



*Agenzia Italiana del Farmaco*  
**AIFA**

**Unità Coordinamento Segreterie Organismi Collegiali**

- Odg Comitato Prezzi e Rimborso (CPR) riunione del 23, 24 e 25 febbraio 2016

23 Febbraio 2016 (ore 11.00/19.30)

Esame procedure rinviate nel precedente CPR del 26, 27 e 28 Gennaio 2016

ARGOMENTI A CARATTERE GENERALE CPR

- Protelos e Osseor (anelato di stronzio) - Ripiano sfondamento tetto di spesa

Istruttoria CPR

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u>  | <u>Farmaco</u> | <u>Azienda</u>          |
|----------------|------------------|--------------------------|----------------|-------------------------|
| <u>10657</u>   | <u>C</u>         | <u>insulina degludec</u> | <u>Tresiba</u> | <u>Novo Nordisk a/s</u> |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u>         | <u>Farmaco</u>        | <u>Azienda</u>   |
|----------------|------------------|---------------------------------|-----------------------|--|
| <u>10831</u>   | <u>N</u>         | <u>fluticasone</u>              | <u>Pavetod</u>        | <u>Genetic s.p.a.</u>  |
| <u>10832</u>   |                  |                                 | <u>Flugenix</u>       |  |
| <u>11164</u>   | <u>M</u>         | <u>adrenalina</u>               | <u>Jext</u>           | <u>Alk-abellä" a/s</u>   |
| <u>11105</u>   | <u>C</u>         | <u>imatinib</u>                 | <u>Imatinib medac</u> | <u>Medac gesellschaft fur klinische<br/>spezialpreparate mbh</u> |
| <u>11172</u>   | <u>M</u>         | <u>polistirensolfonat<br/>o</u> | <u>Sorbisterit</u>    | <u>Fresenius medical care<br/>nephrologica deutschland gmbh</u>  |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>                 | <u>Azienda</u>                |
|----------------|------------------|-------------------------|--------------------------------|-------------------------------|
| <u>11152</u>   | <u>M</u>         | <u>fosfomicina</u>      | <u>Infectofos</u>              | <u>Di renzo s.r.l.</u>        |
| <u>10328</u>   | <u>C</u>         | <u>insulina lispro</u>  | <u>Humalog</u>                 | <u>Eli lilly nederland bv</u> |
| <u>11191</u>   | <u>M</u>         | <u>noradrenalina</u>    | <u>Noradrenalina aguettant</u> | <u>Di Renzo s.r.l.</u>        |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>           | <u>Azienda</u>                   |
|----------------|------------------|-------------------------|--------------------------|----------------------------------|
| <u>10429</u>   | <u>N</u>         | <u>metformina</u>       | <u>Glucophage unidie</u> | <u>Bruno farmaceutici s.p.a.</u> |

|              |          |                     |                 |   |
|--------------|----------|---------------------|-----------------|---|
| <u>10786</u> |          |                     | <u>Slowmet</u>  | <u>Istituto biochimico n savio s.r.l.</u> |
| <u>10459</u> | <u>C</u> | <u>obinutuzumab</u> | <u>Gazyvaro</u> | <u>Roche registration limited</u>         |
| <u>10838</u> |          | <u>varidenafil</u>  | <u>Levitra</u>  | <u>Bayer pharma ag</u>                    |
| <u>11163</u> | <u>N</u> | <u>testosterone</u> | <u>Sustanon</u> | <u>Aspen pharma trading limited</u>       |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>   | <u>Azienda</u>   |
|----------------|------------------|-------------------------|------------------|--|
| <u>10013</u>   | <u>N</u>         | <u>dactinomicina</u>    | <u>Cosmegen</u>  | <u>Orphan europe sarl</u>  |
| <u>10903</u>   |                  | <u>desametasone</u>     | <u>Dermadex</u>  | <u>Teofarma s.r.l.</u>   |
| <u>10729</u>   | <u>C</u>         | <u>fondaparinux</u>     | <u>Arixtra</u>   | <u>Aspen pharma trading limited</u>  |
| <u>10780</u>   | <u>N</u>         | <u>metolazone</u>       | <u>Zaroxolin</u> | <u>Teofarma s.r.l.</u>   |
| <u>10735</u>   | <u>N</u>         | <u>triesifenidile</u>   | <u>Artane</u>    | <u>Teofarma s.r.l.</u>   |
| <u>10316</u>   | <u>C</u>         | <u>tadalafil</u>        | <u>Cialis</u>    | <u>Eli Lilly Italia spa</u>  |
| <u>10815</u>   | <u>N</u>         | <u>testosterone</u>     | <u>Testovis</u>  | <u>Laboratorio farmaceutico sit specialita' igienico terapeutiche s.r.l.</u> |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u>           | <u>Farmaco</u>   | <u>Azienda</u>                                 |
|----------------|------------------|-----------------------------------|------------------|--|
| <u>10423</u>   | <u>C</u>         | <u>brinzolamide + brimonidina</u> | <u>Simbrinza</u> | <u>Alcon laboratories (uk) ltd.</u>            |
| <u>10774</u>   | <u>C</u>         | <u>empagliflozin/metformina</u>   | <u>Synjardy</u>  | <u>Boehringer ingelheim international gmbh</u> |

**24 Febbraio 2016 (ore 09.00/19.30)**

**ARGOMENTI A CARATTERE GENERALE CPR**

- **Approvazione Verbale generale del 26 27 e 28 Gennaio 2016**
- **Metotrexato hospira (metotrexato)**

**Convocazione CPR**

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u> | <u>Azienda</u>              | <u>Orario</u> |
|----------------|-----------------------|-------------------------|----------------|-----------------------------|---------------|
| <u>10797</u>   | <u>M</u>              | <u>esomeprazolo</u>     | <u>Esopral</u> | <u>Bracco s.p.a.</u>        | <u>10:00</u>  |
| <u>10579</u>   | <u>C</u>              | <u>voriconazolo</u>     | <u>Vfend</u>   | <u>Pfizer italia s.r.l.</u> | <u>10:45</u>  |

| <u>Pratica</u> | <u>Procedura</u> | <u>Principio attivo</u>   | <u>Farmaco</u> | <u>Azienda</u>           | <u>Orario</u> |
|----------------|------------------|---|----------------|--------------------------|---------------|
| <u>11398</u>   | <u>M</u>         | <u>(Paleo odoroso (anthoxantum odoratum l.), erba mazzolina (dactylis glomerata l.),loietto perenne (lolium perenne l.), codolina</u> | <u>Oralair</u> | <u>Stallergenes S.A.</u> | <u>11:30</u>  |

|              |          |  |                |                       |              |
|--------------|----------|--|----------------|-----------------------|--------------|
|              |          | <u>comune (phleum pratense l.), erba fienarola (poa pratensis l.)</u>                                      |                |                       |              |
| <u>11399</u> | <u>M</u> | <u>estratto di allergeni standardizzato di una pianta della famiglia delle graminacee, phleum pratense</u> | <u>Grazax</u>  | <u>Alk-Abelló A/S</u> | <u>12:15</u> |
| <u>10352</u> | <u>M</u> | <u>levodopa e inibitori della decarbossilasi</u>   | <u>Duodopa</u> | <u>Abbvie s.r.l.</u>  | <u>15:00</u> |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>    | <u>Azienda</u>                | <u>Orario</u> |
|----------------|-----------------------|-------------------------|-------------------|-------------------------------|---------------|
| <u>10380</u>   | <u>C</u>              | <u>vortioxetina</u>     | <u>Brintellix</u> | <u>Lundbeck Italia s.p.a.</u> | <u>15:45</u>  |

#### Convocazione Generici CPR

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>     | <u>Farmaco</u>                    | <u>Azienda</u>                                      | <u>Orario</u> |
|----------------|-----------------------|-----------------------------|-----------------------------------|---|---------------|
| <u>11249</u>   | <u>M</u>              | <u>azitromicina</u>         | <u>Azylung</u>                    | <u>Inca-pharm s.r.l.</u>                            | <u>16:30</u>  |
| <u>11353</u>   |                       | <u>dexrazoxano</u>          | <u>Enaxozar</u>                   | <u>Pharmaselect international beteiligungs gmbh</u> | <u>16:45</u>  |
| <u>11209</u>   |                       | <u>esmololo</u>             | <u>Esmocard</u>                   | <u>Orpha-devel handels und vertriebs gmbh</u>       | <u>17:00</u>  |
| <u>11208</u>   |                       |                             | <u>Esmocard</u>                   |   |               |
| <u>11250</u>   |                       | <u>stronzio ranelato</u>    | <u>Stronzio ranelato tecnigen</u> | <u>Tecnigen s.r.l.</u>                              | <u>17:15</u>  |
| <u>11234</u>   |                       | <u>tenofovir disoproxil</u> | <u>Tenofovir disoproxil teva</u>  | <u>Teva italia s.r.l.</u>                           | <u>17:30</u>  |

**25 Febbraio 2016 (ore 09.00/17.00)**

#### Convocazione Generici CPR

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>       | <u>Farmaco</u>                   | <u>Azienda</u>   | <u>Orario</u> |
|----------------|-----------------------|-------------------------------|----------------------------------|--|---------------|
| <u>11107</u>   | <u>M</u>              | <u>acido gadoterico</u>       | <u>Dotagraf</u>                  | <u>Bayer s.p.a.</u>  | <u>09:45</u>  |
| <u>11257</u>   |                       | <u>timololo, associazioni</u> | <u>Brimonidina e timololo eg</u> | <u>Eg s.p.a.</u>   | <u>10:00</u>  |
| <u>11256</u>   |                       | <u>bendamustina</u>           | <u>Bendamustina eg</u>           | <u>Eg s.p.a.</u>   | <u>10:15</u>  |
| <u>11296</u>   |                       | <u>bendamustina</u>           | <u>Bendamustina medac</u>        | <u>Medac gesellschaft fur klinische spezialpreparate mbh</u> |               |
| <u>11188</u>   |                       | <u>bupropione</u>             | <u>Bupropione sandoz</u>         | <u>Sandoz s.p.a.</u>   | <u>10:30</u>  |

|              |  |                    |                                 |                                  |              |
|--------------|--|--------------------|---------------------------------|----------------------------------|--------------|
|              |  | <u>cloridrato</u>  |                                 |                                  |              |
| <u>11262</u> |  | <u>rasagilina</u>  | <u>Rasagilina accord</u>        | <u>Accord healthcare limited</u> | <u>10:45</u> |
| <u>11263</u> |  |                    | <u>Rasagilina sandoz</u>        | <u>Sandoz s.p.a.</u>             |              |
| <u>11183</u> |  | <u>metotrexato</u> | <u>Aflamet</u>                  | <u>Sigillata limited</u>         | <u>11:15</u> |
| <u>11286</u> |  |                    | <u>Metotrexato doc generici</u> | <u>Doc generici srl</u>          |              |
| <u>11162</u> |  |                    | <u>Metotrexato doc generici</u> |                                  |              |
| <u>11294</u> |  |                    | <u>Metother</u>                 | <u>Accord healthcare limited</u> |              |
| <u>11267</u> |  |                    | <u>Metotrexato sigillata</u>    | <u>Sigillata limited</u>         |              |
| <u>11184</u> |  |                    | <u>Husmetabo</u>                |                                  |              |
| <u>11181</u> |  | <u>Velos</u>       | <u>Visufarma s.p.a.</u>         |                                  |              |

### Istruttoria CPR

- Specialità medicinale Baxogar (acido ibandronico) - Ricorso TAR Lazio
- Specialità medicinale Keneil (gabapentin) - Ricorso TAR Lazio

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>  | <u>Farmaco</u>  | <u>Azienda</u>                         |
|----------------|-----------------------|--|-----------------|--|
| <u>11088</u>   | <u>C</u>              | <u>blinatumomab</u>  | <u>Blincyto</u> | <u>Amgen europe b.v.</u>               |
| <u>11082</u>   |                       | <u>carfilzomib</u>   | <u>Kyprolis</u> |  |
| <u>10427</u>   |                       | <u>concentrato di enzimi proteolitici arricchiti con bromelina</u> | <u>Nexobrid</u> | <u>Mediwound germany gmbh</u>          |
| <u>11203</u>   |                       | <u>efmoroctocog alfa</u>   | <u>Elocta</u>   | <u>Swedish orphan biovitrum s.r.l.</u> |
| <u>10762</u>   |                       | <u>everolimusâ</u>   | <u>Votubia</u>  | <u>Novartis europfarm ltd</u>          |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>  | <u>Azienda</u>   |
|----------------|-----------------------|-------------------------|-----------------|--|
| <u>10676</u>   | <u>C</u>              | <u>dalbavancina</u>     | <u>Xydalba</u>  | <u>Aziende chimiche riunite angelini francesco acraf spa</u> |
| <u>10474</u>   |                       | <u>mirabegron</u>       | <u>Betmiga</u>  | <u>Astellas pharma s.p.a.</u>                                |
| <u>10757</u>   |                       | <u>pembrolizumab</u>    | <u>Keytruda</u> | <u>Msd italia s.r.l.</u>                                     |
| <u>10537</u>   |                       | <u>secukinumab</u>      | <u>Cosentyx</u> | <u>Novartis europfarm ltd</u>                                |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>                  | <u>Farmaco</u>  | <u>Azienda</u>   |
|----------------|-----------------------|--|-----------------|--|
| <u>11117</u>   | <u>M</u>              | <u>formoterolo e altri anti-asmatici</u> | <u>Pulmelia</u> | <u>Sagaem for life di stefano ceccarelli e c. S.a.s.</u> |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>  | <u>Azienda</u>           |
|----------------|-----------------------|-------------------------|-----------------|--------------------------|
| <u>11198</u>   | <u>M</u>              | <u>gadobutrolo</u>      | <u>Gadovist</u> | <u>Bayer s.p.a.</u>      |
| <u>10756</u>   | <u>C</u>              | <u>panitumumab</u>      | <u>Vectibix</u> | <u>Amgen europe b.v.</u> |

|              |  |                    |                  |                               |
|--------------|--|--------------------|------------------|-------------------------------|
| <u>10478</u> |  | <u>pasireotide</u> | <u>Signifor</u>  | <u>Novartis europharm ltd</u> |
| <u>10794</u> |  | <u>raltegravir</u> | <u>Isentress</u> | <u>Msd italia s.r.l.</u>      |
| <u>10269</u> |  | <u>riociguat</u>   | <u>Adempas</u>   | <u>Bayer pharma ag</u>        |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>                | <u>Azienda</u>                                     |
|----------------|-----------------------|-------------------------|-------------------------------|--|
| <u>11014</u>   | <u>M</u>              | <u>aciclovir</u>        | <u>Aciclovir hikma</u>        | <u>Hikma farmaceutica (portugal) s.a.</u>          |
| <u>11054</u>   |                       | <u>claritromicina</u>   | <u>Claritromicina hikma</u>   |  |
| <u>11210</u>   |                       | <u>gemcitabina</u>      | <u>Gemcitabina sun pharma</u> | <u>Sun pharmaceutical industries (europe) b.v.</u> |
| <u>10884</u>   |                       | <u>linezolid</u>        | <u>Linezolid infomed</u>      | <u>Infomed fluids srl</u>                          |
| <u>11226</u>   | <u>C</u>              | <u>ritonavir</u>        | <u>Norvir</u>                 | <u>Abbvie ltd</u>                                  |
| <u>11213</u>   |                       | <u>travoprost</u>       | <u>Travatan</u>               | <u>Alcon laboratories (uk) ltd.</u>                |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>    | <u>Farmaco</u>    | <u>Azienda</u>                            |
|----------------|-----------------------|----------------------------|-------------------|---|
| <u>11073</u>   | <u>C</u>              | <u>insulina glargine</u>   | <u>Abasaglar</u>  | <u>Eli lilly regional operations gmbh</u> |
| <u>10790</u>   | <u>M</u>              | <u>levotiroxina sodica</u> | <u>Syntroxine</u> | <u>Bracco s.p.a.</u>                      |
| <u>10792</u>   | <u>N</u>              | <u>levotiroxina sodica</u> | <u>Tiche</u>      | <u>Ibsa farmaceutici italia s.r.l.</u>    |
| <u>10793</u>   | <u>C</u>              | <u>raltegravir</u>         | <u>Isentress</u>  | <u>Msd italia s.r.l.</u>                  |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>                        | <u>Farmaco</u>   | <u>Azienda</u>   |
|----------------|-----------------------|--|------------------|--|
| <u>10003</u>   | <u>C</u>              | <u>agomelatina</u>                             | <u>Valdoxan</u>  | <u>Les laboratoires servier</u>  |
| <u>10002</u>   |                       |  | <u>Thymanax</u>  | <u>Servier (ireland) industries limited</u>                                |
| <u>9565</u>    | <u>M</u>              | <u>fattore di von willebrand</u>               | <u>Wilfactin</u> | <u>Lfb - laboratoire francais du fractionnement et des biotechnologies</u> |
| <u>11193</u>   |                       | <u>fattori ix, ii, vii e x in associazione</u> | <u>Confidex</u>  | <u>Csl behring gmbh</u>  |
| <u>11104</u>   | <u>C</u>              | <u>imiquimod</u>                               | <u>Zyclara</u>   | <u>Meda pharma s.p.a.</u>  |
| <u>10070</u>   | <u>M</u>              | <u>diclofenac</u>                              | <u>Solaraze</u>  | <u>Almirall s.a.</u>   |
| <u>10996</u>   | <u>M</u>              | <u>menotropina</u>                             | <u>Meriofert</u> | <u>Ibsa farmaceutici italia s.r.l.</u>                                     |
| <u>11238</u>   |                       | <u>testosterone</u>                            | <u>Tostrex</u>   | <u>Prostrakan limited</u>  |
| <u>10189</u>   | <u>C</u>              | <u>vernakalant cloridrato</u>                  | <u>Brinavess</u> | <u>Cardiome uk limited</u>   |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u>  | <u>Azienda</u>                       |
|----------------|-----------------------|-------------------------|-----------------|--------------------------------------|
| <u>10991</u>   | <u>N</u>              | <u>aciclovir</u>        | <u>Acy</u>      | <u>Farmigea s.p.a.</u>               |
| <u>10959</u>   | <u>M</u>              | <u>tretinoina</u>       | <u>Vesanoid</u> | <u>Cheplapharm arzneimittel gmbh</u> |
| <u>10735</u>   | <u>N</u>              | <u>triesifenidile</u>   | <u>Artane</u>   | <u>Teofarma s.r.l.</u>               |

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u>       | <u>Farmaco</u> | <u>Azienda</u>                     |
|----------------|-----------------------|-------------------------------|----------------|------------------------------------|
| <u>10922</u>   | <u>C</u>              | <u>atazanavir/cobicistat</u>  | <u>Evotaz</u>  | <u>Bristol myers squibb s.r.l.</u> |
| <u>10921</u>   | <u>M</u>              | <u>timololo, associazioni</u> | <u>Loyada</u>  | <u>Santen italy srl</u>            |

**ADDENDUM CPR**

**Istruttoria CPR**

| <u>Pratica</u> | <u>Tipo Procedura</u> | <u>Principio attivo</u> | <u>Farmaco</u> | <u>Azienda</u>      |
|----------------|-----------------------|-------------------------|----------------|---------------------|
| <u>10693</u>   | <u>C</u>              | <u>lenvatinib</u>       | <u>Lenvima</u> | <u>Eisai s.r.l.</u> |