቱምልክትጠፍቶከሆነ፣በጉዳቱምክንያትሆስፒታልመግባትአስፈልጎከሆነ፣መድኃኒቱወይምየህክምናአገልግሎትመስጫግብአቱከጉዳቱበኋላበድጋሚጥቅምላይውሎከሆነየሚገልጹናቸው**(Reaction information)**
* አምስተኛውመረጃ፡ጉዳቱንለማከምየተወሰደውየህክምናአይነትይሆናል**(Treatment information)**
* ስድስተኛውመረጃ፡የጉዳቱውጤትማለትምከጉዳቱበኋላተጠቃሚውተሻለውወይ፣ሞተወይ፣አሁንምበጉዳትላይነውወይየሚሉትይሆናሉ**(Outcome)**
* ሰባተኛውመረጃ፡በጉዳቱምክንያትየደረሰቀሪጉዳትማለትምጠባሳየአካልመጉደልወይምሌላይሆናል(sequelae)
* ስምንተኛውመረጃ፡ስለተጠቃሚውወቅታዊየጤናሁኔታተጨማሪመረጃማለትምየጉበት፣ኩላሊትሁኔታወይምየሌላአካልክፍልየጤናሁኔታሴትከሆነችደግሞእርግዝናይሆናል**(Relevant medical information)**
* ዘጠነኛውመረጃይህንንጎጂባህርይወይምጉዳትሪፖርትያደረገውሰውአድራሻማለትምስም፣ስልክ፣ሙያ፣ኢሜይልአድራሻ፣የጤናተቋሙስምክልልናቸው**(Reporter information)**

በተጨማሪምየመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያየጥራትጉድለትሲያጋጥምየቢጫፎርሙንከጀርባውበኩልያለውንቦታበመጠቀምየመድኃኒቱንወይምየህክምናአገልግሎትመስጫግብአቱንወይምየላቦራቶሪመመርመሪያውንስምናሌሎችመገለጫዎችን፤ያጋጠመውንየጥራትጉድለትማለትምለምሳሌለእንክብሎች (የከለርመቀየር፣የተለየሽታ፣መሰባበር፣መሰነጣጠቅ፣ከቁጥርመጉደል)፤ለሽሮፕናሌሎችፈሳሽመድኃኒቶች ( ብልቃጡላይመድኃኒቱመዝቀጥናቢወዘወዝምአለመላቀቅ)፣ለመርፌመድኃኒቶችናግሉኮሶች ( በውስጡየሚታይወይምየሚስረከረክባእድነገር፣የከለርመቀየር)፤ለላቦራቶሪመመርመሪያዎች ( ትክክለኛያልሆነአጠራጣሪውጤት false positive false negative) እንዲሁምበማንኛውምመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያዎችውጫዊሽፋንላይሊኖሩየሚገቡመረጃዎችበአግባቡአለመኖርእነዚህንናሌሎችንምአጠራጣሪየጥራትሁኔታዎችንበመመሙላትለባለስልጣኑሪፖርትማድረግይቻላል።

በመጨረሻምበቢጫፎርሙላይመረጃዎቹበሙሉከተሞሉበኋላምልክቱንበመከተልበማጠፍናበማጣበቂያውበማጣበቅየፖስታቅርጽሲኖረውየላኪንአድራሻበመጻፍበፖስታቤትመላክይገባልወይምበአካልቦሌከሸዋሱፐርማርኬትከፍብሎበሚገኘውየባለስልጣንመስሪያቤትበአካልበመምጣትመስጠትይቻላል።

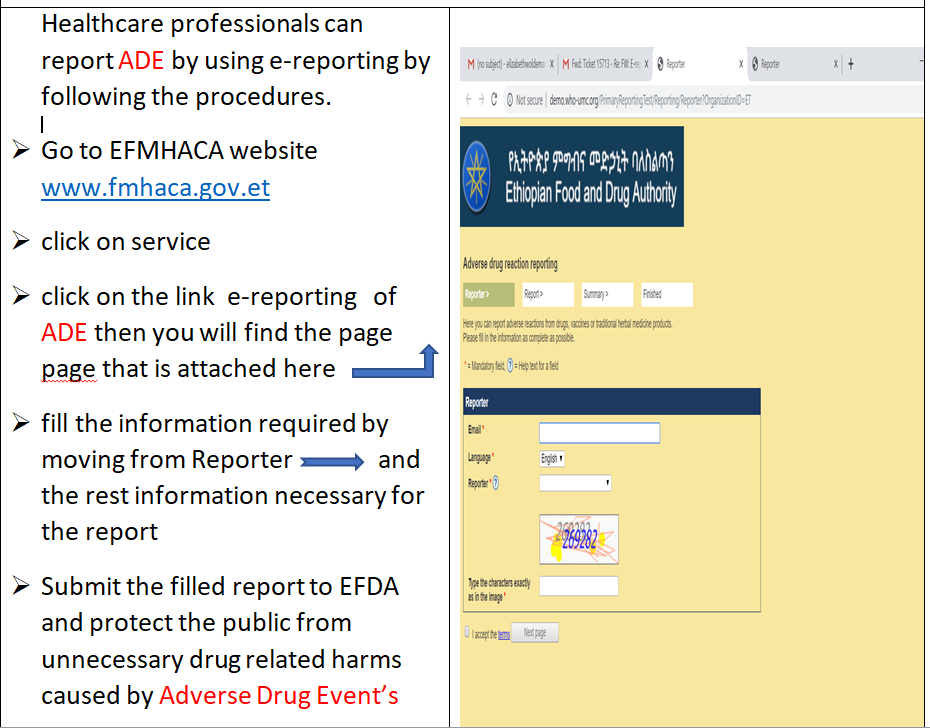
ፖስታመሰልቢጫፎርምይህንይመስላል (The yellow, prepaid report form available at the facility Annex 1)

Annex I : The yellow, prepaid report form available at the facility Annex 1)



1. ሁለተኛውሪፖርትማድረጊያመንገድየባለስልጣኑነጻየስልክመስመርሲሆንቁጥሩም 8482 (toll free line) ሲሆንበማንኛውምየስራሰአትበመደወልስለተከሰተውየመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያዎችጎጂባህርይወይምየጥራትጉድለትበአንደኛውሪፖርትማድረጊያመንገድላይየተጠቀሱትንመረጃዎችበመያዝሪፖርትማድረግይቻላል.
2. ሶስተኛውመንገድበባለስልጣኑዌብሳይትውስጥ[www.fmhaca.gov.et-serivces-e-Reporting](http://www.fmhaca.gov.et-serivces-e-Reporting)በሚለውበመግባትሪፖርትአድራጊውግለሰብስሙንናየኢሜይልአድራሻውንበመሙላትከገባበኋላከላይበአንደኛውመንገድየተጠቀሱትንየመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያስለተከሰተውጎጂባህርይወይምየጥራትጉድለትአስፈላጊመረጃዎችበመያዝእያንዳንዱንገጽእየሞሉወደሚቀጥለውገጽበማለፍመጨረስናመላክይቻላል።ለተጨማሪመረጃዝርዝርመመሪያውንይመልከቱ (See instructions on Annex II).

Annex II: Instruction for web based electronic reporting system

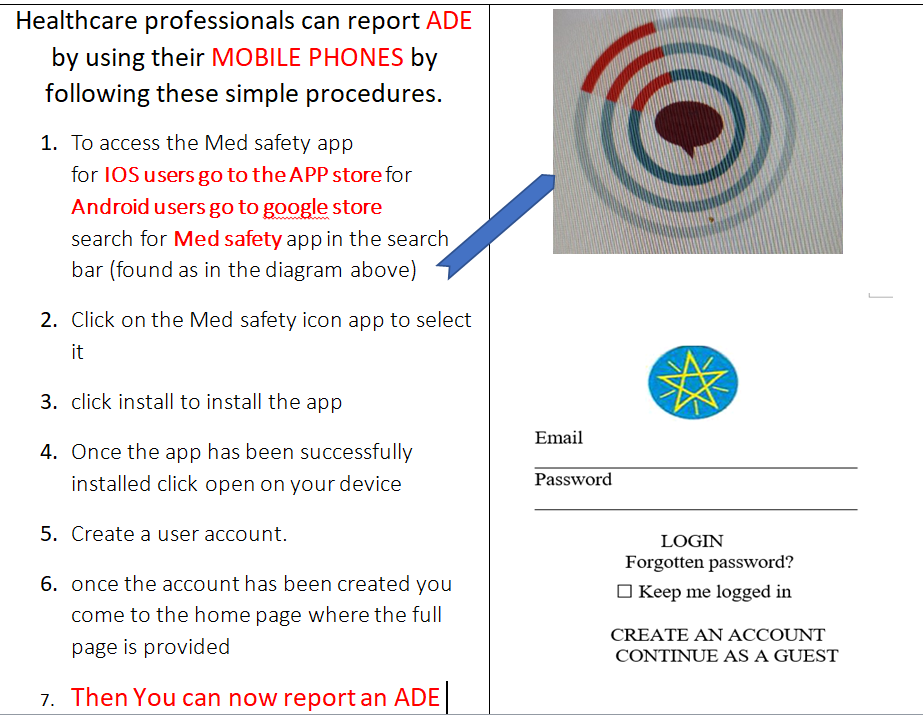


1. አራተኛውመንገድየሞባይልአፕልኬሽኖችንበመጠቀምሪፖርትማድረጊያመንገድሲሆን

በመጀመሪያለአንድሮይድስልክተጠቃሚዎችጎግልስቶርንበመጠቀምለአይፎንተጠቃሚዎችደግሞአፕእስቶርንበመጠቀምmedsafetyየተባለውንአፕልኬሽንማውረድ( ዳውንሎድማድረግ )ያስፈልጋልበመቀጠልምአፕልኬሽኑን install ማድረግከዚያምአፕልኬሽኑንመክፈትናኢትዮጵያየሚለውንምልክትመንካትበመቀጠልምለተጠቃሚውብቻየሚያገለግል user name እና password በመስጠትየግልአካውንትመክፈትያስፈልጋል።

በማስከተልምልክከላይእንደተጠቀሱትሪፖርትማድረጊያመንገዶችሁሉአስፈላጊውንየመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያዎችጎጂባህርይወይምየጥራትጉድለትመረጃዎችበመያዝአፕሊኬሽኑንበመከተልበየገጹእየሞሉወደሚቀጥለውገጽእያለፉመጨረስናለባለስጣኑመላክይቻላል።ለተጨማሪመረጃዝርዝርመመሪያውንይመልከቱ ( See instructions on Annex III).

Annex III, Instructions for mobile based application reporting system



**ሪፖርትከተደረገበኋላምንይደረጋል?**

እነዚህንየተላኩመረጃዎችንበመጠቀምባለስልጣንመስሪያቤቱአስፈላጊምርመራዎችንበማካሄድየተለያዩየማስተካከያእርምጃዎችንይወስዳል። በመሆኑምበመድኃኒትወይምየህክምናአገልግሎትመስጫግብአትወይምየላቦራቶሪመመርመሪያዎችአጠቃቀምላይጎጂባህርይወይምየጥራትጉድለትችግርበሚያጋጥምዎትወቅትከነዚህአራትመንገዶችአንዱንበመጠቀምሪፖርትበማድረግህብረተሰቡንበመድሓኒትምክንያትከሚደርስበትአላስፈላጊጉዳትይከላከሉ ።ከላይከተጠቀሱትሪፖርትማድረጊያመንገዶችበማንኛውምአይነትመንገድቢጠቀሙየሚያስፈልጉትመረጃዎችበመጀመሪያውላይበዝርዝርየተገለጹትናቸው።

**ልብይበሉ!!!!!!**

በተለይምአሁንባለንበትወቅትህብረተሰቡበባለሙያታዞለትከሚጠቀምባቸውመድኃኒቶችበተጨማሪያለባለሙያትእዛዝየተለያዩባህላዊምሆነዘመናዊመድኃኒቶችንእየተጠቀመበመሆኑሊደርሱየሚችሉብዙአይነትጉዳቶችስለሚኖሩእነዚህንሪፖርትበማድረግሀገራዊሀላፊነትዎንይወጡ።

Important website for additional information on Pharmacovigilance

**EFDA**

http://www.fmhaca.gov.et/publications-library/

**WHO**

1.https://www.who.int/medicines/news/glob\_pharmvig\_database\_qa/en/

2. <https://www.who.int/medicines/news/glob_pharmvig_database_media/en/>

3. <https://www.who.int/medicines/publications/drugalerts/en/>

**USFDA**

4.https://www.accessdata.fda.gov/scripts/cderworld/index.cfm?action=drugsafety:main&unit=1&lesson=1&topic=15

5. <https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/medical-product-safety-information>

**6.**[**https://www.fda.gov/about-fda/contact-fda/stay-informed/rss-feeds/medwatch/rss.xml**](https://www.fda.gov/about-fda/contact-fda/stay-informed/rss-feeds/medwatch/rss.xml)