afssaps
Agence française de sécurité sanitaire des produits de santé

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CTA application form/advanced therapies
Afssaps comments

Remark 1 : In the part D3, it is proposed to avoid details on the composition of the advanced therapy MP, so the section D3.11.3. 4 "Combined ATIMP involving a medical device" should be deleted because it is not a category of ATIMP entailed by regulation (EC) n°1394/2007 on advance therapy medicinal procduct (article 1.a).
It is proposed to delete this section and to add items regarding the devices possibly combined in the section D.4, D.5 and D.6.
In addition, details on the device should be provided in the IMPD. In this application form information on the status of the medical device (CE mark or not) should be required as well as the intend purpose of the marketed device.

It is proposed to delete section « D.3.11.4 "product that includes a medical device other than a combined ATIMP" because it doesn't exist.

Remark 2 : We propose to introduce into section D.4 :
D.4.3.Somatic cell therapy product containing devices (Medical device, scaffold, matrix, biomaterial…)

- D.4.3.1 Give a brief description of the device :
- D.4.3.2 What is the name of the device ?
- D.4.3.3 Is this Medical Device implantable — yes ☐ no ☐
- D.4.3.4 Does this product contain :
  - D.4.3.4.1 A medical device — yes ☐ no ☐
    - D.4.3.4.1.1 Does this Medical Device have a CE mark ? — yes ☐ no ☐
    - D.4.3.4.1.2 The notified body is :
  - D.4.3.4.2 Biomaterials ? — yes ☐ no ☐
  - D.4.3.4.3 Scaffolds ? — yes ☐ no ☐
  - D.4.3.4.4 Matrices? — yes ☐ no ☐
  - D.4.3.4.5 Others ? — yes ☐ no ☐
  - D.4.3.4.6 If others, specify

Remark 3 : We propose to introduce into section D.5 :
D.5.5.Gene therapy product containing devices (Medical device, scaffold, matrix, biomaterial…)

- D.5.5.1 Give a brief description of the device :
- D.5.5.2 What is the name of the device ?
- D.5.5.3 Is this Medical Device implantable — yes ☐ no ☐
- D.5.5.4 Does this product contain :
  - D.5.5.4.1 A medical device — yes ☐ no ☐
    - D.5.5.4.1.1 Does this Medical Device have a CE mark ? — yes ☐ no ☐
    - D.5.5.4.1.2 The notified body is :
  - D.5.5.4.2 Biomaterials ? — yes ☐ no ☐
  - D.5.5.4.3 Scaffolds ? — yes ☐ no ☐
  - D.5.5.4.4 Matrices? — yes ☐ no ☐
  - D.5.5.4.5 Others ? — yes ☐ no ☐

D. 5.5.4.6 If others, specify

Remark 4 : We propose to introduce into section D.6 :

D.6.3.Tissue engeneered product containing devices (Medical device, scaffold, matrix, biomaterial…)

D.6.3.1Give a brief description of the device :

D. 6.3.2 What is the name of the device ?

D. 6.3.3Is this Medical Device implantable yes ☐ no ☐

D. 6.3.4Does this product contain :

D. 6.3.4.1 A medical device yes ☐ no ☐

D.6.3.4.1.1 Does this Medical Device have a CE mark ? yes ☐ no ☐

D. 6.3.4.1.2 The notified body is :

D. 6.3.4.2 Biomaterials ? yes ☐ no ☐

D. 6.3.4.3 Scaffolds ? yes ☐ no ☐

D. 6.3.4.4 Matrices? yes ☐ no ☐

D. 6.3.4.5 Others ? yes ☐ no ☐

D. 6.3.4.6 If others, specify

Remark 5 : It is proposed to delete section D.7 because it is not a new category of advanced therapy medicinal products.
Actually, there is no other product including medical device than advanced therapy medicinal product.

Remark 6 : It is proposed to conserve title of the section D.9 :“site where qualified person certified batch release”.

General comment : as a new category of product is introduced in this document (ATIMP), we would like to know if it will be possible to make specific queries on this category of product in the database EUDRACT ?