

**ANNES I**

**SOMMARJU TAL-MCTCVVGTIUVK KVCN-PRODOTT**

Prodott mediċinali li m.g. adux awtorizzati

Dan il-rtqfqvw"ogfk kpcnk"jwyc"uw gw"i cn"o qpkvqtc "cf fk| |lqpcnk0" Fcp"ugt"lkr rgt o gwvk" kfgpvkhkmc| |lqpk"vcø"o cnclt"vcø"kphqt o c| |lqpk" f kfc"fyct"ku-uk i wtv<0"II-rtqhgulqpkuvk"vcn-mwte"vcu-uc c" jw o c"okvnwde"lktter rwtvcy"my cnwpm y g"tgc| |lqpk"cxxtguc"uwurgvvcø" Ctc"ug| |lqpk 60: "fyct"mkh" i cpfjqo"lk w"terrwtvcvk"tgc| |lqpkkgv"cxxtguk0

## 1. ISEM IL-RTQFQVV"OGFK KPCNK

P [ZVJTCEKU 100 o iloN"mqp gpvtcv"i cn"uqnw| |lqpk"i cnn-kphw lqpk

## 2. I CONC"MYCNKVCVVKXC"W"MYCPVKVCVVKXC

Mwnn"oN"vcø"mqp gpvtcv"hkj"322 o i"vcø"qdknvqzczk o cd0"  
Mwplgv"ykg gf"vcø"8 oN"hkj"822 o i"qdknvqzczk o cd0

Qdknvqzczk o cd"jwyc"rtqfqvw"ho gmnwnk"o wtkpk"vcn-oklgnq o c" IU-PU2"rgt o g| |vcø"vgmpqng kle"vcø" FPC" rkmq o dkpcpvk0

G krlgpv"døghhgv"o ci twh<

Mwnn"oN"vcø"mqp gpvtcv"hkj"58 o i"uqtdkvqn0

I cn-nkuvc"u k c"vcø"g krlgpvk."ctc"ug| |lqpk 8030

## 3. I CONC"HCTOC GYVKMC

Mqp gpvtcv"i cn"uqnw| |lqpk"i cnn-kphw lqpk"\*mqp gpvtcv"uvgtknk+0"  
P [ZVJTCEKU jwyc"uqnw| |lqpk"ctc"i cn"qrcngzzgpvk."dnc"mwnwt"i cn"uchte"ctc"i cn"uchte"ctc"hnk-  
mcppgmc"nk"lkuvcø"lmwp"hkj"hc"vkv"htcm"vcn-rtqvgkpc"vteunw kfk"i cn"dqlqf"\*nk"ugt"lkvpg gy"døhkvte| |lqpk"  
hønkplc+"dør J"vcø"707" w" døq o qncnkv<"vcø"499- 52: o Qu o lmi0

## 4. VCI TKH"MNKPKMW

### 4.1 kpfkmc| |lqpkkgv"vgtergyk k

P [ZVJTCEKU jwyc"kpfkmcv"hnk o mkgp"o cø"ogfk kpk"cpvkdcvgtk k"zkgts"hcømwnn"itwrr"vcø"gv<"i cv-  
vtevc o gpv"vcø"cpvte g"nk"vkvkg gf"o cp-pkhu"o kp eddc" *Bacillus anthracis* \*ctc"ug| |lqpk"703+0

P [ZVJTCEKU jwyc"kpfkmcv"hcømwnn"itwrr"vcø"gv<"i cn-rtqhkncuuk"vcø"cpvte g"nk"vkvkg gf"o cp-pkhu"yctc"  
l-gurqpk o gpv"o gvc"vgtcrklk"cnvgtpevkvxk"o c"lmwpwz"zkgts"lgy"o c"lmwpwz"fkurqpkddnk"\*ctc"ug| |lqpk"703+0

### 4.2 Rq qnq kle" w"ogvqfw"vcø"mkh"i cfw"lkipi cvc

P [ZVJTCEKU i cfw"lkipi cvc"jgmm"mkh"kmwp"mnkpkmc o gpv"kpfkmcv0

Vtcvc o gpv"ogfkmw"uwrgtxk lqpk"zkgts"i cfw"lkipi cvc"fgllg o"kmwpw"fkurqpkddnk"hc kn o gpv"hcømc "vcø"  
cxxtgpk o gpv"cpchknvkmw"yctc"n-i qvk"vcø" P [ZVJTCEKU0

Rq qnq kle

Id-fq c "tcmmq o cpcfvc"vcø" P [ZVJTCEKU hørc|lgpvk"cfwnvk"nk"lk pw"o km-cpscu"62 mi"jwyc"kphw lqpk"  
yc fc" qn-xkpk"vcø"38 o ilmi"vcn-rk "vcn- kugo"\*dy+0"Kf-fq c "tcmmq o cpcfvc"vcø" P [ZVJTCEKU  
hørc|lgpvk"cfwnvk"nk"lk pw"cpvcu"o kpp"62 mi"jwyc"kphw lqpk"yc fc" qn-xkpk"vcø"46 o ilmi"dy0"

N-i qvk"vcø"rtg o gfkmc || lqpk"døcpvkuc o kpc"jwyc"ttemmq o cpfcv"scdgn"n-i qvk"vcø" P [ ZVJ TCEKU \*ctc" ug || lqpkkgv"606" w"60: +0"

I cn"o qfkhkmc"hkf-fq c" hømc "vcø"tgc || lqpkkgv"tgncvcvk" o cn-kphw lqpk"\*KTT+"ctc"vcdgmc"30

**Vedgmc"3<"Oqfkhkmc"hkf-fq c"vcø"qdknvqzczk o cd"i cn"tgc || lqpkkgv"tgncvcvk" o cn-kphw lqpk**

Ugxgkvc"vcø"KTT"	Oqfkhkmc"hkf-fq c
Tgc    lqpk" relatata mal-kphw lqpk"vcø" I tcf"3-5	N-kphw lqpk"vcø"qdknvqzczk o cd"i cpfjc"vkycssch"w"i cpfw"lkipi cve"trattament vcø"uquvgpp0 I cmm-gy ygn"grkuqflw"vcø"v et kt."dtqpmqurc ow."lgy"wtvkmctlc" gpgtenk    cve"vcø" I tcf"5."qdknvqzczk o cd"i cpfw"lkyesssch"dø o qf"rgt o cpgpvk0 I cn"v et kt"lgy"wtvkmctlc"tkmqttgpk"vcø" I tcf 4."lgy"i ct-tkmqttgp c"vcø" mycnwpm y g"ukpvq o w"vcø I tcf 5."qdknvqzczk o cd"i cpfw"lkyesssch"dø o qf" rgt o cpgpvk0" Kpmgmc."yctc"nk"u-ukpvq o k"lmwpw"i cffgy"mq o rngvc o gpv."n-kphw lqpk"vkucvø" vkvmq o rnc"dø72 % tar-tcvc" o kmuwc" scdgn"n-kpvgttw    lqpk0" Hkp-pws scu"vcø"ukpvq o k" relatati mal-kphw lqpk."kt-rata tal-kphw lqpk" jklc"fgumtkvc" høvedgmc 50" I cpfjc"vkpi cve"n-premedike    lqpk0
Tgc    lqpk" relatata mal-kphw lqpk"vcø" I tcf"6	N-kphw lqpk"vcø"qdknvqzczk o cd"i cpfjc"vkycssch"ko o gflvc o gpv0 I cpfw"lkipi cve"vtcvc o gpv"vcø"uquvgpp0 Qdknvqzczk o cd"i cpfw"lkyesssch"dø o qf"rgt o cpgpvk0"

Rqrqnc || lqpkkgv"urg lcnk

Anzjani

N-gdfe" c wuc o gpv"hkf-fq c " o jwyc"og vkg "i cn"rc | lgpvk"vcø"gv«"vcø"× 87 ugpc"\*ctc"ug || lqpk"704+0

Popolazzjoni pedjatrika

Id-fq c"ttemmq o cpfcvc"i cmm-rc | lgpvk"rgflvctk k"jklc"dde cve" hws"kn-rk "mkh"lkfjgt" høvedgmc 4" jcy p"vc v0

**Vedgmc"4<"Fq c"rgflvctkmc"ttemmq o cpfcvc"vcø"qdknvqzczk o cd"\*fq c "kdde cv" hws"kn-rk +**

Rk "vcn- kugo" jmi_	Fq c" ]o ilmi" dy_
> 40	38
> 37"uc"62	46
37"lgy"kp scu	54

Ogvqfw"vcø"mkh"i cpfw"lkipi cve"

Qdknvqzczk o cd"i cpfw"lkipi cve" døkphw lqpk" qn-xkpk"i cn"rgtlqfw"vcø"90 o kpwvc0

Rtgmc y | lqpkkgv"nk"i cpfjqo"lkvvk f w"scdgn"vokuu"kn-rtqfqvw"ogfk kpcnk"lgy"scdgn"vci vk"n-prodott øgfk kpcnk

Oøi cpfgmz"v cyycf"kn-mwplgv0"Qdknvqzczk o cd"i cpfw"lk k"fknykv" høuqnw || lqpk"i cmm-kplg || lqpk"vcø" uqfkwo"ejnqtktfg"; o iloN"\*20; ' + "scdgn"lkipi cve"d cnc" kphw lqpk" qn-xkpk"\*ctc"ug || lqpk"808+0"

N-kphw lqpk" qn-xkpk"vcø"qdknvqzczk o cd"fknykv"i cpfjc"vk k" kphw c"i cn"rgtlqfw"vcø"; 2 o kpwvc" døtcvc"vcn-kphw lqpk" fgumtkvc" høvedgmc 5."rgt o g | "vcø"dqt c"vcn-kphw lqpk"lgy"uktkpic"i cmm-kphw lqpk"vcø" hknvtw" hønkle"vcø"2044 o kmtqp0"

Il-rc|lgpvk"lg vkg "nk"lk w"o o qpkvqtlevk" o knn-stkd"i cn"ukplcnk"w"ukpvq o k"vcø"ugpvkvvkxk«"g guukxc" o cvwn"n-kphw lqpk"w"i cn" o knn-kpscukgi c"yctc"n-i qvk"\*ctc"ug| |lqpk 606+0"Kt-tgc| |lqpklgv"tgncvcvk"mal-kphw lqpk" i cpfjqo"lk w" guvkvk"mkh"urlicv"høvcdgmc 30

Il-nkplc"i cpfjc"vk k"onc cn c"døuqnw| |lqpk"i ckn-kplg| |lqpk"vcø"uqfkw o "ejnqtkfg"; o iloN"\*20; '+'hk" tmiem l-kphw lqpk" qn-xkpk0

**Vedgmc"5<"Fq c"vcø"qdknvqzczk o cd."xqnw o "vqvcnk"vcn-kphw lqpk"w"tevc"vcn-kphw lqpk"umqpy"kn-rt "vcn-kug o**

Rk "vcn- kug o "]mi_ *fq c "kddc cv"hwskn-rk +	Xqnw o "vqvcnk"vcn-kphw lqpk"]oN_ ]dqt c"lgy"uktkpic"vcn-kphw lqpk_	Tevc"vcn-kphw lqpk ]oNlj_
<b>&gt; 40 mi"lgy"cfwnv"*38 o ilmi"dy+</b>		
> 40	472	389
<b>&gt; 15 mi"uc"62 mi"*46 o ilmi"dy+</b>		
53"uc"62	472	389
38"uc"52	100	89
<b>15 mi"lgy"cpscu"*54 o ilmi"dy+</b>		
33"uc"37	100	89
7"uc"32	72	5505
503"uc"60;	47	39
403"uc"5	42	3505
303"uc"4	37	10
3"lgy"cpscu	9	609

, "I cn"kuvtw| |lqpklgv"hwskf-fknyk| |lqpk"vcn-prodott"ogfk kpcnk"w"n-w w"vcn-dqt c"lgy"vcu-uktkpic"vcn-kphw lqpk"scdgn"n-c o o kpkvutv| |lqpk."ctc"ug| |lqpk 8080

### 4.3 Kontraindikazzjonijiet

Ugpukvvkxk«"g guukxc"i cu-uwuvcv|c"cvkxc"lgy"i cn"mycnwpm y g"uwuvcv|c"o jwz"cvkxc"nggpmcvc"hku-ug| |lqpk 8030

### 4.4 Vykuullkgv"urg lcnk"w"rtgmcy |lqpklgv"i cm-w w

Vtc cdknkv«

Uedkgz"vkvgllgd"kv-vtc cdknkv«"vcn-rtqfqqv"ogfk kpcnk"dklqnq k k."n-kug o "w"p-pw o tw"vcn-lott tal-prodott c o o kpkvutcv"i cpfjqo"lk w"ttgmqtflcvk0

Tgc| |lqpklgv"tgncvcvk" o cn-kphw lqpk."ugpvkvvkxk«"g guukxc"w"cpchkncuuk

Tgc| |lqpklgv"tgncvcvk" o cn-kphw lqpk"vcø"ugpvkvvkxk«"g guukxc"mkgpw"quugtxcvk"mq o wpg o gpv"y c sv"rtqxl" mnkpk k"do qdknvqzczk o cd"ho kpfkxfyk"doüc kvjqo"0"Okp cddc"t-tkumlw"vcø"tgc| |lqpklgv"ugxgk"lgy" cpchkncuuk"qdknvqzczk o cd"i cfw"lkipi cve"ho c d lgpvk"ko o qpkvqtlevk" o kpp"rgtuwpcn"ko cttg "w" o i o o c t"dkgz"lk o o c pk lcn-cpchkncuuk"0"Kn-rc|lgpvk"i cpfjqo"lk w"o o qpkvqtlevk" o knn-stkd" o cvwn"kn-rgtlqfw"vcø"kphw lqpk"w"i cn" o knn-kpscukgi c"yctc"n-i qvk0

Rgtguu"nk"n-rtqxl"mnkpk k"vygvs w"ho xqnwvkvgtc"doüc kvjqo."n-kphw lqpklgv"vcø"qdknvqzczk o cd"vycs shw"hnk-dkfw"vcø"mycnwpm y g"tgc| |lqpk0" Cddc k"vcn-gurgt lgp| c"do c pvmqtrk" o qpqmmqpcnk"q telp"w cvk"hk- vtcvc o gpv"vcø"mwpfk| |lqpklgv"ogfk k"ugt lk." gpgtcn o gpv"n-kphw lqpklgv"lkuv i w"lk w"mq o rnwvk"l gmm"lk w" o o c pk lcvk"do o qf"zkgtes"0"Kt-tgc| |lqpklgv"tgncvcvk" o cn-kphw lqpk"i cpfjqo"lk w"o o c pk lcvk"mkh" urlicv"høvcdgmc 30"

Il-rtg o g f k m c | | l q p k " d o c p v k u v c o k p c . " g 0 " f k r j g p j { f t c o k p g . " j k l e " t t e m m q o e p f c v c " s c d g n " l k p i c v c " q d k n v q z c z k o c d " \* c t c " u g | | l q p k " 6 0 4 + 0 " F k r j g p j { f t c o k p g " p i c v c " 5 2 m k p w v c " s c d g n " k v - t r a t t a m e n t d o q d k n v q z c z k o c d " h k " r t q x k " m n k p k k " n k " u c t w " d o q d k n v q z c z k o c d 0 " R t g o g f k m c | | l q p k " d o c p v k u v c o k p c " o c " l k r r t g x l g p k z " e p c h k n c u u k " w " v k u v c o " v c d k " l g y " v k v c t f l c " n - d k f w " v c u - u k p v q o k " v c o " u g p u k v k x k v < " g g u u k x c 0

O g p k p k v g " v c n - c p v t c g

Q d k n v q z c z k o c d " o c " l e s u c o z " k n - d e t t k g t c " g o e v q g p g h c n k m c " w " o c " l k r r t g x l g p k z " l g y " l k v t c v c " n - o g p k p k v g " v c n - c p v t c g 0 "

R q r q n c | | l q p k " r g f l e v t k m c

O c " m k g p " j g o o " n - g d f c " u v w f l w " f y c t " k u - u k i w t v < " l g y " k n - R M " v c o " q d k n v q z c z k o c d " h k n - r q r q n c | | l q p k " r g f l e v t k m c " \* c t c " u g | | l q p k " 7 0 4 + 0

K p v g t c | | l q p k l e t f i t - v g u v k l k g v " v c n - n c d q t e v q t l w

N - g u r q p k o g p v " i c n " P [ Z V J T C E K U l k u v c o " l k p v g t h g t k z z k " o c o " v g u v k l k g v " u g t q n c k k " i c m n - c p v t c g 0

U q t d k v q n

M w m n " o N " v c o " P [ Z V J T C E K U h k j " 5 8 o i " v c o " u q t d k v q n " \* c t c " u g | | l q p k l k g v " 4 " w " 8 0 3 + 0 " R t q f q w k " o g f k k p e n k " n k " h k j q o " u q t d k v q n " l k u v i w " l m w p w " h e v c n k " l g m m " l k p i c v c y " q n - x k p k " n k n " k p f k x k f y k " d o k p v q m g t e p | c " g t g f k v e t l c " i c n " h t w e v q u g " \* J H K + 0 " Q d k n v q z c z k o c d " o o i c p f w z " l k p v w c " h o k p f k x k f y k " d o J H K " u c m g o o " o c " l m w p z " j g o o " v k g c " m n k p k m c " u w r g t l w t k " w " o c " l m w p " j g o o " n - g d f c " e n v g t p e v k x c " f k u r q p k d d n k 0 " I c p f j c " v k v k g g f " u v q t l e " f g w e n l e v c " h k t - t k i y c t f " v c u - u k p v q o k " v c n - J H K " o k p p " m w m " r c | l g p v " s c d g n " o c " l k p i c v c " d a n i l - r t q f q v v " o g f k k p e n k 0

I t - v t e d k " w " v - v h c n " n k " i c f j q o " m g o o " v g n s w " l k o z w " \* v c v " n - g v < " v c o " u g p v g l p + " l k p u c d w " h o t k u m l w " r c t v k m q n c t k " o k p c d d c " n k " l k u v c o " l m w p " n k " o c " l m w p w z i c f j q o " g y " f k l e p l q u v k m c v k " d n - J H K 0 "

U q f k w o

D i n i l - o g f k k p c " h k j c " e p s c u " o k p p " 3 o o q n " u q f k w o " \* 4 5 o i + " h o m w m n " m w p l g v v " v c o " 8 o N . " l k k h k g t k " g u u g p | l c n o g p v " : k g n u " o k u - u q f k w o 0 0

**4.5 K p v g t c | | l q p k " o c o " r t q f q v v " o g f k k p e n k " q t c " w " h q t q o " q t c " v c o " k p v g t c | | l q p k**

E k r t q h n q z c e k p

H k " u v w f l w " v c o " k p v g t c | | l q p k . " f q c " y c f c " v c o " q d k n v q z c z k o c d " k p i c v c v " y c g f j c " l g y " k p i c v c v " h n k o m k g p " o c o " e k r t q h n q z c e k p " h o 6 2 k p f k x k f y w 0 " I q z t k p " k p f k x k f y w " t g x g y " q d k n v q z c z k o c d " y c f w " w " 4 2 k p f k x k f y w " t g x g y " q d k n v q z c z k o c d " h n k o m k g p " o c o " e k r t q h n q z c e k p " i c l 9 k l k g o 0 " N - i q v k " v c o " k p h w l q p k " q n - x k p k " v c o " 3 8 o i l m i " q d k n v q z c z k o c d " s c d g n " n - k p h w l q p k " q n - x k p k " v c o " e k r t q h n q z c e k p " l g y " n - k p g u v l q p k " v c o " r k n n q n c " q t e n k " v c o " e k r t q h n q z c e k p " f c t d v g l p " m w n l w o . " o c " d k f k n z " k n - h e t o c m q m k p g v k m c " v c o " q d k n v q z c z k o c d 0 " D n - k u v g u u " o q f . " q d k n v q z c z k o c d " o c " d k f k n z " k n - h e t o c m q m k p g v k m c " v c o " e k r t q h n q z c e k p " o q i v k " o k m n - c n s " l g y " q n - x k p k 0

O c " v y g v c s " n - g d f c " u v w f l w " k g q t " v c o " k p v g t c | | l q p k 0 " R g t g u u " n k " q d k n v q z c z k o c d " j w y c " e p v k m q t r " o q p q m n q p e n k . " k t - t k u m l w " v c o " k p v g t c | | l q p k " j w y c " d e z z 0

**608 H g t v k n v < . " v s c n c " w " v t g f f k i**

V s c n a

O o j g o o z " d a t a f y c t " n - w " w " v c o " q d k n v q z c z k o c d " h o p k u c " v s c n . " o c f e p m q m w . " n - k i I " w o e p c " j k l e " o c i t w h c " n k " v c s u c o " k n - d e t t k g t c " v e n - r n c g p v c 0 " U v w f l k " h o c p p k o e n k " o c " l w t w z " g h h g v k " k g p c " f k t g v k " l g y " k p f k t g v k " h w s " k u - u k u v g o c " t k r t q f w v v k x c " \* c t c " 7 0 5 + 0

D cnc"rtgmcy |lqpk"jw"rtghgtkddnk"nk" o c"lkw cz"P [ ZVJTCEKU ycsv"kv-vscnc0

Vtgffki

Ojwykz"oci twh"lgmm"qdknvqzczk o cd"jwykz"gnk o kpcv"hkn- cnkd"vcu-ukfgt"vcn-dpkgfgo0" Jwyc"oci twh" li l-Ki I"wo cpc"vk k"gnk o kpcv"hkn- cnkd"vcu-ukfgt" o cvwn"n-gy ygn"lgo "yetc"v-ygnkf"w"vqpsqu"i cl mqp gpvtc | |lqpkkgv"dczzk"hvkv"yetc0" I cnjgmm."tkumlw"i cv-vtedk"vcø"v ygnkf"ko tgf fi c" o c"lkuvcz"lk k" gumnw "ycsv" fcp"kn-rgtlqfw"scukt0" Yetc" fcp."n-w w"vcø"qdknvqzczk o cd"lkuvcø"lk k"mmwpukftcv"ycsv"kv- vtgffki ."lgmm"kmwp"jgo o"d qpp"mnkpkmw"dkuu0

Hgtvknkv«

Oc"v y gws w z"uvw flk" f y ct"kn-hgtvknkv«"døqdknvqzczk o cd0

**4.7 Ghhgvtk"hs"kn- kn c"dkgz"kuuws"w"v cffgo"o c i p k**

Qdknvqzczk o cd"lkuvcø"lqmnw"ghhgvt" i kt"hs"kn- kn c"dkgz"kuuws"w"v cffgo"o c i p k"rgtguu"nk"lkuvi w"lug w" w ki "vcø"tcu."uw w f c o g p v."i glc"w"tk o g w c t"y e t c"n-i q v k"vcø"P [ ZVJTCEKU \*ctc"ug | |lqpk"60: +0

**4.8 Ghhgvtk"o jwz"o k z v g s c**

Uq o o c t l w"v c n - p r o f i l v c u - u k i w t v «

Ku-uki wtv«"vcø"qdknvqzczk o cd" kgv"uvw flcvc"dkuu"økpfkxfyk"cfwvkv"døuc kvjqo0

Ku-uki wtv«"vcø"qdknvqzczk o cd" kgv" g x c n y e v c" h k" 5 4 2 k p f k x k f y w" d ø u c k v j q o \* n k" m g n j q o " d g l p" 3 : " w" 9 ; " u g p c + " k v t e v e v k" d ø f q c" y e f c" l g y" v p g l p" q n - x k p k" v c ø" 3 8 o i l m i" h k" v n k g v" u v w f l k" m n k p k k 0

Dø o q f" g p g t e n k" 4 7 2" o k v - 5 4 2 k p f k x k f y w" t g x g y" f q c" y e f c" v c ø" 3 8 o i l m i" q d k n v q z c z k o c d 0" T g c | | l q p k k g v" c x x g t u k" t g n c v c v k" o c ø" u g p u k v k x k v «" g g u u k x c" \* k p m n w" t c z z + " u g g y" h ø ; ' \* \* 4 4 1 4 7 2 + " v c ø" f e y p" n - k p f k x k f y k." d ø m c " y k g g f" v c ø" c p c h k n c u u k" n k" u g " o c v w n" n - k p h w" l q p k l" N - k p h w l q p k" v y c s s h g v" h k" 5 ' \* \* : 1 4 7 2 + " o k p c d d c" u g p u k v k x k v «" g g u u k x c" l g y" c p c h k n c u u k 0

N-cmvct"tgc | |lqpkkgv"cxxtguk"ttcrrqtvcvk"dkø o qf"htgmygpv"mkgpw" w ki "vcø"tcu"\*6 ' ."; 1472+."rtwtkvg" \*6 ' ."; 1472+."w"wtvkmctlc"\*4 ' .".81472+0

N-aktar tgc | |lqpkkgv"cxxtguk"quugtxcvk"dkø o qf"mq o w p k" h n - g y y g n" v n k g v" u k i c v" y e t c" n - d k f w" v c n - k p h w l q p k" m k g p w" r t w t k v g" \* p ? 9 = " 4 0 : ' + " w t v k m c t l c" \* p ? 8 = " 4 0 6 ' + . " w k i " v c ø" t c u" \* p ? 6 = " 3 0 8 ' + . " t c z z" \* p ? 5 = " 3 0 4 ' + . " u q i n c" \* p ? 5 = " 3 0 4 ' + . " u v w t f c o g p v" \* p ? 5 = " 3 0 4 ' + \* l k p m n w f k" u v w t f c o g p v" w" u v w t f c o g p v" m m c w c v" o k n - r q k | | l q p + 0

Ir-tgc | |lqpkkgv"cxxtguk"ugxgtk"nk" gllkp"ug gy"hn-gy ygn"vknkv"uki cv"yetc"n-kphw lqpk<"wtvkmctlc"\*p?3." 206 ' + . " r t w t k v g" \* p ? 3 . " 2 0 6 ' + " w" w k i " h k f - f c j e t" \* p ? 3 . " 2 0 6 ' + 0

N-cmvct"tgc | |lqpk"cxxtguc"quugtxcvk"dkø o qf"mq o w p k" h k" o k g p" 5" u c" 4 6 u k g i c" y e t c" n - d k f w" v c n - k p h w l q p k" k i e n e t l - w k i " v c ø" t c u" \* p ? 5 = " 3 0 4 ' + 0

Nkuvc"hvøvdgmc"vcø"tgc | |lqpkkgv"cxxtguk

Vcdgmc 6"vr r t g g p v c" t g c | | l q p k k g v" c x x g t u k" q u u g t x c v k" d ø q d k n v q z c z k o c d" h k n - 4 7 2 k p f k x k f y w" w o c p k" d ø u c k v j q o" n k" t g x g y" f q c" y e f c" q n - x k p k" v c ø" 3 8 o i l m i" q d k n v q z c z k o c d." u m q p v" k u - U k u v g o c" v c n - M n c u u k h k m c" v c n - Q t i c p k" w" n - h t g m y g p | c 0

Il-htgmygp|c"vct-tgc | |lqpkkgv"cxxtguk"jkle"fghkpkvc"mkh" gl<"mq o w p k" chpc"\*×3132+."mq o w p k"\*×31322"uc" >3132+="w" o j w z" m q o w p k" \* × 3 1 3 . 2 2 2 " u c" > 3 1 3 2 2 + 0" H ø m w n n" m e v g i q t k l c" v c n - h t g m y g p | c." k t - t g c | | l q p k k g v" c x x g t u k" j w o c" r r t g g p v e v k" h n - q t f p k" v c ø" u g t l g v «" n k" f g l l g o" v q p s q u 0

**Vcdgmc 6<"Tgc | |lqpkkgv"cxxtguk"ttcrrqtvcvk"økpfkxfyk"cfwvkv"døuc kvjqo**

Ukuv g o c"vcn-Mncuukhkmc"vcn-Qt i cpk" MedDRA	Mq o wpk"	O j wz"mq o wpk
Fkuvwtdk"hku-ukuv g o c" k o o wpk		Tgc    lqpk"cpchkncvkmc" Ugpukvkvxkv«"g guukxc
Fkuvwtdk"hku-ukuv g o c"pgtxw c	W ki "vcø"tcu	Uvwtfc o gpv Uvwtfc o gpv"kmme wpcv" o knn- rq k    lqpk Krqgugv klc
Fkuvwtdk"hn- i clpglp		Hqvqhdklc
Fkuvwtdk"hkn- y k fpglp" w" hku-ukuv g o c" ncdtkpvmc		Umw o fkv«"hkn- y k fpglp
Fkuvwtdk"xcumwnect		Hngdkvg
Fkuvwtdk"tgurktcvqtlk."vqtc k k" w o gflcuvkpcnk	Uqi nc	Kttkvc    lqpk"hn- i tk o glp" Fkuhqplc" Mqp guvlqpk"vcn- ukpwu" Fkurpgc
Fkuvwtdk" i cuvqg- kpvguvkcpcnk		W ki "hkz- zwhhvglp
Fkuvwtdk"fil- knfc" w" hkv- vguuwwk"vcø" vc v"kn- knfc	Rtwtkvg."wtvkmctlc. tezz	Fgt o cvkvg"cmngt kmc" Tczz" gpgtenk    cv" Vsczzkt"vcn- knfc
Fkuvwtdk" o wumqnv- umngvgtk k" w tat- vguuwwk"mqppgvkxk		W ki "hn- guvtg o kvelkvg" Urc o k"vcn- o wumqnv" Mqpvte    lqpk"kp xqnpvctlc"vcn- o wumqnv" W ki "hkz- zgfcs"
Fkuvwtdk" gpgtenk" w mqpfk    lqpkkvg"vcø" o pglp"lkipi cvc"	W ki "hku- ukv"vcn- kphw lqpk	W ki " Umw o fkv«"hku- ukfgt" Vgtvkt"vcø" dctf" I glc" Pgh c" hku- ukv"vcn- kphw lqpk" W ki " o j wz"mct fklcmw" hku- ukfgt" Ugpukvkvxkv«" W ki "hku- ukv"tat- vkvskd"vcn- xc w

Fgumtk | |lqpk"vct- tgc | |lqpkkvg"cxxtuk" o ci wnc

*Ugpukvkvxkv«"g guukxc" w" cpchkncvkmc*

Ir- tgc | |lqpkkvg" cxxtuk" tter rqtvcvk" hkv-: kpfkxkfyk"nk" i cnkjq o" n- kphw lqpk" døqdknvqzczk o cd" vycs shgv" o kp edde" ugpukvkvxkv«"g guukxc" rquukddnk" kpmwfgy" wtvkmctlc." tezz." uqi nc." rtwtkvg." uvwtfc o gpv." kttkvc | |lqpk" hkn- i tk o glp." fkuhqplc." fkurpgc" w" umw o fkv«" hku- ukfgt" N- kpfkxkfyk"nk" hcfc" døugpukvkvxkv«" g guukxc" mgmj q o" ukpvq o k" rtkp kren o gpv" tgnccvkv" o cn- knfc" d cn" rtwtkvg" w" tezz." w" 8 kpfkxkfyk" tter rqtvcy" uqi nc" N- cxsgpk o gpv" vcø" cpchkncuuk" mkgp" kmmtcvcvgtk | |cv" o kpp" tezz"vcn- wtvkmctlc" fkhhw "dk" rtwtkvg" hws" kn- parti l- mdkte"vcn- kug o." kpmnw "n- i qps." ku- ukfgt." kf- fcjct." n- cffqog." kf- fkti clp." w" u- ucscelp." swi "vcø" pkhu." w" uqi nc

Oc" mkgp" jgo o" gdfc" gxfkfgp | c" nk" t- tgc | |lqpkkvg"vcø" ugpukvkvxkv«"g guukxc" w" t- tczzklkvg kpdfgy" okt- tknczz" vc - kvqmkpc" o c" kg" quugtxat l- gdfc" vkdfkn" mnkpkmc o gpv" ukpkhkmcpvk" hk - kvqmkpk0

*ko owpq gpk kv«*

N- k xknwrr"vcø" cpvkmqtrk" mqvte" qdknvqzczk o cd" mkgp" gxcnycv" hn- kpfkxkfyk" mqnjc" nk" mkgpw" sgf" lkt kxw" fq c" yc fc" w" fq k" fqr rlk"vcø" qdknvqzczk o cd" hk" vnkvg" uvwflk" mnkpk k0" V o kgp" kpfkxkfyk" \*407 ' \* : 1542++" nk" t gxy" mill- kpseu" fq c" yc fc" qn- xkpk" vcø" qdknvqzczk o cd" mkgpw" rq kvkxk" i cn" tkurqpu" i cn" cpvkmqtr" cpvkgtergy vkmw" nk" lk f jgt" o kv- vtcvvc o gpv" \*CVC+0" kv- vkvtk" my cpvkvvkvxk" mkgpw" dczzk" nk" xctle y" o kpp" 3<42" uc" 3<5420" Oc" mkgp" jgo o" gdfc" gxfkfgp | c" vcø" hct o cmqmkpgvkmc" lgy" rtqhn" vcø" vquuk kv«" o kdfwn" hn- kpfkxkfyk" døtkurqpu" i cn" CVC0

Ter rwtvct"vcø" tgc | |lqpkkvg"cxxtuk"uwurgvkv

Jwyc"ko rqtvcvkv"nk"lk w"ttr rwtvcvk"tgc || lqpkkgv"cxxtguk"uwurgwcvk"yctc"n-cyvqtk || c || lqpk"vcn-prodott  
ogfk kpcnk0"Fcplkr rgt ogvkv"o qpkvqtc "mqpvkpy w"vcn-dkncp "dglp"kn-dgpghk lw"t-tkumlw"vcn-prodott  
ogfk kpcnk0"kn-rtqhgulqpkuvk"vcn-mwte"vcu-uc c"jwo c"o kvnwde"lkttr rwtvcy"m y cnwpm y g"tgc || lqpk"  
cxxtguc"uwurgwcvk"rgt og || "vcu-ukuv g o c"vc0"tcr rwtvet"pc || lqpcnk"o pk nc"ho [Crrgpfk k V0](#)

#### 4.9 Fq c'g guukxc

H0mc "vc0"fq c'g guukxc."kn-rc|lgpvk"i c p f j q o "lk w"o o qpkvqtlcvk"i cn"zk"ukplcnk"lg y"ukpvq ok"vc0"ghhgkvk"  
cxxtguk0

### 5. RTQRTLGVCLKGV"HCTOCMQNQ K K

#### 5.1 Rtqrtlgvclkgv"het o cmqfkpc o k k

Mcvgi qtklc"het o cmqvgtergy vkmc<"Ugtk"ko o wpk"w"ko o wpqi nqdwkpk."ko o wpqi nqdwkpk"urg khk k."Mqfk k"  
CVE<"L28DD44

Ogmmcpk o w"vc0"c || lqpk

Qdknvqzczk o cd"jwyc"cpvkmqtr"o qpqmnpknk"lqtdqv"n-cpvk gp"rtqvgvkvx"\*RC+"vc0"B. anthracis0"  
Qdknvqzczk o cd"lqpkdkzzk"n-ktkv"vc0"RC"o ct-tk gvvvtk" gmnwctk"vkgi w."w"lkr rtgxlgpk" f-f wn"kpvtc gmnwctk"  
tal-hcvwt"hgvcnk"vcn-cpvte g"wn-hcvwt"vcn-gfg o c."kn-komponenti tat-vquukpc"gp | k o cvkmc"tgurquceddnk"  
i cmm-ghhgkvk"rcvq gpk k"vcv-vquukpc"vcn-cpvte g0

Ghhgvk"het o cmqfkpc o k k

Qdknvqzczk o cd"lg gn"o c0"RC"nkdgwtw"domquvcv"vc0"fkuvq lc || lqpk"\*Mf+"vc0"chhpkv<"gm y knkdtc"vc0"2055 pO0"  
In vitro, qdknvqzczk o cd"lg gn o c0"RC"o kt-tc | g | "vc0"Co gu."Xqmw o."w"Uvgtpg"vc0"B. anthracis0"N-grkvqrw"  
hws"RC"nk"lg gn"o kgi w"qdknvqzczk o cd"jwyc"mqpvgtxcv"htc | g | "kttr rqtvcvkv"vc0"B. anthracis0

Uvwflk"in vitro h0cpkn k"dde cvc"hws"k gmnwk."dn-w w"vc0"o cmtqhc k"vcn-owtkpc."lkuuw gtkzzw"nk"  
qdknvqzczk o cd"lqppgy vtenk | c"n-ghhgkvk"quuk k"vcv-vquukpc"ngvcnk."mq o dkpc || lqpk"vc0"RC" - "hcvwt"ngvcnk0"

Uvwflk"in vivo f y ct"n-ghhmc lc"hk hpkgm" Pgy " \ gncpf" Y j kyg"\*P \ Y + "w"ho cmmmk"e { pq o qni wu"uhkfcvk"dn-  
kurqtk"vct-tc | c"Co gu"vc0"B. anthracis pet o g | | "vct-tqvc"vc0"kpnc | | lqpk."wtgy" kgfc"fkrgpfgpvk"hws"kf-  
fq c"hku-uqrctcxkxp | c"yctc"v-vtcvc o gpv"doqdknvqzczk o cd0"N-gurqpk o gpv"i cn"urqtk"vc0"B. anthracis  
kttk wnc"homqg pvte | | lqpkkg"fgllg o"lk fkgfw"vc0"RC"hku-ugtw"vcn-hpkgm" P \ Y" w"vcn-makakki  
e { pq o qni wu0" Y ct"v-vtcvc o gpv"doqdknvqzczk o cd"mkgp" j g o o "vpcssku"hn-mqg pvte | | lqpkkgv"vc0"RC"  
h0oc qtep | c"vcn-cppk o cnk"nk"dc si w" cllkp0"kn-mqg pvte | | lqpkkgv"vc0"RC"hn-cppk o cnk"nk" cfw" rnc gdq"  
fkgfw"ucmg o o" o kgvw0

Ghhmc lc"

O kp eddc"nk" o jw y kgz"hcvkddnk lg y"gvkmw"nk"lky y gvwsw"rtqvk"mnkpk k"mmqpvtnncvkv"hn-dpgf o kp"do cpvte g"nk"  
vkvvkg gf"o ep-pkhu."n-ghhmc lc"vc0"qdknvqzczk o cd"o qi vk" d cnc"o qpqvgtckle"o gvc"o seddnc"o c0" rnc gdq"  
i cv-vtcvc o gpv"vc0"cpvte g"nk"vkvvkg gf"o ep-pkhu" jkle"dde cvc"hws"uvwflk"vcn-ehhmc lc"hk hpkgm" P \ Y" w"  
h0c cmmmk"e { pq o qni wu0

H0fc y p"n-kuvwflk."n-cppk o cnk" gy"uhkfcvk"dk"urqtk"vc0"B. anthracis cgtquqnk | | cvk"\*kt-tc | | c"Co gu+"  
do c f y ct"422zNF72 w" o kpp" j g o o "0kn"sw f fkg o" gy"kvvtcvkvk"doqdknvqzczk o cd"ho rwpvk"vc0" o kgp"  
fkhhgtgpvk0"Hk"uvwfli tat-vtcvc o gpv"vc0"cpvte g"nk"vkvvkg gf"o ep-pkhu."n-cppk o cnk"pi cvc y"vtcvc o gpv" y ctc"  
nk" y tgy" ukplcnk"mnkpk k"lg y" ukpvq o k"vc0"cpvte g"ukuv g o kmc0"Hk"uvwflk" f y ct"kn-rtqhkneuvk"vc0" y ctc"n-  
gurqpk o gpv."n-cppk o cnk" gy"kvvtcvkvk" y ctc" gurqpk o gpv"i cn"B. anthracis k fc" sedgn"n-k xknwrr"vcu-  
ukpvq o k0"kn- o cmmmk"e { pq o qni wu" gy"kvvtcvkvk"hn- kp"vc0"epcnk k"rq kvkxc"vc0"gnvvtqmk o knw o kpgzzgp | c"  
\*GEN+"hku-ugtw"i cn"RC"vc0"B. anthracis dk" o kgp" o gflw"vc0" o c f y ct"62 ukgi c" y ctc"n-kuhfc"do B.



*anthracis*0"Hn-kuvwflk tat-trattament tal-hpkm" P \ Y ."n-cppk o cnk" gy "kvvtcvcvk" yctc"epcnk k"rq kvkxc"vcø" GEN" i cn"RC"Igy"gnxc | |lqpk"uquvpwvc"vcv-vg o rgtevcwte"vcn- kug o "økn" hws" o kn-nkplc"dc k."dk" o kgp" o gflw" vcø" o cf yct"52 ukgi c" yctc"n-kuhkfc0"Ku-uqrtcxkxgp|c" kgv" gxcn y cvc" yctc 4: lwo" yctc"n-kuhkfc" døB. *anthracis* fl-kuvwflk" fgumtkvkv" jcy p"vc v0

N-ghhkmc lc"vcø"fq c"yc fe"vcø"qdknvqczk o cd" qn-xpk"d cnc" o qpqvgterkle"i cv-vtevc o gpv"vcø"cpvtc" g"nk" kvkvg gf" o ep-pkhu" kgv" gxcn y cvc" hk"uvwflw" ykg gf" o knn-uvwflk"vcn-hpkm" P \ Y "w"vknkv"uvwflk" hkn-makakki e{pq o qniwu" \*CR424."CR426" w"CR523+= "n-kuvwflk"mqnjc" mkgpw"mmqpvqncvk" dkn-rnc gdq."tcpfqok | cvk."w" konformi mal- I NR0" N-kuvwflk"CT255."CR424" w"CR523" mkgpw" dnkpf gf="n-kuvwflw"CR426" mkgp" dnkpf gf" i cmn-itwrr0"

**Vedgmc 7<"Kt-tevk"vcø"uqrtcxkxgp|c"hk"uvwflk" f yct"n-ghhkmc lc"vcn- o qpqvgterkle" døqdknvqczk o cd" \*38 o ilmi+**

Rtqrqt   lqp"vcø"uqrtcxkxgp c"hk"v o kg o "n-kuvwflw * ' " ]kuuqrtcxkxgylp_+		xcnwt"r <sup>2</sup>	95 ' "EK <sup>3</sup>		
Rnc gdq	Qdknvqczk o cd"38 o ilmi"				
<b>Vtevc o gpv"- hpkm" P \ Y "</b>					
Uvwflw"CT255 <sup>1</sup>	0 *2135+	8307" ' " *:135+	202235 ,	*204 ; 2."20 : 83+	
<b>Vtevc o gpv"- Ocmcmk"e{pq o qniwu</b>					
Uvwflw"CR426 <sup>1</sup>	8 ' " *3138+	6809 ' " *9137+	20228 : ,	*202 : ; ."208 : 3+	
Uvwflw"CR424 <sup>1</sup>	2*2139+	5305 ' " *7138+	2022 : 7 ,	*2029 ; ."207 : 9+"	
<b>Rtqhknucuk"vcø" yctc"n-gurqpk o gpv"- Makakki e{pq o qniwu</b>					
Uvwflw"CR523 <sup>4</sup>	3 :- il ukgi c yctc"n- gurqpk o g nt	2*218+	100 ' " *818+	202234 ,	*20693."30222+
	46 ukgi c yctc"n- gurqpk o g nt	--	: 5 ' " *718+	202264 ,	*20452."20 ; ; 8+
	58 ukgi c yctc"n- gurqpk o g nt	--	72 ' " *518+	202567	*-20259."20 : : 4+

EK<"Kpvgtxcn"vcø"mwphkfgp|c

<sup>1</sup> Uqrtcxkxgp|c"xcnwwvc"4: lwo" yctc"n-kuhkfc"vcn-kurqtk."n-cppk o cnk"tcpfqok | |cvk"mqnjc"rq kvkxk"i cmn-dcvgtk o lc"sedgn"kv-vtevc o gpv."kv-vtevc o gpv"dgfc"rgt o g | |"vcø" kgfc"ukpkhkmcpvk" hkv-vg o rgtevcwte"vcn- kug o "n-kuvwflw"CT255+"Igy" døtk wncv"rq kvkx"hn-epcnk k"vcn-gngvvtqmk o knw o kpgzzgp|c"vcn-cpvk gp"rq kvkx"n-kuvwflk"CR426" w"CR424+0

<sup>4</sup> Il-xcnwt"r" jwyc" o kpp"Vguv"vcø"Dquej nqq" døpc c"yc fe"\*dø o qfkhkmc"vcø"Dgtigt-Dqqu"vcø" i c o c ?20223+ " o gvc" o seddgn" o cn-rnc gdq

<sup>5</sup> Ipvgtxcn"vcø"mwphkfgp|c" g cvv"vcø"; 7 ' "vcø" fkhgtgp|c" hkt-tevk"vcø"uqrtcxkxgp|c

<sup>4</sup> Uqrtcxkxgp|c"xcnwwvc"4: " yctc"n-kuhkfc"vcn-kurqtk."

€ Vhkuugt" ukpkhkmcp|c" uvcvkvmc" hkn-nkxgn"vcø"20247

Rqrqnc | |lqpk"rgflcvtkmc

N-C gp|klc"Gytqrge"i cmn-Ogfk kpk" f fkhgtktgt l-qddnkiw"nk"lk w" rrtg gpvcvk"tk wncvk"vcn-kuvwflk" døP [ ZV J TCEKU høykg gf"lgy" kmvet"mcvgiqtllk"vcn-rqrqnc | |lqpk"rgflcvtkmc" hkv-vtevc o gpv"vcø" kphg | |lqpk" dc knctk"\*ctc"ug | |lqpk 604"i cn" kphqt o c | |lqpk" f yct"n-w w"rgflcvtkmw+0

Dan il-prodott o gfk kpcnk" kg"cyvqtk| |cv"vc v": ktmwuvcp|k" g g | |lqpcnkø0" Fcp"khkuugt"nk" o kp cddc"nk"n-  
o ctfc"jkle"tctk" w"i cn"tc wpklkgv"vcø"gvkmc" o c"mkgpz" rquukddnk"nk"vkpmkugd" kphqt o c | |lqpk" u k c" f y c t" f c p"  
il-rtqfqv" o gfk kpcnk0  
N-C gp|kle"Gytqrge"i cmn-Ogfk kpk"ugt"vkttgxgfk"mwmm"vkr"vcø" kphqt o c | |lqpk" f k f c"nk"vq tq "mwmm"ugpc" w"  
ugt"vc qtpc" fcp"ku-Uq o o c t l w"vcn-Mctevgtkuvk k"vcn-Rtqfqv."umqpv"kn-d qpp0

## 5.2 Vei tkh"het o cmqmkpgvkmw

### Cuuqtdk o gpv

Il-het o cmqmkpgvkmw"vcø"qdknvqzczk o cd" jkle"nkpgetk" hkn-medda tad-fq c"vcø"4 o ilmi" \*2047 fctdc"n-kpsc"u"  
fq c"temmq o c p f c v c + " u c" 38 o i l m i" y c t e" i q v k" y k g g f" q n- x k p k" h ø k p f k x k f y k" d ø u c k v j q o" 0" Y c t e" i q v k"  
y k g g f" q n- x k p k" v c ø" q d k n v q z c z k o c d" 38 o i l m i" h ø k p f k x k f y k" w o c p k" d ø u c k v j q o. " k t k g n" w" p k u c. " k u- E o c z w" n-  
CWE<sub>inf</sub> o g f l k" m k g p w" v c ø" 622 ± ; 304 o e i l o N" w" 7392 ± 3582" o e i l w o l o N. " t k u r g v k x c o g p v" 0" k p- p q h u" c l l c"  
vcø"qdknvqzczk o cd"mkppgv"vcø" o c f y c t" 42 l w o" \* o g f l c + 0

### Fkuvtkdw | |lqpk

Il-xqpw o "vcø"fkuvtkdw | |lqpk" o g f l w" v c ø" q d k n v q z c z k o c d" h k" u v c v" h k u u" m k g p" v c ø" 9 ; 0 9 ± 3 ; 0 4 o N i m i" w" c m d c t" o k n n-  
xqpw o "vcn-rnc o c." w" fcp" lkuuw g t k z z k" z k" f k u v t k d w | | l q p k" v c v- v g u u w v k 0

### Dklqvtcuht o c | |lqpk

O c" u c t" g d f c" u v w f l w" h q t o c n k" v c n- o g v c d q n k o w" d ø q d k n v q z c z k o c d 0  
O c f e p m q n n w. " k f- f k u r q k | | l q p k" v c ø" c p v k m q t r k" o q p q m n q p c n k" g p g t e n o g p v" v k p x q n x k" f- f k u v t k d w | | l q p k" n k n" j k p p"  
m i l l- k u r c | l w" x c u m w n e t k" d ø c u u q t d k o g p v" r q v g p | l e n k" h k v- v g u u w v k. " w" m e v c d q n k o w" o k p p" r t q v g c k" i c n" r g r v k f k"  
i c t" w" c k f k" c o o k p k k" n k" u w u u g i y g p v g o g p v" l k w" k p m q t r q t e v k" h k t- t k g t x c" g p f q g p c" l g y" l k w" g n k o k p e v k 0

### Gnk o kpc | |lqpk

Il-xcnwtk" o g f l k" v c v- v p g k l e" v c ø" q d k n v q z c z k o c d" m k g p w" v c ø" 5057 ± 20 ; 54 o N i f l m i" w" c h p c" k i c t" o k t- r a t a  
v c ø" h k n v t c | | l q p k" i n q o g t w n e t k. " n k" l k p f k m c y" n k" r t e v k m c o g p v" o c" j g o o" n- g d f c" v p g k l e" o k n n- m n k g y k" v c ø"  
q d k n v q z c z k o c d 0

### Rqrqnc | |lqpk lkgv"urg lcnk

#### *Ghhgvk"vcu-sess, l-ett/r -razza*

Il-RM"vcø"qdknvqzczk o cd" kgv" gxcn y c v c" r g t o g | | v c ø" c p e n k k" v c n- P K t a l- r q r q n c | | l q p k" d n- w w" v c ø" m c o r l w p k"  
v c u- u g t w" o k p p" 592 k p f k x k f y w" d ø u c k v j q o" n k" t g x g y" f q c" y c f c" q n- x k p k" h ø 6 r t q x k" m n k p k 0" C d d c k" v c ø"  
d i n l- c p e n k k. " k u- u g u u" \* p k u c" m q p v t c" t k g n+. " k t- t c | | c" \* o j w z" M e y m e u k" m q p v t c" M e y m e u k+. l g y" n- g v" \* c p | l e p k"  
m q p v t c" i c c i + 0" o c" m g n n j q o" g d f c" g h h g v v" u k p k h k m c p v k" h w s" k n- p a m e t r i t a l- R M" i c n" q d k n v q z c z k o c d 0"  
O c f e p m q n n w. " n- k u v w f l k" m n k p k k" v c ø" q d k n v q z c z k o c d" o c" k p m n w f g y z" p w o t w" d k g l l g f" v c ø" k p f k x k f y k" n k"  
i c p f j q o" 87 u g p c" w" c m v e t" d k g z" l k k" f f g v g t o k p e v l g m m" k n- R M" v c i j q o" j k l k g z" f k h h g t g p v k" o k p p" k p f k x k f y k"  
k i c t" h n- g v" 0" O k v- 542 k p f k x k f y w" h k" u v w f l k" m n k p k k" v c ø" q d k n v q z c z k o c d. " ; 0 6 ' " \* 521542+ " m g n n j q o" 87 u g p c" w"  
c m v e t. " h k n y c s v" n k" 4 ' " \* 81542+ " m g n n j q o" 97 u g p c" w" c m v e t 0

#### *Ghhgvk"tgncvck"ocf-fesu"vcn- kugo*

It-vpg klc" hørk" vcn- kugo" i qnk" \*32; mi+ "mkppgv" dglp" ykg gf" wkg qt" 5: ' "qi nc" o knk" hørqrqnc | |lqpk"  
vcø" tghgtgp | c0" Ycte" fq c " k d d c e v" h w s" k n- r k " \* 38 o i l m i + " f c p" k y c u e n" i c n" k g f c" h n- C W E <sub>inf</sub> v c ø" 34 ' . " n k"  
o j k z" m n k p k m c o g p v" u k p k h k m c p v k 0

#### *Popolazzjoni pedjatrika*

Il-fet o cmqmkpgvkmw"vcø"qdknvqzczk o cd" o c" kgvz" gxcn y c v c" h k v- v h e n 0" K t- t e m m q o c p f c | | l q p k l k g v" v e f- f q c "  
h ø V e d g n n e 4 " u g | | l q p k" 604+ " j w o c" f g t k x c v k" o k p p" u k o w n c | | l q p k l k g v" d n- w w" v c ø" e r r t q " v c n- P K t a l-  
r q r q n c | | l q p k" o c u w d" d k g z" l e s d g n" o c n- g u r q p k o g p v" q u u g t x e v" v c ø" c f w n v" i c n" q d k n v q z c z k o c d" d ø f q c" v c ø"  
38 o i l m i 0

### 5.3 Vei tkh"vcø"scdgn"n-w w"mnkpkmw"fyct"ku-ukiwv«

Vei tkh"o jwz"mnkpkmw"kdde cv"hws"uwvflk"mqpxgp|lqpcnk"vcø"ukiwv«"hct o cmqng kmc."ghhgv"vquukmw"o kpp"fq k"trkgvww"v"ghhgv"vquukmw"hws"ku-ukuvgo c"trktqfwwkxc"n-k xknwrr."o c"lwtk"n-gdfc"rgtkmmw"urg lcnk"i cmm-dpgf o kpø

Ng lqpkkgv"hu-ukuvgo c"pgtxw c" gpvtcnk"\*EPU+\*dcwvgtk."kphlc o oc||lqpk."g o qtte klc"n-w"zk"mwvvcv"pgmtq k+"fgjtw"hk"hpkgm"P \ Y"kphgvvcvk"dn-cpvtc g"nk"o c"desi wz" cllkpw"hn-makakki e{pq o qni wu"nk"pi cvcy"qdknvqzck o cd" qn-xlpk"\*x 6"o ilmi+"Igy"mqpvqtqnn"ogvc" kgv"kmmpqphgt o cvc"n- o ctfco"kn-dkfnkgv"o kmtqumqrk k"hn-cppk o ckn"nk"o c"desi wz" cllkpw"nk"t gxgy"qdknvqzck o cd"mkgpw"okp edde"n-rtg gp|c"vcø"dcvvgtk"gmuvtxcmmwnc"tk"n"o jwz"n-effett tco"qdknvqzck o cd"Oc" kgv"kgv"kvk"mccvc"n-gdfc"tgnc||lqpk"dglp" id-fq c"n-t-tkurqpu"i cn"kuvqrcvqng klc"vcn-o q 0"Oc"fgjtg"n-gdfc"ng lqpk"hn-o q "fgncvcv"o cncv-vtcvc o gpv"hk"hpkgm"P \ Y"kphgvvcvk"dn-cpvtc g"nk"desi w" cllkpw"n-hølw o 4:+"Igy"hn- o cmmmk"e{pq o qni wu"\*uc"lw o "78+"yctc"i qk"ykg gf"vcø"qdknvqzck o cd"dfq k"uc"38 o ilmi"n-w"uc"54 o ilmi"lfq c."tkurgvwxco gpv"0"Oc" kg"quugtxcv"n-gdfc"ghhgv"pgy tqmq o rqtvcvwx"tgncvcv"o cø"qdknvqzck o cd"nø o cmmmk"e{pq o qni wu"o cecswu"kphgvvcvk"dn-cpvtc g"nk"desi w" cllkpw"yctc"vtcvc o gpv"do"qdknvqzck o cd"o

Uct"uwvflw"ykg gf"fyct"n-k xknwrr"vcn-g o dtklw"n-n-hgvw"hk"hpkgm"P \ Y"vsc"n-w"do"uc kvjq o "nk"pi cvcy"4 fq k" qn-xlpk"vcø"qdknvqzck o cd"uc"54 o ilmi"\*fctdvglp"kf-fq c"wo cpc"n-w"dc k"vcø"o ilmi+"hn-lkg o"vcn-guvc||lqpk"8."32."35."w"39"Oc" kgv"quugtxcv"n-gdfc"gxkfgp|c"vcø" uctc"nkn-q o o"vsknc"lgy"nkn-feti o kp cddc"qdknvqzck o cd"0"n-gurqpk o gpv"mw o wncvwxk"hn-hpkgm"P \ Y"\*32.222 o eiÉlw o l o N+"hkp-PQCGN"vcø"54 o ilmi"lfq c"\*p?6 fq k+"kdde cvk"n-w"lkg o"vcn-CWE<sub>0-37</sub> mkgpw"ocfyct"fctdvglp"n-CWE"ogflw"mmq o dkpcv"vcn-kt kgn"n-w"p-pkuc"n-w"ocpk"dkf-fq c"mnkpkmc" qn-xlpk"vcø"38 o ilmi"0"kn-xcnwtk"vcu-E<sub>ocz</sub> yctc"54 o ilmi"lfq c"mkgpw"vcø"33:2 o eiÉlw o l o N

Oc"uctwz"uwvflk"do"qdknvqzck o cd"fyct"kn-mct kpq gpk kv«."n-ghhgv"vquukmw"n-w"kn- gpk"n-n-hgtvknkv«o

### 80 VCI TKH"HCTOC GYVKMW

#### 803 Nkuvc"vcø"g krlgpvk

Kuvfkpc  
Uqtdkvqn"\*G642+  
Rqn{uqtdcvg":2"\*G655+  
J {ftqejnqtke"cekf"\*G729."i cmm-c wuvc o gpv"vcn-r J+  
Uqfkwo"j {ftqzkgf"\*G746."i cmm-c wuvc o gpv"vcn-r J+  
Kn o c"i cmm-kplg||lqpkkgv

#### 804 Kpmq o revkdkvckgv

Dan il-prodott ogfk kpcnk"o øi cpfwz"lkv cmcv"o cø"rtqfqqv"ogfk kpcnk"q tclp" nkg"fcym"ko ugo o klc"nøug||lqpk 8080

#### 805 o kgp"mg o o "kfw o "vclld"kn-rtqfqqv"ogfk kpcnk

Mwplgv"o jwz"o khvw

9 upkp

Uqnv||lqpk"fn y kvc"nødqt c"vcn-kphw lqpk

Yctc"n-f-fknyk||lqpk"nødqt c"vcn-kphw lqpk."n-kuvcdknk"«mk o kmc."hk kmc"n-w"o kmtqdkmc"ycsv"n-w w"pv ygtkgv"i cn": uki cv"nøvg o rgtcvwtc"vcn-mc o tc"\*42ÅE- 47ÅE+"Igy"hn-htk "\*4ÅE- : ÅE+0

Mil-ncv" o kmtqdklqng kmw."kn-rtqfqv"i cfw"lkwv c"ko ogflvc o gpv." nkgh"lgmm"kn- o gvqfw"vcø"  
hvw ltkmqvkvw | |lqpk"lkr rtgmmwfk"t-tkumlw"vcø"mqpv c o kpc | |lqpk" o kmtqdkmc0

Lgmm" o c"lkwv cz"ko ogflvc o gpv."k - okgp"vcn- c pc"wn-mqpfk | |lqpk"lgy"ycsv"n-w w"jwoc"t-  
tgurpucddknv<"vcn-wvgpv0

Uqnw | |lqpk" fkykvc"houktkpic"i cmm-kphw lqpk"

Nefetdc"vmwp" kgv"kr rtgretcvc uqnw | |lqpk" fkykvc"vcø" P [ ZVJTCEKU."fkp"i cfw"lkwv"vcø"  
ko ogflvc o gpv" w" o c"vpc c kpz0" Mycnwpm y g"rtqfqv" o jwz" w cv"i cfw"lkwv"vcø" o c0

### 806 Rtgmcy |lqpk"lgy"urg lcnk"i cmm- c pc

C gp"hk"htk "4ÅE" - :ÅE+0

Vci onwz" hkn-htk c0

C gp"hk-rcmmgv" qtk kpcnk"ucdkgz"vknscø" okf-fcy n0

I cmm-mqpfk | |lqpk"lgy"vcø" c pc"yetc" f-fkyk | |lqpk"vcn-rtqfqv" o gfk kpcnk"etc"ug | |lqpk"8050

### 807 In-pcvwte"vcn-mqpvqkvtw" w"vcø" fcm"nk" jgo o" q"hkj

822 o i18" o N"vcø"mqp gpvtcv" hømwp lgv" \* kg "vcv-vkr"K+"døvrr"vcn-ncuvmw" w" døi cvw"vcn-rqn {rtqr {ngpg"  
døuk knm"vcn-cnwo kplw0

Rcmmgv" hkj"mwplgv ykg gf0

### 808 Rtgmcy |lqpk"lgy"urg lcnk"i ct-tkok" w"i c"ko o epk ct"kg qt

Uvtw | |lqpk"lgy"ko rqtvcpvk"i cmm-rtgretc | |lqpk

€ Il-mqp gpvtcv"i cnuqnw | |lqpk"i cmm-kplg | |lqpk"i cfw"lk k"urg | |lqpcv" xk ycnogpv"i cnuhcm" w"  
umwnwte o gpv" scdgn" o c"lkwv"vcø" P [ ZVJTCEKU jwyc"uqnw | |lqpk" etc"i cnuqrcngzzgpk."dnc"  
mwnwt"i cnuchte" etc"i cnuchte" etc" hkn-mcpggmc"nk"lkuvcø" lmw" hkj c" hvkv" htem"vcn-rtqvgkpc" vtcunw kfk"  
i cnuqqlt" \*nk" lkwv g y" døkntv | |lqpk" hønplc+0

€ Ct ok" n-mwplgv" lggm" ku-uqnw | |lqpk" vmwp" umwnwtevc" lgy" kmwp" hkj c" rctvk gmnk" dcttcpkp" \*etc"ug | |lqpk"5+0

€ V cy ycfz" kn-mwplgv0

Rtgretc | |lqpk" w" fkyk | |lqpk" hkn-dqt c"vcn-kphw lqpk"

30 Kmmcnmwnc" n- o knk ite o ok"vcø" qdknvqzczk o cd" og vkg c"dknk"vk o onvkrnkmc" f-fq c"vcø" o i lmi"  
temmq o epfvc" høvedgmc 4" \*etc"ug | |lqpk"604+ "dkn-rk "vcn- kugo"vcn-rc | lgv" kpfkxkfy cnk"  
hømknqite o ok0

40 Kmmcnmwnc" n-xqno" o og vkg "hø o knknkvtk"vcø" qdknvqzczk o cd"mqp gpvtcv"i cnuqnw | |lqpk"i cmm-  
kphw lqpk" w"pwotw"vcø"mwplgvk" o og vkg c"i cf-fq c"dknk"vk ffxkfk" f-fq c"mncmwncvc" hømknk ite ok"  
\*rcuu"3+ "dkn-mqp gpvtc | |lqpk."322 o i l o N0" Mwnn"mwplgv" wpmw" lkr rgtogvkv" n-i qvk"vcø"8 o N"vcø"  
qdknvqzczk o cd"mqp gpvtcv"i cnuqnw | |lqpk"i cmm-kphw lqpk0

50 C i cnu" dqt c"vcø" kphw lqpk"vcø" fcsu"zkgtes"vcø"uqfw o "ejnqtkfg"; o i l o N" \*20; ' + "uqnw | |lqpk"  
i cmm-kplg | |lqpk0"K dgf" xqno"vcø"uqnw | |lqpk" o knn-dqt c"vcn-kphw lqpk" fcsu"kn-xqno" kmmcnmwncv"  
hømknkvtk"vcø" qdknvqzczk o cd" hkn-rcuu 4"vcø" jcy p" hws0" Ct ok" u-uqnw | |lqpk"nk"p kdfgv" o knn-dqt c"vcn-  
kphw lqpk0

60 K ded il-xqno" o og vkg "vcø" qdknvqzczk o cd"mqp gpvtcv"i cnuqnw | |lqpk"i cmm-kphw lqpk" \*kmmcnmqncv"  
mill-rcuu"4+ " o knn-mwplgv" \*k+ "vcø" P [ ZVJTCEKU0" Ct ok" mycnwpm y g" rqt | lqpk"nk" o c" lmwz" kpvw c"nk"  
lkhfc" hkn-mwplgv" \*k+ "vcø" P [ ZVJTCEKU0

70 Kvtcuhtkz" n-xqno" o og vkg "vcø" qdknvqzczk o cd"mqp gpvtcv"i cnuqnw | |lqpk"i cmm-kphw lqpk"i cmm-  
dqt c"oci wnc"vcn-kphw lqpk0"

80 Csgd" kn-dqt c"vcn-kphw lqpk" dkn-oqf"vcø"vc v" hws"dkgz"v cncv"ku-uqnw | |lqpk0" V cy ycfkgz0

90 N-kphw lqpk"i cfw"lkwv"vcø" hws" rgtlqfw"vcø"; 2 okpvc" dkt-rata tal-kphw lqpk" fgumtkvc" hømcdgmc 5"  
\*etc"ug | |lqpk 604+."dn-w w"vcø" hknvtw" hønplc"vcø"2044 o kmtqp0"

:0 Ku-uqmw | lqpk"rrtgrctvc"jklc"uvcdnk"i cn": uki cv"oc wpc"hovgo rgtcvwtc"vcn-mc o tc"vcø"42ÅE"uc" 47ÅE"lgy": uki cv"oc wpc"hkn-htk "hovgo rgtcvwtc"vcø"4 E"uc": ÅE0

Prgretc | lqpk"w"fknyk | lqpk"hku-uktpic"i cnn-kphw lqpk

30 Kmmcnmwnc"n-o knnk i tc o ok"vcø"qdknvqzczk o cd"og vkg c"dknk"vk o o wnvkrnkmc" f-fq c"vcø" o ilmi" temmq o epfcvc"hovcdgnc 4"\*ctc"ug | lqpk"604+"dkn-rk "vcn- kugo"vcn-rc | lgpv"kpfxkfy cnk" hømknqi tc o ok0

40 Kmmcnmwnc"n-xqno" o og vkg "hø o knnkvtk"vcø"qdknvqzczk o cd"mqp gpvtcv"i cn"uqmw | lqpk"i cnn-kphw lqpk"w"pw otw"vcø"mwplgvk" og vkg c"i cf-fq c"dknk"vk ffxkfk" f-fq c"mcmcnmwncvc" hø o knnk i tc o ok"\*rcuu"3+"dkn-mqp gpvtc | lqpk"322 o ilo N0" Mwnn"mwplgvv"wpkmw"lkr rgt o gtti l-i qvk" vcø"8 o N"vcø" P [ ZVJTCEKU mqp gpvtcv"i cn"uqmw | lqpk"i cnn-kphw lqpk0

50 Ci gn"uktpic"vcø"fcsv"zkgts"i cnn-xqno"vcø"vcn-kphw lqpk"nk"i cpfjc"vkpi cvø

60 Dn-w w"vcø"uktpic"oci wnc"w"hnvtw"hnkplc"vcø"2044 okmtqp."k dgf"kn-xqno" o og vkg "vcø" qdknvqzczk o cd"mqp gpvtcv"i cn"uqmw | lqpk"i cnn-kphw lqpk"\*kmmcnmwncv" o kn-rcuu 4+0" Ct ok" mycnwpm y g" rqt | lqpk"lmpwz"kpww c"nk"lkhfc"hn-mwplgvv"\*k+"vcø" P [ ZVJTCEKU0

70 K dgf"co o qpv"zkgtes"vcø"uqmw | lqpk"i cnn-kplg | lqpk"vcø"uqfkw o "ejnqtktfg"; o ilo N"\*20; ' + "dkgz" tipprepara l-xqno"vcø"vcn-kphw lqpk"urg khkmcv"hovcdgnc 40

80 cncv"lqmw | lqpk"dkn-o qf0"V cy ycfkgz0

90 Nefctdc"vmwpp" kgv"kr rrtgrctvc"uqmw | lqpk"fknykvc"vcø"qdknvqzczk o cd."ci vkjc"ko og flcvc o gpv0" Vc kpz"uqmw | lqpk"hovuktpic0" Ct ok"n-rtqfqw"nk" o c"lmpwz"kpww c0

Rimi

Mwnn"hfcn"vcn-rtqfqw" ogfk kpcnk"nk" o c"lmpwz"kpww c"lgy"umctv"nk"lkdscø"yctc"n-w w"vcn-rtqfqw"i cpfw" lkpvtg o c"mkh"lkvqndw"n-nk klkgv"nqmcnk0

**7. DETENTUR TAL-CYVQTK \ C \ LQPK" I €WSGI KF"HSUQ**

UHN"Rjct o cegwkecnu" Fgwvuejncpf" I odJ Marie-Ewtkg-Uvtcuug": 9;75;"N3/4ttcej Il- gt o cplc

**8. PWOTW\*K+"VCN-CYVQTK \ C \ LQPK" I €WSGI KF"HSUQ**

GW13142136:71223

**9. DATA TAL-GY-YGN"CYVQTK \ C \ LQPK" IVK FKF"VCN-CYVQTK \ C \ LQPK**

Data tal-gy ygn"cyvqtk | c | lqpk<"3:"vc"øPqxo dtw"4242

**10. FCVC"VCø"TGXK LQPK"VCV-TEST**

kphqt o c | lqpk"fgvenlcvc"fyet"fcv"kn-rtqfqw" ogfk kpcnk"vkpued"hw s"ku-ukv"ngvwtqpkmw"vcn-C gp|klc" Gytqrge"i cnn-Ogfk kpk" jwr<llyyyog o c>gwtrcogw>."w"hw s"ku-ukv"ygd"vcn- }w"hw s"ku-ukv"ngvwtqpkmw"vcn- {kugo"vcn-Kuvcv"Ogo dtwl" C gp|klc"\*nkpm+; @0

ANNEX II

- A. OCPKHCVVWT"VCU-UWUVCP\C"DKLQNO KMC"CVVKXC"W"  
OCPKHCVVWT"TGURQPUCCDNK"I CNN TW "VCN  
LOTT
- D0 MQPFK\ \LQPKLGV"LG Y"TGUVTK\ \LQPKLGV"TKI Y CTF"  
IL-RTQXXKUV C"W"N-W W
- E0 MQPFK\ \LQPKLGV"W"TGMYK KVK"Q TC"VCN  
CYVQTK\ \C\ \LQPK" I CWSGI KF"HSUQ
- D. MQPFK\ \LQPKLGV"LG Y"TGUVTK\ \LQPKLGV"HKT-  
TKI Y CTF"VCN-W W"UK I WT"W"GHHGVVKX"VCN-PRODOTT  
OGFK KPCNK
- E. QDDNKI W"URG KHKMW"DKGZ"OK WTK"VC"Y CTC"N-  
CYVQTK\ \C\ \LQPK" LK W"MQORNWVK" I CNN  
CYVQTK\ \C\ \LQPK" I CWSGI KF"HSU"VC V"  
KTMWUVCP\F" G G\ \LQPCNK

A. OCPKHCVVWT\*K+"VCU-UWUVCP \ C1K+"DKLQNO KMC\* K"CVVXC1K"W"  
OCPKHCVVWT\*K+"TGURQPUCDDNK" I CNN TW "VENDOTT

Kug o "w"kpftk | | "vcn- o ephcwwt\*k+"vcu-uwuvcp | c\*k+"dklqno kmc\* k"cvvxc1k

Nqp | c "Dkqni keu. "Kpe0"  
323"Kpvgtpcvkqpcn" Ftkxg  
Rqtvu o qwj. "P J "25 : 23"  
N-kuvck "Wpkv"vcn-C o gtmc

Kug o "w"kpftk | | "vcn- o ephcwwt\*k+"tгурqucddnk" i cmm- tw "vcn-lott

Cegtvrjct o c "D0X0"  
Dquejuvtccv"73  
6 : 33" I E. "Dtgfc  
N-Olanda

D0 MQPFK \ \ LQPKLGV"LG Y "TGUVTK \ \ LQPKLGV"TK I Y CTF"KN-RTQXXXKUV" W" N-  
W W"

Rtqfqw" o gfk kpcnk"nk"lkipi cvc"dk-tk gvc"vcv-vedkd

E0 MQPFK \ \ LQPKLGV"WTGMYK KVK"Q TC"VQNYVQTK \ \ C \ \ LQPK" I EV  
VSGI KF"HSUQ

€ Terrqtvk"rgtlqfk k" c qtpevk"fyct"ku-ukiwtv<<"\*RUWtu+

Ir-tgmyk kvk"dkgz"lk w"rrtg gpvcv"RUWtu" i cn fcp"kn-rtqfqw" o gfk kpcnk"jwoc" o pk nc"hnk-nkuvc"  
tad-fcvk"vc0"tghgtgpc|c"vcn-Wplqpk"\*nkuvc"GWTF+ rtgxkuvc"umqpv"n-Ctvkmqnv"329e\*9+"vcf-Fktgwxk"  
42231 : 51MG" w"mycnwpm y g" c qtpe o gpv"uwuugi y gpvk" r rwdnkmcv" hws"kn-pqtvcn" gngvvtqpkmw"  
Gytqrgy"vcn- o gfk kpk0

D. MQPFK \ \ LQPKLGV"LG Y "TGUVTK \ \ LQPKLGV"HKT-TKI Y CTF"VCN-W W"UK I WT"W"  
GHHKMC K"VCN-RTQFQVV"OGFK KPCNK"

€ Rlep"vc0" guvlqpk"vct-tkumlw"\*TOR+

Id-fgypvwt"vcn-cyvqtk | | c | | lqpk" i cv-vsg i kf" hku-uws" \*OCJ+ i c pfw"lygvcs"n-cvwxkvc1kgy" w"n-  
kpvgtxgpvk" o g vkg c vc0"het o cmqxx knep|c"fgvvcnlevk"hn-TOR" o csdwn"kr rtg gpvcv"hnk-Oqfwnw"30 : 04"  
tal-cyvqtk | | c | | lqpk" i cv-vsg i kf" hku-uws" w"mycnwpm y g" c qtpe o gpv"uwuugi y gpvk" o csdwn"vcn-  
TOR0

TOR" c qtpev" i c pfw"lk k"rrtg gpvcv

€ Meta l-C gp|klc" Gytqrgc" i cmm-Ogfk kpk"vkvnd" fkp"n-kphqt o c | | lqpk=

€ Mwmm" o gvc"u-ukuv g o c"vcn- guvlqpk"vct-tkumlw"vk k" o qfkhkmcvc"urg lcn o gpv" o kp eddc"nk"vcuen"

kphqt o c | | lqpk" f kfc"nk"vkuvc0"vycuenc" i cn"dkfnc"ukpkhkmcpvk"hnk-rtqhkndg1p"kn-dgpghk l w" w"t-tkumlw"

lgy" o kp eddc"nk"lcpvnc cs" i cp"ko rqtvcpvk"\*het o cmqxx knep|c"lgy" o kpk o k | | c | | lqpk"vct-tkumlk+0

E. QDDNKIW"URG KHKMW"DKGZ"OK WTK"VCØ"YCTC"N-CYVQTK\|C\|LQPK"LK W"  
 MQORNWVK" I CNØYVQTK\|C\|LQPK" I CWSGI KF"HUWS"VC V"  
 KTMWUVCP\K"G G\|LQPCNK

Rgtguu"nk"fkp"jk"errtqxc||lqpk"vc v" ktmwuvcp|k'g g||lqpenk"w"umqpvn-Ctvkmqnv 36\*:+vct-Tgiqncogpy"  
 \*MG+ 94814226."n-OCJ"i cpfw"lygwes."hk - okgp"uvkrwncv."kn-ok wtk"nk" gllkx

Fgumtk  lqpk	Fevc"okuvppkic
<p>Ucdkgz"lk k"xxcnkfcv"kn-ogvqfw"vcn-RM"vcØ"qdknvqzck ocd"*IEN-382+"            hku-ugtw"wo cp."n-OCJ"i cpfw"lkuuqvqogvvt-tk wncvk"oknn-            xcnkfc  lqpk"vcn-cpenk k"i cmn-curgvvt"nk" gllk"scdgn"n-w w"vcn-cpenk k"            i cmn-cpenk k"vcn-mc o rlpw"i cmn-kuvwflw"mnkpkmw"CJ723&lt;"kpvgtgtgp c"            okpp"RC"*85"w":5+."GH."NH"w"CFCu."w"rtguvc  lqpk"tal-cpenk k"hku-            ugtw"g o qnkvmw"w"nkr go kmwØ"kn-rctcngnk o w"i cpfw"lkygwes"            dØmc o rlpw"oci o wnc"oknn-kuvwflw"r rlcpcv."qrgp-ncdgn"w"hw s"kn-rquv"            CJ7230</p> <p>Ucdkgz"lk k"gxncycv"kt-tkurqpu"mnkpkmw."ku-uk i wtv«"w"v-vqngteddkv«."            kpmnw "kv-vwn"vcn-oc tfc"wu-uqr tecxkxgp c"nØkpfkxkyk"dØmc klgv"            uwurgvvcv."rtqcdcdnk."lgy"kmmpqht o cvk"vcØ"cpvtc g"nk"vkvk g f"ocp-            pkhu"nk" gy"kvtevcvk"Øqdknvqzck ocd."n-OCJ"i cpfw"lygwes."umqp"            rtqvqmnm"ocsdwn."w"lkuuqvqogvvt-tk wncvk"vct-terrqt"hkpcnk"i cmn-            kuvwflw"vcØ"hc k 6.qrgp-ncdgn"w"hw s"kn-rquv"CJ723" o cn-qmmqtgtgp c"vcØ"            vkhski c"vcØ"cpvtc g"hkn-rcllk k"hglp"qdknvqzck ocd"jwyc"cyvqtk cv"w"            fkurqpkddnkØ</p>	<p>I cpfw"lk k"uqvqoguo            flimkien mar-rapport            mnkpkmw"hkpcnk"vcn-kuvwflw"            CJ723</p> <p>I cpfjqo"lk w"uqvqoguo k"            rcr rqtvk"cpypcnk"</p> <p>Ir-ter rqtv"hkpcnk"ugllgt"lk k"            rrtqxfw"ojwz"cmvt"vctf"            okpp"34-il zcjet"yctc"n-            c ct"i qvk"vcØ"            qdknvqzck ocd"lgy"vcn-            c ct" dkt"vcf-data hØmc "            vcØ" dkt"vcf-data            tgvqturgwvxk</p>

Prodott medicinali li mg. adux awtozzat



**ANNEX III**

**TIKKETTAR U HWNLGVVVC VCI TKH**

Prodott mediceinali li m.g. adux awtorizzat

Prodott mediceinali li m.g, adux awtorizzat

**A. TIKKETTAR**

VCI TKH"NK" I CPFW"LKF JGT"HWBOMMGVV"VCø"DCTTC

KARTUNA

1. ISEM TAL-RTQFQVV"OGFK KPCNK

P [ ZVJTCEKU 100 o iloN"mqp gpytev"uvgtkn  
qdknvqzczk ocd"

2. FKMLCTC \ \LQPK"VCU-UWUVCP \ C\*K+"CVVKXC\*K+

1 o N<"100 o i"vcø"qdknvqzczk ocd0

3. NKUVC"VCø"G KRLGPVK

G krlgpvk<"kuvfkpc."uqtdkvn."G655."j { ftqejnqtke"cekf."uqfkw o"j { ftqzkg."kn o c"i cnn-kplg ||lqpkkgv0

4. I CONC"HCTOC GYVKMC"W"MQPVGPPW

Mqp gpytev"i cn"uqnw ||lqpk"i cnn-kphw lqpk  
822 o i18 oN  
mwplgw ykg gf

5. OQF"VCø"MKH"W"OPGLP"LKPI CVC

Cstc"n-hwnlgv"vcø"vci tkh"scdgn"n-w w0  
KX"yctc"f-fknyk ||lqpk0  
I cn"w w"vcø"fctdc"dkuu0  
V cy fwz0

Mqfk k"ST"i cpfjc"vk k"kpmm"e"- y y0qdknvqzczk ocd-uhn0gw

80 VYKUUKLC"URG LCNK"NK"N-RTQFQVV"OGFK KPCNK" I CPFW"LKP COO"HGLP"OC"  
LKFJKTZ"W"OC"LKPVNC CSZ"OKV-VHCN

7. VYKUUKLC\*KGV+"URG LCNK"Q TC."LGMM"OG VKG C

8. FCVC"VCø"UMCFGP \ C

LKU

9. MQPFK \ \LQPKLGV"URG LCNK"VCø"MKH"LKP C GP

C gp"hk"htk 0"  
Vci onwz"hkn-htk c0"

C gp"hkn-remmgw"qtk kpcnk"ucdkgz"vknscø"okf-fcy n0

10. RTGMCY \LQPKLKV"URG LCNK" I CTKOK"VCø"RTQFQVVK"OGFK KPCNK"O JWZ"  
W CVK"LG Y"UMCTV"OKPP"FC Y P"KN-RTQFQVVK"OGFK KPCNK."LGMM"JGOO"  
D QPP

11. KUGO "W"KPFKTK \ \ "VCF-DETENTUR TAL-CYVQTK \ \ C \ \ LQPK" I CWSGI KF"  
HKU-SUQ

UHN"Rjcto cegwkecnu" Fgwvuejncpf" I odJ  
Marie-Ewtkg-Uvtcuug":  
9;75;"N¾ttcej  
Il- gt o cplc

12. PWOTW\*K+"VCN-CYVQTK \ \ C \ \ LQPK" I CWSGI KF"HSUQ

GW13142136:71223

13. NUMRU TAL-LOTT

Nqvw

14. MNCUUKHKMC \ \ LQPK" GPGTCNK"VCø"MKH"LKP I CVC

15. KUVTW \ \ LQPKLKV"FYCT"N-W W

380 KPHQTOC \ \ LQPK"DN-DTCKNNG

Il- wuvkhkmc || lqpk"dkgz"oe"lmwpz"kpmmw "kn-Dtcknng"jklc"c gwcvc0

17. KFGPVKHKMCVWT"WPKMW"- DCTEQFG"4F

dcteqfg"4F"nk"lmqmmw"n-kf gpvkhkmcvwt"wpkmw"kpmmw 0

18. KFGPVKHKMCVWT"WPKMW"- DATA LI TINQARA MILL-DPKGFGO

RE"  
UP"  
NN

VC I TKH"OKPKOW"NK" I CPFW"LKF JGT"HWS"KMMGVVK" - I CT"G YNGPKP  
VKMMGVVC"HWS"KN-KUNJETT

1. ISEM TAL-RTQFQVV"OGFK KPCNK"W"OPGLP" I CPFW"LKPI CVC

P [ ZVJTCEKU 100 o iloN"mqp gpytev"uvgtknk  
qdknvqzck ocd"  
KX"yctc"f-fknyk| |lqpk0

2. OGVQFW"VCø"MKH" I CPFW"LKPI CVC

I cn"w w"vcø"fctdc"dkuu0

3. FCVC"VCø"UMCFGP \ C

LKU

4. NUMRU TAL-LOTT

Nqvw

5. IL-KONTENUT SKONT IL-RK ."KN-XONWO."LG Y"RCTVK"KPFKXKF Y CNK

822 o i18 oN

80 Q TCLP

Prodott mediċinali li m.g, adux awtorizzat

Prodott mediceinali li m.g, adux awtorizzat

D0 HWNLGVV"VC6"VCI TKH

**Hwnlgvv"vcø"vc i tkh<"kphqt o c | |lqpk"i cmm-pazjent**

**P [ ZVJTCEKU 100 o iloN"mqp gpvtcv"i cñ"uqñw | |lqpk"i cmm-kphw lqpk  
qdknvqzczk o cd**

Dan il-rtqfqqv"ogfk kpcnk"jwyc"uw gv"i cñ"o qpkvqtc "c f f k | |lqpcnk0" Fcp"ugt"lkr rgt o gwvk" kfgpvkhkmc | |lqpk"vcø"o cñclt"vcø"kphqt o c | |lqpk" f k f c" f y c t"ku-uk i wtv<0"Kpvk"vkuvco"vi kp"dknk"tirrapporta my cnwpm y g"ghhgv"ugmqpfctlw"nk"lkuvco"Imqñqm0"Ctc"v-v o kg o "vcø"ug | |lqpk 6"dkgz"vmwp"vch"mkh"i c p f g m" vktter rqtvc"ghhgvk"ugmqpfctlk0

**Cste"ugy" fcp"kn-hwnlgvv"mqñw"scdgn"vkd f c"vw c" f k p"kn-ogfk kpc"rgtguu"nk"hk j" kphqt o c | |lqpk"  
k o r q t v e p v k"i c n k m 0**

- q o o" f c p"kn-hwnlgvv0"Lkuvco"Imqñqm"d qpp"vgt co"vcstej0"
- Lgmm"kmqñqm"cmvct"o kuvqsuklkgv."uvcsuk"nk-vcdkd."nknn-kurk lct"lgy"nknn-kphgt o kgt"vkgi gm0
- Lgmm"kmqñqm"zk"ghhgv"ugmqpfctlw"mgñng o"nk-vcdkd."nknn-kurk lct"lgy"nknn-kphgt o kgt"vkgi gm0 Dan lkpmmwfk"zk"ghhgv"ugmqpfctlw"rquukddnk"nk"o j w y k g z"gnp m c v" h ø f c p"kn-hwnlgvv0"Ctc"ug | |lqpk 60

**Høfcp"kn-hwnlgvv**

- 30 Zøkpjw"P [ ZVJTCEKU w"i cñzkgz"lkw c"
- 40 Zøi c p f g m"v m w p"v c h" s c d g n"o c"v k t k g x k"P [ ZVJTCEKU
- 50 Mkh"ugt"lki c v c"P [ ZVJTCEKU
- 60 Ghhgvk"ugmqpfctlk"rquukddnk"
- 70 Mkh"vc gp"P [ ZVJTCEKU
- 80 Mqpvgpw"vcñ-r c m m g v v" w" k p h q t o c | | l q p k" q t c

**1. Zøkpjw"P [ ZVJTCEKU w"i cñzkgz"lkw c**

P [ ZVJTCEKU hk j"ku-uwuvc p | c"cvkxc"qdknvqzczk o cd0"Qdknvqzczk o cd"jwyc"cpvkqtr"o qpqñqpcnk."vkr"vcø"rtqvgkpc"nk"vg gn"o co"v"vkpcvkc"v-vquukp"rtqfqqv"o knn-dcvgtlk"nk"lkmmcy cy"n-cpvte g0

P [ ZVJTCEKU lkw c"o co"ogfk k p k"cpvkdklqv k"dkgz"lkvtevc"cfwvkw"vhen"dn-cpvte g"mme y c v c"o kv-vg kf"vc p-khu"tal-dcvgtlk"\*cpvte g"nk"kvkvg g f"o c p-khu+0"

P [ ZVJTCEKU lkuvco"lkw c"ymqñ"lgmm"uvclv" glv"homwpvcv"o co"dcvgtlk"lgy"urqtk"vcñ-cpvte g"k f c"o ø i c p f g m"n-gd f c"ukpvq o w"vcñ-o c t f c."w"lgmm"o c"lmwp"j g o o"n-gd f c"v t c w c o g p v" k g q t" f k u r q p k d d n k" w" z k g t c s 0

**2. Zøi c p f g m"v m w p"v c h" s c d g n"o c"v k t k g x k"P [ ZVJTCEKU**

**O c"i c p f g m z"v k p i c v c"P [ ZVJTCEKU**

- lgmm"kpvk"cmngt kmw"i cñ"qdknvqzczk o cd"lgy"i cñ"zk"uwuvc p | c"q t c"vcø" f k p"kn-ogfk k p c"\*k o p k n c" h k u - u g | | l q p k" 8 + 0

**Vykuuklgy" w" r t g m c y | l q p k l g v"**

Kellem lit-vcdkd."nknn-kurk lct"lgy"nknn-kphgt o kgt"vkgi gm"scdgn"vkpi c v c"P [ ZVJTCEKU<

lgmm"kpvk"\*lgy"kv-vkhgnlvkhnc"vkgi gm+"i c p f g m"kp v q n g t e p | c" g t g f k v c t l c"i c n" h t w e v q u g" \* J H K + . " f k u w t d" g p g v k m w" t e t k . " l g y" l g m m" k v - v k h g n l v k h n c" v k g i g m" o c" l k u v c z l v k u v e z" l k d s c ø l v k d s c ø" l k g w l v k g w" k m g n" l g y" z q t d" g n w" o k p c d d c" n k" l q u u w l v q u u j c" o c" l k h n c z l v k h n c z . " l k t t g o g v v k l v k t t g o g v v k" l g y" k m q n n w l k m q n j c" g h h g v k" o j w z" r l c g x q n k" d c n" p g h c" h k - c s s . " w k i " h n - k u v q p m w" l g y" f k l c t g c 0

Zk"mwncpv"tgc | |lqpklgy"cmngt k k"nk"lkuv i w"lug w"yctc"v-vtcvc o gpv" d ø P [ ZVJTCEKU lkuv i w"lmwpw" ugxgtk0"Vkuvco"vkpi c v c"cpvkuvco kpc"scdgn"o c"vkpi c v c"P [ ZVJTCEKU dkgz"lkvpc scu"kt-tkumlw"vcø" t g c | | l q p k l g v" c m g t k k 0

**Ogfk kpk"q tc"w"P [ZVJTCEKU**

I kf"nk-vcdkd"lgy"nknn-kurk lct"vki gm"lgmm"sgf"vw c."w clv"fcn l-c ct"lgy"vkucv"vw c"zk"ogfk kpk"q tc0  
Vkuvcv"vkpi cve"cpvkdklvk k\*g 0"ekrtqhnqzcekp+"dkgz"li kpw"hkv-trattament tal-cpvtc g"nk"vkvvk gf"o cp-pkhu0

**Vscnc"wtgffki**

Lgmm"kpvk"vsknc"lgy"sgf"vtgffce."vc ugd"nk"vkucv"vmwp"vsknc"lgy"sgf"vkr rlepc"nk"lmqnmqmvctdklc."kvnqd"ki-parir  
tat-vcdkd"vki gm"scdgn"vkpi cvcngm"fkp"kn-ogfk kpc0

Ojwz"oci twh"lgmm"P [ZVJTCEKU mkucvz"kmwp"vcv"uctc"i cv-vctdklc"hn- wh"vki gm0

Ojwz"oci twh"lgmm"P [ZVJTCEKU i cffkz"hn- cnkd"vcu-ukfgt0"Kpvk"v-vcdkd"vki gm"ugt"vkffg kgfw"  
lgmm"i cpfmgz"vtgffce"yctc"nk"vkt kgxk"P [ZVJTCEKU0

**Ugysep"w"v cffko"vcv"o cipi**

P [ZVJTCEKU lkuvcv"lkmmy c"ghhg"vkv"ugmqpfctk"d cn"wi "vcv"tcu."uvwtfcogpv"i glc"wtkogvet0"FcP"  
lkuvcv"lchhg"vkv"n- kn"vki gm"dkgz"kuuvs"lgy"v cffgo"o cipi0

**P [ZVJTCEKU hkj"uqtdkvqn"G642+**

Uqtdkvqn"jwyc"uqtu"vcv"htwevqg"\*vkr"vcv" | qmmqt+0"lgmm"kpvk"\*lgy"kdpgmldkpvgm+"i cffgm"kpvmngtcp|c"  
gtgfkvtlc"i cn"htwevqg"\*jgtgfkvt{"htwevqg"kpvmngtcepe"- JHK+."fkuvtd" gpgvkmw"tctk."kv-vcdkd"vki gm"  
lkuvcv"lkffg kgfk"nk"\*lgy"kv-vkhgnlvkhnc"vki gm+"o0i cffgmz"vkpi cve"fkp"kn-ogfk kpc0"Rc|lgpvk"dv JHK"oc"  
lkuvi wz"kmkuutw"n-htwevqg."nk"lkuvcv"lkmmy c"ghhg"vkv"ugmqpfctk"ugt0

I cffgm"vi kf"nk-vcdkd"vki gm"scdgn"oc"vkpi cve"fkp"kn-ogfk kpc"lgmm"kpvk"\*lgy"kdpgmldkpvgm+"i cffgm"  
JHK"lgy"lgmm"kv-vkhgnlvkhnc"vki gm"oc"lkuvcv"lkuvcv"lkg wlykg w"knng"lgy"zqtd" gnw"cmvet"i cz"kuuwjqo"  
oc"lkhn wz."lktgogv"lgy"kuuw"ghhg"vkv"urle gxqk"d cn"pgh c."dwi cy ykg "hn-kuvqpmw"lgy"fkltgc0

**P [ZVJTCEKU hkj"uqfkw o**

Din il-ogfk kpc"hkjc epscu"okpp"3 o o qn"uqfkw o"\*45 o i+"h0mwnn"mwplg"v"vcv"8 o N"vcv"P [ZVJTCEKU."  
lk khgk"guugp|lcnogpv"÷ kgngu"o ku-uqfkw o0

**3. Mkh"ugt"lkipi cve"P [ZVJTCEKU**

P [ZVJTCEKU ugt"lkipi cve"ngm"okpp"vcdkd"lgy"kphtogkt0"kv-vcdkd"lgy"n-kphtogkt"vki gm"ugt"  
lkmcmwnc"ff-q c"umqpv"kn-rk "vki gm"lgy"vcv-vkhgnlvkhnc"vki gm+0

It-vcdkd."n-kphtogkt"lgy"n-kurk lct"vki gm"ugt"k gll"n-ogfk kpc"i cmn-kphw lqpk0"  
ku-uqnv||lqpk"vcv"P [ZVJTCEKU ugt"vkpi cve"d cnc"kphtogkt"lqpk"\*ftrr+"hws"rgtlqfw"vcv";2 okpvc" q"  
xkpc." gpgtcnogpv"hd-fkigi "vki gm0"Ugt"vk k"o o qpvqtlcv"ycsv"nk"vkpi cve"P [ZVJTCEKU w"ymqnm"  
i cn"okm-kpsc"ukgi c"yctc"n-kphw lqpk0

Scdgn"oc"vkpi cve"P [ZVJTCEKU." gpgtcnogpv"vkpi cve"ogfk kpk"dkgz"lkr rtgxlgpw"lgy"kpessuw"t-  
tgc||lqpkkgv"cmgt k k0

Lgmm"i cffgm"cmvet"okuvqsukkgv"fyct"n-w w"vcv"fkp"kn-ogfk kpc."uvcsv"nk-vcdkd."nknn-kurk lct"lgy"nknn-  
kphtogkt"vki gm0

**4. Ghhg"vkv"ugmqpfctk"rquukddnk**

D"cn"mwnn"ogfk kpc"q tc."fkp"kn-ogfk kpc"vkucv"vkmmy c"ghhg"vkv"ugmqpfctk."i cmngoo"oc"lkfjtwz"  
h0mwncff0

I kf"nk-vcdkd"vki gm"lgy"nknn-rgtuwpc"nk"vcv"vkm"n-kphw lqpk"okppwhkj"lgmm"vkppqvc"zk"ykg gf"okm-  
ghhg"vkv"ugmqpfctk"nk" gllkpc"



cmm."tczz."svwi "vcø"pkhu"lgy"v ct kt"- fcy p"lkui w"lmwpw"ukplcnk"vcø"tgc | |lqpk"cnngt kmc"\*ugpukvkvxkxk<"  
g guukxc+0

### Ghhgvk"ugmqpfctlk"q tc"døP [ ZVJTCEKU lkpmnwfw<

Mq o wpk\*Ikuvi w"lchhgvy cy"uc"rgtuwpc"3" o kpp"mwnn"32+

- W ki "vcø"teu
- Uqi nc
- W ki "hku-ukv"vcn-kphw lqpk
- cmm."tczz"vcnfc."kpmnw "tczz"ko scddg "dkn- cmm"\* qttksklc+

O j wz"mq o wpk \*lkui w"lchhgvy cy"uc"rgtuwpc"3" o kpp"mwnn"322+

- Tgc | |lqpklgv"cnngt k k
- Uvwtfc o gpv
- Tnemnim
- Ugpukvkvxkxk<"xk ycnk"i cf-fcy n"\*hqvqhdklc+
- Umw o fkv<"hkn-ykfpglp
- Kttkvc | |lqpk"hkn-itk o glp
- Xw k" ctzc
- Mqp guvlqpk"vcu-ukpwu
- Svw i "vcø"pkhu
- W ki "hkz-zwhhvglp
- Gm goc."vsczzkt"tal- knfc
- Mqpvtc | |lqpklgv"kpqxqpvctlk"vcn- o wumqmw."urc ok"vcn- o wumqmw
- I glc
- Vgtvkt"vcø"detf"\*ugpuc | |lqpk"vcø"mgu c+
- Umw o fkv<"hku-ukfgt"
- W ki "dø o qf" gpgtcnk."w w ki "nk"lchhgvy c"t- tk nglpkf- fkti clp."ku-ukfgt."kz-zg fcs."kn- o wumqmk."
- il-nkicogpvk."n-i gtws."lgy"n-i cfc o"
- Pgh c."w ki "lgy"hgdkvg"\*xkpk"kphlc o o cvk+"hku-ukv"vcn-kphw lqpk

### Terrwtvet"vcn-ghhgvyk"ugmqpfctlk

Lgmm"kmqnmqm"zk"ghhgvy"ugmqpfctlw."mgng o "nk-vedkd."nkn-kurk lct"lgy"nkn-kphgt o kgt"vkgi gm0 Fcp"lkpmnwfk"  
zk"ghhgvy"ugmqpfctlw"rquukddnk"nk" o j w y l g z "gngpmcv"ho fcp"kn-hwnlgv0" Vkuvcø" y m q m "vktter rqtvc"ghhgvyk"  
ugmqpfctlk" fktgvvc o gpv" rgt o g | |vcu-ukv g o c"vcø"ter rwtvet"pc | |lqpcnk" o pk nc"ho [Crrgpfk k V0](#)"Dknk"  
tirrapporta l-ghhgvyk"ugmqpfctlk"vkuvcø"vi kp"dkgz"vk k" r r t q x f w v c "c m v c t "k p h q t o c | |lqpk" f y c t "k u - u k i w t v < " v c ø "  
din il- o g f k k p c 0

### 5. Mkh"vc gp" P [ ZVJTCEKU

q o o "din il- o g f k k p c " h g l p " o c " v k f j k t z " w " o c " v k p v n c c s z " o k v - v h c n 0

Vw ez" fkp"kn- o g f k k p c " y e t c " f - f e v c " v c ø " o g v c " v k u m e f k " n k " v k f j g t " h w s " k n - m c t v w p c " w " h w s " k v - v k m m g v v c " y e t c " L K U 0 " K f -  
f e v c " v c ø " o g v c " v k u m e f k " v k t t g h g t k " i c n n - c c t " w t p e v c " v c ø " f e m " k z - z c j e t 0

C gp"hk"htk "4ÅE - :ÅE+0"

Vci onyz"hkn-htk c0

C gp"hkn-rccmmgv"qtk kpcnk"ucdkgz"vknscø" okf-fcy n0

Yetc" f-fkn y k | |lqpk" hødqt c"vcn-kphw lqpk."n-kuvcdknkxk<"mk o kmc."hk kmc" w" o k m t q d k m c " y c s v " n - w " w " p v y g t k g v "  
i cn": uki cv"ho v g o r g t e v w t c " v c n - m c o t c " \* 4 2 Å E - 4 7 Å E + " l g y " h k n - h t k " \* 4 Å E - : E + 0

Yetc" f-fkn y k | |lqpk"vcø" P [ ZVJTCEKU høukt k p i c " i c n n - k p h w l q p k . " f k p " i c p f j c " v k p i c v c " k o o g f l e v c o g p v "  
w" o c " v k p c k p z 0 " M y c n w p m y g " r t q f q v " n k " o c " l m w p z " k p v w c " i c p f w " l k p v t g o c 0

80 Mqpvppw"vcn-rcmmgvw"wkphqt o c | |lqpk"q tc

Zøhkj"P [ ZVJTCEKU

- Ku-uwuvcp|c"cvkxc"jk"qdknvqzczk o cd0"Mwmn" o N"vcø"mqp gpvtcv"hkj"322 o i"vcø"qdknvqzczk o cd0" Mwplgvw"ykg gf"vcø"8 o N"hkj"822 o i"vcø"qdknvqzczk o cd0
- N-e krIgpvil-q tc"jw o c"kvkfkpc."uqtdkvqn"\*G642+."rqn{uqtdcvg :2"\*G655+."j {ftqejnqtke"cekf" \*G729+"w"uqfkw o "j {ftqzkfg"\*G746+0"Ctc"ymqmn"ug| |lqpk"4"øP [ ZVJTCEKU hkj "uqtdkvqnø0

Mkh"lkfjgt"P [ ZVJTCEKU w"n-mqpvppw"vcn-pakkett

P [ ZVJTCEKU jwyc"mqp gpvtcv"i cn"uqnw| |lqpk" ct"i cn"qrcngzzgpvk."dnc"mwnwt"i cn"kuhet" ct"i cn" kuhet" ct"hkn-mcpggnc0

P [ ZVJTCEKU jwyc"fkurqpkddnk"hørcmmgvk"nk"hkjq o "mwplgvw"ykg gf0

Fgyppwvt"vcn-Cyvqtk| |c| |lqpk"i cv-Vsgi kf"hku-Uws

UHN"Rjct o cegwkecnu" Fgwuejnepf" I o d J

Marie-Ewtkg-Uvtcuug" :

9;75;"N¾ttcej

Il- gt o cplc

Ocpkhwvt"

Cegtvrjct o c"D0X0

Dquejuvtccv"73

6:33" I E."Dtgfc

N-Olanda

Fcp"kn-hwnlgw"mkgp"tkxgfw"n-c ct"hö

Din il-ogfk kpc"mkpgv"cyvqtk| |cvc"vc v"÷ ktmwuvcp|k" g g| |lqpenkø0" Fcp"khkuugt"nk" o kp eddc"nk"n-marda jkle"tctk"w"i cn"tc wplkgv"vcø"gvkmc"mkgp"k o rquukddnk"nk"vkpmkugd"kphqt o c | |lqpk"mq o rnwvc"fyct"fkp"il-ogfk kpc0

N-C gp|kle"Gytqrgc"i cmm-Ogfk kpk"ugt"vkttgxgfk"mwmm"vkr"vcø"kphqt o c | |lqpk" fkc"fyct"fkp"kn-ogfk kpc" mwmm"ugpc"w"fcv"kn-hwnlgw"ugt"lk k" c qtpcv"mkh"og vkg 0

Uqtuk"q tc"vcø"kphqt o c | |lqpk

kphqt o c | |lqpk"fgvenlcvc"fyct"fkp"kn-ogfk kpc"vkpued hws"ku-uky"ngvvtqpkmw"vcn-C gp|kle"Gytqrgc"i cmm-Ogfk kpk"<[jwvrllyy0goc0gw0qr0gw0](#)> J go o "wmqmn"nkpmu"i cn"ukvk"ngvvtqpk k"q tc"fyct"o ctf"tctk"w" mwtc0

Dan il-hwnlgw"jwyc"fkurqpkddnk"hkn-nkpi yk"mqmjc"vcn-WG| GG"hku-uky"ngvvtqpkmw"vcn-C gp|kle"Gytqrgc"i cmm-Ogfk kpk0

Kmvet"vci tkh"<[yy0qdknvqzczk o cd-uhn0gw](#)> Mqfk k"ST"i cfw"lk k"kpmmw "